REGULATION OF THE DRUG AND FOOD SUPERVISORY BODY

NUMBER 11 OF 2020

ON

CRITERIA FOR AND MANAGEMENT OF REGISTRATION OF HEALTH SUPPLEMENTS[1]

BY THE GRACE OF GOD ALMIGHTY

HEAD OF DRUG AND FOOD SUPERVISORY BODY,

Considering:

a. that in order to protect the public from health supplement which does not fulfill safety, benefit, and quality requirements, regulation on registration of health supplement is necessary;

b. that in accordance with provisions under Article 4 of Regulation of the President Number 80 of 2017 on Drug and Food Supervisory Body, Drug and Food Supervisory Body is authorized to issue distribution license for health-supplement products in accordance with safety, benefit, and quality requirements;

c. that provisions on registration of health supplement as addressed under Regulation of the Head of Drug and Food Supervisory Body Number HK.00.05.41.1381 of 2005 on Management of Registration of Food Supplements, are no longer compatible with the development of science and technology within the sector of health supplement, thus it needs to be replaced;

d. that based on considerations as referred to in letter a, letter b, and letter c, it is deemed necessary to establish Regulation of the Drug and Food Supervisory Body on Criteria for and Management of Registration of Health Supplements;

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In view of:

1. Regulation of the President Number 80 of 2017 on Drug and Food Supervisory Body (State Gazette of the Republic of Indonesia of 2017 Number 180);
2. Regulation of the Drug and Food Supervisory Body Number 26 of 2017 on Organization and Working Procedures of Drug and Food Supervisory Body (Official Gazette of the Republic of Indonesia of 2017 Number 1745);
3. Regulation of the Drug and Food Supervisory Body Number 12 of 2018 on Organization and Working Procedures of Technical Task Unit of Drug and Food Supervisory Body (Official Gazette of the Republic of Indonesia of 2017 Number 784), as amended by Regulation of the Drug and Food Supervisory Body Number 29 of 2019 on Amendment to Regulation of the Drug and Food Supervisory Body Number 12 of 2018 on Organization and Working Procedures of Technical Task Unit of Drug and Food Supervisory Body (Official Gazette of the Republic of Indonesia of 2019 Number 1274);

HAS DECIDED:

To establish:

REGULATION OF THE DRUG AND FOOD SUPERVISORY BODY ON CRITERIA FOR AND MANAGEMENT OF REGISTRATION OF HEALTH SUPPLEMENTS.

CHAPTER 1
GENERAL PROVISIONS

Article 1

Under this Regulation of the Body, the following definitions are employed:

1. Registration of Health Supplement, hereinafter referred to as Registration, is procedures for registration and evaluation of Health Supplement in order to obtain distribution license.
2. Health Supplement is product which is intended to complete the needs of nutrients, maintain, increase and/or repair health functions, have nutritional value and/or

physiology effect, contain one or more components in the forms of vitamin, mineral, amino acid and/or other non-plant-based component which may be combined with plant.

3. Distribution License is approval form of Registration of Health Supplement in order to be able to be distributed within Indonesian territories, which is issued by the Head of Drug and Food Supervisory Body.
4. Electronic Registration of Health Supplement, hereinafter referred to as e-Registration, is Registration of Health Supplement which is performed online by utilizing information technology and communication facilities.
5. Pharmaceutical Industry is enterprise which possesses license in accordance with provisions under laws and regulations to perform the manufacturing activities of drug and drug component.
6. Traditional Medicine Industry, hereinafter abbreviated as IOT [*Industri Obat Tradisional*], is industry which produces all kinds of traditional medicine items.
7. Traditional Medicine Small Business, hereinafter abbreviated as UKOT [*Usaha Kecil Obat Tradisional*], is business which produces all kinds of traditional medicine items, excluding items in the form of tablet and effervescent.
8. Food Industry is company which produces processed foods.
9. Importer is enterprise taking form as incorporated entity or unincorporated entity which imports Health Supplement into Indonesian territories.
10. Good Manufacturing Practices are all aspects of manufacturing activities which aim to guarantee that the product which is produced always meets quality requirements which are determined in accordance with its consumption purposes.
11. Good Drug Manufacturing Practices, hereinafter abbreviated as CPOB [*Cara Pembuatan Obat yang Baik*], are drug manufacturing practices which aim to guarantee that quality of drug which is produced is in accordance with the requirements and consumption purposes.
12. Good Traditional Medicine Manufacturing Practices, hereinafter abbreviated as CPOTB [*Cara Pembuatan Obat Tradisional yang Baik*], are all aspects of manufacturing activities of traditional medicines which aim to guarantee that the

product which is produced always meets quality requirements which are determined in accordance with its consumption purposes.

13. Good Processed Foods Manufacturing Practices, hereinafter abbreviated as CPPOB [*Cara Produksi Pangan Olahan yang Baik*], are a practice, method, or technique of increasing added value of processed foods by using the existing production factors.
14. Bulk Product is component which has finished the processing and only requires packing activity in order to be final product.
15. Contracted Health Supplement is Health Supplement, of which, the whole or part of manufacturing stages are transferred based on contract.
16. License is the transfer of right and authority for using research and development result which relates to safety, benefit, quality and transfer of technology in the course of manufacturing, and/or the use of trade name, as well as sale of a Health Supplement.
17. Licensed Health Supplement is Health Supplement, of which, all manufacturing stages are performed locally based on license.
18. New Registration is Registration of Health Supplement which is yet to possess Distribution License in Indonesia.
19. Registration of Variation is Registration of Health Supplement with modification to administrative, safety, benefit, quality aspects and/or marking on Health Supplement which has possessed Distribution License.
20. Registration of Minor Variation using Notification is Registration of Variation for certain aspects which do not affect safety, benefit, and/or quality aspects of Health Supplement, as well as do not alter information in approval of Distribution License.
21. Registration of Minor Variation which Requires Approval is Registration of Variation which is not included in the category of Registration of Minor Variation using Notification and Registration of Major Variation.
22. Registration of Major Variation is Registration of Variation which affects administrative, safety, benefit, and/or quality aspects of Health Supplement.
23. Re-Registration is Registration of Health Supplement for extension of validity period of Distribution License without being followed with modification.

