REGULATION OF THE PRESIDENT OF THE REPUBLIC OF INDONESIA

NUMBER 6 OF 2023

ON

HALAL CERTIFICATION OF DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL EQUIPMENT

BY THE GRACE OF GOD ALMIGHTY

THE PRESIDENT OF THE REPUBLIC OF INDONESIA,

Considering:

that in order to provide legal certainty and guarantees for the community on the halal status of drugs, biological products and medical equipment that enter, circulate and traded within Indonesian territory and to implement the provisions of Article 142 paragraph (4) of Regulation of the Government Number 39 of 2021 on the Organization of Halal Product Guarantee, it has been deemed necessary to establish Regulation of the President on Halal Certification of Drugs, Biological Products, and Medical Equipment.

Observing:

1. Article 4 paragraph (1) of the 1945 Constitution of the Republic of Indonesia;
2. Law Number 33 of 2014 on Halal Product Guarantees (State Gazette of the Republic of Indonesia of 2014 Number 295, Supplement to the State Gazette of the Republic of Indonesia Number 5604) as amended several times, most recently by Regulation of the Government in Lieu of Law Number 2 of 2022 on Job Creation (State Gazette of the Republic of Indonesia of 2022 Number 238, Supplement to the State Gazette of the Republic of Indonesia Number 6841);
3. Regulation of the Government Number 39 of 2021 on the Organization of Halal Product Guarantee (State Gazette of the Republic of Indonesia of 2021 Number 49, Supplement to the State Gazette of the Republic of Indonesia Number 6651).

HAS DECIDED:

To establish:

REGULATION OF THE PRESIDENT ON HALAL CERTIFICATION OF DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL EQUIPMENT.

Article 1

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

1. Halal Products are products which have been declared halal in accordance with Islamic sharia.
2. Biological Products are products containing biological materials derived from humans, animals, or microorganisms which are made by conventional means or through biotechnological methods.

3. Medical Equipment are non-medicated instruments, apparatuses, machines and/or implants used to prevent, diagnose, cure and relieve diseases, treat sick people, restore health in humans, and/or establish structures and improve bodily functions.
4. Halal Certificate is an acknowledgment of the halal status of a product issued by the Halal Product Assurance Agency based on a written halal fatwa or the determination of halal status of products by the Indonesian Ulema Council, Provincial Indonesian Ulema Council, Regency/City Indonesian Ulema Council, Aceh Ulema Consultative Council, or Halal Fatwa Products Committee.
5. Non-Halal Information is a non-halal statement of a product.
6. Business Actors are individuals or business entities in the form of legal entities or non-legal entities that organize business activities within Indonesian territory.
7. Central Government is the President of the Republic of Indonesia who holds the power of government of the Republic of Indonesia assisted by the Vice President and ministers as referred to in the 1945 Constitution of the Republic of Indonesia.
8. Minister is the minister who organizes government affairs in the health sector.

Article 2

(1) Drugs, Biological Products, and Medical Equipment that enter, circulate and are traded within Indonesian territory are required to be certified halal.

(2) Drugs as referred to in paragraph (1) include drug ingredients, over-the-counter drugs, limited non-prescription drugs, potent drugs, traditional medicines, health supplements, and quasi-drugs.

(3) Drugs as referred to in paragraph (1) are exempted for narcotics and psychotropic drugs.

(4) Biological Products as referred to in paragraph (1) shall at least consist of enzymes, monoclonal antibodies, hormones, stem cells, gene therapy, vaccines, blood products, recombinant DNA products, and immunosera.

(5) Medical Equipment as referred to in paragraph (1) include in-vitro reagents and calibrators, software, and objects or materials used alone or in combination, to prevent fertilization, disinfect Medical Equipment, and for in-vitro testing of specimens from the human body, and may contain drugs that do not achieve their primary function on the human body through pharmacological, immunological or metabolic processes to be able to assist in the desired function or work.

(6) Medical Equipment as referred to in paragraph (1) and paragraph (5) are only derived from animals and/or contain animal elements.

Article 3

Halal Certificate as referred to in Article 2 shall be granted to drugs, Biological Products, and Medical Equipment which are originated from halal materials and halal manufacturing practices.

Article 4

(1) Halal manufacturing practices as referred to in Article 3 are guidelines used in the series of activities for the manufacture of halal drugs, Biological Products, and Medical Equipment.

(2) The halal manufacturing practices as referred to in paragraph (1) is part of the Halal Product process which includes the provision of materials, processing, storage and packaging.

(3) The halal manufacturing practices as referred to in paragraph (1) aims to ensure the halal status of drugs, Biological Products, and Medical Equipment.

(4) The halal manufacturing practices as referred to in paragraph (1) are required to fulfill the following criteria:

a. commitment and responsibility;

b. materials;

c. processes;

d. products; and

e. monitoring and evaluation.

