

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

### What is this application for?

Sanofi Pasteur Pty Ltd is seeking 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).

### Who will be eligible for vaccination with IMOJEV™?

The vaccine is intended for people travelling to areas where JEV is found. It would be prescribed by registered medical practitioners to persons over 12 months of age, if approved by the Regulator and registered by the Therapeutic Goods Administration (TGA).

### 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The GM vaccine is based on the existing vaccine for Yellow fever in which two genes have been replaced by similar genes from JEV.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 nine clinical trials in Australia, Thailand, India 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 are proposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the proposed release poses **negligible** risks to people and the environment. However, a range of licence conditions have been proposed to ensure that there is appropriate oversight of the ongoing release. Full details of the proposed licence conditions are set out in the RARMP, which is now available for comment.

### How can I have my say?

You are invited to submit your comments on the consultation version of the RARMP that has been prepared for application DIR 098. The full consultation RARMP and Executive and Technical Summaries are available on the OGTR website (<<http://www.ogtr.gov.au>> under “What’s New”) or via Freecall 1800 181 030. Your advice would be appreciated on any risks to **the health and safety of people** or to **the environment** that may be posed by the proposed release; however issues such as **patient safety, vaccine efficacy** and **labelling** do **NOT** fall within the scope of the evaluations conducted under the Act as these are the responsibility of other agencies and authorities, primarily the TGA. Please note that the consultation period closes on **22 June 2010** and written submissions are required by that date.

### What are the next steps in the evaluation process?

Matters raised in submissions relating to the protection of people or the environment during the proposed release are taken into account in finalising the RARMP, which then forms the basis of the Regulator’s decision on whether to issue a licence.