24. Marking is complete information on benefit, safety, and consumption method, as well as other information in connection with product, which is put on Label [*Etiket*] and/or Brochure which is written on Packaging of Health Supplement.
25. Composition is qualitative and quantitative structure of active component.
26. Formula is qualitative and quantitative structure of active component and additional component.
27. Officer is employee within the scope of Drug and Food Supervisory Body which is assigned by authorized official to perform examination based on assignment order.
28. Businesses are registrants who file application for Registration of Health Supplement, in the forms of Pharmaceutical Industry, Traditional Medicine Industry, Traditional Medicine Small Business, Food Industry, Importer and/or enterprise within the scope of marketing of Health Supplement, as the owner or holder of distribution license.
29. Holder of Distribution License is registrant who has obtained Distribution License.
30. Principal [*Pemberi Kontrak*] is registrant who transfers activities of manufacturing of Health Supplement through cooperation agreement with Businesses within the sector of Health Supplement in accordance with provisions under laws and regulations.
31. Contractor [*Penerima Kontrak*] is Businesses who accept the work to perform activities of manufacturing Health Supplement, which is granted by Principal based on cooperation agreement in accordance with provisions under laws and regulations.
32. Day is business day.
33. Head of the Body is Head of Drug and Food Supervisory Body.
34. Drug and Food Supervisory Body, hereinafter abbreviated as BPOM [*Badan Pengawas Obat dan Makanan*], is non-ministerial governmental Agency which organizes governmental affairs within the sector of Drug and Food supervision.

CHAPTER II
CRITERIA

First Division
General

Article 2

Health Supplement which is distributed must meet the following criteria:

a. safety, benefit, and quality; and
b. Marking.

Second Division
Safety, Benefit, and Quality

Article 3

(1) Criteria for safety, benefit and quality as referred to under Article 2 letter a encompass:
   a. the use of raw material in accordance with the provisions of Indonesian Pharmacopoeia, Indonesian Herbal Pharmacopoeia, pharmacopoeia of another state or acknowledged scientific reference;
   b. verification of safety and benefit through empirical and/or scientific manners; and
   c. implementation of Good Manufacturing Practices which is performed in accordance with provisions under laws and regulations.

(2) Good Manufacturing Practices as referred to in paragraph (1) letter c encompass:
   a. CPOB;
   b. CPOTB; and/or
   c. CPPOB.

Article 4

Verification of safety and benefit through empirical and/or scientific manners as referred to under Article 3 paragraph (1) letter b is performed based on scientific reference, non-clinical data, and/or clinical data, in accordance with the latest development of science and technology within the sector of Health Supplement.

Article 5

(1) Health Supplement may contain active component and additional component.

(2) In case active component as referred to in paragraph (1) is in the forms of plant, it should meet the following requirements:
   a. it has been attached with information on the origin of plant, part which is used and preparation method; and
   b. standardization, qualitative test, and/or quantitative test of active compound on raw material and final product have been performed.

(3) In case, on the packaging of Health Supplement, contents of active component as referred to in paragraph (2) are put on, quantitative test should be performed.

Article 6

(1) Additional component as referred to under Article 5 paragraph (1), may take form as:
   a. preservative;
   b. coloring;
   c. sweetener;
   d. flavor;
   e. anticaking agent;
   f. emulsifier;
   g. coating;
   h. stabilizer;
   i. solvent; and/or
   j. other additional component.

(2) Additional component as referred to in paragraph (1) is additional component which is permitted to be used in the course of manufacturing of Health Supplement in accordance with provisions under laws and regulations.

Article 7

(1) Active component as referred to under Article 5 and additional component as referred to under Article 6 which are originated from non-plant-based component, should attach document on the source of procurement.

(2) Against document on the source of procurement as referred to in paragraph (1), evaluation is performed in accordance with provisions under laws and regulations.

Article 8

(1) Stability test for the fulfillment of quality criteria as referred to under Article 2 letter a is performed on the temperature and humidity in zone IVb.

(2) In case the product is unstable in referral to zone IVb as referred to in paragraph (1), Businesses should give justification and perform stability test on proper temperature and humidity.

Third Division

Marking

Article 9

(1) Businesses, in the course of performing Marking of Health Supplement, should comply with Marking requirements.

(2) Requirements for Marking of Health Supplement as referred to in paragraph (1) encompass the inclusion of information which is complete, objective, and not misleading.

Article 10

(1) Marking as referred to under Article 9 should fulfill the following requirements:

a. be directly printed or closely affixed to the container and/or packaging;

b. be not easily come-off; and

c. be not broken by water, friction, or sunlight impact.

(2) In case Health Supplement is packaged in stripe or blister, Marking should be directly printed on packaging.

Article 11

(1) Marking as referred to under Article 9 paragraph (1) should at least include statement and/or information on:

a. name of product;

b. name and address of industry and/or Businesses;

c. name and address of Principal and/or Contractor;

d. name and address of Licensor and/or Licensee;

e. size, content, net weight;

f. composition in qualitative and quantitative manners;

g. additional component in qualitative manner;

h. efficacy claim;

i. consumption instruction/usage method;

j. counter indication, side effect, and warning if any;

k. number of Distribution License;

l. batch number/production code;

m. expiration;

n. storage condition;

o. 2D Barcode; and

p. other information in relation to safety, quality or origin of certain component in accordance with provisions under laws and regulations.

(2) Statement and/or information as referred to in paragraph (1) are in accordance with document which has been approved by BPOM.

(3) Inclusion of statement and/or information as referred to in paragraph (1) is included in Appendix I, which is an integral part to this Regulation of the Body.

Article 12

(1) Statement and/or information as referred to under Article 11 should use Indonesian language, Arabic number, and Latin character.

(2) In case the statement and/or information as referred to in paragraph (1) use language other than Indonesian language, Businesses should enclose the translation of statement and/or information in Indonesian language, which is produced by sworn translator in Indonesia.

(3) It is exempted from provisions as referred to in paragraph (2), for statement and/or information which are enclosed using English, which is not necessary to be translated by sworn translator.

(4) If Businesses are unable to perform provisions as referred to in paragraph (2), statement and/or information which are enclosed should be:

a. translated into English in the state of origin; and

b. verified by local public notary.

