THE STAR, THURSDAY 4 MAY 2017

Dengue vaccine not for all ages

The Star 4/5/17 mLS-14

Only those aged between nine and 45 will be administered the medicine

By LOH FOON FONG
foonfong@thestar.com.my

PETALING JAYA: Malaysians should not be too worried about getting severe dengue symptoms from the use of the dengue vaccine because it is not allowed for use by a susceptible age group here, the Malaysian Paediatric Association (MPA) said.

Committee member Datuk Dr Zulkifli Ismail said the vaccine, the first introduced in the world by Sanofi Pasteur, was only allowed for individuals aged nine to 45 and not in younger children, who could develop such symptoms after vaccination.

He said the phenomenon described by dengue expert Dr Scott Halstead many years ago in patients who had secondary dengue infection was not seen in those who had received the vaccine.

Dr Halstead, who first identified the antibody-dependent enhancement (ADE) phenomenon, said infection with one of the four strains of the virus allows a second dengue infection to cause severe illness, including dengue haemorrhagic fever.

His ADE theory holds that the longer the interval between infection with different dengue strains, the more severe the disease.

ADE was observed following a study on mice and later in Cuba when a less serious outbreak of the type 1 dengue virus was followed by a more severe wave of type 2 dengue cases one to two decades later.

A similar phenomenon was seen in babies born to mothers infected with the dengue virus. It significantly increases the likelihood of the children contracting a severe case of the disease.

Dr Zulkifli, who is also the Asia Pacific Paediatric Association secretary-general, was commenting on a recent statement by Health director-general Datuk Dr Noor Hisham Abdullah that one of the possible adverse effects of dengue vaccination was that people could develop severe dengue or get dengue shock syndrome.

The National Pharmaceutical Regulatory Agency had announced on its website recently that the vaccine was approved for a post-registration (phase 4) study in Malaysia by the Drug Control Authority for two years and may be used in those aged nine to 45.

Using Sanofi Pasteur's data from phase 3 clinical trials of the vaccine, Dr Halstead and fellow researcher Dr Philip K. Russell showed that – during year three of the trial – the dengue hospitalisation rate was higher among children aged five or younger who received the vaccine than in the control groups that did not.

The trials involved more than 35,000 children in 10 dengue-endemic countries.

The data showed that 54.2% of the children were seronegative, which means their blood tested negative for the virus, upon enrolment in the trials.

Dr Halstead and Dr Russell published their findings in the journal *Vaccine* in February last year. Dr Russell had said the company did not directly address the ADE phenomenon nor provided a good explanation for the high risk of hospitalisation among seronegative children.

While the company maintained that it only vaccinated children over age nine, Dr Russell said age was "only a surrogate here for being dengue naive (not exposed to dengue previously). They need to directly address ADE in phase 4 studies."

Dr Zulkifli argued that there may be many other reasons for the presumably dengue-naive children getting severe dengue as children are not, and should never be, regarded as "little adults" physiologically.

He said the only way to have proper results on the vaccine's effectiveness on the ground is for it to be used in line with what was approved by the regulatory authorities, and with proper monitoring.