QUESTIONS & ANSWERS ON LICENCE DECISION DIR 098 FOR COMMERCIAL RELEASE OF A GENETICALLY MODIFIED LIVE VIRAL VACCINE TO PROTECT AGAINST JAPANESE ENCHPALITIS

What is this licence for?

Sanofi Pasteur Pty Ltd has received approval under the *Gene Technology Act 2000* for the commercial release in Australia of IMOJEV®, a live viral vaccine genetically modified (GM) to protect against *Japanese encephalitis virus* (JEV). The Therapeutic Goods Administration (TGA) has registered the GM vaccine for use in Australia.

Who will be eligible for vaccination with IMOJEV®?

The GM vaccine is intended for people travelling to, or resident in, areas where the disease occurs and may be prescribed by registered medical practitioners to persons over 12 months of age.

What is JEV?

Japanese encephalitis virus is a mosquito borne virus, which is found in most Asian and tropical regions. However, it does not occur in Australia. JEV can cause inflammation in the nervous system requiring hospital treatment. Between 5-30% of infected people die from the disease and those that survive may suffer from damage to the nervous system.

What is the vaccine?

The GM vaccine is based on the existing vaccine for Yellow fever in which two genes have been replaced by similar genes from JEV. Previous clinical studies have shown that this GM vaccine protects adults and children against JEV.

Has the vaccine previously been trialled in Australia?

Yes. The vaccine has been the subject of clinical trials in Australia, Thailand, India, Philippines and the USA. The Regulator has previously issued five DNIR licences for experimental research and clinical trials of this vaccine. The clinical trials in Australia were also conducted in accordance with the requirements of the TGA.

What licence conditions have been imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concluded that the dealings associated with this release pose **negligible** risks to people and the environment. However, a range of licence conditions have been imposed to ensure that there is appropriate oversight of the ongoing release. The GM vaccine is also subject to regulation by other federal and state agencies including the TGA and Australian Quarantine and Inspection Service (AQIS). These other agencies may impose further requirements for, or limitations on, the commercial release of this vaccine.

Want more information?

A number of documents relating to this decision are available on the OGTR website or via Freecall 1800 181 030. These documents include the finalised RARMP, an Executive Summary, a Technical Summary and a copy of the full licence.