



DECREE OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA
NUMBER HK.01.07/MENKES/1258/2022
ABOUT
SUBSTITUTION OF IMPORTED MEDICAL EQUIPMENT WITH INTERNAL MEDICAL DEVICES
STATE ON HEALTH SECTOR ELECTRONIC CATALOG

BY THE GRACE OF GOD ALMIGHTY

MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

- Considering:
- a. that in order to improve health resilience and the growth of the domestic medical device industry, it is necessary prioritize the use of domestic medical devices in the implementation of government procurement through health sector electronic catalog;
 - b. that in the administration of sectoral electronic catalogs health managers can make a selection of the use domestic medical devices, so it is necessary to determine provisions for the implementation of substitution of imported medical devices with domestic medical devices;
 - c. that based on the considerations referred to in letters a and b, it is necessary to stipulate a Decision Minister of Health regarding Substitution of Medical Devices Import With Domestic Medical Devices In Catalog Health Sector Electronics;

In view of: 1. Law Number 36 Year 2009 concerning Health (State Gazette of the Republic of Indonesia Year 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);

2. Presidential Regulation Number 16 of 2018 concerning Government Procurement of Goods/Services (State Gazette Republic of Indonesia Year 2018 Number 33) as has been amended by Presidential Regulation Number 12 Year 2021 concerning Amendments to Presidential Regulation No 16 of 2018 concerning the Procurement of Goods/Services Government (State Gazette of the Republic of Indonesia Year 2021 Number 63);
3. Presidential Instruction Number 2 of 2009 concerning Use of Domestic Products in Procurement Government goods/services;
4. Presidential Instruction Number 6 of 2016 concerning Acceleration of the Development of the Pharmaceutical and Appliance Industry Health;
5. Presidential Instruction Number 2 of 2022 concerning Acceleration of Increase in Product Use in Country and Products of Micro, Small and Business Enterprises Cooperatives for the Success of the National Movement Proud to be Made in Indonesia in Procurement Pelaksanaan Government goods/services;
6. Regulation of the Minister of Industry Number 02/M IND/PER/1/2014 concerning Improvement Guidelines Use of Domestic Products in Procurement Government Goods/Services (State Gazette of the Republic of Indonesia) Indonesia Year 2014 Number 45);
7. Regulation of the Minister of Health Number 17 of 2017 on the Pharmaceutical Industry Development Action Plan and Medical Devices (State Gazette of the Republic of Indonesia Year 2017 Number 353);
8. Regulation of the Minister of Health Number 5 of 2022 about the Organization and Work Procedure of the Ministry of Health (State Gazette of the Republic of Indonesia Year 2022 Number 156);

DECIDE:

To stipulate : DECREE OF THE MINISTER OF HEALTH CONCERNING SUBSTITUTION IMPORTED MEDICAL EQUIPMENT WITH INTERNAL MEDICAL DEVICES STATE ON SECTORAL ELETRONIC CATALOG HEALTH.

FIRST : Implementation of substitution of imported medical devices with medical devices domestic health in the sectoral electronic catalog health is carried out through the freezing mechanism (*freeze*) and *unfreezing*, based on the following criteria:

a. freezing (*freeze*):

1. medical device products that are suitable for needs health services have been produced in country and already has a distribution permit; and/or
2. The production capacity of medical devices has met plan for medical equipment needs with specifications products that are suitable for service needs health.

b. unfreezing :

1. Imported medical devices can be reopened freezing if national needs have not been fulfilled by the production capacity of the tool industry domestic health, which is proven based on the Medical Device Needs Document and Data on Production Capacity of Internal Medical Devices Country; and/or
2. medical devices that will be reopened freezing has parameters and/or product specifications that can not be produced in Indonesia.

SECOND : Forming a Team for Substitution of Imported Products with Products Domestic In the Health Sector Electronic Catalog, hereinafter referred to as the Substitution Team, with the following structure:

following:

a. Director:

1. Secretary General

2. Director General of Pharmacy and Medical Devices

b. Chairman: Head of the Bureau of Procurement of Goods and Services

c. Member:

1. Secretary of the Directorate General of Pharmaceuticals and Devices

Health

2. Secretary of the Directorate General of Health Services

3. Secretary of the Directorate General of Public Health

4. Secretary of the Directorate General of Prevention and
Disease Control

5. Secretary of the Directorate General of Health Workers

THIRD

: Substitution Team as referred to in the SECOND Dictum

on duty:

a. conduct a weekly review of medical devices

imports that will be *frozen* and

opening freezing (*unfreeze*), according to the criteria

as referred to in the FIRST Dictum; and

b. conduct an evaluation of medical devices that have been

substitution is made to the sectoral electronic catalog
health.

FOURTH: Implementation of substitution of medical devices as intended

in the FIRST Dictum in the following manner:

a. the main unit of users of medical device products composes

data-based plan for medical device needs

historical 3 (three) years.

b. the main unit of users of medical device products inputs the plan for

the need for medical devices in the SIRUP application

Government Goods/Services Procurement Policy Institute.

c. Bureau of Planning and Budget issues Documents

Medical Equipment Needs.

d. Directorate General of Pharmacy and Medical Devices

compiling Production Capacity Data Documents and

compiling Equipment Production Adequacy Data Documents

National Health.

e. The Substitution Team conducts a study once a week

based on the Document of Equipment Production Sufficiency Data

National Health and issue recommendations

freezing and opening *freeze*

(*unfreeze*) to the Bureau of the Procurement of Goods and Services.

f. The Bureau of the Procurement of Goods and Services freezes

(*freeze*) and the opening of the freeze (*unfreeze*)

based on the recommendations as referred to in letter e.

FIFTH : To support the implementation of the tasks of the Substitution Team as referred to in the THIRD Dictum, the leadership each echelon I unit in the membership of the Substitution Team can form a Work Team as needed.

SIXTH : This Ministerial Decree shall come into force on the date of stipulation.

Set in Jakarta
on July 6, 2022

MINISTER OF HEALTH
REPUBLIC OF INDONESIA,

signed.

BUDI G. SADIKIN

Salinan sesuai dengan aslinya

Kepala Biro Hukum
Sekretariat Jenderal Kementerian Kesehatan,



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