

**MINISTER OF HEALTH
OF THE REPUBLIC OF INDONESIA**

REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA
NUMBER 10 OF 2021
REGARDING
IMPLEMENTATION OF VACCINATION IN THE CONTEXT OF THE CORONA VIRUS
DISEASE 2019 (COVID-19) PANDEMIC MANAGEMENT

WITH THE GRACE OF GOD ALMIGHTY

MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

- Considering :
- a. whereas the Minister of Health Regulation Number 84 of 2020 regarding Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Management is no longer relevant with the development and legal needs for the implementation of vaccination for the Corona Virus Disease 2019 (COVID-19) and therefore requires revision;
 - b. whereas based on the considerations as referred to in letter a and to implement the provision of Article 16 of President Regulation Number 99 of 2020 regarding Procurement of Vaccines and Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management as amended by President Regulation Number 14 of 2021 regarding Amendment of the President Regulation Number 99 of 2020 regarding Procurement of Vaccines and Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management, it is necessary to stipulate the Minister of Health Regulation regarding Implementation of Vaccination in the Context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management;
- Bearing in Mind :
- 1. Article 17 paragraph (3) of the 1945 Constitution of the Republic of Indonesia;

2. Law Number 4 of 1984 regarding Outbreak of Communicable Diseases (State Gazette of the Republic of Indonesia of 1984 Number 20, Supplement to State Gazette of the Republic of Indonesia Number 3273);
3. Law Number 39 of 2008 regarding State Ministries (State Gazette of the Republic of Indonesia of 2008 Number 166, Supplement to the State Gazette of the Republic of Indonesia Number 4916);
4. Law Number 36 of 2009 regarding Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to State Gazette of the Republic of Indonesia Number 5063);
5. Law Number 6 of 2018 on Health Quarantine (State Gazette of the Republic of Indonesia of 2018 Number 128, Supplement to the State Gazette of the Republic of Indonesia Number 6236);
6. Law Number 2 of 2020 regarding Stipulation of Government Regulation in Lieu of Law Number 1 of 2020 regarding State Finance Policy and Financial System Stability for the Handling of the Corona Virus Disease 2019 (COVID-19) Pandemic and/or In the Context of Encountering Threats that are Dangerous for the National Economy and/or Financial System Stability to become Law (State Gazette of the Republic of Indonesia of 2020 Number 134, Supplement to the State Gazette of the Republic of Indonesia Number 6516);
7. President Regulation Number 35 of 2015 regarding Ministry of Health (State Gazette of the Republic of Indonesia of 2015 Number 59);
8. President Regulation Number 99 of 2020 regarding Procurement of Vaccine and Implementation of Vaccination in the Context of the Corona Virus Disease 2019 (COVID-19) Management (State Gazette of the Republic of Indonesia of 2020 Number 227) as amended by President Regulation Number 14 of 2021 regarding Amendment of President Regulation Number 99 of 2020 regarding Procurement of Vaccine and Implementation of Vaccination in the Context of the Corona Virus Disease 2019 (COVID-19) Management (State Gazette of the Republic of Indonesia of 2021 Number 66);

9. Minister of Health Regulation Number 25 of 2020 on Organization and Working Procedure of the Ministry of Health (State Gazette of the Republic of Indonesia of 2020 Number 1146);
10. Minister of Health Regulation Number 28 of 2020 regarding Implementation of Vaccine Procurement in the Context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management (State Gazette of the Republic of Indonesia of 2020 Number 1229) as amended several times by Minister of Health Regulation Number 79 of 2020 regarding Amendment of the Minister of Health Regulation Number 28 of 2020 regarding Implementation of Vaccine Procurement in the Context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management (State Gazette of the Republic of Indonesia of 2020 Number 1266);

HAS DECIDED:

To Stipulate : REGULATION OF THE MINISTER OF HEALTH REGARDING IMPLEMENTATION OF VACCINATION IN THE CONTEXT OF THE CORONA VIRUS DISEASE 2019 (COVID-19) PANDEMIC MANAGEMENT

CHAPTER I GENERAL PROVISIONS

Article 1

In this Minister Regulation, what is meant by:

1. Vaccine is a biological product containing antigen in the form of dead or weakened live microorganisms, intact or in part, or in the form of microorganism toxin that has been processed into toxoid or recombinant protein, which are added with other substances, which when is given to someone will give specific active immunity against certain diseases.
2. Corona Virus Disease 2019 which will be referred as COVID-19 is a contagious

disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV-2).

3. Vaccination is the provision of Vaccine that is specifically given to create or increase a person's immunity in an active manner against a disease, so that they will not be sick or only experience mild illness and will not become a source of infection if they are someday exposed to such disease.
4. Program Vaccination is the implementation of Vaccination for the public in which its funding is borne or charged to the government.
5. Mutual Cooperation Vaccination is the implementation of Vaccination for employees, families, and other related individuals in a family in which its funding is borne or charged to a legal entity/business entity.
6. Health Service Facility is a tool and/or place used to carry out health service efforts, whether promotive, preventive, curative, or rehabilitative, which is carried out by the Government, Regional Government, and/or the public.
7. Adverse Event Following COVID-19 Vaccination is a medical event that is presumed to be related to a COVID-19 vaccination.
8. One Data COVID-19 Vaccination Information System is the information system formed to support the Vaccination process starting from the preparation, implementation, reporting, monitoring, and evaluation by utilizing integrated information technology.
9. Central Government is the President of Republic of Indonesia who holds governmental power of the Republic of Indonesia assisted by the Vice President and ministers as referred to in the 1945 Constitution of the Republic of Indonesia.
10. Regional Government is the head of region as the Regional Government's element who leads the implementation of governmental affairs which shall be the authority of the autonomous region.
11. Minister is the minister who carries out governmental affairs in the health sector.
12. Director General is the director general at the Ministry of Health who holds the tasks and responsibilities in the sector of disease prevention and management.

