Australian Government

Department of Health

Office of the Gene Technology Regulator

Gene Technology Technical Advisory Committee
Videoconference 14 April 2016[1]
Communiqué

This Communiqué covers matters considered at the 11th video conference of the Gene Technology Technical Advisory Committee (14 April 2016)

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 NOT INVOLVING AN INTENTIONAL RELEASE OF A GMO (DNIR)

The Regulator may seek GTTAC advice on RARMPs prepared for a DNIR application. DNIR licences are for dealings with a GMO that is not intentionally released into the environment. DNIR licences include research work with GMOs required to be undertaken in physical containment facilities (eg certified by the Regulator) or clinical trials undertaken in clinical facilities.

ADVICE ON DNIR RARMPS

DNIR 564 – Phase I/IIa Study of DVC1-0101 in subjects with intermittent claudication secondary to peripheral artery disease

IDT Australia is seeking approval to conduct a Phase I/IIa clinical trial using GM Sendai virus to treat leg pain in individuals with peripheral artery disease. The GMO produces human fibroblast growth factor 2 (hFGF-2), which is anticipated to stimulate the growth of new blood vessels and in doing so, ease the pain. The proposed study would be conducted at a single clinical site in Adelaide, SA, and would involve eighteen trial participants.

GTTAC noted the key points in the RARMP, including that none of the risk scenarios identified posed risks greater than negligible. GTTAC also noted that the trial would need to meet the

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

Therapeutic Goods Administration requirements and would require approval from, and oversight by, a human research ethics committee

Key points discussed by the committee:

- results from previous clinical trials and studies in rodents in relation to safety of the hFGF-2 protein
- appropriate patient treatment post-injection to avoid leakage from the injection sites.

RESOLUTION – GTTAC advised the Regulator that:

Resolution:

- The Regulator should consider clarifying elements of the protocol around the ankle/brachial index and the application of appropriate dressings
- The Regulator should further consider the potential for adverse effects related to angiogenesis which may occur as a result of accidental exposure to the GMO.

OTHER ADVICE

Update on the Review of the Gene Technology Regulations 2001

Members received an update from the OGTR on the Regulator's technical review of the Gene Technology Regulations 2001, including an outline of the next steps in the process. The review will aim to ensure appropriateness and clarity of regulatory coverage of organisms generated with new technologies.

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.