Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
Videoconference 13 October 2015[1]
Communiqué

This Communiqué covers matters considered at the 8th video conference of the Gene Technology Technical Advisory Committee (13 October 2015)

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 ministerial 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 major issues discussed by GTTAC.

DEALINGS INVOLVING THE INTENTIONAL RELEASE OF A GMO (DIR)

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

The Regulator must seek advice from GTTAC on RARMPs for all DIR applications. The Regulator must also seek GTTAC advice during the preparation of the RARMP for DIR applications which do not qualify as limited and controlled under Section 50A of the Act.

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 CONSULTATION RARMPS – COMMERCIAL RELEASE

DIR 137 – Commercial supply of genetically modified live attenuated influenza vaccines

AstraZeneca Pty Ltd is seeking approval for import, transport, storage and disposal of genetically modified (GM) influenza vaccines, for the purpose of their commercial supply as therapeutic products. Two types of GM influenza (flu) vaccines are proposed: a seasonal flu vaccine to target currently circulating flu viruses; and a contingency flu vaccine to target a pandemic flu strain, should one arise.

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

Before the GM vaccines can be used as therapeutics, regulatory approval must also be obtained from the Therapeutic Goods Administration (TGA). Subject to approval by the Regulator and the TGA, the GM vaccines would be manufactured overseas and imported into Australia. They would be administered as a nasal spray by qualified professionals at healthcare facilities.

GTTAC previously provided advice on matters relevant to the preparation of the RARMP for DIR 137 (August 2015), and was asked to provide advice on the consultation RARMP prepared by the Regulator. GTTAC noted the key points in the consultation RARMP including the conclusion that this release poses negligible risks to the health and safety of people and the environment.

GTTAC discussed the low likelihood of accidental exposure during import, transport, storage or disposal occurring and leading to any illness or adverse reaction. The committee noted that reassortment of genomic segments between two flu viruses occurring in humans is very rare, and that if it did occur with the GMO, the overwhelming majority of resulting flu viruses would be attenuated. The committee also discussed the nature of facilities in which administration might occur.

RESOLUTION – GTTAC advised the Regulator that:

1. The Regulator should consider clarifying the description of facilities in which administration of the GM vaccine may occur; and
2. The committee agrees with the overall conclusions of the RARMP.

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 at http://www.ogtr.gov.au.