Article 13

In case there is change in composition of Health Supplement, thus affecting benefit aspect, the name of product as referred to under Article 11 paragraph (1) letter a should be changed.

Article 14

In case it is legally proven that there is another party who is more eligible to use the name of product and/or design on Marking prior to approval date of Distribution License, name of product as referred to under Article 11 paragraph (1) letter a and/or Marking design should be changed.

Article 15

Inclusion of Marking in the forms of information on nutritional value should be in conformity with the test result from accredited laboratory in Indonesia or industrial laboratory in Indonesia which possess CPOB/CPOTB certificate.

Article 16

(1) Businesses may include efficacy claim in Marking of Health Supplement when filing Registration application.

(2) Efficacy claim as referred to in paragraph (1) may take form as:
   a. general or nutritional claim;
   b. functional claim; and/or
   c. claim of lowering the disease risk.

(3) Health Supplement is not designated for the prevention or treatment claim of a disease.

(4) Further provisions on efficacy claim as referred to in paragraph (2) are in accordance with Regulation of the Drug and Food Supervisory Body which addresses matters on claim of Health Supplement.

Article 17

Further provisions on Marking as referred to under Article 11 are in accordance with Regulation of the Drug and Food Supervisory Body which addresses matters on Marking of Health Supplement.

CHAPTER III
REGISTRATION OF HEALTH SUPPLEMENT

First Division
General

Article 18

(1) Health Supplement which will be distributed within Indonesian territories must fulfill criteria as referred to under Article 2.

(2) In order to guarantee that Health Supplement which is distributed within Indonesian territories fulfills criteria as referred to in paragraph (1), Businesses must distribute Health Supplement which has possessed Distribution License.

(3) Distribution License as referred to in paragraph (2) is obtained by filing application for Registration.

(4) Application for Registration as referred to in paragraph (3) is submitted by Businesses to Head of the Body.

Article 19

(1) Obligation of Distribution License as referred to under Article 18 paragraph (2) is exempted for Health Supplement which is imported into Indonesian territories for special use.

(2) Import of Health Supplement for special use as referred to in paragraph (1) is performed in accordance with provisions under laws and regulations.

Article 20

Businesses as referred to under Article 18 paragraph (4) may take form as Pharmaceutical Industry, IOT, UKOT, Food Industry, Importer or enterprise within the sector of marketing of Health Supplement.

Second Division

Requirements

Sub-Division 1

General

Article 21

(1) Application for Registration is filed by Businesses to BPOM via e-Registration.

(2) Registration as referred to in paragraph (1) consists of:

a. New Registration;

b. Variation Registration; and

c. Re-Registration.

Article 22

Application for Registration as referred to under Article 21 paragraph (1) encompasses:

a. Local Health Supplement;
b. Exported Special Health Supplement; and
c. Imported Health Supplement.

Sub-Division 2

Local Health Supplement

Article 23

Local Health Supplement as referred to under Article 22 letter a encompasses:

a. Health Supplement which is manufactured locally;
b. Health Supplement which is manufactured based on contract;
c. Health Supplement which is manufactured based on License; and/or
d. Health Supplement which is manufactured based on patent.

Article 24

(1) Application for Registration of Health Supplement which is manufactured locally as referred to under Article 23 letter a is filed by Businesses.
(2) Businesses as referred to in paragraph (1) should fulfill these requirements:
    a. possessing license for Pharmaceutical Industry, IOT, UKOT or Food Industry; and
    b. has implemented Good Manufacturing Practice that is proven by certificate.
(3) Food Industry as referred to in paragraph (2) letter a which manufactures Health Supplement must obtain recommendation letter indicating have been implementing CPOTB.

Article 25

(1) Health Supplement which is manufactured based on contract as referred to under Article 23 letter b encompasses:
    a. a part of manufacturing process; or

b. all manufacturing processes.

(2) Application for Registration as referred to in paragraph (1) is filed by Principal.

(3) Principal as referred to in paragraph (3) acts as Holder of Distribution License.

(4) Principal as referred to in paragraph (3) should fulfill the following requirements:

a. possessing license for Pharmaceutical Industry, license for Industry in the sector of Traditional Medicine, license for Food Industry or license for enterprise within the sector of marketing of Health Supplement;

b. possessing certificate of Good Manufacturing Practice; and

c. possessing document of contract.

(5) Certificate of Good Manufacturing Practice as referred to in paragraph (4) letter b is exempted for enterprise within the sector of marketing of Health Supplement.

(6) In case Principal as referred to in paragraph (3) takes form as enterprise within the sector of marketing of Health Supplement, it should have laboratory of quality testing with a pharmacist as the person in charge and examination is performed periodically.

Article 26

(1) Document of contract as referred to under Article 25 paragraph (5) letter c at least should contain agreement on:

a. validity period of contract;

b. name and composition of Health Supplement which is contracted; and

c. manufacturing process which is performed by Contractor.

(2) Contractor of manufacturing of Health Supplement should possess certificate of Good Manufacturing Process in accordance with the form of item which is contracted.

Article 27

(1) Principal and Contractor are held liable for safety, benefit, and quality of manufactured Health Supplement.

(2) Principal may file for addition and or change of production site (alternative site) in order to anticipate force majeure (*keadaan kahar*) as addressed in the agreement of contract.

(3) Principal must register addition and or change of production site (alternative site) as referred to in paragraph (2) as Registration of Major Variation.

(4) Contractor is prohibited from transferring the manufacturing of contracted Health Supplement to third party.

Article 28

(1) Application for Registration of Health Supplement that is manufactured based on License as referred to under Article 23 letter c is filed by Businesses as Licensee.

(2) Licensor in the course of filing of Registration of Health Supplement that is manufactured locally based on License consists of:
   a. industry overseas; or
   b. research agency as the owner of local formula and technology.

(3) Licensee as referred to in paragraph (1) should fulfill the following requirements:
   a. possessing license for Pharmaceutical Industry, industry within the sector of Traditional Medicine and Food Industry;
   b. possessing Certificate of Good Manufacturing Practice for the form of item that is licensed;
   c. possessing document of License agreement; and
   d. possessing Certificate of Free Sale or Certificate of Pharmaceutical Product with the following provisions:
      1. issued by authorized governmental authority in state of origin or other agency that is appointed by government of state of origin with appointment letter; and
      2. validated by representative official of Government of the Republic of Indonesia in country in question.

