FACTS ABOUT QDENGA (DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED))

Q1: Which dengue vaccine and what indication(s) is being registered?
A1: The Drug Control Authority (DCA) in its 393rd meeting has granted Takeda (M) Sdn Bhd's Qdenga (Dengue tetravalent vaccine (live, attenuated) (Germany) a Conditional Registration on 8th February 2024.

Qdenga is indicated for the prevention of dengue disease containing dengue serotypes 1, 2, 3 and 4 (live, attenuated) which are produced in vero cells by recombinant DNA technology.

Q2: What are the conditions of the registration?
A2: Since the application was based on rolling submission of the latest data, the Product Registration Holder (PRH) will need to ensure all outstanding documents are submitted and deemed satisfactory by NPRA according to the timeline given.

Apart from that, the PRH is required to monitor the safety profile of the registered vaccine through analysis of data from a registry of the vaccine recipients, and inform NPRA as soon as possible of any untoward events. The PRH is also required to conduct all activities planned under the Risk Management Plan (RMP).

The validity of this conditional approval is two (2) years. During this period, the DCA will periodically be updated with all necessary information related to the quality, safety and efficacy of this vaccine. The registration can be revoked if the conditions are not fulfilled by the PRH or if the benefit over risk of the vaccine is no longer deemed beneficial.

Q3: Why is Qdenga vaccine granted a conditional registration?
A3: Although the current final analysis clearly shows a positive benefit over risk, certain confirmatory data is still needed. Further monitoring of the efficacy and safety in Malaysia will be needed in order to ensure that the benefit over risk of this vaccine remains favourable.

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Q4: How does Qdenga work?
A4: Dengue disease is caused by infection with dengue virus, which is transmitted to humans through the bite of Aedes mosquitos. This vaccine contains attenuated versions of the 4 virus serotypes (1, 2, 3 and 4). These versions cannot cause the disease, but they 'teach' the immune system (the body's natural defences) to defend the body against the virus.

When a person is given the vaccine, the immune system identifies the attenuated serotypes as foreign and makes antibodies against them. When a person is later exposed

to the virus, the immune system recognises it and can quickly make many more antibodies, which then neutralise the virus before it can cause dengue disease.

Q5: What benefits of Qdenga have been shown in studies?

A5: This vaccine was shown to be effective at preventing fever due to dengue disease in children and adolescents in the 12 months following the second injection. In a main study in 8 countries in Latin America and the Asia Pacific region, about 20,000 children between the ages of 4 and 16 years were given Qdenga or placebo (a dummy injection). The study showed a reduction by 80% in the number of fever cases caused by confirmed dengue disease in those who received the vaccine (61 cases in 12,700 children) compared with those given placebo (149 cases in 6,316 children).

The vaccine also reduced hospitalisation due to dengue by 90%. In the 18 months after receiving the second injection, 0.1% (13 out of 12,700) of children given the vaccine were hospitalised because of confirmed dengue, compared with 1.0% (66 out of 6,316) of children given placebo.

Q4: Who can take the Qdenga vaccine?

A4: Qdenga can be taken by individuals from the age of 4 years and above regardless of whether they have previously been infected with the Dengue virus.

Q5: Who should not take Qdenga vaccine?

A5: Qdenga should not be taken by the following individuals:

- Individuals with hypersensitivity to the active substances or to any of the excipients [α,α-Trehalose dehydrate, Poloxamer 407, Human serum albumin, Potassium dihydrogen phosphate, Disodium hydrogen phosphate, Potassium chloride, Sodium chloride or hypersensitivity to a previous dose of Qdenga.
- Individuals with congenital or acquired immune deficiency, including immunosuppressive therapies such as chemotherapy or high doses of systemic corticosteroids (e.g. 20 mg/day or 2 mg/kg body weight/day of prednisone for 2 weeks or more) within 4 weeks prior to vaccination, as with other live attenuated vaccines.
- Individuals with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function.
- Pregnant women
- Breast-feeding women

Q6: How is Qdenga vaccine given?

A6: Qdenga is given as a subcutaneous injection (preferably in the upper arm in the region of deltoid) as a 0.5 mL dose at a two-dose (0 and 3 months) schedule.

Q7: How long will Qdenga vaccine provide protection?

A7: Currently, there is no data available to inform about the duration of protection that the vaccine will provide. This however will be made known once updated data is available.

Q8: Can people who have previously been infected with the Dengue virus take the Qdenga vaccine?

A8: Available data indicate that Qdenga is safe when given in people with evidence of prior dengue disease. Since previously infected individuals can be at risk of dengue (i.e. reinfection) of other strains, vaccination may be offered to them.

Q9: Can children receive Qdenga vaccine?
A9: Currently in Malaysia, the vaccine is indicated for individuals 4 years of age and above. Hence, children below the age of 4 years old should not take the vaccine until an approval from the Drug Control Authority has been given.

Q10: What are the side effects of Qdenga vaccine?
A10: In clinical studies, the most frequently reported reactions in subjects 4 to 60 years of age were injection site pain (50%), headache (35%), myalgia (31%), injection site erythema (27%), malaise (24%), asthenia (20%) and fever (11%).

These adverse reactions usually occurred within 2 days after the injection, were mild to moderate in severity, had a short duration (1 to 3 days) and were less frequent after the second injection of Qdenga than after the first injection.

During marketing of Qdenga vaccine in Malaysia, NPRA will monitor its use to ensure effectiveness and safety. Please inform your healthcare provider or report any side effects to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

For further information regarding Qdenga, please refer to the Package Insert and Patient Information Leaflet.

https://quest3plus.bpfk.gov.my/pmo2/detail.php?type=product&id=MAL24026010A

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