Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

PRESS STATEMENT
15 March 2022

FDA Philippines Grants Emergency Use Authorization of CoronaVac (Sinovac) for Pediatric Group

On 11 March 2022, the Food and Drug Administration (FDA) granted the Emergency Use Authorization (EUA) of CoronaVac Vaccine, manufactured by Sinovac Life Sciences, for the prevention of COVID-19 in 6 to 17 years old individuals. The FDA recommends the vaccine for use in individuals 6 years of age and above in a two-dose schedule with 4 weeks spacing

CoronaVac is the third vaccine authorized by the FDA against COVID-19 for the pediatric age group in addition to the two mRNA vaccines manufactured by Pfizer (age 5 to 17 years old) and Moderna (age 12 to 17 years old). CoronaVac is an inactivated vaccine, which is stable in conditions requiring refrigerator temperature of 2 to 8 degrees Celsius.

The Panel of Vaccine Experts reviewed the clinical data submitted by IP Biotech Inc., the distributor-importer of the product. Based on the evidence submitted which includes clinical trials and real-world effectiveness data, CoronaVac was found to have acceptable immunogenicity and safety profile in pediatric groups. The assessment done ensured that the benefits outweigh the known and potential risks of the product based on the totality of evidence presented and available data.

Post authorization monitoring and surveillance measures are in place involving the FDA, DOH, and EUA holder. The FDA-DOH pharmacovigilance system is a shared commitment with all stakeholders utilizing the COVID-19 vaccines. The FDA also continuously commits to ensure proper vaccine handling and storage through the Field Regulatory Operations Office in coordination with the National Vaccination Program of the DOH. The EUA holder is mandated to submit regular reports and updated data on quality, manufacturing, clinical trials and safety evidence to the FDA.

The FDA urges parents and guardians to have their children vaccinated by healthcare providers, who are trained to recognize and manage adverse reactions. FDA is working closely with the program implementors and professionals for proper pharmacovigilance to ensure the safety of the recipients of the COVID-19 Vaccine. The FDA acknowledges the importance of protecting the young from COVID-19 especially during this time where the country eases out to the new normal.

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