(4) Document of License agreement as referred to in paragraph (3) letter c at least should contain information on:
   a. validity period of License; and
   b. name of product and composition of Health Supplement that is licensed.

(5) Requirement as referred to in paragraph (3) letter d is exempted for Licensor who is originated from research agency as the owner of local formula and technology.

(6) Licensee is held liable for safety, benefit, and quality of Health Supplement that is manufactured based on License.

Article 29

(1) Application for Registration of Health Supplement that is manufactured based on patent as referred to under Article 23 letter d is filed by:
   a. Businesses as the owner of patent right in accordance with provisions under laws and regulations; or
   b. Businesses which are appointed by owner of patent right.

(2) Patent right as referred to in paragraph (1) should be proven with patent certificate.

(3) In case application for Registration is filed by Businesses as referred to in paragraph (1) letter b, it should be proven with the document on assignment of patent right.

(4) Document on assignment of patent right as referred to in paragraph (3) is in accordance with provisions under laws and regulations within patent sector.

Sub-Division 3

Health Supplement which is Specially Manufactured for Export

Article 30

(1) Application for Registration of Health Supplement that is manufactured locally and specifically for export is filed by Businesses.

(2) Businesses as referred to in paragraph (1) should possess license for Pharmaceutical Industry, IOT, UKOT, Food Industry or enterprise within marketing sector.

Article 31

(1) Manufacturing of Health Supplement which is special for export as referred to under Article 30 paragraph (1) should fulfill the following provisions:
   a. fulfilling the aspects of safety, benefit and quality; and
   b. produced by implementing Good Manufacturing Practice as proven with certificate.

(2) Provisions as referred to in paragraph (1) are exempted if Businesses are able to attach approval document from destination country.

Article 32

Health Supplement which is specially manufactured for export is prohibited from being distributed in Indonesian territories.

Sub-Division 4

Imported Health Supplement

Article 33

(1) Application for Registration of Imported Health Supplement is filed by Businesses.

(2) Imported Health Supplement as referred to in paragraph (1) takes form as:

a. bulk product; or

b. final product.

Article 34

(1) Imported Health Supplement in the forms of bulk product as referred to under Article 33 paragraph (2) letter a should be imported by Importer who possesses:

a. identifier as Importer;

b. enterprise within the sector of marketing of Health Supplement; and

c. Certificate of Good Manufacturing Practice in accordance with the item form of product.

(2) Certificate of Good Manufacturing Practice as referred to in paragraph (1) letter c is exempted for enterprise within the sector of marketing of Health Supplement.

(3) In case the import of Health Supplement is in the form of bulk product as referred to under Article 33 paragraph (2) letter a, which is imported by enterprise within the marketing sector, it should be accompanied with cooperation agreement with industry that possesses certificate of Good Manufacturing Practice.

Article 35

In case the import of Health Supplement is in the forms of final product as referred to under Article 33 paragraph (2) letter b into Indonesian territories that is performed by producer Importer, it may only be allowed in the forms of item other than production facilities which are possessed in accordance with business license or industrial license.

Article 36

(1) In case the imported Health Supplement which is imported into Indonesian territories in the forms of final product, Marking should have been affixed to when entering Indonesian territories.

(2) Marking as referred to in paragraph (1) should be in accordance with information and/or statement in decree on approval of Registration that has been approved by BPOM.

Article 37

(1) Businesses as referred to under Article 33 paragraph (1) should fulfill the following requirements:

a. possessing Importer license within the sector of Health Supplement in accordance with provisions under laws and regulations;

b. possessing agency appointment letter and right to perform Registration from industry in state of origin which are still valid for a time period of 3 (three) years at minimum at the time of Registration;

c. attaching method and result of testing of quality of raw material and final product;

d. attaching the result of testing of quality of final product from accredited laboratory in Indonesia or industrial laboratory in Indonesia which possesses certificate of Good Manufacturing Practice with validity period of 1 (one) year at maximum after it was issued by laboratory;

e. attaching result of toxicity test and pharmacodynamic test in accordance with the use character of product;

f. attaching result of tolerability test in the forms of clinical test in Indonesian population;

g. attaching sample of product, packaging, and original Marking which are distributed in the state of origin;

h. attaching list and address of all storage facilities of product which are used; and

i. employing pharmacist as the person in charge that is proven with duty-stamped affidavit.

(2) Agency appointment letter as referred to in paragraph (1) letter b should contain information on:

a. validity period of appointment as agent;

b. name and form of item; and

c. industrial signature in state of origin.

(3) If, at the time of Registration, confirmation on safety profile of Health Supplement is necessary, Businesses should attach toxicity test as referred to in paragraph (1) letter e.

(4) If, at the time of Registration, confirmation on benefit profile of Health Supplement is necessary, Businesses should attach result of pharmacodynamic testing as referred to in paragraph (1) letter e.

(5) If, at the time of Registration, confirmation on benefit and/or safety profiles of Health Supplement is necessary, Businesses should attach tolerability test against population of Indonesian residents as referred to in paragraph (1) letter f.

Article 38

Businesses which file application for Registration of imported Health Supplement should attach Certificate of Free Sale or Certificate of Pharmaceutical Product with the following provisions:

a. certificate is still valid;

b. certificate is issued by authorized governmental authority or another agency that is appointed by government of state of origin, being accompanied with certificate of appointment from authorized governmental authority; and

c. certificate which has been validated by local representative official of Government of the Republic of Indonesia.

Article 39

(1) Officer performs audit against storage facilities as referred to under Article 37 paragraph (1) letter h.

(2) Audit as referred to in paragraph (1) is performed before Businesses submitting documents of application for registration of account and Registration document.

Article 40

(1) Industry of state of origin as referred to under Article 38 letter b should fulfill the following requirements:
   a. possessing certificate of Good Manufacturing Practice in accordance with the form of imported item;
   b. certificate of Good Manufacturing Practice which is issued by authorized governmental authority in state of origin.

(2) In case Certificate of Good Manufacturing Practice as referred to in paragraph (1) takes form as Good Manufacturing Practice within Food sector, Importer should attach document of Site Master File (SMF) from producer in state of origin.

