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

What is this application for?

Novotech (Australia) Pty Ltd is seeking approval for a clinical trial 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 GM 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?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration, which address the safety of trial participants. 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 proposed 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 drafted 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 the draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 185 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed clinical trial. Please note that issues such as **patient safety, quality and efficacy of a therapeutic products, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **4 November 2021**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is

included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR Website

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