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STATEMENT ON THE CLINICAL USE OF THE DENGUE VACCINE QDENGA FOR AUSTRALIANS

A new dengue chapter is being developed for the Australian Immunisation Handbook. In the interim, refer to this statement, complemented by the Australian Immunisation Handbook, for clinical practice guidance.

Key Points

- Qdenga is the only dengue vaccine available in Australia to protect against serious disease caused by the dengue virus (Table 1).
- Qdenga is a **live-attenuated tetravalent dengue vaccine** registered for use in **people aged ≥4 years**.
- Qdenga is **contraindicated in people who are immunocompromised** (see Vaccination for people who are immunocompromised), including those who will be receiving immunosuppressive treatment within 4 weeks of vaccination. People living with HIV who are not immunocompromised can receive Qdenga (see Table. Levels of immunocompromise in children and adults with HIV).
- Qdenga is given as a two-dose schedule, with doses **administered subcutaneously at least 12 weeks (3 months) apart**. Completion of both doses is important to maximise the level and duration of protection. There is currently insufficient evidence to inform recommendations on the use of booster doses.
- **Recommendations on the use of Qdenga** (Table 2) differ according to an individual's risk of dengue exposure (including occupational exposure risk), history of previous dengue infection, and local epidemiological circumstances.
- In the pivotal phase 3 clinical trial, vaccine efficacy against virologically-confirmed dengue (VCD) was approximately 80% at 12 months post-vaccination with efficacy estimates ranging from around 60% to over 95%[1], depending on a person's baseline serostatus or the dengue virus serotype. Clinical trial data demonstrated sustained protection for up to 4.5 years following vaccination.[2]
- Most injection site reactions and systemic adverse events reported following Qdenga vaccination are mild to moderate and resolve within a few days.
- People **can receive Qdenga at the same time as other vaccines**, including inactivated vaccines (such as hepatitis A), live parenteral vaccines (such as live Japanese encephalitis vaccine [Imojev], MMR and yellow fever) and oral live vaccines (such as cholera and typhoid). A live parenteral vaccine can be given either at the same time as another live parenteral vaccine, or at least 4 weeks apart.

Table 1 Dengue vaccine available for use in Australia in 2026

	Qdenga (Live attenuated tetravalent dengue vaccine)
Registered age group	≥4 years
Number of doses for completion of course	2 x 0.5mL doses
Interval between the 2 doses	12 weeks (3 months)
Route of administration	Subcutaneous injection
Booster dose recommendation	None
Contraindications	• People who are immunocompromised (see Vaccination for people who are immunocompromised) • People with a history of anaphylaxis after a previous dose of Qdenga or component of Qdenga
Interval between infection and vaccine	Following dengue infection, short-lived cross protection against all serotypes occurs. Consider **deferring administration of Qdenga for a period of 6 months** after a confirmed or likely history of dengue.
National Immunisation Program (NIP) funding	None

Table 2 Qdenga recommendations by population and risk factors

Population	Qdenga vaccine recommendation
*Travellers **to a dengue endemic area***	
Travellers with a history of dengue, regardless of travel duration	Recommended for people aged ≥4 years with a confirmed or likely history of dengue^ who are travelling to dengue-endemic areas.
Travellers without a history of dengue planning **longer** term or **repeated** travel	Recommended for people aged ≥4 years without a confirmed or likely history of dengue^ who are planning to live, work, or spend prolonged or repeated periods in dengue-endemic areas.
Travellers without a history of dengue planning **shorter** term travel	Can be considered for people aged ≥4 years without a confirmed or likely history of dengue^ who are planning shorter-term travel to dengue-endemic areas, based on an individual risk-benefit assessment.*
People at occupational risk	
Laboratory workers	Recommended in laboratory workers who may be exposed to dengue virus.
Other groups	
People in dengue-receptive areas** of Australia in the context of local outbreaks	Can be considered in people aged ≥4 years during an outbreak in dengue-receptive areas** of Australia, according to advice of the local public health authorities.

^Includes laboratory-confirmed dengue or a likely history of dengue determined by a clinician on the basis of a compatible clinical and epidemiological history (e.g. a dengue-compatible illness during or within 14 days of return from a dengue-endemic area). Routine serology to establish previous dengue infection is not recommended.

*Assessment may consider factors such as destination-specific dengue risk (including outbreak activity), duration of stay, likelihood of mosquito exposure and anticipated future travel, including repeated travel to dengue-endemic areas. See 'What are the considerations for Qdenga in shorter-term travellers without a history of dengue?'

