Australian Government
Department of Health
Office of the Gene Technology Regulator

27 June 2017

Issue of licence DIR 148 to Sanofi-Aventis Australia Pty Ltd (Sanofi) for the commercial supply Dengvaxia, a live attenuated GM dengue vaccine

On 8 March 2017, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 148 from Sanofi.

The Regulator has now issued a licence in response to application DIR 148, authorising the import, transport, storage and disposal of the genetically modified (GM) dengue vaccine, known as Dengvaxia, for the purpose of commercial supply as a therapeutic.

The use of Dengvaxia will require its registration by the Therapeutic Goods Administration (TGA), and inclusion in the Australian Register of Therapeutic Goods. Subject to TGA approval, the GM dengue vaccine would be administered by subcutaneous injection by a healthcare professional.

The Regulator's decision to issue the licence was made after consultation on the RARMP with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

The Regulator considered all submissions provided during the consultation process that related to the health and safety of people or the protection of the environment. The comments were considered in the context of current scientific information and used in finalising the RARMP. The finalised RARMP informed the Regulator's decision to issue the licence.

The finalised RARMP concludes that this commercial supply poses negligible risks to people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of the release.

Appendices A and B of the RARMP summarise the advice received from prescribed experts, agencies and authorities, and indicates how issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the document. Seven submissions were received from members of the public on the consultation RARMP and the issues raised, and their consideration, are summarised in Appendix C of the RARMP.

The finalised RARMP, together with a summary of the RARMP, a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR 148 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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