Article 2

This Minister Regulation shall be a guidance for the Central Government, Regional Government, provincial Regional Government, regency/city Regional Government, health workers, stakeholders, and the public in the implementation of COVID-19 Vaccination.

Article 3

- (1) Implementation of COVID-19 Vaccination shall be conducted by the Central Government.
- (2) The Central Government in implementing the COVID-19 Vaccination, shall involve the provincial Regional Government and regency/city Regional Government as well as the legal entities/business entities.
- (3) Implementation of COVID-19 Vaccination as referred to in paragraph (1) and paragraph (2) shall be conducted through the Program Vaccination or Mutual Cooperation Vaccination.
- (4) Vaccine recipients in the Program Vaccination service as referred to in paragraph (3) shall not be charged of fees/shall be free.
- (5) Employees, families, and other related individuals in a family as the recipients of COVID-19 Vaccine in the Mutual Cooperation Vaccination service as referred to in paragraph (3) shall not be charged of fees/shall be free.

Article 4

The implementation of COVID-19 Vaccine aims to:

- a. reduce the transmission/spread of COVID-19;
- b. decrease the number of illnesses and deaths caused by COVID-19;
- c. achieve herd immunity; and
- d. protect the public from COVID-19 in order to maintain productivity in a social and economic manner.

Article 5

The scope regulation of implementing Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) pandemic management, shall include:

- a. planning of COVID-19 Vaccination necessities;
- b. target of the COVID-19 Vaccination implementation;
- c. distribution of COVID-19 Vaccinations, supporting equipment, and logistics;
- d. implementation of COVID-19 Vaccination service;
- e. cooperation in COVID-19 Vaccination implementation;
- f. monitoring and managing the Adverse Event Following COVID-19 Vaccination;
- g. communication strategy;
- h. recording and reporting;
- i. funding; and
- j. guidance and supervision.

CHAPTER II PLANNING OF COVID-19 VACCINATION NECESSITIES

Part One General

Article 6

- (1) In the context of COVID-19 Vaccination implementation, arrangement of plan of Vaccination necessities based on the number of targets for either the Program Vaccination or the Mutual Cooperation Vaccination shall be prepared.
- (2) In the context of arranging the plan of COVID-19 Vaccination necessities as referred to in paragraph (1), the legal entity/business entity shall report the number of employees, families, and other related individuals within a family that will participate in the Mutual Cooperation Vaccination to the Minister.
- (3) The report as referred to in paragraph (2) shall contain at least the number of people, by name and by address, as well as the identification number.
- (4) The plan of Vaccination necessities as referred to in paragraph (1) shall be stipulated by a Minister Decree.
- (5) The plan of Vaccination necessities as referred to in paragraph (1) shall be arranged based on the developments of disease epidemiology and considerations

from the Committee of the Corona Virus Disease 2019 (COVID-19) Handling and National Economic Recovery.

- (6) The plan of Vaccination necessities as referred to in paragraph (1) and paragraph (4) shall be the guidance in procuring of COVID-19 Vaccines, supporting equipment, and logistics as necessary for the implementation of either Program Vaccination or Mutual Cooperation Vaccinations.
- (7) Procurement of COVID-19 Vaccine either for Program Vaccination or Mutual Cooperation Vaccination as referred to in paragraph (6) shall be implemented in accordance with the provisions of the laws and regulations regarding the procurement of COVID-19 Vaccines.

Part Two Types of COVID-19 Vaccines

Article 7

- (1) The types of COVID-19 Vaccines shall be stipulated with a Minister Decree shall be in accordance with the provisions of laws and regulations.
- (2) The types of COVID-19 Vaccines as referred to in paragraph (1) shall be used to determine the plan of COVID-19 Vaccination necessities as referred to in Article 6.
- (3) The types of COVID-19 Vaccines as referred to in paragraph (1) for COVID-19 Vaccination must already obtain the emergency use authorization, or issuance of the distribution license number (*nomor izin edar* or NIE) from the National Agency of Food and Drugs in accordance with the provisions of the laws and regulations.
- (4) The types of COVID-19 Vaccines for the implementation of Mutual Cooperation Vaccination shall be different from the types of COVID-19 Vaccines used for the Program Vaccination.

