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FDA’s limited approval of Dengvaxia proves PH blunder, says Pimentel

By Ellson Quismorio

The United States’ Food and Drug Administration (FDA) conditional approval of Dengvaxia proved that Philippine health authorities blundered in using the anti-dengue fever vaccine for the mass inoculation of Filipino children, a former House leader said Friday.

Surigao del Sur 2nd district Rep. Johnny Pimentel

(Facebook / MANILA BULLETIN)

“After going over the US FDA’s official press statement announcing the approval of Dengvaxia, it is clear that they approved the vaccine for use only in children previously infected with dengue,” Surigao del Sur 2nd District Rep. Johnny Pimentel said, referring to seronegative patients.

The US FDA said the use of the vaccine can only occur under certain strict conditions: only children aged between nine and 16, who have previously confirmed infections, and who live in endemic areas, may receive the dose.

“While there is no cure for dengue disease… approval is an important step toward helping to reduce the impact of this virus,” said Anna Abram, a senior FDA official.

“The US FDA disapproved the vaccine for use in children who never had dengue infection,” Pimentel stressed.

“But in our case, children were vaccinated wholesale, regardless whether they had or did not have prior dengue infection,” the Mindanao lawmaker said, adding that the act was “indiscriminate.”

Pimentel is a former chairman of the House Committee on Good Government and Public Accountability, which conducted a joint inquiry with the House Committee on Health into the Philippines’ controversial anti-dengue vaccination program using Dengvaxia.

Some 730,000 school children received Dengvaxia shots under the program that was launched during the tail-end of the Aquino administration in April 2016.

It was eventually abandoned by the Duterte administration in December 2017 when its manufacturer, French pharmaceutical firm Sanofi Pasteur admitted that the vaccine could be harmful to seronegative patients.

A study published in the New England Journal of Medicine later confirmed previous findings that children who never had dengue infection, but who were given Dengvaxia shots anyway, had an increased risk of hospitalization and a severe case of the debilitating mosquito-borne disease from the third year after vaccination.

“Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. This is because, in people who have not been infected with dengue virus, Dengvaxia appears to act like a first dengue infection – without actually infecting the person with wild-type dengue virus – such that a subsequent infection can result in severe dengue disease,” said the FDA statement dated May 1.

Over 100 kids vaccinated with Dengvaxia have died.

The Philippine government is spending another P213 million this year to deploy an additional 425 nurses to monitor school children who received Dengvaxia shots, according to Pimentel.

The lawmaker said the nurses will visit public schools to check on the health condition of vaccinees, while others will be assigned to hospitals to keep close tabs on admissions of vaccinees.

The P213 million is on top of the P1.16 billion that Congress earmarked in 2018 “to provide the necessary health and medical assistance to Dengvaxia vaccinees,” Pimentel said. (With a report from AFP)