



Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

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Addressing misinformation on the regulation of mRNA vaccines

Misinformation has been circulating that Pfizer and Moderna were required to obtain a licence from the Gene Technology Regulator for the mRNA COVID-19 vaccines, Comirnaty and Spikevax. The misinformation implies that appropriate health and safety checks of the vaccines have not been undertaken.

The Therapeutic Goods Administration (TGA) is responsible for assessing all COVID-19 vaccines before they can be used in Australia. The TGA rigorously assesses any COVID-19 vaccine for safety, quality and effectiveness. The TGA's decision to approve a new vaccine is always made on the basis that the benefits outweigh the risks for the intended population.

The Office of the Gene Technology Regulator (OGTR) has a different role. OGTR regulates dealings (defined activities) with genetically modified organisms (GMOs) and the Pfizer and Moderna vaccines are not GMOs.

Misinformation and confusion has also stemmed from incorrect use of specific terminology, particularly where the terminology may have more than one meaning. For example, 'transfect' may mean 'enter into a cell with transient expression of a protein'. This is the meaning that applies to the two mRNA vaccines. It may also mean 'enter into the cell's nucleus to stably integrate in the genome'. This is a meaning that does not apply to the two mRNA vaccines.

The OGTR continues to engage with researchers and developers of new therapeutics using mRNA technologies and, should these be captured by the definitions within the *Gene Technology Act 2000*, they will be assessed and regulated by the OGTR.

This extends to domestic production of a vaccine that may involve the use of a GMO in its manufacturing. It is the GMO in the manufacturing process that would be assessed and authorised by the OGTR, not the resulting vaccine product. Safety, quality and effectiveness for a therapeutic vaccine product would continue to be addressed by the TGA.
