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

What is this application for?

Clinical Network Services (CNS) Pty Ltd is seeking approval to conduct clinical trials of a 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 purpose of the trials is to assess the safety, tolerability and efficacy of the newly developed vaccine. The GM vaccine would be administered to up to 350 healthy adult volunteers by intranasal spray at specialised clinical facilities located in Melbourne, Sydney, Brisbane, Adelaide and/or Perth over a five year period.

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.

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 wild type RSV.

Has the GM vaccine been previously tested or used?

This GM vaccine has not previously been trialled in people. Animals inoculated with the GMO produced an immune response which protected them against later infection by RSV.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the proposed release poses negligible risks to people or the environment. However, a range of licence conditions would limit the scale, location and duration of the release, as well as restrict the spread and persistence of the GMO and its introduced genetic material. Proposed control measures include administration of the GM vaccine only by qualified and trained medical staff in clinical facilities; excluding persons at risk of severe RSV disease from handling the GM vaccine and 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. Full details of the draft licence conditions are set out in the RARMP, which is now available for comment.

How can I comment on this application?

You are invited to submit your comments on the consultation version of the RARMP that has been prepared for application DIR 161. The full consultation RARMP and a summary are available on the What's New page of the OGTR website or via the Freecall number below. Your advice would be appreciated on any risks to the health and safety of people or to the environment that may be posed by the proposed release. Please note that the consultation period closes on **25 May 2018** and written submissions are required by that date.

Submissions relating to the protection of people or the environment in connection with the proposed release are taken into account in finalising the RARMP, which will then inform the Regulator's decision on whether or not to issue a licence.

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