CHAPTER III
TARGET OF THE COVID-19 VACCINATION IMPLEMENTATION

Part One
Criteria and Priority of COVID-19 Vaccine Recipients

Article 8

- (1) Implementation of COVID-19 Vaccination shall be carried out gradually in accordance with the availability of COVID-19 Vaccines.
- (2) In implementing the COVID-19 Vaccination as referred to in paragraph (1), the criteria for the COVID-19 Vaccine recipient shall be in accordance with the Vaccine indication that is available and assessment from the Indonesian Technical Advisory Group on Immunization and/or Strategic Advisory Group of Experts on Immunization of the World Health Organization (SAGE WHO).
- (3) Based on the availability of COVID-19 Vaccines as referred to in paragraph (1), the stipulated priority group of COVID-19 Vaccine recipients, shall be as follows:
 - a. health workers, assistant of health workers, and supporting staff working at Health Service Facilities;
 - b. elderly communities and public service staff/worker;
 - c. vulnerable communities from geospatial, social, and economic aspects; and
 - d. other communities.
- (4) Based on the criteria of COVID-19 Vaccine recipients as referred to in paragraph (2), the Minister may alter the priority of COVID-19 Vaccine recipients as referred to in paragraph (3) after considering the recommendations from the Indonesian Technical Advisory Group on Immunization and considerations from the Committee of the Corona Virus Disease 2019 (COVID-19) Handling and National Economic Recovery.
- (5) Each person can only sign up to one of the priority groups of the COVID-19 Vaccine recipients as referred to in paragraph (3).

Article 9

- (1) The implementation of COVID-19 Vaccination towards prioritized groups of COVID-19 Vaccine recipients as referred to in Article 8 paragraph (3) shall be conducted through the Program Vaccination.

- (2) Other than the Program Vaccination as referred to in paragraph (1), the implementation of COVID-19 Vaccination may be conducted through the Mutual Cooperation Vaccination.

Article 10

Representatives of foreign states and non-profit international organizations that are currently stationed in Indonesia may participate in the implementation of Program Vaccination or Mutual Cooperation Vaccination.

Part Two

Priority Areas of COVID-19 Vaccine Recipients

Article 11

- (1) Based on the availability of COVID-19 Vaccines, the Minister shall determine the priority areas of COVID-19 Vaccines recipients.
- (2) The priority areas of COVID-19 Vaccines recipients as referred to in paragraph (1) consists of provinces/regencies/cities with a high amount of confirmed COVID-19 cases and provinces/regencies/cities with special considerations.
- (3) Provinces/regencies/cities areas as referred to in paragraph (2) shall be determined based on the data of cases contained in the COVID-19 information system in accordance with the provisions of laws and regulations.

Part Three

Data Collection of Targets

Article 12

Based on the criteria and the priority group of COVID-19 Vaccine recipients as referred to in Article 8 and the priority areas of COVID-19 Vaccine recipients as referred to in Article 11, the Minister shall determine the number of COVID-19 Vaccines target recipients.

Article 13

- (1) In order to determine the number of COVID-19 Vaccine target recipients as referred to in Article 12, the data collection of COVID-19 Vaccine target recipients for either the Program Vaccination or Mutual Cooperation Vaccination shall be carried out.
- (2) The data collection of targets as referred to in paragraph (1) shall be conducted through the arrangement of COVID-19 Vaccination planning.

- (3) The result of the data collection of COVID-19 Vaccine target recipients as referred to in paragraph (1) shall be contained in the One Data COVID-19 Vaccination Information System.
- (4) The data of targets in the information system as referred to in paragraph (3) shall be arranged based on the criteria of COVID-19 Vaccine recipients and the willingness of the target in the provision of COVID-19 Vaccine, which shall be contained by name and by address, as well as the identification number.

Article 14

Each person that is determined as COVID-19 Vaccine target recipient based on the data collection as referred to in Article 13 must participate in the COVID-19 Vaccination in accordance with the provisions of laws and regulations.

CHAPTER IV DISTRIBUTION OF COVID-19 VACCINES, SUPPORTING EQUIPMENT, AND LOGISTICS

Part One General

Article 15

- (1) The distribution of COVID-19 Vaccines that is necessary for the implementation of COVID-19 Vaccination shall be conducted and managed in accordance with the proper drug distribution methods.
- (2) The distribution of supporting equipment and logistics necessary for implementing COVID-19 Vaccinations must be carried out in accordance with the proper medical device distribution methods or other standards to ensure quality.
- (3) The distribution as referred to in paragraphs (1) and (2) shall be conducted in accordance with the provisions of laws and regulations.

Part Two Implementation of Distribution

Article 16

- (1) The Central Government and Regional Government shall be responsible for the distribution of COVID-19 Vaccines, supporting equipment, and logistics that are necessary for the implementation of Program Vaccination.

- (2) The distribution of COVID-19 Vaccines, supporting equipment, and logistics as referred to in paragraph (1) shall be conducted in stages from the Central Government, provincial Regional Government, and regency/city Regional Government.

