



Australian Government

Department of Health

Office of the Gene Technology Regulator

14 January 2016

Issue of licence DIR 137 to the AstraZeneca Pty Ltd (AstraZeneca) for the commercial supply of attenuated GM influenza vaccines

On 17 September 2015, the Gene Technology Regulator invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 137 from AstraZeneca.

The Regulator has now issued a licence in response to application DIR 137, authorising the import, transport, storage and disposal of the genetically modified (GM) attenuated influenza vaccines, known as FluMist[®], for the purpose of their commercial supply as a therapeutic.

Before the GMO can be used as a vaccine, it must also be assessed for quality, safety and efficacy by the Therapeutic Goods Administration (TGA), and included in the [Australian Register of Therapeutic Goods](#). Subject to TGA approval, the GM influenza vaccines would be administered as a nasal spray by healthcare professionals at locations where influenza vaccines are normally available.

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.

Issues were raised during the consultation process, which related to the health and safety of people and the protection of the environment, were considered in the context of current scientific information in reaching the conclusions set out in the finalised RARMP and in making the 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 indicate how issues raised relating to risks to human health and safety or the environment were considered in the document. No submissions were received from the public.

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 137](#) page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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