



SINGAPORE, 8 DECEMBER 2017

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.
HSA UPDATES NO 10/2017

HSA FURTHER UPDATES ON DENGVAXIA®

Sanofi’s recent findings confirm the Health Sciences Authority (HSA) Singapore’s earlier assessment in 2016, 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 In addition, we had set a higher minimum recommended age of 12 years old instead of 9 years old due to the concerns that young children could have a higher risk of severe dengue following vaccination. We were the only regulatory agency at that time to recommend a higher recommended age.

HSA’s review of the data for Sanofi’s dengue vaccine

3 In 2016, when HSA reviewed the data that was submitted by Sanofi for registration of Dengvaxia®, the data suggested a potential risk of severe dengue in those who do not have past dengue infections when they become infected subsequently.

HSA’s risk mitigation measures

4 To mitigate these risks, HSA had at that time already recommended that individuals interested in getting the vaccine should consult their doctors on the benefits and risks of the vaccination. Educational materials and the package insert (PI) of Dengvaxia® had in 2016 included relevant information on this potential risk of severe dengue in those who do not have past dengue infections and that individuals with an unknown history of previous dengue infection should consider serostatus testing if available to determine their past infection status. HSA had shared this with the media and public in October 2016. Healthcare professionals also were informed of HSA’s concerns regarding the risks of vaccination, especially among those who do not have previous dengue infection.

5 Subsequently, the Ministry of Health, Singapore, had worked with medical laboratories in public healthcare institutions to make serological testing available to medical practitioners. Serology testing to identify previous dengue infection was made available at the major hospitals in Singapore.

Current situation

6 In Singapore, dengue vaccination is not part of the national immunisation programme, which means that the vaccine is only given to individuals where the benefits outweigh the risk, instead of the population at large. The necessary safeguards are in place in Singapore, such as the availability of serological testing to determine prior dengue infection.

7 HSA will further strengthen the warnings and recommendations in the prescribing information of Sanofi's dengue vaccine to ensure safe use of the vaccine. All healthcare professionals have been issued advisories on Sanofi's recent findings and the recommendation not to vaccinate individuals who do not have previous dengue infection. HSA will monitor the vaccine closely to ensure its continued safety and efficacy.

Dengvaxia® in Singapore

8 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.

9 For more information, please refer to the following HSA Updates found on our website:

1 DEC 2017 Update on Dengvaxia® following latest Sanofi study
http://www.hsa.gov.sg/content/hsa/en/News_Events/HSA_Updates/2017/dengvaxia_update.html

OCT 2016 Approval of Dengvaxia® in Singapore: Scientific review and findings, approved age range and recommendations
http://www.hsa.gov.sg/content/hsa/en/News_Events/HSA_Updates/2016/hsa-approves-dengvaxiavaccine.html

**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/>.

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