**Dengue receptive areas are areas where the mosquito vector (*Aedes aegypti or Aedes albopictus*) may be present; outbreaks are defined by public health authorities

What is dengue?

- Dengue is a mosquito-borne disease caused by the dengue virus and is reported by the WHO to be the fastest growing communicable disease globally. There are an estimated 100 million annual symptomatic cases worldwide.[3]
- There are 4 distinct serotypes of the dengue virus (DENV1–4). Infection with one serotype results in lifelong protection against that serotype, but only short-term cross-protection against the other serotypes.[4]
- Dengue virus is spread predominantly by *Aedes aegypti* and *Aedes albopictus* mosquitoes, which are active during the day, breed in still water, and reside in urban environments.[4]
- The incubation period is typically 5–7 days (range 3–14 days) following the bite of an infected mosquito.
- Most dengue virus infections are asymptomatic or cause a self-limited illness.
- Symptomatic dengue disease may present as an influenza-like illness with fever, headache, myalgia, arthralgia and rash. More serious manifestations of dengue may require hospitalisation for clinical management.[4]
- Severe dengue (previously referred to as dengue haemorrhagic fever and dengue shock syndrome) can occur with any dengue infection but is more likely during a second dengue infection.[4] It can be associated with severe bleeding, organ impairment or shock and can sometimes result in death.

Where are Australians at risk of acquiring dengue?

- Dengue is not endemic in Australia. It is, however, widespread in many countries that are popular destinations for Australian travellers. The following resources contain information on areas with dengue activity:
  - WHO: https://worldhealthorg.shinyapps.io/dengue_global/
  - CDC: https://www.cdc.gov/dengue/areas-with-risk/index.html
  - ECDC: https://www.ecdc.europa.eu/en/dengue-monthly
  - DengueMap: https://www.healthmap.org/dengue/en/
- Almost all notified dengue cases diagnosed in Australia are acquired overseas by travellers returning from endemic countries.[5]
- Although uncommon in Australia, dengue outbreaks have occurred in the past in northern and central Queensland and the Torres Strait where *Ae. aegypti* or *Ae. albopictus* mosquito vectors are present. These have been initiated from the introduction of the virus by infected travellers returning from overseas leading to a localised outbreak.[6]

- Australians most commonly acquire dengue while travelling to endemic areas of South-East Asia and the wider Indo-Pacific.[5] Five of the ten most visited destinations for Australian travellers (Indonesia, Thailand, India, Vietnam and Fiji) are classified as having frequent or continuous dengue transmission.[7] These destinations account for nearly one-third of short-term overseas travel undertaken by Australian residents.[8]
- Dengue risk varies by destination, season and local outbreak activity. Reported incidence has increased across many endemic regions over the past two decades.[9,10] A traveller's individual risk should therefore be assessed during pre-travel consultation.

What is the Qdenga vaccine?

- Qdenga is a tetravalent live attenuated vaccine. It is produced in Vero cells and contains serotype-specific surface protein genes of the four dengue serotypes with a dengue type 2 virus backbone.
- A complete Qdenga schedule consists of two 0.5mL doses administered subcutaneously, with a recommended minimum interval of 12 weeks (3 months) between doses. Completion of both doses is important to maximise the level and duration of protection.
- Qdenga was registered with the Therapeutic Goods Administration in April 2026 for people aged ≥4 years and became available in Australia through private prescription in October 2026. It is not funded under the National Immunisation Program (NIP).

What adverse events can occur after receiving Qdenga?

