Questions & Answers on licence application DIR 217 – Commercial supply of nadofaragene firadenovec for bladder cancer treatment

What is this application for?

FERRING Pharmaceuticals Pty Ltd has submitted an application for the commercial supply of a bladder cancer treatment. The applicant is seeking approval for the import, transport, storage, and disposal of the genetically modified (GM) therapeutic for treatment of patients in Australia. The use of the GM therapeutic in patients will also require a separate approval by the Therapeutics Goods Administration, which considers safety and efficacy of the therapeutic in people receiving the treatment as part of their approval process. A permit from the Department of Agriculture, Fisheries and Forestry will also be required for import of the GM therapeutic into Australia.

How has the GM therapeutic been made?

The GM therapeutic has been modified by removing DNA sequences for patient safety and introduction of a gene encoding a human protein that stimulates an immune response. These modifications aim to trigger an enhanced immune response in and around bladder cancers.

What is the purpose of the commercial supply?

The applicant proposes to supply the GM therapeutic to Urology and Oncology departments of hospitals for administration to patients with certain types of treatment-unresponsive bladder cancer.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of stakeholder consultation. In the first round, the Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial release. Following public release of the draft RARMP, submissions will again be sought from stakeholders, this time including the public. The RARMP will then be finalised taking into account submissions received and inform the Regulator's decision whether or not to issue a licence.

How can I comment on this application?

The comprehensive RARMP for this application is expected to be released for public comment in **July 2025**. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR 217. A summary of the application is available on the OGTR website or by contacting the OGTR.

The Office of the Gene Technology Regulator

Tel: 1800 181 030 E-mail: ogtr@health.gov.au

OGTR website www.ogtr.gov.au