

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

What is this application for?

Takeda Pharmaceuticals Australia Pty Ltd is seeking approval for the import, storage, transport, 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. 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 type of dengue virus. However, a subsequent infection with a different type of dengue virus can lead to potentially life-threatening dengue haemorrhagic fever or dengue shock syndrome.

How has the dengue vaccine been genetically modified?

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 factors on the surface of the viral particle that are recognised by the immune system. The vaccine contains 4 live strains of dengue virus that are based on a weakened (attenuated) serotype 2 strain. In 3 of the strains, genes that are important for human immune system recognition have been replaced with equivalent genes from serotypes 1, 3, and 4. In this manner the vaccine is intended to provide immunity against all 4 dengue virus 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 *Aedes* mosquito lives.

Who approves the use of Qdenga?

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.

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, and Great Britain.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of consultation. In the first round, the Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial release. The consultation version of the RARMP will be publicly released and submissions will again be sought from stakeholders, this time including the public. The RARMP

will then be finalised, taking into account submissions received, and will inform the Regulator's decision whether or not to issue a licence.

How can I comment on this application?

While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR 196. A summary of the application is available on the [OGTR website](#) or by contacting the OGTR. The consultation version of the RARMP for this application is expected to be released for public comment in **late August 2023**. Its release will be advertised in print media, and it will be available on the OGTR website along with a range of supporting information.