- In clinical trials and post-marketing safety surveillance of Qdenga, frequently reported adverse events included injection site pain or redness, muscle pain, fever, headache, malaise, and rash.[11-13]
- Adverse events were generally similar following both dose 1 and dose 2.
- Overall, there was no difference in rates of systemic adverse events following receipt of Qdenga compared with placebo. Systemic adverse events observed in post-marketing safety surveillance tended to occur during the second week following vaccination (median onset day 8).
- A small to moderate increase in injection site adverse events was observed following receipt of Qdenga compared with placebo (reported rates ranged from around 17% to 71% for Qdenga and from 11% to 50% for placebo).[1,14,15]
- Baseline seronegative people generally reported higher rates of injection site and systemic adverse events compared to baseline seropositive people.
- Most injection site and systemic adverse events, regardless of previous dengue exposure, were mild to moderate and resolved within a few days.
- Aggregate rates of serious adverse events (regardless of nature) were low in clinical trials (ranged from 0.0 to 5.0% for Qdenga and 0.0 to 6.0% for placebo).[1,14,15] Clinical trials are not powered to detect rare events.
- Although no increased risk of anaphylaxis following receipt of Qdenga was observed in clinical trials, post-marketing safety surveillance and studies from Brazil reported hypersensitivity reactions, including anaphylaxis, after Qdenga vaccination. The rate for cases that met the Brighton Collaboration Level 1 Criteria for anaphylaxis was around 29 per million doses, which is greater than the internationally observed rate of anaphylaxis following vaccination of around 1 case per million doses.[16,17] Most cases occurred following the first dose of Qdenga with rates reported up to 86 per million doses.[13,18-21]
- Vaccine-associated enhanced disease (VAED) was observed with another dengue vaccine (Dengvaxia) that is no longer available. Some people without previous dengue infection who were vaccinated with Dengvaxia had an increased risk of severe dengue with subsequent infection.[22] In contrast, millions of doses of Qdenga have been administered globally and VAED has not been observed following vaccination with Qdenga.

How effective is Qdenga?

- In the phase 3 trial, Qdenga demonstrated high vaccine efficacy against VCD at 12 months post-vaccination (80.2%)[1] and against hospitalisation due to dengue up to 4.5 years after vaccination (93.7%)[2] in immunocompetent people aged 4–16 years. Additionally, observational studies demonstrated high vaccine effectiveness against hospitalisation up to 12 months after vaccination (87.9%) in people aged 10–14 years.[23,24]
- Serotype-specific protection against VCD is greatest for DENV2 with efficacy estimates around 98% during the 12-month post-vaccination period.[1] Efficacy against DENV1 (~74%) was lower compared to DENV2.[1] It was also lower for DENV3 (~63%) particularly for those who have never had dengue (seronegative).[1,2] Evidence of protection from vaccination for DENV-4 is uncertain due to limited case numbers in the trials.[1,2]
- There is evidence that protection from vaccination may be lower in people who have not previously had dengue (75% efficacy against VCD) compared to people who have had dengue in the past (82%).[1]
- There is no efficacy data in adults, however, immunogenicity data[14,15,25] demonstrates seroprotection in dengue-naïve adults aged 18 years and over that is similar to that seen in children aged 4–17 years.

- Clinical trial data demonstrate sustained protection for up to 4.5 years following vaccination.[2] There is currently insufficient evidence to inform recommendations on the use of booster doses and future clinical studies will further assess duration of protection and the need for booster doses.

Can Qdenga be co-administered with other vaccines?

- Yes, Qdenga can be given at the same time as other vaccines, including non-live vaccines (such as hepatitis A), live parenteral vaccines (such as live Japanese encephalitis vaccine [Imojev], MMR and yellow fever), and oral live vaccines (such as cholera and typhoid).
- If a person does not receive Qdenga at the same time as other live parenteral vaccines, a period of at least 4 weeks should separate Qdenga from other live parenteral vaccines.
- Studies where Qdenga was coadministered with yellow fever, hepatitis A and HPV vaccines suggested no safety concerns. However, there is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time.[11,12,14,26,27]
- In separate clinical studies of adults who received Qdenga at the same time as either yellow fever or hepatitis A vaccine, there was no effect on immune responses to the yellow fever or hepatitis A vaccines.[14,26] Dengue antibody responses were similar when Qdenga was administered alone compared with when co-administered with hepatitis A vaccine. When Qdenga was coadministered with yellow fever vaccine, dengue antibody responses were lower for most DENV serotypes (except DENV4) than when Qdenga was administered alone; however, the clinical significance of this finding is unknown.[14,26]

What are the considerations for Qdenga in shorter-term travellers without a history of dengue?

There are several important factors for consideration when deciding to offer Qdenga vaccine to people **without a confirmed or likely history** of dengue who are planning shorter-term travel to dengue endemic or dengue outbreak areas:

