Australian Government
Department of Health
Office of the Gene Technology Regulator

16 July 2018

Decision to issue licence DIR 161 to Clinical Network Services (CNS) Pty Ltd for clinical trials of a genetically modified (GM) vaccine against respiratory syncytial virus

The Regulator has issued licence DIR 161, authorising 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 facilities. The purpose of the trials is to assess the safety, tolerability and efficacy of the newly developed vaccine.

Both the risk assessment and risk management plan (RARMP) and the licence were finalised taking into account input received during consultation with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils. The Regulator thanks submitters for their contributions.

The finalised RARMP concludes that the clinical trials pose negligible risks to the health and safety of people and the environment and does not require specific risk treatment measures. However, licence conditions have been imposed to restrict spread and persistence of the GMO and its genetic material in the environment and to limit the release in size, location and duration, as these were important considerations in the evaluation process.

The finalised RARMP, a summary of the RARMP, the Licence, and Questions and Answers about this decision, can be obtained online from the DIR 161 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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