Article 5

(1) The commitment and responsibility as referred to in Article 4 paragraph (4) letter a shall be in the form of a written statement from the head of the management of the company which contains the commitment and responsibility to develop and implement halal manufacturing practices.

(2) The commitment and responsibility as referred to in paragraph (1) shall encompass the following elements:

a. halal policy;

b. head of management; and

c. human resource development.

Article 6

(1) Materials as referred to in Article 4 paragraph (4) letter b are elements used to make or produce products required by halal manufacturing practices including:

a. raw materials which include active substances and additives;

b. packaging, lubricants, grease, or sanitizers which are in direct contact with materials or products;

c. sanctification auxiliary materials which are in direct contact with production facilities to produce products; and

d. media for validating the results of sanctification of facilities which are in direct contact with materials or products.

(2) Additives as referred to in paragraph (1) letter a are all materials other than active substances used in the manufacture of raw materials and finished products.

(3) The sanctification auxiliary materials or media as referred to in paragraph (1) letter c and d shall apply to the products that use the production facilities in conjunction with the products for which halal certification is not submitted and does not contain any prohibited materials.

(4) Materials as referred to in paragraph (1) originate from animals, plants, microbes, materials produced through chemical processes, biological processes, or genetic engineering processes.

(5) Materials used in halal manufacturing practices:

a. are required to be halal certified, except for materials which are categorized as non-critical materials in accordance with the provisions of laws and regulations;

b. does not originate from prohibited materials in accordance with Islamic sharia and the provisions of laws and regulations;

c. not produced from production facilities which are also used to manufacture non-halal products;

d. must not be mixed with and/or come into contact with any prohibited materials in accordance with Islamic sharia and the provisions of laws and regulations;

e. animal materials and their derivative products must be sourced from halal animals slaughtered in accordance with Islamic sharia, except for halal animals which according to Islamic sharia do not need to be slaughtered;

f. must meet the security and health aspects in accordance with the provisions of laws and regulations; and

g. materials in the form of alcohol/ethanol may be used as long as the alcohol/ethanol in question does not originate from the khamr industry which is medically harmless and is not misused.

Article 7

(1) The process as referred to in Article 4 paragraph (4) letter c which is required to be prepared by Business Actors consists of:

a. separate place and equipment from non-halal product processing facilities and equipment; and

b. written and documented procedures.

(2) Separate place and equipment from non-halal product processing facilities and equipment as referred to in paragraph (1) letter a and written and documented procedures as referred to in paragraph (1) letter b shall include places, equipment and devices for:

a. processing;

b. storage; and

c. packaging.

(3) Production facilities used to produce Halal Products may be used in conjunction with production facilities used to produce products that are not submitted for halal certification.

(4) Products which are not submitted for halal certification as referred to in paragraph (3) shall be in the form of products which are not derived from materials containing prohibited materials.

(5) Business Actors who use production facilities used to produce Halal Products which are used in conjunction with production facilities used to produce products that are not submitted for halal certification as referred to in paragraph (3) must submit the following documents:

a. product name;

b. list of products and materials used;

c. product processing; and

d. sanctification or tannery in production facilities that are used jointly.

Article 8

In addition to fulfilling the provisions as referred to in Article 7, drugs, Biological Products, and Medical Equipment which are submitted for halal certification must also fulfill:

a. requirements of safety, expediency/efficacy, and quality as proven by distribution license in accordance with the provisions of laws and regulations; and

b. good manufacturing practices in accordance with the provisions of laws and regulations.

Article 9

(1) Products as referred to in Article 4 paragraph (4) letter d shall be:

a. sourced from halal materials, processed in accordance with Islamic sharia, using equipment, production facilities, packaging systems, and storage that are not contaminated with non-halal materials;

b. must not use any names which refer to prohibited products or contain pornography, as well as not possess any sensory characteristics/profiles which refer to prohibited products or which have been declared prohibited based on the fatwa of the Indonesian Ulema Council;

c. its packaging and labeling shall ensure the halal status and quality of packaging materials used with non-misleading packaging designs, signs, symbols, logos, names and pictures;

d. packaged and labeled without violating Islamic sharia principles; and

e. clearly identified and traceable and the fulfillment of halal manufacturing method is guaranteed.

(2) The provisions as referred to in paragraph (1) letter b and letter d are only for over-the-counter drugs, limited non-prescription drugs, traditional medicines, health supplements, quasi-drugs, and Medical Equipment for which the use does not require the assistance of health workers.

Article 10

(1) The monitoring and evaluation as referred to in Article 4 paragraph (4) letter e shall be an internal audit procedure and management review which are prepared, implemented, documented, maintained, and reported by Business Actors to the Halal Product Assurance Agency.

(2) The monitoring and evaluation as referred to in paragraph (1) shall be conducted in order to fulfill the requirements for the submission of halal certification.

