Questions & Answers on licence DIR 161 – Clinical trials of a genetically modified (GM) vaccine against respiratory syncytial virus

What is this application for?

The Gene Technology Regulator has issued a licence to Clinical Network Services (CNS) Pty Ltd to conduct clinical trials of a live attenuated genetically modified (GM) respiratory syncytial virus (RSV) vaccine. RSV causes a range of respiratory diseases in people, including pneumonia and bronchiolitis. There are currently no available vaccines against RSV.

The clinical trials are permitted to take place between July 2018 and July 2023. The GM vaccine may be administered to up to 350 healthy adult volunteers by intranasal spray at specialised clinical trial sites.

What is the purpose of the clinical trials?

The purpose of the trials is to assess the safety, tolerability and efficacy of the newly developed vaccine.

How has the GM vaccine been created?

The vaccine contains a GM strain of RSV. A natural RSV strain was attenuated by making a small deletion and introducing a large number of point mutations into its genome. These changes reduce viral transcription, protein expression and viral replication during infection, compared with unmodified RSV.

What controls are proposed for this release?

A range of licence conditions have been imposed to limit the size, location and duration of the release, as well as restrict the spread and persistence of the GMO and its genetic material. Control measures include administration of the GM vaccine only by qualified and trained medical staff in clinical trial sites; excluding persons at risk of severe RSV disease from handling the GM vaccine or participating in the trials; instructing trial participants in measures to minimise the potential for transmission of the GMO to other people; and ensuring appropriate waste disposal. A full list of the control measures is detailed in the licence.

What other regulatory processes apply to this trial?

Clinical trials must be conducted in accordance with requirements of the *Therapeutic Goods Act 1989*, which is administered by the Therapeutic Goods Administration (TGA). Before commencing, the trials would require approval from a Human Research Ethics Committee, and submission of a Clinical Trial Notification to the TGA. Import of the GM vaccine, which will be manufactured in the USA, will require a permit from the Department of Agriculture and Water Resources.

Want more information?

A number of documents relating to this decision are available on the DIR 161 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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