(3) Certificate of Good Manufacturing Practice as referred to in paragraph (1) letter a should have validity period of 1 (one) year at minimum at the time of Registration.

(4) In case certificate of Good Manufacturing Practice as referred to in paragraph (3) does not contain validity period, Businesses should attach the industrial inspection result from state of origin of at least for 2 (two) recent years.

(5) Inspection result as referred to in paragraph (4) is issued by authorized governmental authority in state of origin.

(6) Officer may perform local examination against the fulfillment of requirements and/or provisions of Good Manufacturing Practice as referred to in paragraph (1).

Article 41

Importer is held liable for safety, benefit and quality of imported Health Supplement.

Third Division

Category

Article 42

New Registration as referred to under Article 21 paragraph (2) letter a consists of:

a. Category 1 (one) for single active component or combination which safety and benefit profiles have been known; and

b. Category 2 (two) for:

   1. single active component or new combination;
   2. new posology;
   3. new claim;
   4. new form of item; and
   5. its safety and benefit profile are yet to be known.

Article 43

(1) Priority registration as referred to under Article 21 paragraph (2) letter b consists of:

   a. Category 3 i.e. Registration of Minor Variation with notification;
   b. Category 4 i.e. Registration of Minor Variation with approval; and
   c. Category 5 i.e. Registration of Major Variation.

(2) Registration of Variation as referred to in paragraph (1) is addressed in Appendix II which is an integral part to this Regulation of the Body.

Article 44

(1) Category of Re-Registration as referred to under Article 21 paragraph (2) letter c is Category 6.

(2) Re-Registration as referred to in paragraph (1) is not accompanied with modification.

Article 45

In case Health Supplement which is manufactured locally specially for export as referred to under Article 30 paragraph (1), for new Registration, Registration of Variation and Re-Registration, it is Category 7.

Fourth Division
Management of E-Registration

Sub-Division 1
Registration of Account

Article 46

(1) Businesses should perform registration of account when filing new application for Registration of Health Supplement, registration of variation of Health Supplement, and re-registration of Health Supplement.

(2) Registration of account as referred to in paragraph (1) is initially started with registration of company's account.

(3) Registration of company's account as referred to in paragraph (2) has the purpose of obtaining user id (*nama pengguna*) and password (*kata sandi*).

Article 47

(1) Registration of account as referred to under Article 46 paragraph (1) is performed through subsite of e-registration online service of Drug and Food Supervisory Body with the address of https://asrot.pom.go.id/asrot.

(2) Businesses should fill-out Registration data on app as referred to in paragraph (1) electronically.

(3) Businesses should submit supporting document for Registration data as referred to in paragraph (2) to be verified by Officer.

(4) In case, based on result of verification as referred to in paragraph (3), Registration document is declared to be complete and veracious, Businesses obtain user id (*nama pengguna*) and password (*kata sandi*).

Article 48

(1) User id (*nama pengguna*) and password (*kata sandi*) as referred to under Article 47 paragraph (4) are company's confidential data.

(2) Company is held liable in case there is misuse of user id (*nama pengguna*) and password (*kata sandi*) as referred to in paragraph (1).

Article 49

(1) Registration of account as referred to under Article 46 and Article 47 may only be performed 1 (one) time, provided that there is no modification to data of Businesses.

(2) In case there is modification to data as referred to in paragraph (1), Businesses should:

a. submit notification on modification to data; or

b. file re-registration of account.

Sub-Division 2

Registration Document

Article 50

Registration document is confidential document which is used in limited manner only for evaluation purpose by authorized officer.

Article 51

(1) Registration document as referred to under Article 50 encompasses:

a. Administrative Document;

b. Safety, Benefit and Quality Document; and

c. Marking Document.

(2) Registration document as referred to in paragraph (1) may use Indonesian language and/or English.

(3) Marking Document as referred to in paragraph (1) letter c should be accompanied with design of packaging which will be distributed.

(4) Minimum information which must be addressed by Businesses on design of packaging as referred to in paragraph (3) is addressed in Appendix I which is an integral part to this Regulation of the Body.

Sub-Division 3
Filing of New E-Registration Application

Article 52

(1) New e-Registration stages consist of:
   a. pre-Registration; and
   b. Registration.

(2) Pre-Registration stage as referred to in paragraph (1) letter a encompasses:
   a. stage of examination and assessment of administrative document;
   b. examination of formula's data;
   c. determination of category; and
   d. determination of Registration fee.

Article 53

(1) Officer performs evaluation during the pre-Registration stage as referred to under Article 52 paragraph (1) letter a.

(2) Evaluation of pre-Registration stage as referred to in paragraph (1) is performed for no longer than 15 (fifteen) Days since the application for pre-Registration was received.

Article 54

(1) Decision on evaluation during pre-Registration stage as referred to under Article 53 takes form as:
   a. accepted; or
   b. refused.

(2) Decision on evaluation as referred to in paragraph (1) is issued using format of form as addressed in Appendix III which is an integral part to this Regulation of the Body.

Article 55

(1) Decision on being accepted during pre-Registration stage as referred to under Article 54 paragraph (1) letter a prevails for no longer than 20 (twenty) Days since the issuance date.

(2) Decision as referred to in paragraph (1) becomes the basis for Registration stage.

(3) In case application during pre-Registration stage is accepted, Businesses should submit Registration document in complete and veracious manner in conformity with the time period as referred to in paragraph (1).

(4) If Businesses are unable to fulfill provisions as referred to in paragraph (3), Businesses should repeat the process of filing of Registration through filing of application for pre-Registration stage.

Article 56

(1) Registration stage as referred to under Article 52 paragraph (1) letter b encompasses evaluation of safety, benefit, quality and Marking documents.

(2) Safety, benefit, quality and Marking documents as referred to in paragraph (1), which should be handed over by Businesses, consist of:

a. decree on the result of evaluation of pre-Registration as referred to under Article 54 paragraph (1) letter a; and

b. Registration Document as addressed in Appendix IV which is an integral part to this Regulation of the Body.

Sub-Division 4

Filing of Application for E-Registration of Variation

Article 57

(1) Filing of application for e-Registration of Variation is performed by Businesses by attaching document of Registration of Variation in accordance with modification which is filed.