Article 17

- (1) The Central Government is responsible for the distribution of COVID-19 Vaccines, supporting equipment, and logistics that are required for the implementation of COVID-19 Vaccinations to the provincial regions.
- (2) The implementation of the distribution of COVID-19 Vaccines, supporting equipment, and logistics as referred to in paragraph (1) may be conducted through PT Bio Farma (Persero) or direct appointment of a business entity by the Central Government in accordance with provisions of laws and regulations regarding COVID-19 Vaccine procurement.
- (3) The distribution of supporting equipment and logistics as referred to in paragraph (2) shall be exempted with respect to the procurement that is conducted through electronic catalogue (e-catalog).
- (4) The Provincial Regional Government shall be responsible for the distribution of COVID-19 Vaccines to the regency/city area in their territory.
- (5) The Regency/city Regional Government shall be responsible for the distribution of COVID-19 Vaccines to the Health Service Facility in their territory.
- (6) The distribution of COVID-19 Vaccines by provincial Regional Government and regency/city Regional Government as referred to in paragraph (4) and paragraph (5) shall be conducted in accordance to the provisions of laws and regulations.
- (7) If unavailability or shortage of COVID-19 Vaccine in certain area occurs, the Minister can relocate COVID-19 Vaccines from another area.
- (8) In relocating COVID-19 Vaccine as referred to in paragraph (7), the Minister shall coordinate with provincial Regional Government or regency/city Regional Government.

Article 18

- (1) In order to accelerate the implementation of Vaccination, maintain safety, quality, and efficacy of the Vaccine, the Minister may distribute COVID-19 Vaccines to:

- a. regency/city area, or
 - b. Health Service Facility or COVID-19 Vaccination service posts.
- (2) The implementation of the distribution of COVID-19 Vaccines as referred to in paragraph (1) may be conducted through PT Bio Farma (Persero) or direct appointment of a business entity by the Minister in accordance with the provisions of the laws and regulations regarding COVID-19 Vaccine procurement.
 - (3) In conducting the distribution of COVID-19 Vaccines as referred to in paragraph (1), PT Bio Farma (Persero) may cooperate with third parties.
 - (4) If the distribution of COVID-19 Vaccines reaches the regency/city areas as referred to in paragraph (1) letter a, the regency/city Regional Government is responsible for distributing COVID-19 Vaccines to Health Service Facility or COVID-19 Vaccination service posts in their territory.
 - (5) In distributing COVID-19 Vaccines as referred to in paragraph (1), the Minister shall coordinate with the provincial health service office and district health service office.
 - (6) In distributing COVID-19 Vaccines to Health Service Facility and COVID-19 Vaccination service posts, PT Bio Farma (Persero) or a business entity shall coordinate with the Ministry of Health, provincial health service office and district health service office.

Article 19

- (1) The distribution of COVID-19 Vaccines for Mutual Cooperation Vaccination shall be carried out by PT Bio Farma (Persero) to public/private Health Service Facility that is in cooperation with legal /business entities.
- (2) In distributing COVID-19 Vaccines for Mutual Cooperation Vaccination as referred to in paragraph (1), PT Bio Farma (Persero) may cooperate with third parties.
- (3) The amount of COVID-19 Vaccines distributed as referred to in paragraph (1) must be in accordance to the legal /business entity's needs for COVID-19 Vaccine.

CHAPTER V
IMPLEMENTATION OF COVID-19 VACCINATION SERVICE

Part One
Schedule and Stages of COVID-19 Vaccine Administration

Article 20

- (1) Schedule and stages of COVID-19 Vaccine provision for the Program Vaccination shall be determined based on the availability of COVID-19 Vaccine, priority groups of COVID-19 Vaccine recipients, and the type of COVID-19 Vaccine.
- (2) The determination of schedule and stages of COVID-19 Vaccine as referred to in paragraph (1) shall be conducted based on recommendations from the Indonesian Technical Advisory Group on Immunization and considerations from the Committee of the Corona Virus Disease 2019 (COVID-2019) Handling and National Economic Recovery.
- (3) Schedule and stages for COVID-19 Vaccine provision as referred to in paragraph (1) and paragraph (2) shall be determined by the Minister.

Part Two
Standard of COVID-19 Vaccination Service

Paragraph 1
Organizer of COVID-19 Vaccination Service

Article 21

- (1) Program Vaccination service shall be carried out in a Health Service Facility owned by the Central Government, Regional Government, or public/private parties that fulfils the criteria.
- (2) Health Service Facility as referred to in paragraph (1) shall be in the form of:
 - a. Sub District Health Centre (hereinafter shall be referred to as “Puskesmas”) or auxiliary Puskesmas;
 - b. clinics;
 - c. hospitals; and/or
 - d. local health units in Port Health Office.

- (3) In addition to implementing Program Vaccination at the Health Service Facility as referred to in paragraph (2), Program Vaccination services may also be conducted at COVID-19 Vaccination service posts.
- (4) Health Service Facility and COVID-19 Vaccination service posts as referred to in paragraph (2) and paragraph (3) must cooperate/coordinate with Puskesmas, provincial health service office and/or district health service office in providing the Program Vaccination service.

Article 22

- (1) The Mutual Cooperation Vaccination service may only be conducted at a public/private Health Service Facility that fulfils the requirements.
- (2) Health Service Facility as referred to in paragraph (1) shall not be a place for Program Vaccination service.
- (3) The implementation of Mutual Cooperation Vaccination as referred to in paragraph (1) shall be conducted through cooperation between legal entity/business entity with public/private-owned Health Service Facility.
- (4) For legal entity/business entity that owns a Health Service Facility that fulfils the requirements, then the Mutual Cooperation Vaccination service may be held at the relevant Health Service Facility.
- (5) In conducting the Mutual Cooperation Vaccination service, Health Service Facility as referred to in paragraph (1) and paragraph (4) must coordinate with the district/city health service office.

