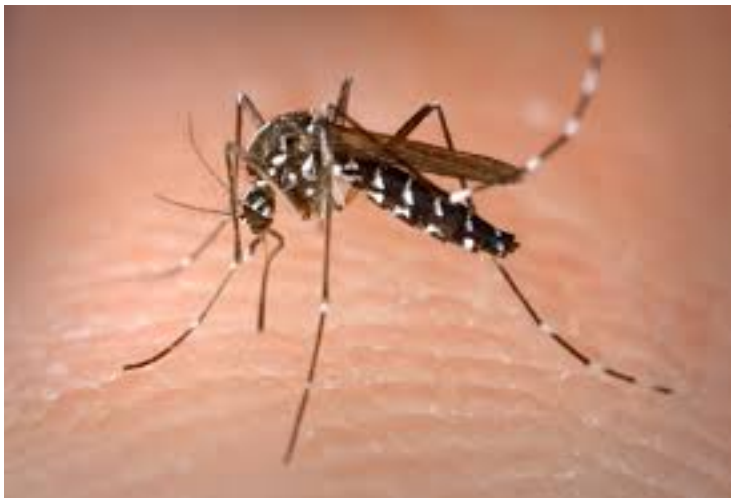
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Sanofi under fire after dengue vaccine furore

22 March 2018 | Analysis | By Priyanka Bajpai

Dengue fever is a mosquito-borne disease caused by four virus serotypes (1 to 4) as categorised by the World Health Organisation. Overall, the disease is seen as a threat to about half of the world's population. Some 400 million people are believed to be infected annually.



Singapore - In December 2015, Dengvaxia, the world's first promising vaccine against dengue virus developed by French pharmaceutical company Sanofi Pasteur, was licensed and approved for commercial use in 11 countries namely Mexico, the Philippines, Indonesia, Brazil, El Salvador, Costa Rica, Paraguay, Guatamala, Peru, Thailand, as well as Singapore in October last year. It is approved but not yet launched in Honduras, Malaysia, Australia, Argentina, Venezuela, Bolivia, Bangladesh and Cambodia.

However, recently Dengvaxia faced a major setback after Sanofi released the findings of a new study based on six years' worth of clinical trial data that showed dengue vaccine could worsen symptoms for those not previously infected with dengue.

The analysis confirmed that Dengvaxia provides persistent protective benefit against dengue fever in those who had prior infection. The French manufacturer however warned that for people who are not previously infected with the disease, the symptoms could worsen after immunisation.

Following the disclosure, the Philippines Department of Health (DoH) has suspended the dengue vaccine, amid widespread fears about its safety and growing public furore over its use in 830,000 school children and piqued congressional curiosity about how Dengvaxia entered the Health department's multibillion-peso, anti-dengue vaccination program. More than 80,000 school children had received the vaccine last year in the world's first public dengue immunisation programme.

FDA suspends sale & distribution of Dengvaxia

The incidence of dengue has grown dramatically around the world in recent decades. The actual numbers of dengue cases are underreported and many cases are misclassified.

The Food and Drug Administration (FDA) has imposed administrative sanctions on French drugmaker Sanofi Pasteur.

Suspension of the certificate of product registration of the controversial dengue vaccine Dengvaxia for one year and an emblematic fine of 100,000 pesos (about $2,000) has also been ordered on the company. The administrative sanctions cover administrative lapses on the part of the Sanofi, including skirting the regulatory requirement of post-marketing surveillance reports.

Dengue vaccine market

According to the global dengue vaccine market report 2017-2021, rapid growth in disease prevalence is one of the primary causes of driving the market. The prevalence and incidence of dengue is rising rapidly. Global warming and population density are two primary factors that attribute to the rise in dengue cases worldwide. As per the NIH, 3.6 billion people that reside in tropical and subtropical regions are at risk of dengue transmission. Global estimates vary, but nearly 0.05 to 0.2 billion cases of dengue infections are reported annually. In 2011, annual cases of severe dengue were around 0.5 million, and mortality due to dengue was above 20,000 as per the NIH. As per the NIH, in 2012, the upper bound total was 3.97 billion for people at risk of dengue in 128 countries globally.

Status of Dengvaxia in other markets

After the official release of the statement from Sanofi that people who have had no previous infection of the disease might be at a higher risk of worsened symptoms after immunisation, other countries where the vaccine has been approved and licensed are also monitoring the anti-dengue vaccine closely.

Brazil has already recommended restricted use of the anti-dengue vaccine to those previously infected with dengue. However, the drug has not been suspended entirely unlike the Philippines.

Singapore is also aware of the situation and is taking preventive measures. Singapore's Health Sciences Authority (HSA) is working with Sanofi to strengthen risk warnings on the drug's packaging. Healthcare professionals and physicians have been advised to monitor and not administer dengue vaccine to patients who have not been previously infected by the virus.

It is known that Sanofi has spent 20 years developing the world's first dengue vaccine at a cost of around 1.5 billion euros (S$2.4 billion).

HSA agrees that Sanofi Pasteur's findings confirm its 2016 assessment of a postulated risk of higher incidence of severe dengue following vaccination of those not previously infected. In the current scenario, HSA has suggested people looking for immunisation against the disease should first consult their doctors on the after benefits and risks of the vaccine. In order to increase awareness amongst the population, HSA has also shared this information with healthcare professionals, the media, as well as the public.

Singapore government is keeping no stones unturned on this issue. The authority is also working with the health ministry in parallel to offer serological testing, which will help identify previous dengue infection in the Singapore population. Also, in Singapore, dengue vaccination is not part of the national immunisation programme. This will further curb immunisation to the population in large and will only be administered to individuals where the benefits outweigh the risk. HSA has also assured that it would further strengthen the warnings and recommendations in the prescribing information to ensure safe use of Sanofi's vaccine, as well as increasing the awareness within the common man about the pros and cons of Dengvaxia vaccine.

Sanofi's standing on the issue

The French drug manufacturer, Sanofi has maintained that there has been no evidence of severe dengue in vaccinated individuals in the real-world experience with the vaccine.

The company has confirmed that the long-term safety evaluation of Dengvaxia showed significantly fewer hospitalisations due to dengue in vaccinated people over nine years old compared with those who had not been vaccinated. Sanofi plans to discuss the regulatory filing for Dengvaxia with new labelling recommendations with the US FDA. The vaccine is still under review by the European health regulators.