

Questions & Answers on licence DIR 196 – commercial supply of a genetically modified (GM) dengue vaccine, Qdenga

What does this licence allow?

Takeda Pharmaceuticals Australia Pty Ltd has received an approval under the *Gene Technology Act 2000* for the import, transport, storage, and disposal of a genetically modified (GM) dengue vaccine, Qdenga, as part of its commercial supply in Australia as a human vaccine against dengue virus.

What is dengue?

Dengue is a mosquito-borne disease caused by dengue viruses. A 'strain' is a genetic variant or subtype of a microorganism. Strains of dengue virus can also be categorised into 4 distinct 'serotypes' based on proteins on the surface of the viral particle that are recognised by the immune system. People infected for the first time can develop sudden and painful fever. The infection usually resolves after a week and the person has life-long immunity to that particular serotype of dengue virus. However, a subsequent infection with a different serotype of dengue virus can potentially lead to a more serious outcome, including life-threatening dengue haemorrhagic fever or dengue shock syndrome.

How has the dengue vaccine been genetically modified?

Qdenga contains 4 GM attenuated (weakened) strains of dengue virus. These vaccine strains are based on a non-GM serotype 2 strain. One of the GM strains contains serotype 2 dengue genes that produce proteins that are recognised by the human immune system. In each of the other 3 strains, these genes have been replaced with equivalent genes from one of the other 3 dengue serotypes. As a result of these modifications, the vaccine is intended to stimulate an immune response that will provide protection against all 4 dengue serotypes.

Why is the dengue vaccine being supplied in Australia?

Dengue is exotic to Australia, but Australians can be infected when they travel to neighbouring tropical regions where dengue is endemic. When a person infected with dengue returns, the disease is brought into Australia and sporadic outbreaks occur in the warmer parts of Australia, where the disease-transmitting mosquito lives.

What regulatory processes apply to this commercial supply?

The Gene Technology Regulator (the Regulator) has specific responsibility to protect the health and safety of people, and to protect the environment from any risks posed by gene technology. For this type of application, the activities assessed by the Regulator are the import, transport, storage, and disposal of the GM vaccine.

The use of the vaccine in people will also require approval by the Therapeutic Goods Administration (TGA). The TGA considers the safety and efficacy of the vaccine in people being vaccinated as part of their approval process, and also determines conditions for the use of the vaccine.

The import of the vaccine will also require a permit from the Department of Agriculture, Fisheries and Forestry (DAFF).

Has Qdenga been used previously?

Qdenga has not previously been approved for commercial use in Australia.

Internationally, Qdenga has been approved by health authorities in Indonesia, the European Union, Great Britain, Brazil, Argentina, and Thailand.

What controls have been imposed for this commercial supply?

The licence is for an ongoing commercial supply. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that the supply of this GM dengue vaccine poses negligible risks to the health and safety of people or the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the commercial supply.

Want more information?

A number of documents relating to this decision are available on the [DIR-196](#) page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

The Office of the Gene Technology Regulator

Tel: 1800 181 030 E-mail: ogtr@health.gov.au

[OGTR Website](#)