Food and Drug Administration Director Wu Hsiu-mei speaks at a Central Epidemic Command Center news conference in Taipei yesterday.
Photo courtesy of the Central Epidemic Command Center

An emergency use authorization (EUA) for Medigen Vaccine Biologics Corp's (□□□□) COVID-19 vaccine — MVC-COV1901 — for people aged 20 and older was issued by the Food and Drug Administration (FDA) yesterday.

Minister of Health and Welfare Chen Shih-chung (□□□) said a specialists' meeting was held at the FDA on Sunday to review Medigen's application to manufacture and distribute its COVID-19 vaccine, and the panel approved it.

FDA Director Wu Hsiu-mei (□□□) said the meeting consisted of 21 specialists from the fields of chemistry, manufacturing and controls, pharmacy, toxicology, clinical medicine, public health, law and medical ethics.

There were no major concerns over the safety of the vaccine, she said, adding that it also met the standards that the FDA had previously published for the manufacture or importation of COVID-19 vaccines.

One of the two most important standards was that the geometric mean titer of neutralizing antibodies produced in individuals who received the Medigen vaccine must be at least 0.67 times that prodcued in those who received the AstraZeneca vaccine, using the 95 percent lower confidence limit, she said.

The geometric mean titer of neutralizing antibodies of Medigen vaccine recipients was 3.4 times that of those who received the AstraZeneca vaccine, Wu said.

The AstraZeneca vaccine was chosen for comparison because it is being administered in more than 100 nations and it was the only vaccine available in Taiwan at the time of the testing, she said.

The other important standard was that the sero-response rate of Medigen vaccine recipients be higher that 50 percent, using the 95 percent lower confidence limit, Wu said, adding that the sero-response rate was 95.5 percent, exceeding the requirement.

At the specialists' meeting, 18 members voted to approve the vaccine, one voted for further discussion after asking for more information and one voted to not approve the vaccine, she said, adding that the convener of the meeting was not allowed to vote.

The Medigen vaccine is only suitable for people who are aged 20 or older, and each person should get two doses at least 28 days apart, Wu said.

Under the EUA, the company must provide a safety report every month, she said.

A report on the effectiveness of the vaccine, from administering it in Taiwan and other nations, must be provided after one year, she added.

The vaccine would also be reviewed by the Advisory Committee on Immunization Practices before it is added to the national COVID-19 vaccination program, Chen said, adding that if it gains approval, a small number of doses could be available as soon as next month.

Meanwhile, about 1.7 million people in the sixth, eight, ninth and 10th priority groups for vaccination, and people born before 1974 who selected the AstraZeneca vaccine using the national online vaccination booking system before noon yesterday, would begin receiving text messages from the center today, Chen said.

After receiving a text message, they can book an appointment for a vaccination between Friday

and Thursday next week, he said.

The vaccination booking system has been temporarily closed and it would be reopened for new registrations when more vaccine doses become available, he added.

People who edit their preference and select the AstraZeneca vaccine when the system is reopened would be eligible for vaccination after the approximately 4.95 million people who had chosen the AstraZeneca vaccine before midday yesterday, Chen said.

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