



Australian Government

Department of Health

Office of the Gene Technology Regulator

8 March 2017

Invitation to comment on the commercial supply of Dengvaxia, an attenuated genetically modified dengue vaccine

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is assessing licence application DIR 148 from Sanofi-Aventis Australia Pty Ltd (Sanofi) for the import, transport, storage and disposal of Dengvaxia, an attenuated genetically modified (GM) dengue vaccine, for the purpose of its commercial supply as a therapeutic product. Before it can be used commercially, Dengvaxia must also be registered by the Therapeutic Goods Administration (TGA), which has regulatory responsibility for assessing quality, safety and efficacy of therapeutic goods. If approved by both the Regulator and the TGA, Dengvaxia would be available under prescription, for administration by healthcare professionals.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared. It concludes that the proposed dealings associated with the commercial supply would pose negligible risk to human health and safety or to the environment. Draft licence conditions are proposed to ensure ongoing oversight of these activities.

The Regulator welcomes written submissions to finalise the RARMP to inform the decision on whether or not to issue the licence. The consultation RARMP and related documents can be obtained from the OGTR website under [What's New](#) or by contacting the Office. Please quote application DIR 148 in any correspondence.

Submissions should be received by close of business on **5 May 2017**.

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