

The Covid-19 Vaccine Can Be Used in Indonesia



Head of the Food and Drug Supervisory Agency Penny K Lukito (left) hands over an Emergency Use Authorization (EUA) Certificate for the Coronavac Covid-19 Vaccine to the President Director of Bio Farma, Honesti Basyir, in Jakarta on January 11, 2021. With this EUA, the Covid-19 Vaccine 19 can already be used in Indonesia.

(Jakarta 11/1) Indonesia has been able to use the Covid-19 Vaccine under the name Coronavac from Sinovac after the issuance of an Emergency Use of Authorization (EUA) from the National Food and Drug Supervisory Agency (POM Agency), which was set in Jakarta on January 11, 2021.

Previously, on January 8, 2021, in the Fatwa Commission session of the Indonesian Ulema Council (MUI), it was also decided that both the CoronaVac vaccine, as well as the Covid-19 Fill and Finish product being worked on at Bio Farma under the name Cov2Bio, had the status of Holy and Halal. This decision is contained in Fatwa Number 02 of 2021 concerning the Covid-19 Vaccine from Sinovac Life Sciences Co. Ltd. China and PT. Bio Farma (Persero) on January 11, 2021.

Thus, vaccines imported by the Holding Holding for Pharmaceutical SOEs meet the halal aspect and are guaranteed safety, with harmless side effects, and can be given to health workers as the priority

group.

This Emergency Use Permit is marked by an efficacy value equivalent to 65.3% taken from the interim report three months after the second injection of the Phase 3 Clinical Trial, which was carried out in Bandung since last August 2020, which was given to 1,620 volunteers.

Head of the POM Agency, Penny K Lukito, said that the 65.3% result means that CoronaVac can reduce the number of Covid-19 cases by 65.3%. "The 65.3% figure from the results of the clinical trial in Bandung shows the hope that this vaccine will be able to reduce the incidence of COVID-19 by 65.3%," said Penny Lukito.

The 65.3% figure in Bandung will also be juxtaposed with the efficacy rate in Brazil, which produces 78%, and Turkey produces 91%. The efficacy results from the three countries were recorded above the efficacy threshold set by the World Health Organization (WHO), which is 50%.

He continued, in addition to efficacy, the POM Agency also evaluates the body's ability to produce antibodies (immunogenicity) and the ability of antibodies to neutralize the SARS-COV2 virus, which is 99.23%.

In addition to looking at the efficacy, the POM has also ensured that Sinovac as the producer of CoronaVac, has met the aspects of Good Manufacturing Practice (GMP) in terms of quality by conducting audits and supervision starting from raw materials, manufacturing processes to finished vaccine products in accordance with the assessment of supporting data. Vaccines, such as the audit conducted at Sinovac Life Science at the end of October 2020 and the fill and finish facility located at Bio Farma, Bandung, in early 2021.

Apart from the POM Agency, the Covid-19 vaccine was also assessed by the Fatwa Commission of the Indonesian Ulema Council, from the aspect of halal and thayib. Head of MUI Fatwa Asrorun Niam Sholeh said that LPPOM MUI had completed field audits of the Sinovac Covid-19 vaccine in two locations, namely Sinovac's head office in Beijing and Biofarma's head office in Bandung.

"Regarding the halal aspect, after a long discussion with the auditor's explanation, the Fatwa Commission meeting agreed that the Covid-19 vaccine produced by Sinovac and the certification submitted by Bio Farma was Halal and Holy," said Asrorun.

Meanwhile, the President Director of Bio Farma, Honesti Basyir, expressed his gratitude to the POM Agency and those who have carried out the task of supervising and assisting the implementation of phase 3 clinical trials in Bandung, as well as the preparation of fill and finish production facilities for the Covid-19 Vaccine at BioFarma.

"Alhamdulillah, today, January 11, 2021, the POM Agency has issued an Emergency Use Authorization (EUA) for the Coronavac / Inactivated SARS-Cov 2 Single dose Vaccine from Sinovac for health workers spread across 34 provinces in Indonesia. Indonesia. As of today, the Covid-19 vaccine has arrived at the Provincial Health Office, to be further given to health workers as needed," said Honesti.

Honesti added, Bio Farma also expressed his gratitude to the MUI Fatwa Commission for auditing Bio Farma's readiness to distribute and produce Fill and Finish the Covid-19 vaccine according to Islamic sharia principles Muslims in Indonesia can carry out vaccinations calmly.

"We don't also forget to thank the Indonesian Ulema Council, which has provided halal certificates for both the Covid-19 vaccine in the form of finished products, as well as those that Bio Farma themselves will produce. The halal aspect is very important in Indonesia, considering that the

majority of Indonesian people are Muslim," concluded Honesti,

Furthermore, Bio Farma will continue to distribute the Coronavac vaccine for health workers in 34 provinces. It was recorded that as of January 11, 2021, 1,060,440 doses of Coronavac had been distributed to health workers. (ed/ss)