Article 23

- (1) The maximum tariff for the Mutual Cooperation Vaccination service shall be determined by the Minister.
- (2) The cost of the Mutual Cooperation Vaccination service conducted by a public/private-owned Health Service Facility must not exceed the amount determined by the Minister as referred to in paragraph (1).

Article 24

The requirements for Health Service Facility as mentioned to in Article 21 and Article 22 shall be as follows:

- a. have health workers to implement COVID-19 Vaccination;
- b. have a cold chain facility which must be in accordance with the types of COVID-19 Vaccines used or in accordance with the provisions of laws and regulations; and
- c. have an operational permit for Health Service Facility or a determination by the Minister in accordance with the provisions of laws and regulations.

Article 25

In the context of implementing the Program Vaccination, the district/city health service office and provincial health service office shall conduct data collection and determination of Health Service Facility that performs Program Vaccination, as well as determining the distribution of COVID-19 Vaccines, supporting equipment, and logistics in implementing COVID-19 Vaccination.

Article 26

- (1) The implementation of Program Vaccination for the priority group of COVID-19 Vaccine recipients, as referred to in Article 8 paragraph (3), shall be conducted at the Health Service Facility that has been determined by the district health service office based on the results of the data collection and determination of Health Service Facility as referred to in Article 25.
- (2) If the Health Service Facility is unable to fulfill the necessities in respect to the Program Vaccination services as referred to in paragraph (1) and/or does not fulfill the necessary prerequisites, the district health service office and Puskesmas may establish COVID-19 Vaccination service posts as referred to in Article 21 paragraph (3).

Article 27

The data collection and determination results of the Health Service Facility that performs COVID-19 Vaccination as referred to in Article 25, shall be compiled in the One Data COVID-19 Vaccination Information System.

Article 28

- (1) In conducting COVID-19 Vaccination, the Health Service Facility as referred to in Article 21 and Article 22, shall form an implementation team that has the following functions:
 - a. registrations/verification;

- b. screenings (*anamnesis*), physical examination and providing education and approval of medical action;
 - c. preparing and providing COVID-19 Vaccine;
 - d. conducting post observation after COVID-19 Vaccination, providing a mark of COVID-19 Vaccination completion, and providing a COVID-19 Vaccination certification;
 - e. conducting data collection and inputting data with respect to COVID-19 Vaccination results;
 - f. conducting management of medical waste; and/or
 - g. managing the workflow of COVID-19 Vaccination services.
- (2) In implementing COVID-19 Vaccination services as referred to in paragraph (1), the implementation team shall apply the disease prevention and control principles or health protocols for COVID-19 prevention and handling in accordance with the provisions of laws and regulations.

Article 29

- (1) The provision of COVID-19 Vaccines shall be conducted by authorized doctors, nurses or midwife, who have competence and authority in accordance with the provisions of laws and regulations.
- (2) In the event that the provision of COVID-19 Vaccines is conducted by a midwife or nurse as referred to in paragraph (1), the provision of COVID-19 Vaccines must be conducted under the supervision of a doctor in accordance with the provisions of laws and regulations.

Part 2

Facilities and Infrastructures, Supporting Equipment, and Logistics

Article 30

- (1) Facilities and infrastructures with respect to the implementation of COVID-19 Vaccination shall include warehouse and COVID-19 Vaccine cold chain facility as well as supporting equipment and logistics.
- (2) Warehouses and COVID-19 Vaccine cold chain facilities as referred to in paragraph (1) must have a proper drug distribution certificate or a proper governmental pharmacy installation.
- (3) The supporting equipment and logistics as referred to in paragraph (1) must at least include syringes, alcohol swabs, personal protective equipment (face shields,

hazmat suits, gloves and surgical masks), cold chain, backup power source (genset), safety boxes and alcohol-based antiseptic fluids.

- (4) In addition to the supporting equipment and logistics as referred to in paragraph (3), the implementation of COVID-19 Vaccination must be supported through the provision of hand washing facilities and basic fire safety equipment.

Part 3 Service Administration

Article 31

The administration of Program Vaccination and the Mutual Cooperation Vaccination shall refer to the standard of service, and standard operating procedures that have been determined by the respective head of the Health Service Facility, in accordance with the Vaccination technical guidelines.

Article 32

- (1) Every person who has been given COVID-19 Vaccine shall be given a Program Vaccination statement letter or a Mutual Cooperation statement letter in the form of COVID-19 Vaccination card or an electronic certificate.
- (2) If required by a traveler, the COVID-19 Vaccine statement letter shall be incorporated in an International Certificate of Vaccination (ICV).

CHAPTER VI COOPERATION IN COVID-19 VACCINATION IMPLEMENTATION

Article 33

- (1) In implementing COVID-19 Vaccination, the Ministry of Health may cooperate with other ministries/institutions, provincial Regional Government, regency/city Regional Government, State-owned enterprises or private business entities, professional/social organizations as well as other parties as deemed necessary.
- (2) Other parties as referred to in paragraph (1) shall include the Indonesian National Army/National Police of Republic of Indonesia and international institutions/agencies related to the health sector.

