Questions & Answers on licence application DIR 148 – Commercial supply of an attenuated genetically modified dengue vaccine

What does this licence allow?

Sanofi-Aventis Australia Pty Ltd has received an approval under the *Gene Technology Act 2000* for the import, transport, storage and disposal of a live genetically modified (GM) dengue vaccine, Dengvaxia, as part of its commercial supply in Australia.

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 without intervention 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 severe dengue, which is potentially life-threatening. There are currently no anti-viral treatments or vaccines against dengue viruses.

How has the dengue vaccine been genetically modified?

Dengvaxia contains four GM attenuated viral strains to protect against the four main types of dengue virus. These vaccine strains are based on a non-GM Yellow fever virus, YF 17D, which has been safely used as a Yellow fever vaccine for over 60 years. In each of the GM strains, two YF 17D genes are replaced with the equivalent genes from one type of dengue virus.

Why is the dengue vaccine being released in Australia?

Dengue is exotic to Australia but Australians can be infected when they travel to tropical regions where dengue is endemic. When a person infected with dengue returns, the disease is brought into Australia, resulting in sporadic outbreaks in the warmer parts of Australia where the disease-transmitting *Aedes* mosquitoes live.

Who approves use of Dengvaxia?

The Therapeutic Goods Administration (TGA) has responsibility for assessing the quality, safety and efficacy of vaccines for use in humans in Australia. Before it can be used commercially, Dengvaxia must be assessed by the TGA and included in the Australian Register of Therapeutic Goods. It would only be available under prescription for injection by a healthcare professional.

Has Dengvaxia previously been used?

Dengvaxia is currently available in 14 countries. Some clinical trials of this vaccine were conducted in Australia between 2006 and 2012, authorised by the Gene Technology Regulator, a Human Ethics and Research Committee and the Therapeutic Goods Administration.

What controls have been imposed for this GMO?

The licence is for ongoing commercial supply. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that commercial supply of the GM virus poses negligible risks to the health and safety of people and the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the release. The TGA may impose conditions on use of the GMO.

Want more information?

Several documents relating to this decision are available on the DIR 148 page of the OGTR website. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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