Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee

14 December 2020

Communiqué

This Communiqué covers matters considered at the 23rd video conference of the Gene Technology Technical Advisory Committee (14 December 2020)

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. Information on how to obtain copies of DIR applications and RARMPs is provided at the end of this document.

ADVICE ON APPLICATIONS – COMMERCIAL RELEASE

DIR 180 – Commercial supply of genetically modified COVID-19 vaccine

Licence application DIR 180 from AstraZeneca Pty Ltd is for the import, transport, storage and disposal of a genetically modified (GM) COVID-19 vaccine as part of its commercial supply as a vaccine in Australia.

The Committee discussed the issues OGTR had identified for consideration in the consultation RARMP being prepared by the Regulator, which included the potential for complementation and recombination of the GMO with other adenoviruses. The Committee agreed this is a low risk as it would be unlikely that a related adenovirus would be present in the muscle at the same time as the vaccine, as adenoviruses primarily infect the respiratory system.

The Committee discussed the possibility of the GMO integrating into the human genome. The Committee agreed that the rate would be extremely low and noted the history of safe use of similar vaccines.

GTTAC noted the application did not specify the disinfectant or its concentration proposed for decontaminating accidental spills. Other topics discussed by the Committee included consideration of matters that are the remit of the Therapeutic Goods Administration, such as the safety of the vaccine for people under 18 years of age or over 65.

Resolutions

- The Regulator should consider:
    - risks that may be associated with possible integration of the adenoviral vector into human genomes
    - those matters identified in the agenda paper
    - appropriate methods for decontaminating any spills.

DIR 182 – Commercial supply of recombinant COVID-19 vaccine (Ad26.CoV2.S)

Licence application DIR 182 from Janssen-Cilag Pty Ltd is for the import, transport, storage and disposal of a GM human adenovirus-based COVID-19 vaccine, as part of its commercial supply as a vaccine in Australia.

GTTAC noted that issues raised during the discussion of DIR 180 were also relevant to application DIR 182.

Other topics discussed by the Committee included consideration of matters that are the remit of the Therapeutic Goods Administration:

- the effect of previous exposure to adenovirus on vaccine potency
- the chance of antibody dependent enhancement occurring and leading to any harm
- allergic responses to vectored and mRNA vaccines in general.

Resolutions

- The Regulator should consider:
    - risks that may be associated with possible integration of the adenoviral vector into human genomes
    - those matters identified in the agenda paper
    - appropriate methods for decontaminating any spills.

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 (DIR) of GMOs into the environment, please call the OGTR on 1800 181 030 or email ogtr@health.gov.au. DIR RARMPs are also available on the OGTR website.