Questions & Answers on licence application DIR 185 – Clinical trial with genetically modified *Bordetella pertussis* for the prevention of whooping cough

What does this licence allow?

Novotech (Australia) Pty Ltd is conducting a clinical trial of with genetically modified (GM) *Bordetella pertussis* for the prevention of whooping cough in Australia. The bacteria *B. pertussis* is the cause of the disease commonly known as whooping cough. *B. pertussis* infection can initially cause tiredness, runny nose, sneezing, low-grade fever, and cough. Symptoms would eventually lead to intense and frequent coughing with the characteristic 'whooping' sound. The infection is serious in unvaccinated infants or partially vaccinated children, as it can lead to lung complications and in some cases death. The purpose of this clinical trial is to assess an inhaled GM vaccine, for the prevention of whooping cough, which is different to the intramuscular injection of other pertussis vaccines currently in use. Up to 300 healthy participants would receive the GM vaccine at clinical trial sites and hospitals in Australia.

How has the Novotech (Australia) Pty Ltd vaccine been made and how does it work?

The vaccine contains pertussis bacteria that has been modified by altering genes responsible for the disease. Once administered, the GM bacteria cannot cause disease but triggers an immune response, preparing the body to fight a future whooping cough infection.

What other regulatory processes apply to this trial?

Notification of the clinical trial must be submitted to the Therapeutic Goods Administration (TGA). If the vaccine is to be registered in the Australian Register of Therapeutic Goods (ARTG) for commercial use, the safety, quality and efficacy of the vaccine including patient safety data obtained from this clinical trial would be assessed by TGA. Before commencing, the trials would require ethics approval, and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GM vaccine will also require approval from the Department of Agriculture, Water and the Environment.

Has the GM vaccine been previously tested or used?

Phase 1 and 2 clinical trials looking at the safety and efficacy of the GM vaccine were completed in Sweden and the United States of America. The published data showed a good efficacy and safety profile in participants with no vaccine related serious adverse events. Similarly, preclinical studies with the GM vaccine in animal models showed good efficacy and safety.

What controls are imposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial under limited and controlled conditions, a number of licence conditions have been imposed to restrict when and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM vaccine. For example, there are conditions relating to preparation and administration of the GM vaccine, secure transport and storage of the GM vaccine and appropriate waste disposal. Full details of these control measures are included in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR-185 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.

The Office of the Gene Technology Regulator

OGTR website

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