- **destination-specific dengue risk and outbreak activity:** Qdenga should only be considered for people travelling to areas where dengue is endemic or where an outbreak is occurring. (see Where are Australians at risk of acquiring dengue?)
- **duration of stay and anticipated future travel:** Qdenga may be considered for a person who is anticipated to make frequent or repeated trips to dengue-endemic areas. For example, a person who travels to an endemic area for 1–2 weeks every 6 months.
- **the likelihood of contact with mosquitoes that can spread dengue:** Dengue is spread by *Ae. aegypti* or *Ae. albopictus* which are day-biting mosquitoes that breed in small water containers and are often found in urban environments. Assessment for Qdenga vaccination may consider factors that influence the likelihood of mosquito exposure, including planned activities and anticipated time spent outdoors during the day
- **immune status and pregnancy:** Qdenga is a live vaccine and is contraindicated in people who are immunocompromised (see Vaccination for people who are immunocompromised). Qdenga is not recommended in pregnancy. However, if travel to a country with dengue virus transmission is unavoidable, vaccination may be considered following an individual risk-benefit assessment and discussion of the potential risks, benefits and uncertainties (see contraindications and precautions).
- **personal preferences and risk tolerance:** Some travellers may place a high value on reducing their risk of dengue through vaccination, while others may prefer to rely on mosquito avoidance measures or may weigh the potential benefits and limitations of vaccination differently. Individual preferences should be considered as part of shared decision-making.

Is dengue serology recommended before administering Qdenga vaccine?

- No, routine serological testing to establish previous dengue infection is not recommended before vaccination.
- Instead, previous dengue infection can be identified based on laboratory confirmation at the time of illness or a likely history of dengue determined by a clinician on the basis of a compatible clinical and epidemiological history (e.g. a dengue-compatible illness during or within 14 days of return from a dengue-endemic area).
- Serological testing has important limitations, including potential cross-reactivity with antibodies generated following exposure to other flavivirus infections or vaccinations, making interpretation difficult.
- Practical considerations also limit the usefulness of serology, especially for travellers seeking advice shortly before departure, as Qdenga requires two doses administered 12 weeks (3 months) apart.

What is recommended if a person can only receive a single dose prior to travel?

- The recommended Qdenga schedule consists of two doses administered at least 12 weeks (3 months) apart.
- If only 1 dose can be administered prior to departure, it is still recommended to be given. This is based on clinical trial data that showed efficacy of 82% against VCD in the 3-month period following a single dose of Qdenga.[28] Observational studies from an outbreak setting showed 59% effectiveness against symptomatic dengue and 75% effectiveness against hospitalisation following a single dose of Qdenga, and these results were sustained for the 12-month observation period. [23,24,29]
- A plan should be made for receipt of the second dose, either on return from travel or with a suitable vaccination provider in the destination country when the second dose is due.

- Vaccination should not replace mosquito bite avoidance measures, which remain important regardless of vaccination status.

Contraindications and precautions to the use of Qdenga

Immunocompromised people

- Qdenga is contraindicated in people who are immunocompromised (see Vaccination for people who are immunocompromised), including those who will be receiving immunosuppressive treatment within 4 weeks of vaccination.
- People living with HIV who are not immunocompromised can receive Qdenga (see Table. Levels of immunocompromise in children and adults with HIV).

Pregnancy and breastfeeding

- Pregnant individuals are not recommended to receive Qdenga, However, if travel to a country with dengue virus transmission is unavoidable, vaccination may be considered following an individual risk-benefit assessment and discussion of the potential risks, benefits and uncertainties.
- A theoretical concern with live attenuated vaccines is that the vaccine virus can cross the placenta and affect the fetus. Studies of Qdenga have shown temporary vaccine viraemia in some vaccine recipients, but the clinical significance of this finding for pregnant individuals or the fetus is unknown.
- There is a limited amount of data from the use of Qdenga in pregnant individuals. A study that reviewed data from earlier clinical trials to assess pregnancy and newborn outcomes in individuals who were inadvertently vaccinated shortly before or during pregnancy showed no evidence of increased adverse pregnancy outcomes.[30]
- The risk of severe dengue is higher in pregnant individuals than non-pregnant women of child-bearing age, with potential complications for both the pregnant individual and their fetus.[31] Pregnant individuals should be advised of both the risks associated with travelling to areas with dengue activity, as well as how to avoid mosquito bites.

Anaphylaxis

- Qdenga is contraindicated in people with a history of anaphylaxis to a previous dose of Qdenga or to any component of the Qdenga vaccine.
- Anaphylaxis has been reported in individuals who have received Qdenga (see *What adverse events can occur after receiving Qdenga?*). As with all injectable vaccines, observation for a minimum period of 15 minutes is advised. Appropriate medical treatment and supervision must always be readily available in the event of a rare anaphylactic reaction following administration of a vaccine. In rare cases after any vaccination, anaphylaxis can occur beyond 15 minutes and recipients should be aware of symptoms to monitor.

Please refer to the Therapeutic Goods Administration Product Information for further information on Qdenga.

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