

AstraZeneca assures safety of its COVID-19 vaccine

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AstraZeneca has assured the safety of its COVID-19 vaccine.



(Photo by THOMAS KIENZLE / AFP)

In a statement dated March 14, the company said safety is of paramount importance and the company is continually monitoring the safety of its vaccine.

This, following a recent concern raised around thrombotic events.

“AstraZeneca would like to offer its reassurance on the safety of its COVID-19 vaccine based on clear scientific evidence,” it said.

The company said a careful review of all available safety data of more than 17 million people vaccinated in the European Union (EU) and UK with COVID-19 Vaccine (ChAdOx1-S [recombinant]) (COVID-19 Vaccine AstraZeneca) COVAX Supply has shown “no evidence

of an increased risk of pulmonary embolism, deep vein thrombosis (DVT) or thrombocytopenia, in any defined age group, gender, batch or in any particular country.” “So far across the EU and UK, there have been 15 events of DVT and 22 events of pulmonary embolism reported among those given the vaccine, based on the number of cases the company has received as of March 8,” it said.

AstraZeneca said this is much lower than would be expected to occur naturally in a general population of this size and is similar across other licensed COVID-19 vaccines.

“Furthermore, in clinical trials, even though the number of thrombotic events was small, these were lower in the vaccinated group. There has also been no evidence of increased bleeding in over 60,000 participants enrolled,” it said.

Ann Taylor, Chief Medical Officer, said: “Around 17 million people in the EU and UK have now received our vaccine, and the number of cases of blood clots reported in this group is lower than the hundreds of cases that would be expected among the general population. The nature of the pandemic has led to increased attention in individual cases and we are going beyond the standard practices for safety monitoring of licensed medicines in reporting vaccine events, to ensure public safety.”

In terms of quality, AstraZeneca said, there are also “no confirmed issues related to any batch of our vaccine used across Europe, or the rest of the world.”

It added: “Additional testing has, and is, being conducted by ourselves and independently by European health authorities and none of these re tests have shown cause for concern.”

“During the production of the vaccine more than 60 quality tests are conducted by AstraZeneca, its partners and by more than 20 independent testing laboratories. All tests need to meet stringent criteria for quality control and this data is submitted to regulators within each country or region for independent review before any batch can be released to countries,” the company said.

It stressed that the safety of the public will always come first. AstraZeneca said the company is keeping the issue under close review but “available evidence does not confirm that the vaccine is the cause.”

On March 12, the Department of Health and the Food and Drug Administration said there is no reason to halt AstraZeneca vaccination in the country.

“The DOH and FDA are aware that a few countries in the European Union have recently paused their vaccination campaign with COVID-19 vaccine AstraZeneca following reports of blood clots in people who received the vaccine,” read their joint statement.

“This has been decided as a precautionary measure, while they conduct a full investigation to determine causality between the vaccination and the reported adverse events following immunization,” it further read.

“Moreover, the European Medicine Authority (EMA) has also emphasized that there is currently no indication that vaccination has caused these conditions, which are not listed as side effects with this vaccine, saying, the position of EMA’s safety committee PRAC is that the vaccine’s benefits continue to outweigh its risks and the vaccine can continue to be administered while investigation of cases of thromboembolic events is ongoing. PRAC is already reviewing all cases of thromboembolic events, and other conditions related to blood clots, reported post-vaccination with COVID-19 Vaccine AstraZeneca,” the statement read.

Source: <https://mb.com.ph/2021/03/15/astrazeneca-assures-safety-of-their-covid-19-vaccine/>