Questions & Answers on licence DIR-132 – Commercial supply of a genetically modified virus for cancer therapy

What does this licence allow?

Amgen Australia Pty Ltd (Amgen) has received approval from the Gene Technology Regulator (the Regulator) for import, transport, storage and disposal of a genetically modified (GM) *herpes simplex virus 1* (HSV-1), referred to as Talimogene laherparepvec (the GMO), for the purpose of supply as a human therapeutic. Before the GMO can be used as a human therapeutic, Amgen also needs approval from the Therapeutic Goods Administration (TGA).

How has the GMO been modified?

The GM virus has been modified by removing two viral replication genes, substantially reducing its ability to reproduce and spread beyond the (injected) tumour tissue. Additionally, a viral gene which helps the virus evade the immune system has been removed, and a gene encoding a human protein that stimulates some types of immune cells has been introduced. These modifications cause the GMO to trigger an enhanced immune response in and around the injected tumour, helping to kill the tumour cells as well as the virus.

How would the GMO be used?

The GMO is intended for use as a prescription only treatment for patients with skin cancer (metastatic melanoma) and other suitable solid tumours that are unable to be removed by surgery. Subject to TGA approval, the GMO would be administered in clinical facilities by injection directly into tumours.

Will the GMO be harmful to people or animals?

The Risk Assessment and Risk Management Plan (RARMP) did not identify any substantive risks to people or the environment. The GMO has been used in clinical trials on skin cancer and several types of advanced solid tumours in multiple countries, including the United Kingdom, Canada, South Africa, the USA and Australia. Unmodified HSV-1 is a common infection in the Australian population. The GMO has a substantially reduced ability to reproduce, spread and cause disease compared to unmodified HSV-1, and is sensitive to the same anti-viral treatments. Humans are the only known natural hosts of HSV-1, so the GMO is extremely unlikely to infect animals. The TGA are also assessing the safety of the use of the GMO as a therapeutic.

What other regulatory approvals are required?

Amgen must also obtain regulatory approval from the TGA for use of the GMO in treatment of cancer patients. Medicines and other therapeutic goods for sale in Australia are required to be assessed for quality, safety and efficacy under *the Therapeutic Goods Act 1989*. The TGA is currently assessing an application from Amgen. As the GMO will be manufactured overseas, Amgen will also need import approval from the Department of Agriculture.

What controls have been imposed for this GMO?

The licence is for ongoing commercial supply. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that commercial supply of the GM virus poses negligible risks to the health and safety of people and the environment. However, general conditions have been imposed to ensure that there is ongoing oversight of the release. The TGA may impose conditions on use of the GMO.

Want more information?

A number of documents relating to this decision are available on the DIR-132 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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