Article 11

(1) Further provisions on the guidelines of halal manufacturing practices for drugs, Biological Products, and Medical Equipment as referred to in Article 4 to Article 10 shall be regulated by a Regulation of the Minister.

(2) The Regulation of the Minister as referred to in paragraph (1) shall be drawn up in coordination with the relevant ministries/agencies.

Article 12

(1) Mandatory halal certification for drugs, Biological Products, and Medical Equipment which do not yet have Halal Certificates shall be conducted in phases.

(2) The phasing of the mandatory halal certification as referred to in paragraph (1) is conducted by taking into account the availability of product constituent materials and/or halal manufacturing practices have not been discovered.

Article 13

(1) The phasing of the mandatory halal certification for drugs as referred to in Article 12 paragraph (1) is conducted in accordance with the provisions of laws and regulations.

(2) The phasing of the mandatory halal certification for Biological Products as referred to in Article 12 paragraph (1) shall be conducted until 17 October 2039.

(3) The phasing of the mandatory halal certification for Medical Equipment as referred to in Article 12 paragraph (1) shall be differentiated based on the risk class which includes:

a. class-A risk;

b. class-B risk;

c. class-C risk; and

d. class-D risk.

(4) The division of risk classes as referred to in paragraph (3) shall be in accordance with the provisions of laws and regulations.

(5) The phasing of mandatory halal certification for class-A risk to class-C risk Medical Equipment as referred to in paragraph (3) letter a to letter c shall be conducted in accordance with the provisions of laws and regulations.

(6) The phasing of mandatory halal certification for class-D risk Medical Equipment as referred to in paragraph (3) letter d shall be conducted until 17 October 2039.

Article 14

(1) Drugs, Biological Products, and Medical Equipment originating from prohibited materials may be circulated and traded within Indonesian territory provided that Non-Halal Information is mandatory to be included.

(2) Inclusion of the Non-Halal Information as referred to in paragraph (1) for drugs and Biological Products take the form of the name of the material with a different color in the product composition.

(3) Inclusion of Non-Halal Information as referred to in paragraph (1) for Medical Equipment take in the form of name of the material with different color on the product marking.

Article 15

(1) Drugs, Biological Products, and Medical Equipment which materials are not yet sourced from halal materials and/or the manufacturing practices are not yet halal may be circulated by including information on the origin of materials until the halal materials and/or halal manufacturing practices are discovered.

(2) Information on the origin of materials as referred to in paragraph (1) for drugs and Biological Products for which materials have not been sourced from halal materials shall be Non-Halal Information in the form of the name of the material with different colors in the product composition.

(3) Information on the origin of materials as referred to in paragraph (1) for Medical Equipment for which materials have not been sourced from halal materials shall be Non-Halal Information in the form of material names with different colors on the product marking.

(4) The information on the origin of materials as referred to in paragraph (1) for those with halal materials but the manufacturing practices is not yet halal shall be a Non-Halal Information in the form of the writing “made from halal material and in an effort to fulfill the halal process” which is included on the product

marking.

(5) Provisions regarding the inclusion of information on the origin of materials as referred to in paragraph (1) for drugs and Biological Products shall be regulated by a regulation of the agency that organizes government affairs in the drug and food supervision sector.

(6) Provisions on the inclusion of information on the origin of materials as referred to in paragraph (1) for Medical Equipment shall be regulated by a Regulation of the Minister.

Article 16

(1) Provisions on the inclusion of Non-Halal Information for drugs, Biological Products, and Medical Equipment are based on statements by Business Actors.

(2) The statement of Business Actors as referred to in paragraph (1) must be proven with supporting documents.

Article 17

The Central Government shall conduct guidance and supervision on the organization of Halal Product guarantees for drugs, Biological Products and Medical Equipment.

Article 18

(1) Drugs, Biological Products, and Medical Equipment which have not been certified halal as of 17 October 2021 may still enter, circulate and be traded within Indonesian territory in accordance with the phase of the types of products that are required to be certified halal.

(2) Drugs, Biological Products, and Medical Equipment that enter, circulate, and are traded as referred to in paragraph (1) shall have licenses in accordance with the provisions of laws and regulations.

Article 19

Applications for halal certification submitted by micro- and small-scale Business Actors for traditional medicines and Medical Equipment shall refer to the provisions on halal standards established by the Halal Product Assurance Agency in accordance with the provisions of laws and regulations in the organization of Halal Product guarantees.

Article 20

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

For public cognizance, it is hereby ordered that this Regulation of the President be promulgated in the State Gazette of the Republic of Indonesia.

Established in Jakarta,

On 19 January 2023

THE PRESIDENT OF THE REPUBLIC OF INDONESIA,

Signed.

JOKO WIDODO

Promulgated in Jakarta,

On 19 January 2023

THE MINISTER OF STATE SECRETARY OF THE REPUBLIC OF INDONESIA,

Signed.

PRATIKNO

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2023 NUMBER 14