

### WORLD HEALTH ORGANIZATION

## **Q&A** on dengue vaccine

### 10 December 2017

We know there are still many concerns about the dengue vaccine, and we have received many questions following our post earlier this week. Here are some answers to the most frequently asked questions.

### What exactly did WHO recommend with regard to introducing the dengue vaccine?

WHO published a position paper on the dengue vaccine in July 2016. It did not make a blanket recommendation to countries to introduce the dengue vaccine but rather recommended that countries consider the introduction of the dengue vaccine only in areas where epidemiological data indicate a high burden of disease.

The paper recommended a number of conditions that should be met by countries if they wanted to consider introducing the vaccine, as well as issues, benefits and risks that countries should think through when they decide whether or not to introduce the vaccine.

This position was based on the evidence and data that were available at that time. It was guided by advice from the WHO Strategic Advisory Group of Experts on immunization (SAGE), following their meeting and statement in mid-April 2016.

WHO position papers on vaccines are intended for use by public health officials and national immunization programme managers, to guide government decisions about introducing new vaccines. Position papers are updated when significant new data emerge or the epidemiological situation changes.

# What were the 'conditions' WHO said countries should take into account in considering whether to introduce the dengue vaccine, and were these met in the Philippines when the dengue vaccine was introduced?

WHO said countries should consider the introduction of the dengue vaccine only in areas where epidemiological data indicate a high burden of disease (i.e. where at least 70% of people being considered for vaccination have already been infected with the dengue virus).

WHO also recommended that the vaccine should not be given to children below 9 years of age, and that people who do receive the vaccine should have three doses.

In the July 2016 position paper, WHO pointed to important knowledge gaps about the performance of the vaccine, in particular in people who had not been infected with dengue before receiving the vaccine. The paper acknowledged that in children 9 years of age or older, the data available at that time did not show evidence of enhanced risk of hospitalization or severe dengue in individuals previously uninfected by dengue, but it also noted in light of the limited data available, a theoretical increased risk in all age groups for hospitalization/severe dengue in people who had not been infected with dengue before receiving the vaccine could not be ruled out. Therefore, WHO requested the manufacturer to generate data on the longer-term benefits and risks of dengue vaccination in seronegative individuals.

Further, WHO's position paper recommended that countries which want to introduce the dengue vaccine should have a comprehensive dengue control strategy, strong capacity in place to monitor and manage any adverse events following vaccination, and a dengue surveillance system able to detect and report hospitalized and severe dengue cases.

WHO acknowledged at a press conference with the Philippine Department of Health in mid-April 2016 that these conditions appeared to be met in the three regions in which the dengue vaccination effort was ongoing at that time.

### What has changed since the dengue vaccine programme started in the Philippines?

On 30 November 2017, the manufacturer of the dengue vaccine released new data, based on a longer (6 years) follow-up and additional analysis of people who participated in clinical trials of the vaccine. The manufacturer said the new data confirmed that the vaccine provides significant, durable protection from dengue for people who had already been infected with dengue prior to vaccination. However, the manufacturer also alerted that there is an increased risk of severe dengue and hospitalization several years after vaccination among people in all age groups who had not been exposed to dengue prior to vaccination.

### What is WHO doing in light of this new information?

WHO is working with vaccine experts to assess the new information and implications for dengue vaccination programmes.

On 6 and 7 December 2017, WHO's Global Advisory Committee on Vaccine Safety (GACVS) met at WHO Headquarters and reviewed the new data on the dengue vaccine. The committee's findings are expected to be released in the coming week.

In view of the new data, WHO is seeking advice from SAGE to complement its dengue vaccine recommendations. We expect to release a further detailed Q&A on the use of the vaccine before the end of the year, as well as an update of the position paper in 2018.

### How is WHO working with the Philippine Department of Health?

Through its country office in the Philippines, WHO is in close contact with the Department of Health (DOH), sharing information and supporting their strategic and operational response to the new information. WHO is also taking part in the DOH Task Force Steering Group on this issue.

### What should I do if my child or I had the vaccine and start feeling unwell?

Anyone can get infected with dengue whether or not they have been vaccinated. WHO continues to advise anyone (vaccinated or not) who has signs of dengue—high fever, severe headache, pain behind the eyes, muscle and joint pain, nausea, vomiting, swollen glands and/or rash—to seek medical care.