



SINGAPORE, 1 DECEMBER 2017

## HSA UPDATES

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### HSA UPDATES ON ADDITIONAL RISK OF DENGVAXIA® IN INDIVIDUALS WITH NO PRIOR DENGUE EXPOSURE

Following the introduction of the dengue vaccine Dengvaxia® in Singapore in 2016, pharmaceutical company Sanofi Pasteur recently issued results from its analysis of six years of clinical data. The supplemental study further assessed the long-term safety and efficacy of Dengvaxia®, and the results confirmed the Health Sciences Authority’s (HSA) earlier assessment that there is a postulated risk of a higher incidence of severe dengue following vaccination in individuals who do not have previous dengue infection.

2 As a precautionary measure, HSA had at that time required the package insert (PI) of Dengvaxia® to include relevant information on this postulated risk and to include the recommendation for individuals with unknown history of prior exposure to consider serostatus testing, if available, to determine past infection status. HSA and the Ministry of Health (MOH) had also informed medical practitioners of this recommendation upon approval of the vaccine in October 2016. Subsequently, MOH had worked with medical laboratories in public healthcare institutions to make serological testing available to medical practitioners. Technical briefings on the regulatory decision of Dengvaxia® registration were also organised for members of the local media and healthcare professionals, to emphasise and elaborate on these concerns. At that time, Singapore was the only country that required this recommendation for this vaccine.

3 HSA is now working with Sanofi to strengthen the PI to include the warning of an increased risk of hospitalisation for dengue and clinically severe dengue in vaccinated individuals not previously infected by dengue. The PI will also advise on an assessment of prior dengue infection in individuals before vaccination, and vaccination should not be recommended in individuals who have not been previously infected with dengue.

#### Dengvaxia® in Singapore

4 In October 2016, HSA approved the dengue vaccine Dengvaxia® for the prevention of dengue infection caused by dengue virus serotypes 1, 2, 3 and 4 in individuals aged 12 to 45 years. For more information on the approval of Dengvaxia®, please refer to the relevant [HSA Update](#).

**HEALTH SCIENCES AUTHORITY  
SINGAPORE  
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▪ **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at [www.twitter.com/HSAsg](http://www.twitter.com/HSAsg).

▪ **About HSA Updates**

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