Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

22 July 2019

Communiqué

This Communiqué covers matters considered at the 17th video conference of the Gene Technology Technical Advisory Committee (22 July 2019)[1]

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 Legislative and Governance Forum on Gene Technology.

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.

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) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 598 – A Phase 1, double blind, randomized, placebo-controlled study to evaluate the safety and immunogenicity of Dengusiil in healthy adults

PPD Australia has applied for a licence to conduct a Phase 1 clinical trial to investigate the safety and immunogenicity of a genetically modified (GM) vaccine against dengue virus.

GTTAC noted key points in the RARMP, which identified one risk that was assessed as low, and concluded that risks could be managed to protect human health and safety and the environment. In addition to topics addressed in the resolutions below, GTTAC discussed the information that would be provided to trial participants, and the possibility that a participant could withdraw from the trial.

[1] The video conference was held at Department of Health facilities in Canberra, Sydney, Brisbane, Adelaide, Perth and Melbourne.

Resolutions

- The committee agrees with the overall conclusions of the draft risk assessment.
- The Regulator should further consider:
  - the potential for exposure to the GMO in bodily fluids of the patient
  - the potential for transmission of the GMO if the patient travels to a location where the mosquito vectors are present
  - the need for a protocol documenting procedures to be followed in the event of a needle-stick injury.

DNIR-601 RARMP – BacTRL-IL-12 Phase 1 Trial in Humans with Various Cancers

Clinical Network Services has applied for a licence to conduct a Phase 1 clinical trial to investigate the safety and efficacy of a GM bacteria (*Bifidobacterium longum*) modified to deliver a therapeutic plasmid into solid tumour cells. The clinical trial would involve adult patients with solid tumours for which there are no other standard therapy options available.

GTTAC noted the key points in the RARMP including that the assessment did not identify substantive risks associated with the proposed dealings. In addition to topics addressed in resolutions below, GTTAC discussed other matters, including:

- the low likelihood that other plasmids would be transferred into tumour cells
- the limited ability of the GM plasmid to transfer to other bacteria and function
- the sensitivity of the GMO to environmental conditions.

Resolutions

- The committee agrees with the overall conclusions of the draft risk assessment.
- The Regulator should further consider the potential for the bacteria to colonise the gut of the patient, and whether fecal testing data is required, or whether patients with gastro-intestinal cancer should be excluded from the trial.
- The Regulator should consider:
  - Including in the RARMP the strain of the bacteria
  - Seeking further information from the applicant on whether the following have been considered:
    - staggering of the treatment groups
    - excluding trial participants from corneal donation.

ENQUIRIES AND RISK ASSESSMENT AND RISK MANAGEMENT PLANS

For all enquiries and to obtain copies of applications or RARMPs for dealings involving the intentional release of GMOs into the environment, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au. RARMPs are also available on the OGTR website.