(2) Filing of application for e-Registration of Variation as referred to in paragraph (1) uses format as addressed in Appendix V which is an integral part to this Regulation of the Body.

Sub-Division 5

Filing of Application for E-Re-Registration

Article 58

(1) In case Health Supplement will still be distributed, Businesses must file application for e-Re-Registration to extend validity period of Distribution License.

(2) Filing of application for e-Re-Registration as referred to in paragraph (1) is performed by Businesses no sooner than 180 (one hundred and eighty) days and no longer than 1 (one) day prior to the expiration of validity period of Distribution License.

Article 59

(1) Number of Distribution License of Health Supplement is declared to be invalid if Health Supplement, of which, the validity period of Distribution License has expired and Businesses do not file application for e-Re-Registration in accordance with provisions as referred to under Article 58 paragraph (2).

(2) Businesses may refile application for New e-Registration for Health Supplement which fulfills provisions as referred to in paragraph (1).

Article 60

Businesses, in the course of filing application for e-Re-Registration, should attach the following documents:

a. approval of Distribution License and approved Marking;

b. approval on variation and the latest Marking that is approved;

c. formula of product;

d. affidavit that product is still in production and distribution by declaring the latest batch number which was produced;

e. the latest import document for Imported Health Supplement;
f. agency appointment letter and right to perform Registration from industry in state of origin which are still valid; and
g. result of real time (*berkala*) stability test up to expiration period.

Sub-Division 6

Priority Service

Article 61

(1) Businesses which perform e-Registration may be given with priority service.
(2) Priority service as referred to in paragraph (1) is given to Businesses which fulfill the following criteria:
    a. Businesses within the sector of Health Supplement which have been registered at BPOM and possess number of Distribution License for Health Supplement;
    b. registration of priority service only applies for Registration of new product locally;
    c. have never been involved in crime within drug and food sector;
    d. have compliance of administrative document by not performing forgery of document, has performed renewal of production license;
    e. employing pharmacist or pharmaceutical technical employee as the person in charge for registration;
    f. not using service bureau for the administration of distribution license;
    g. have never received reprimand in relation to violation and/or been listed in public warning (*peringatan publik*) in relation to case of chemical substance of illegal Health Supplement drug within the last 2 (two) years;
    h. have never received serious reprimand other than reprimand as referred to in letter g for the last 2 (two) years; and
    i. priority is given to company which has possessed reporting system for side effect.

(3) Procedures for priority service as referred to in paragraph (1) are addressed in Appendix VI which is an integral part to this Regulation of the Body.

Fifth Division
Responsibility of Businesses

Article 62

(1) Businesses are held responsible for:
   a. completeness of documents which are handed over;
   b. veracity and validity of information which are written in Registration document;
   c. modification to data and information of product which is undergoing the process of filing for application for Registration or has possessed number of Distribution License; and
   d. provision of comparing standard in accordance with the needs in the event of supervision.

(2) Businesses must produce or import Health Supplement which has obtained Distribution License within the deadline of 1 (one) year at maximum since the approval date of Distribution License.

(3) Responsibility of Businesses as referred to in paragraph (1) should be declared in writing in affidavit that uses format as addressed in Appendix VII which is an integral part to this Regulation of the Body.

(4) Board of commissioners, board of directors and/or executives of company of Businesses should have never been legally proven and/or have never been involved in crime within drug and food sector.

Sixth Division
Evaluation and Handing Down of Decision

Sub-Division 1
General

Article 63

(1) BPOM performs evaluation of every filing of application for Registration which has been completely received.

(2) Evaluation as referred to in paragraph (1) encompasses assessment of criteria on safety, benefit, quality, and Marking.

(3) Evaluation as referred to in paragraph (2) is performed in conformity with established time period.

Sub-Division 2
Evaluation Time Period

Article 64

Time period for evaluation of Health Supplement product for New e-Registration as referred to under Article 52 is performed with the following provisions:

a. Category 1 (one) is 30 (thirty) Days at maximum; and

b. Category 2 (two) is 50 (fifty) Days at maximum.

Article 65

Time period for evaluation of Health Supplement product for e-Registration of variation as referred to under Article 57 is performed with the following provisions:

a. Category 3 (three) is 5 (five) Days at maximum;

b. Category 4 (four) is 7 (seven) Days at maximum; and

c. Category 5 (five) is 30 (thirty) Days at maximum.

Article 66

Time period for evaluation of Health Supplement product for e-Re-Registration as referred to under Article 58 which is category 6 (six) is performed within 10 (ten) Days at maximum.

Article 67

Time period for evaluation of Health Supplement product for special Registration for export as referred to under Article 45 which is category 7 (seven) is performed within 3 (three) Days at maximum.

Article 68

Time period for evaluation of Health Supplement product, of which, application for e-Registration is filed as referred to under Article 52 is started since:

a. the retrieval of Registration document in complete manner; and
b. the retrieval of document on modification to status on payment of Registration fee up to the issuance of decision.

Sub-Division 3

Assessment Team and National Committee for Assessment of Health Supplement

Article 69

Evaluation as referred to under Article 63 is performed by:

a. Assessment Team of Safety, Benefit, and Quality; and/or
b. National Committee for Assessment of Health Supplement which hereinafter written as KOMNAS for Assessment of Health Supplement.

Article 70

(1) Assessment Team as referred to under Article 69 letter a consists of officer which is determined by Head of the Body.
(2) KOMNAS for Assessment of Health Supplement as referred to under Article 69 letter b may consist of:
    a. academic;

b. researcher;
c. practitioner; and
d. regulator, of whom, due to its expertise and experience, needed to give suggestion, response and input toward safety, benefit and quality criteria of Health Supplement for:
    1. New Registration of Category 2 as referred to under Article 42 letter b; and
    2. Registration of Major Variation of Category 5 as referred to under Article 43 paragraph (1) letter c.

(3) Assessment Team and KOMNAS for Assessment of Health Supplement as referred to under Article 69 are established under Decree of Head of the Body.

Sub-Division 4

Hearing

Article 71

(1) Head of the Body may request clarification from Businesses through hearing mechanism that is transmitted in writing.
(2) Head of the Body transmits notification in writing to Businesses for the organization of hearing as referred to in paragraph (1).

