Questions & Answers on licence application DIR 137 – Commercial supply of attenuated genetically modified influenza vaccines

What does this licence allow?

AstraZeneca Pty Ltd (AstraZeneca) has received an approval under *the Gene Technology Act 2000* for the import, transport, storage and disposal of genetically modified (GM) influenza vaccines, known as FluMist®, for the purposes of commercial supply in Australia. Before the GMO can be used as a vaccine, it must also receive approval from the Therapeutic Goods Administration (TGA).

What other regulatory approvals are required?

The Therapeutic Goods Administration (TGA) has responsibility for assessing the quality, safety and efficacy of vaccines for use in humans. Before they can be supplied and used commercially, the GM influenza (flu) vaccines must be assessed by the TGA and included in the Australian Register of Therapeutic Goods. Since these vaccines are manufactured overseas, a permit from the Department of Agriculture and Water Resources would also be required for their import.

Is Australia the first country where these GM flu vaccines will be used?

No, similar vaccines were first marketed in the US as FluMist® during the 2003/2004 flu season and in the EU as Fluenz® during the 2012/2013 flu season. They are currently authorised in the USA and Canada as FluMist Quadrivalent, and in the EU as Fluenz Tetra.

Where and how will the vaccines be administered?

If approved by the TGA, the GM vaccines would be distributed to facilities where flu vaccines are normally available. Qualified health professionals would administer the vaccines to patients as a nasal spray, subject to any conditions imposed by the TGA.

How are the GM flu vaccine strains modified?

The GM vaccines are based on attenuated human flu strains which have reduced ability to grow and cause disease. These attenuated strains are modified by incorporation of antigens from current circulating flu strains to provide protection against these flu strains. As flu viruses change rapidly, every year the World Health Organisation (WHO) and the Australian Influenza Vaccine Council (AIVC) issue advice on the composition of flu vaccines for the coming flu season. Based on the AIVC's advice, seasonal flu vaccines, including other types of flu vaccines currently approved for use in Australia, are reformulated every year. The FluMist® composition would vary each year based on the recommended antigens for the upcoming flu season.

What controls have been imposed for this GMO?

The licence is for ongoing commercial supply. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that commercial supply of the GM virus poses negligible risks to the health and safety of people and the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the release. The TGA may impose conditions on use of the GMO.

Want more information?

Several documents relating to this decision are available on the DIR 137 page of the OGTR website. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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