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SALINAN

PRESIDENTIAL REGULATION OF THE REPUBLIC

OF INDONESIA NUMBER 101 OF 2021

ABOUT

THE IMPLEMENTATION OF PATENTS BY THE GOVERNMENT AGAINST

THE DRUG FAVIPTRAVIR

BY THE GRACE OF GOD ALMIGHTY THE

PRESIDENT OF THE REPUBLIC OF INDONESIA,

Weigh

- a. that the spread of *Corona Uirus Disease 2019* (COVID-19) has been declared by the *World Health Organization* (WHO) as a *global* pandemic and the Government has also designated the non-natural disaster of the spread of *Corono Virus Disease: se 2019* (COVID-19) as a national disaster;
- b. that in connection with the very urgent need in efforts to combat *Corona Virus Disease 2019* (COVID-19 in Indonesia), it is necessary to establish an access policy to Favipiravir drugs that are currently still protected by patents;
- c. that based on the provisions of Article 109 paragraph (3) of Law No. 13 of 2016 on Patents as amended by Law No. 11 of 2020 on Work Copyright, The Implementation of Patents by the Government is stipulated by Presidential Regulation;
- d. that based on the considerations referred to in letter a, letter b, and letter c, it is necessary to establish a Presidential Regulation on the Implementation of Patents by the Government on the Drug Favipiravir;
1. Article 4 paragraph (1) of the Constitution of the Republic of Indonesia of 1945;

Remember

2. The law...



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2. Law No. 13 of 2016 on Patents (State Gazette of the Republic of Indonesia year 2010 Number 176, Supplementary State Gazette of the Republic of Indonesia Number 5922) as amended by Law No. 11 of 2020 on Cipta Kerja (State Gazette of the Republic of Indonesia Year 2020 Number 245, Supplementary State Gazette of the Republic of Indonesia Number 6573);

DECIDE:

SET

THE PRESIDENTIAL REGULATION ON THE
IMPLEMENTATION OF PATENTS BY THE GOVERNMENT
AGAINST THE DRUG FAVIPIRAVIR.

Article 1

- (1) The government carries out patents on drugs. Favipiravir.
- (2) The implementation of patents by the Government on the drug Favipiravir is intended to meet the availability and urgent need for the treatment of *Corona Virus Disease 2019* (COVID-19).
- (3) The implementation of patents by the Government on the drug Favipiravir is carried out for a period of 3 (three) years since this Presidential Regulation came into force.
- (4) If after a period of 3 (three) years as referred to in paragraph (3) the pandemic has not ended, the implementation of the patent by the Government is extended until the *Pandemic Corona Virus Disease 2019* (COVID-19) is set to expire by the Government.

Article 2

The implementation of patents by the Government on the drug Favipiravir as referred to in Article 1 paragraph (1) contains the name of the active substance, the name of the patent holder, the patent application number / patent number, and the title of the invention as stated in the Annex which is an integral part of this Presidential Regulation.

Article 3...



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Article 3

- (1) The Minister who organizes government affairs in the health sector appoints the pharmaceutical industry as the executor of the Favipiravir drug patent as referred to in Article 1 paragraph (1) for and on behalf of the Government in accordance with the provisions of the laws and regulations.
- (2) The pharmaceutical industry as referred to in paragraph (1) carries out its duties as the executor of Favipiravir drug patents on a limited basis, to meet domestic needs, and is noncommercial.
- (3) The pharmaceutical industry as referred to in paragraph (1) shall meet the requirements:
 - a. have facilities and are able to carry out patents;
 - b. not transferring the implementation of the patent to another party; and
 - c. have a good way of production, circulation, and supervision in accordance with the provisions of the laws and regulations.

Article 4

The pharmaceutical industry as referred to in Article 3 provides a reward to patent holders of 1% (one percent) of the net selling value of the drug Favipiravir.

Article 5

- (1) The reward as referred to in Article 4 is carried out annually.
- (2) Reward as referred to in the verse
 - (1) it is carried out in accordance with the period of time referred to in Article 1 paragraph (3) and paragraph (4).

Article O

This Presidential Regulation comes into effect on the date it is promulgated.

In order to...



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In order for everyone to know, order the promulgation of this Presidential Regulation with its placement in the State Gazette of the Republic of Indonesia.

Set in Jakarta
November 10, 2021

PRESIDENT OF THE REPUBLIC OF
INDONESIA,

ttd.

JOKO WIDODO

Diundangkan in vJakarta
On November 10, 2021

MINISTER OF LAW AND HUMAN RIGHTS OF
THE REPUBLIC OF INDONESIA,

ttd.

YASONNA H. LAOLY

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2021 NUMBER 254

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MINISTRY OF STATE SECRETARIAT OF THE
REPUBLIC OF INDONESIA

De Eng Legislation and Legal
Administration,



Silvanna Djaman



PRES I DEC
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ATTACHMENT
PRESIDENTIAL REGULATION OF THE REPUBLIC
OF INDONESIA NUMBER 101 OF 2021
ABOUT
IMPLEMENTATION OF PATENTS BY THE
GOVERNMENT ON THE DRUG
FAVIPIRAVIR

NAME OF ACTIVE SUBSTANCE, NAME OF PATENT HOLDER, PATENT
APPLICATION NUMBER/ PATENT NUMBER, AND TITLE OF
INVENTION

No	NAME OF ACTIV E SUBS TANC E	NAME OF PATENT HOLDER	PATENT APPLICATION NUMBER/ NUMBER PATENT	TITLE OF INVENTION
1.	Favipiravir	Fujifilm Toyama Chemical Co., Ltd.	W0020 1000982/ IDP0032152	Organic Amina Salt from 6-Fluoro-3- Hydroxy-2- Pirazincarbonile and Its Manufacturing Method
			W00201301813/ IDP000045023	Sodium Salt from 6— Fluoro—3-Hydroxy—2— Pyrrazina Carboxamide
			W00201301812/ IDP000040569	Meglumina salt from 6-Fluoro-3-Hydroxy-2- Pyrrazin Carboxamide



			W0020 1103243/ IDP000046 140	Insulated Tablets and Powders Contains 6-Fluoro- 3- Hydroxy-2- Pirazinakarbokididide
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W002009O2268 .



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			W00200902268/ IDP000034309	Pharmaceutical Composition Containing Pyrrazin Derivatives, and Methods of Use of Pirazin Derivatives in Combined
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PRESIDENT OF THE REPUBLIC OF
INDONESIA,

Ltd..

JOKO WIDODO

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REPUBLIC OF INDONESIA

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~~for~~ Legal democracy,

Silvanna Djaman