- (3) In implementing COVID-19 Vaccination, the provincial Regional Government and regency/city Regional Government may cooperate with state/regional owned enterprises or private business entity, professional/social organizations, Indonesian National Army/National Police of Republic of Indonesia, and other relevant parties deemed necessary.
- (4) The cooperation between the provincial Regional Government and regency/city Regional Government as referred to in paragraph (3) shall be implemented after coordinating with the Ministry of Health.
- (5) Cooperation as referred to in paragraph (1) and paragraph (2) shall include:
 - a. support in providing medical workers;
 - b. COVID-19 Vaccination places;
 - c. Logistics/transportation;
 - d. COVID-19 Vaccine Warehouse and storage including stock piling;
 - e. security; and/or
 - f. socialization and community mobilization.
- (6) In addition to the scope of cooperation as referred to in paragraph (5), cooperation may also be carried out in regard to the provision of non-health personnel and medical waste management.
- (7) The cooperation as referred to in paragraph (1) until paragraph (6) shall be performed in accordance with the provision of laws and regulations.

Article 34

- (1) In order to thoroughly and continuously implement COVID-19 Vaccination service, the implementation of COVID-19 Vaccination shall be coordinated by:
 - a. Minister in the Central Government level;
 - b. governor in the provincial level; and
 - c. regent/mayor in the regency/city level.
- (2) The Minister, governor and regent/mayor shall coordinate the implementation of COVID-19 Vaccination in the following stages:
 - a. planning;
 - b. implementation; and
 - c. monitoring and evaluation.
- (3) The planning stage as referred to in paragraph (2) letter a shall include mapping of targets, availability of the implementing personnel, Health Service Facility,

implementing schedule, quantity, types of COVID-19 Vaccines, and other logistical needs.

- (4) The implementation stage as referred to in paragraph (2) letter b shall include the confirmation on the availability of the implementing personnel, places, COVID-19 Vaccine, standard operating procedures, cold chain facility, logistics management, personal protective equipment, waste management, and administration and reporting.
- (5) The monitoring and evaluation as referred to in paragraph (2) letter c shall include monitoring and evaluation which will be conducted starting from the planning, implementation, and post-implementation, including surveillance of an Adverse Event Following COVID-19 Vaccination.
- (6) The stages as referred to in paragraph (2) shall be conducted through the utilization of the One Data COVID-19 Vaccination Information System.

CHAPTER VII MONITORING AND MANAGING THE ADVERSE EVENT FOLLOWING COVID-19 VACCINATION

Article 35

- (1) If an Adverse Event Following COVID-19 Vaccination occurs in a person who has gotten the COVID-19 Vaccine, the Health Service Facility or health service offices shall record and report as well as investigate the same in accordance with the provisions of laws and regulations.
- (2) Based on the record and report results as well as investigation as referred to in paragraph (1), a field etiology assessment shall be conducted by the Regional Committee for Assessment and Management of an Adverse Event Following Immunization and causality assessment shall be conducted by the National Committee for the Assessment and Management of an Adverse Event Following Immunization in accordance with the provisions of laws and regulations.
- (3) In the event that the causality assesment results prepared by the National Committee for the Assessment and Management of an Adverse Event Following Immunization as referred to in paragraph (2) there are allegation of being influenced by COVID-19 Vaccine products, National Food and Drug Agency shall conduct sampling and testing in accordance with the provisions of laws and regulations.

Article 36

- (1) If an Adverse Event Following COVID-19 Vaccination as referred to in Article 35 requires medical care and treatment, then health services shall be conducted in accordance with the relevant medical indications and treatment protocols.
- (2) The funding for the medical services related to the medical indications and treatment protocols as referred to in paragraph (1) shall be conducted as follows:
 - a. For active participants of the National Health Insurance Program, shall be charged through the National Health Insurance mechanism with class III of health services; and
 - b. For non-active participants of the National Health Insurance Program and non-participants of the National Health Insurance program, their payments shall be funded through other financing mechanisms derived from the state revenues and expenditures budget which shall be implemented in accordance with the provisions of laws and regulations in the field of state finance.
- (3) The health services for active participants of the National Health Insurance Program as referred to in paragraph (2) letter a shall be conducted in the Health Service Facility that cooperates with the Social Security Administration for Health (*Badan Penyelenggara Jaminan Sosial Kesehatan*).
- (4) Excluded from the provisions as referred to in paragraph (3), shall be the health services for active participants of the National Health Insurance Program in emergency situation which may be performed in all Health Service Facility in accordance with the provisions of laws and regulations.
- (5) The health services as referred to in paragraph (2) letter b for non-active participants of the National Health Insurance Program and non-participants of the National Health Insurance Program shall be covered through other funding mechanisms derived from the Ministry of Health's budget.
- (6) The health services for non-active participants of the National Health Insurance Program and non-participants of the National Health Insurance program as referred to in paragraph (2) letter b shall be given equivalent to class III of health services of the National Health Insurance Program.
- (7) Claims by non-active participants of the National Health Insurance Program and non-participants of the National Health Insurance Program for any health services as referred to in paragraph (6) shall be conducted through a claim mechanism by

referring to COVID-19 patients reimbursement technical guidelines for hospitals that provide COVID-19 services in accordance with the provisions of laws and regulations.