Article 72

(1) Businesses may file application for hearing through written request that is submitted to BPOM.
(2) Hearing mechanism as referred to in paragraph (1) is performed for 1 (one) time.

Article 73

Head of the Body transmits decision on the evaluation result of hearing in writing to Businesses no later than 30 (thirty) Days since the application letter for hearing was received by BPOM.

Sub-Division 5
Issuance of Decision

Article 74

(1) Head of the Body issues decision on result of evaluation of Health Supplement which is filed by Businesses through the filing of application for Registration.

(2) Decision as referred to in paragraph (1) takes form as:
   a. approval;
   b. request of additional data; or
   c. refusal.

Article 75

(1) Head of the Body issues Decree on Approval as referred to under Article 74 paragraph (2) letter a if, based on evaluation result, it has fulfilled provisions and/or requirements for Registration of Health Supplement.

(2) Approval as referred to in paragraph (1) is decision on:
   a. Distribution License;
   b. Registration of minor variation with notification;
   c. Registration of minor variation with approval;
   d. Registration of major variation;
   e. Re-registration; or
   f. Special registration for export.

Article 76

Issuance of decision in the forms of approval of Distribution License as referred to under Article 74 paragraph (2) letter a is in accordance with format as addressed in Appendix VIII which is an integral part to this Regulation of the Body.

Article 77

Issuance of decision in the forms of approval of Registration as referred to under Article 75 and Article 76 is performed electronically and not requiring stamp and wet signature.

Article 78

In case, based on evaluation, BPOM issues decision in the forms of approval of Application for Registration of Variation as referred to under Article 75 paragraph (2) letter b, letter c, and letter d, Businesses should fulfill the following provisions:

a. must exercise such decision no later than 6 (six) months since the date of issuance of approval;
b. old packaging may be in distribution for 1 (one) year at maximum since the date of issuance of approval; and
c. Health Supplement with old packaging that is produced before the exercise of approval of Registration of Variation may be distributed, provided that it still fulfills quality requirement, unless for variation with modification to composition.

Article 79

Businesses must report the amount, batch number, and expiration date of the last batch which was distributed, to Head of the Body before the issuance of approval for Registration of Variation.

Article 80

(1) Head of the Body issues decision in the forms of request of additional information as referred to under Article 74 paragraph (2) letter b if, based on evaluation result, it is still yet to fulfil provisions and/or requirements for Registration of Health Supplement.
(2) Decision in the forms of request of additional data as referred to in paragraph (1) is issued and transmitted to Businesses in writing using format as addressed in Appendix IX which is an integral part to this Regulation of the Body.
(3) Businesses should submit additional data as referred to in paragraph (1) no later than 60 (sixty) days since the date of letter on request of additional data.

(4) If additional data is still required, Businesses should re-submit additional data to BPOM within the maximum of 40 (forty) days since the date of the second letter on request of additional data.

(5) BPOM performs evaluation toward additional data as referred to in paragraph (1) in conformity with time periods as referred to under Article 64, Article 65, Article 66, Article 67 and/or Article 68.

Article 81

(1) Application for Registration is refused by BPOM if Businesses are unable to submit additional data in conformity with time periods as referred to under Article 80 paragraph (3) and paragraph (4).

(2) Businesses may take Registration document which is refused as referred to in paragraph (1) within maximum time period of 20 (twenty) Days.

Article 82

(1) Head of the Body issues decision in the forms of refusal as referred to under Article 74 paragraph (2) letter c if based on evaluation result, Businesses fail to fulfill provisions and/or requirements of Registration.

(2) Decision on refusal as referred to in paragraph (1) in accordance with format as addressed in Appendix X which is an integral part to this Regulation of the Body.

Sub-Division 6

Application for Review

Article 83

(1) In case Businesses object to decision in the forms of refusal as referred to under Article 82 paragraph (1) which is issued by BPOM, Businesses may file application for review.

(2) Application for review as referred to in paragraph (1) is filed by Businesses as attached with completeness of new data or data which have been filed, with justification.

(3) Application for review as referred to in paragraph (1) may only be filed if in the process of evaluation of Registration, supporting document in the forms of pre-clinical data and/or clinical data are required.

(4) Application for review as referred to in paragraph (1) is submitted in writing by Businesses to Head of the Body no later than 30 (thirty) Days since the date of issuance of refusal letter.

Article 84

(1) Businesses may file application for review as referred to under Article 83 paragraph (1) for 1 (one) time.

(2) Head of the Body issues decision on the filing of application for review as referred to in paragraph (1) within maximum time period of 100 (one hundred) Days since the application letter for review was received.

(3) Decision as referred to in paragraph (1) takes form as:
   a. approval; or
   b. refusal.

Article 85

(1) Businesses may file application for New Registration if based on evaluation, Head of the Body issues decision in the forms of:
   a. refusal against application for Registration as referred to under Article 82 which is filed by Businesses; or
   b. refusal against application for review as referred to under Article 84 paragraph (3) letter b which is filed by Businesses.

(2) Application for New Registration as referred to in paragraph (1) should be filed by Businesses and be accompanied with new supporting data.

Seventh Division

Product which Registration is Unable to be Performed

Article 86

Product which is Registration is unable to be performed may take form as:

a. form of injection and eye drop items;
b. product which contains vitamin, mineral, amino acid substances and/or other substance exceeding maximum threshold as addressed in Appendix XI which is an integral part to this Regulation of the Body;
c. product which contains other substance which is based on health consideration and/or based on research, endangering the health as addressed in Appendix XII which is an integral part to this Regulation of the Body;
d. product which contains ethyl alcohol with the content level greater than 1% (one percent) and in the forms of oral fluid item;
e. product which contains drug, drug chemical substance, narcotic or psychotropic; and
f. product which contains animal or plant which is protected in accordance with provisions under laws and regulations.

CHAPTER IV

VALIDITY PERIOD OF DISTRIBUTION LICENSE

Article 87

(1) Distribution License is valid for time period of 5 (five) years, provided that it is not in contradiction with provisions under laws and regulations.
(2) Distribution License as referred to in paragraph (1) may be extended through the mechanism of e-Re-Registration.
(3) Validity period of Distribution License as referred to in paragraph (1) is exempted for Registration based on cooperation and/or agency appointment agreement with validity period of shorter than 5 (five) years.

