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FDA takes action against Sanofi

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Philippines' Food and Drug Administration (FDA) has suspended the sale of the controversial Dengvaxia dengue vaccine for a year.

FDA has also imposed a P100,000-administrative fine on Sanofi for failing to comply with post-marketing authorization requirements for the vaccine.

FDA is tasked to determine whether a health product – like drugs, vaccines, food, and cosmetics – is safe and effective for the public to consume. When an FDA issues a certificate of product registration, it means the product is allowed to be sold in the country.

Under the FDA's post-marketing surveillance stage, a company is required to submit several documents to ensure the product is still safe to use even after its release in the market.

In Sanofi's case, the FDA had issued its certificate of product registration on December 22, 2015. Sanofi, however, failed to submit the necessary post-marketing authorization requirements after being allowed to sell its dengue vaccine.