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GOVERNMENT NOTICES

Invitation to comment on draft assessment for the supply of attenuated genetically modified influenza vaccines

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 137 from AstraZeneca Pty Ltd for import, transport, storage and disposal of attenuated genetically modified (GM) influenza vaccines for the purpose of their commercial supply as therapeutic products. The Therapeutic Goods Administration has regulatory responsibility for assessing quality, safety and efficacy of vaccines, and is evaluating an application from AstraZeneca for the registration of the GM influenza vaccines. If approved by both the Regulator and the TGA, the GM influenza vaccines would be administered as a nasal spray by healthcare professionals at facilities where influenza vaccines are normally dispensed.

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 inform the decision on whether or not to issue a 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 137 in any correspondence.

Submissions should be received by close of business on **13 November 2015**.

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