Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
18 December 2023
Communiqué

This Communiqué covers matters considered at the 37th videoconference of the Gene Technology Technical Advisory Committee (18 December 2023)

The Gene Technology Technical Advisory Committee (GTTAC) is a statutory advisory committee established under the *Gene Technology Act 2000* (the Act) to provide scientific and technical advice to the Gene Technology Regulator (the Regulator) and the Gene Technology Ministers' Meeting.

The Regulator seeks advice from GTTAC on licence applications to work with Genetically Modified Organisms (GMOs) and on Risk Assessment and Risk Management Plans (RARMPs) prepared for applications. The purpose of this Communiqué is to provide a brief overview of GTTAC's consideration of applications and RARMPs and, in accordance with the Gene Technology Regulations 2001, to publish committee resolutions given to the Regulator. The Communiqué also provides an overview of any other deliberations of the committee. It does not include information which is treated as Confidential Commercial Information in accordance with the Act.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO

Dealings involving the Intentional Release (DIR) of a GMO into the environment can involve a limited and controlled release (clinical trial or field trial) or a commercial (general) release.

For commercial releases, the Regulator must seek GTTAC advice twice. The first consultation is on matters to consider when preparing the RARMP and the second is on the RARMP itself. For limited and controlled releases, the Regulator must seek GTTAC advice only once on the RARMP.

The RARMP for every DIR licence application is issued for public consultation.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 202 – Commercial supply of a live attenuated vaccine containing canine distemper virus and a genetically modified canine parvovirus (Nobivac Puppy DP Plus) for dogs

Licence application DIR 202 from Intervet Australia Pty Ltd is for the import, transport, storage, supply and disposal of a GM parvovirus vaccine for dogs.

The Office of the Gene Technology Regulator (OGTR) is preparing a RARMP for the application which is expected to be released for public consultation in April 2024, and had identified the following as key issues to be considered in preparing the RARMP:

- Potential for accidental exposure of humans and animals to the GMO leading to harm;
- Potential for complementation and recombination of the GMO with other CPV strains;
- Potential for the GMO to be harmful to environment.

GTTAC discussed the methods used to test for residual plasmid in the vaccine. Members considered the sensitivity of the proposed functional assay and discussed whether a more sensitive method, such as PCR, might be appropriate. The Committee recommended that the Regulator seek further information from the applicant on the methods used to test for residual plasmid.

The Committee discussed the potential for reversion to virulence of the GMO. Members considered that data could be available in relation to production of the original attenuated vaccine. GTTAC recommended that the Regulator seek further information on potential reversion to virulence, noting that the likelihood of this scenario would be low.

Members considered the presence of dingoes in the Australian environment and recommended that potential risks associated with exposure of dingoes to the vaccine or vaccinated animals be addressed in the RARMP.

Resolutions

- The Committee agreed that the following issues should be considered by the OGTR when preparing the RARMP:
    - Potential for accidental exposure of humans and animals to the GMO leading to harm
    - Potential for complementation and recombination of the GMO with other CPV strains
    - Potential for the GMO to be harmful to the environment
- The Committee recommended that the office:
    - seek further information from the applicant that there is no plasmid in the vaccine and provide comment on the sensitivity of the assay used to determine this.
    - seek information on the potential for reversion to virulence predominantly based on the small group sizes of the animal studies.
    - Address the potential response of dingoes in the Australian environment to this vaccine in the RARMP.

DEALINGS NOT INVOLVING THE INTENTIONAL RELEASE OF A GMO

The Regulator may seek GTTAC advice on RARMPs prepared for an application for Dealings Not involving an Intentional Release (DNIR) into the environment. DNIR licences include research work with GMOs undertaken in physical containment facilities (e.g. certified by the Regulator) and clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 683 – Clinical trial of genetically modified alphavirus replicon-based vaccine for the prevention of COVID-19

Novotech Australia Pty Limited has applied for a licence to conduct laboratory-contained research to develop a COVID-19 vaccine using a self-amplifying mRNA platform.

GTTAC discussed the sensitivity of the assay used to assess the presence of mRNA in tissues and recommended that the OGTR seek clarification from the applicant. Members also discussed the trial exclusion criteria and proposed licence conditions.

The Committee considered the capacity of the modified mRNA to transfer between cells, noting that there is little evidence to suggest it could replicate in other cells. Members discussed the

biodistribution of the GMO and suggested that this should be considered in the RARMP, noting that it would be unlikely to change the conclusion of the risk assessment.

Resolutions

- The risk assessment describes all plausible risk scenarios by which the proposed dealings could give risk to risks relating to the health and safety of people and the environment
- Given the genetic modifications made to the Venezuelan equine encephalitis virus, the risks associated with the GMO are negligible
- The Committee recommended that the office clarify the nature and sensitivity of the assay used to analyse mRNA in tissues.
- The Committee suggested that the office address the potential impact of the composition of the vaccine on the tissue and intracellular distribution of the GMO in the RARMP but noted this is unlikely to impact the risk characterisation.
- The Committee asked that the wording in Paragraph 61 of the RARMP be checked and revised as appropriate.
- The Committee agreed with the overall conclusion of the RARMP.

ENQUIRIES

For all enquiries, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au.