

# Philippines halts sale of Sanofi's dengue vaccine (Update)

December 5 2017

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The Philippines has suspended the sale and distribution of Sanofi's dengue vaccine, authorities said Tuesday, after the French pharmaceutical giant last week warned it could worsen symptoms for people who had not previously been infected.

Regulators on Friday froze the country's world-first public dengue immunisation programme, that has seen more than 733,000 children receive the Dengvaxia vaccine.

Authorities have now ordered a blanket suspension for private use as well.

"Whether (the vaccine) is used in the public health programme or used by a private practitioner, it is the same product that was licensed. Everyone is covered by the FDA advisory," health undersecretary Gerardo Bayugo told AFP.

The Philippine Food and Drug Administration (FDA), a regulatory agency under the health department, said in a public advisory on Monday it had pulled the vaccine from the market to "protect the general public".

"The (FDA) immediately directed Sanofi to suspend the sale/distribution/marketing of Dengvaxia and cause the withdrawal of Dengvaxia in the market pending compliance with the directives of the FDA," the advisory said.

Sanofi's announcement has caused major fears in the Philippines—where the mosquito-born disease is extremely prevalent—particularly for parents of the children immunised in the public programme.

More than 1,000 people in the Philippines died from dengue last year, out of more than 211,000 suspected cases, according to the government.

Sanofi on Monday sought to allay fears about the new study that led it to release the warning, saying Dengvaxia would not cause anyone who was immunised to die.

Philippine authorities have given conflicting messages on the safety or otherwise of the vaccine.

Presidential spokesman Harry Roque said Sunday that the government would "leave no stone unturned" in making those responsible for putting "hundreds of thousands of young lives at risk" accountable for their actions.

The justice department then on Monday formally launched an inquiry over "the alleged danger to public health".

But Roque also said on Monday there was "no danger" for people who had been immunised with Dengvaxia.

"The worst that can happen is for those who have not had dengue before... they may get infected with dengue but falling under our previous classification of 'mild', having fever and bruises," Roque said.

When asked to comment on the Philippine government's decision to suspend all sales of Dengvaxia, Sanofi said on Tuesday it would continue to work with authorities and highlighted its proposal to re-label the

vaccine.

The proposed label update would "include the new data findings and instructions to ensure that physicians can make appropriate vaccination decisions with their patients," said a Sanofi statement emailed to AFP.

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