Article 37

- (1) If an Adverse Event Following COVID-19 Vaccination occurs that is influenced by COVID-19 Vaccine products based on causality assessment results as referred to in Article 35 paragraph (3), and such event results in disability or death, the Government shall provide a compensation.
- (2) The compensation as referred to in paragraph (1) shall be in the form of disability compensation or death compensation.

Article 38

- (1) The disability as referred to in Article 37 is a state of diminishment or loss of limbs, or loss of bodily functions that directly results in a reduction or loss of the ability to carry out work for at least 6 (six) months.
- (2) The disability as referred to in paragraph (1) shall be based on the risk level which consists of:
 - a. severe disability;
 - b. moderate disability; or
 - c. mild disability.
- (3) Severe disability as referred to in paragraph (2) letter a shall include:
 - a. loss of both lower limbs;
 - b. paralysis of both lower limbs;
 - c. loss of both upper limbs;
 - d. paralysis of both upper limbs;
 - e. paralysis of 1 (one) lower limb and 1 (one) upper limb;
 - f. loss of 1 (one) lower limb and 1 (one) upper limb;
 - g. loss of vision of both eyes;
 - h. mute and deaf;
 - i. permanent severe mental illness; or
 - j. extensive defects of the nervous system, respiratory, cardiovascular, digestive, or urogenital organs.
- (4) Moderate disability as referred to in paragraph (2) letter b shall include:
 - a. loss of 1 (one) lower limb;
 - b. paralysis of 1 (one) lower limb;

- c. loss of 1 (one) upper limb;
 - d. paralysis of 1 (one) upper limb;
 - e. loss of vision in 1 (one) eye;
 - f. moderate mental illness;
 - g. loss of 1 (one) index finger or thumb of the right hand;
 - h. loss of 2 (two) fingers or more of the right hand;
 - i. partial defects of the nervous system, respiratory, cardiovascular, digestive, or urogenital organs;
 - j. mute; or
 - k. deaf
- (5) Mild disability as referred to in paragraph (2) letter c shall include:
- a. mild mental illness;
 - b. loss of 1 (one) finger or toe;
 - c. reduced eye function;
 - d. loss of auricle, without the total loss of hearing; or
 - e. change in the classification or function of organs that are of lower value than before getting injured/sick.
- (6) A person who has a disability with the criteria as referred to in paragraph (2) shall be determined by a doctor in accordance with the provisions of laws and regulations.

Article 39

- (1) To obtain a disability compensation or death compensation as referred to in Article 37 paragraph (2), the applicant must submit an application letter.
- (2) The application letter to obtain disability compensation as referred to in paragraph (1) shall contain at least:
- a. the identity of the applicant, his/her family, or his/her proxy; and
 - b. the description of the Adverse Event Following COVID-19 Vaccination incurred.
- (3) The application letter as referred to in paragraph (2) must attach:
- a. a copy of the applicant's identity;
 - b. proof of report with respect to the case incurred to the Health Service Facility where COVID19 Vaccination was carried out;
 - c. certificate of disability from a doctor;
 - d. family relationship certificate if the application is submitted by the family; and
 - e. a special power of attorney if the request for compensation is submitted by the applicant's proxy.

- (4) In providing a certificate of disability as referred to in paragraph (3) letter c, the doctor shall take into account the assessment results conducted by the National Committee for the Assessment and Management of the Adverse Event Following Immunization or the Regional Committee for the Assessment and Management of the Adverse Event Following Immunization.
- (5) The application letter to obtain death compensation as referred to in paragraph (1) shall contain at least:
 - a. the identity of the heirs or their proxies; and
 - b. the description regarding the Adverse Event Following COVID-19 Vaccination incurred.
- (6) The application letter as referred to in paragraph (5) must attach:
 - a. a copy of the applicant's identity;
 - b. death certificate from Health Service Facility and signed by a doctor;
 - c. certificate of inheritance made or legalized by the authorized official, if the application is submitted by the heirs; and
 - d. a special power of attorney, if the application is submitted by the heir's proxy.
- (7) In providing a death certificate as referred to in paragraph (6) letter b, the doctor shall take into account the assessment results conducted by the National Committee for the Assessment and Management of the Adverse Event Following Immunization or the Regional Committee for the Assessment and Management of the Adverse Event Following Immunization.
- (8) Claims and payments against any disability compensation or death compensation as referred to in paragraph (1) shall be carried out in accordance with the provisions of laws and regulations.

Article 40

Provisions on the amount of disability compensation or death compensation shall be determined by the Minister after obtaining an approval from the Minister of Finance.

CHAPTER VII COMMUNICATIONS STRATEGIES

Article 41

- (1) In order to foster broad public's acceptance of COVID-19 Vaccination, the Central Government and Regional Government must develop and implement

communication strategies by improving the public's understanding, attitudes and behaviors so that the public shall be motivated to obtain COVID-19 Vaccination.

- (2) The communication strategies as referred to in paragraph (1) are intended to:
 - a. improve people's understanding regarding COVID-19 Vaccination;
 - b. equip the public with the precise and correct information to avoid misinformation/hoax;
 - c. increase public and stakeholders' participation in the implementation of COVID19 Vaccination; and
 - d. increase people's willingness to obtain COVID-19 Vaccination.
- (3) In implementing the communication strategies, the Central Government and Regional Government may involve relevant stakeholders, social organizations, religious/community leaders, and other health development partners.
- (4) The Central Government and Regional Government shall carry out monitoring and evaluation with respect to the communication strategies as referred to in paragraph (1).

