



Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

19 August 2010

NOTIFICATION OF DECISION

ISSUE OF LICENCE DIR 098 TO SANOFI PASTEUR PTY LTD FOR THE COMMERCIAL RELEASE OF A LIVE GM VIRAL VACCINE

The Gene Technology Regulator has made a decision to issue a licence in respect of application DIR 098 from Sanofi Pasteur Pty Ltd. The applicant has received approval for the commercial release of a genetically modified live viral vaccine to protect against Japanese encephalitis (IMOJEV[®]). The TGA has registered the GM vaccine for use in Australia by people over the age of 12 months. The vaccine is intended for people travelling to, or resident in, areas where the disease occurs and will be prescribed by registered medical practitioners and administered in medical facilities.

The decision to issue the licence was made after extensive consultation on the Risk Assessment and Risk Management Plan (RARMP) with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee, and relevant local councils, as required by the *Gene Technology Act 2000* and corresponding State and Territory laws.

Issues relating to the health and safety of people and the protection of the environment raised during the consultation process on this application were considered in finalising the RARMP and in making the decision to issue the licence.

The Executive Summary, Technical Summary and complete finalised RARMP, together with a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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