(4) Validity period of Distribution License as referred to in paragraph (3) is in conformity with validity period of cooperation and/or agency appointment agreement.

Article 88

Health Supplement, of which, the validity period of its Distribution License has expired and not extended, is declared as Health Supplement which does not possess Distribution License.

CHAPTER V
FEES

Article 89

(1) Businesses which file application for Registration for pre-Registration and Registration stages are imposed with fees as non-tax state revenue in accordance with provisions under laws and regulations.

(2) In case filing of application for Registration as referred to in paragraph (1) is refused, fees which have been paid by Businesses cannot be withdrawn.

CHAPTER VI
RE-EVALUATION

Article 90

(1) Head of the Body may perform re-evaluation against distributed Health Supplement.

(2) Re-evaluation as referred to in paragraph (1) is performed if, based on monitoring result, new development on safety, benefit, and quality of Health Supplement which affects the public health and safety is found.

(3) Data and/or information on safety criteria which affects the health and safety as referred to in paragraph (2) may be obtained through the reporting of side effect.

(4) Against evaluation as referred to in paragraph (1), Head of the Body issues decision in the forms of:

a. modification to Marking;

b. correction of composition/formula;
c. granting of limitation for use;
d. recall of product from distribution;
e. suspension of Distribution License; and/or
f. annulment of Distribution License.

(5) Decision as referred to in paragraph (4) is transmitted in writing to Businesses to be followed up.

CHAPTER VII
SANCTIONS

Article 91

(1) Businesses which violate Article 18 are imposed with administrative sanctions in the forms of:
a. reprimand;
b. product recall of Health Supplement from distribution;
c. annulment of Registration process;
d. postponement of service for Registration of Health Supplement product;
e. prohibition from filing application for Registration of Health Supplement; and/or
f. annulment of Distribution License.

(2) Sanctions as referred to in paragraph (1) are imposed by Head of the Body.

(3) Administrative sanction in the forms of postponement of service for Registration of product as referred to in paragraph (1) letter d is granted based on the following considerations:
a. Businesses deliberately distribute Health Supplement product which is not in conformity with Marking and/or Distribution License document that has been approved by BPOM;
b. ads of Health Supplement is not in conformity with provisions under laws and regulations;
c. Businesses violate provisions within the sectors of production, distribution, and/or importation within the sector of Health Supplement; and/or

d. Businesses do not perform reporting in relation to modification to safety, benefit, and quality criteria of Health Supplement.

(4) Administrative sanction in the forms of postponement of service of Registration of Health Supplement product as referred to in paragraph (1) letter d applies for 6 (six) months at maximum.

(5) Administrative sanction in the forms of prohibition from filing of Registration application as referred to in paragraph (1) letter e is issued if:

a. when filing application for Registration, Businesses deliberately give counterfeit or forged Registration document; and/or

b. Businesses deliberately add component other than component that has been approved by BPOM in distribution license document.

(6) Administrative sanction in the forms of prohibition from filing of application for Registration as referred to in paragraph (1) letter e applies for 3 (three) years at maximum.

(7) Administrative sanction in the forms of annulment of Distribution License as referred to in paragraph (1) letter f is imposed based on the following considerations:

a. if based on research and/or monitoring of Health Supplement that has possessed distribution license, in the distribution, it is proven that it does not fulfill criteria and requirements for Registration of Health Supplement;

b. ads of Health Supplement that is not in conformity with provisions under laws and regulations;

c. Health Supplement which is distributed is not in accordance with Marking and/or document which was approved when obtaining Distribution License or approval for modification to data;

d. not performing production or import for 2 (two) consecutive years;

e. Distribution License which is possessed by Pharmaceutical Industry, IOT, UKOT, Industry within the Food sector or Importer as Holder of Distribution License is revoked;

f. committing violation within the sectors of production, distribution, and/or importation within Health Supplement sector;

g. validity period of certificate of Good Manufacturing Practice has expired and not extended;

h. Holder of Distribution License gives counterfeit or forged Registration document;

i. Holder of Distribution License fails to perform reporting in relation to modification to safety, benefit and quality criteria of Health Supplement; and/or

j. upon application from Holder of Distribution License.

Article 92

Procedures for imposition of administrative sanctions as referred to under Article 91 are performed in accordance with Decree of Head of the Body which addresses follow-up of supervisory result.

CHAPTER VIII
TRANSITIONAL PROVISIONS

Article 93

(1) Businesses which file application for Registration prior to the entry into force of this Regulation of the Body is still processed based on Regulation of the Head of Drug and Food Supervisory Body Number HK.00.05.41.1381 of 2005 on Management of Registration of Food Supplement.

(2) Distribution License of Health Supplement which has been issued prior to the entry into force of this Regulation of the Body, continue to prevail up to the expiration of validity period of Distribution License and within 2 (two) years at maximum, it must adjust itself with this Regulation of the Body.

CHAPTER IX
FINAL

Article 94

All Food Supplements which have been registered prior to the entry into force of this Regulation of the Body should be construed as Health Supplement, provided that it is not in contradictory with this Regulation of the Body.

Article 95

When this Regulation of the Body enters into force, Regulation of the Head of Drug and Food Supervisory Body Number HK.00.05.41.1381 of 2005 on Management of Registration of Food Supplement is revoked and declared to be invalid.

Article 96

This Regulation of the Body enters into force on promulgation date.

For the purposes of public cognizance, it has been ordered that the promulgation of this Regulation of the Body should be achieved through its publication in the Official Gazette of the Republic of Indonesia.

Established in Jakarta
on 11 June 2020
HEAD OF DRUG AND FOOD SUPERVISORY BODY,
signed.
PENNY K. LUKITO

Promulgated in Jakarta
on 12 June 2020
DIRECTOR GENERAL OF
LAWS AND REGULATIONS
MINISTRY OF LAW AND HUMAN RIGHTS OF
THE REPUBLIC OF INDONESIA,
signed.
WIDODO EKATJAHJANA

OFFICIAL GAZETTE OF THE REPUBLIC OF INDONESIA OF 2020 NUMBER 610