CHAPTER IX RECORDING AND REPORTING

Article 42

- (1) Every Health Service Facility that carries out COVID-19 Vaccination services both Program Vaccination and Mutual Cooperation Vaccination must conduct recording and reporting.
- (2) The recording and reporting as referred to in paragraph (1) shall be conducted electronically through the One Data Covid-19 Vaccination Information System.
- (3) If the Health Service Facility cannot be connected to the One Data Covid-19 Vaccination Information System as referred to in paragraph (2), the recording and reporting may be conducted manually to be submitted to the regency/city health service office.
- (4) Manual recording and reporting as referred to in paragraph (3) shall be inputted by the Health Service Facility or regency/city health service office officials into the One Data Covid-19 Vaccination Information System by using the facilities in the regency/city health service office.

CHAPTER X FUNDING

Article 43

- (1) Funding for the Program Vaccination implementation shall be borne to the State Revenues and Expenditure Budget and the Regional Revenues and Expenditure Budget.
- (2) Funding for the Mutual Cooperation Vaccination implementation shall be borne to the legal entity/business entity conducting the Mutual Cooperation Vaccination.
- (3) Funding for monitoring and managing the Adverse Event Following COVID-19 Vaccination shall be borne to the State Revenues and Expenditure Budget.
- (4) Funding for health services for the COVID-19 Vaccine recipients who are undergoing health complications due to Adverse Event Following COVID-19 Vaccination shall be borne to the budget of the Ministry of Health or the National Health Insurance program organized by the Health Social Security Administration for Health (*Badan Penyelenggara Jaminan Sosial Kesehatan*) in accordance with the laws and regulations.

ARTICLE XI GUIDANCE AND SUPERVISION

Article 44

- (1) The guidance and supervision on the implementation of the provisions of this Minister Regulation shall be carried out by the Ministry of Health, Ministry of Finance, Ministry of Foreign Affairs, Ministry of State-Owned Enterprises, Ministry of Home Affairs, Ministry of Communication and Informatics, Public Prosecutor's Office, Indonesian National Army/National Police of the Republic of Indonesia, National Agency of Drug and Food Control, Financial and Development Supervisory Agency, Corruption Eradication Commission, National Public Procurement Agency, provincial health service office, and regency/city health service office in accordance with their respective duties and functions.
- (2) The guidance and supervision as referred to in paragraph (1) shall be directed for the successful implementation of COVID-19 Vaccination.
- (3) In the context of guidance and supervision as referred to in paragraph (1), periodical and continuous monitoring and evaluation shall be conducted on the implementation of COVID-19 Vaccination.

CHAPTER XII
TECHNICAL GUIDELINES FOR IMPLEMENTING THE COVID-19 VACCINE

Article 45

- (1) For the optimal establishment of COVID19 Vaccination, the Technical Guidelines for the Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management shall be stipulated.
- (2) Technical Guidelines for the Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management as referred to in paragraph (1) shall contain a technical description of the planning of COVID-19 Vaccination necessities, targets, distribution, service implementation, cooperation, monitoring and management of Adverse Event Following COVID-19 Vaccination, communication strategies, recording and reporting, funding, and guidance and supervision.
- (3) Technical Guidelines for Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management as referred to in paragraph (1) shall be stipulated by the Minister.

CHAPTER XIII
OTHER PROVISIONS

Article 46

- (1) In the implementation of COVID-19 Vaccination, the Government shall take over the legal responsibility of the provider of COVID-19 Vaccine.
- (2) The takeover of legal responsibility by the Government against the provider of COVID-19 Vaccine as referred to in paragraph (1) in so far:
 - a. the provider of COVID-19 Vaccine requires the takeover of legal responsibility; and
 - b. the provider of COVID-19 Vaccine has conducted the production and distribution process in accordance with the proper methods of drugs manufacture and/or the proper methods of drugs distribution.
- (3) The takeover of legal responsibility as referred to in paragraph (1), shall include the provision of compensation by the Government as referred to in Article 37.

- (4) The takeover of legal responsibility as referred to in paragraph (1) and paragraph (3) shall be carried out in accordance with the provisions of laws and regulations.

CHAPTER XIV CLOSING PROVISIONS

Article 47

When this Minister Regulation comes into force, Minister of Health Regulation Number 84 of 2020 regarding Implementation of Vaccination in the context of the Corona Virus Disease 2019 (COVID-19) Pandemic Management (State Gazette of the Republic of Indonesia of 2020 Number 1559), shall be revoked and declared invalid.

Article 48

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

For public cognizance, hereby ordering the promulgation of this Minister Regulation by its placement in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta
on February 24, 2021

MINISTER OF HEALTH
REPUBLIC OF INDONESIA,

(signed.)

BUDI G. SADIKIN

Promulgated in Jakarta
on February 25, 2021

DIRECTOR GENERAL
OF LAWS AND REGULATIONS
OF THE MINISTRY OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

(Signed)

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2021 NUMBER 172

SSEK Translation
March 2, 2021



True Copy

Head of Legal Bureau and Organization
Secretary General of the Ministry of Health,

(Signed and Stamped)

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