Ref No: MC22-018819

Ms Elizabeth Hart elizmhart@gmail.com

Dear Ms Hart

Thank you for your correspondence of 4, 7 October and 9 November 2022 to the Minister for Health and Aged Care, the Hon Mark Butler MP regarding the COVID-19 Vaccine Claims Scheme (the Scheme). The Minister has asked me to reply. I have addressed the three pieces of your correspondence below.

Your letter seeks clarification on whether the Government has established a medical indemnity scheme for health professionals administering COVID-19 vaccines, following media releases by the former government on 2 July 2021 and 28 August 2021. I can advise that rather than putting in place a medical indemnity scheme for health professionals, the former Government established the no-fault Scheme, which commenced operations on 13 December 2021.

Importantly, this means that a person making a claim under the Scheme, does not need to establish that another party was at fault. The injured person, does, however, need to provide evidence (detailed in the Scheme Policy) to establish that the harm (or a person's death) was likely caused by a Therapeutic Good Administration (TGA) approved vaccine or its administration, to be able to access compensation under the Scheme. While a medical indemnity scheme for health professionals administering the COVID-19 vaccine was not established per se, the creation of the no-fault Scheme was intended to support increased participation by health professionals in the COVID-19 Vaccination roll-out.

I can advise that the TGA closely monitors the safety of COVID-19 vaccines and has a wellestablished and robust system in place to capture reports of suspected adverse effects of all medicines including the COVID-19 vaccines.

Informed Consent

Informed consent should be obtained for every COVID-19 vaccination, as per usual consent procedures for other vaccinations.

To this end, the Australian Government has made a range of accurate, evidence-based resources available to ensure people can be informed about COVID-19 vaccines. These cover the different COVID-19 vaccines in Australia and information on preparing for vaccination and what to do after vaccination. These also include expert health advice from the Australian Technical Advisory Group on Immunisation (ATAGI) to assist people with their decision-making, and are available at:

https://www.health.gov.au/resources/collections/covid-19-vaccination-patient-resources.

For more information, visit the Australian Immunisation Handbook at:

https://immunisationhandbook.health.gov.au/contents/vaccination-procedures/preparing-for-vaccination, which has information about 'valid consent', including criteria for consent to be legally valid or check with your state or territory health authority about these laws at: https://www.health.gov.au/health-topics/immunisation/immunisation-contacts.

For written consent, vaccination providers can use the 'Consent form for COVID-19 vaccination', which is available at: https://www.health.gov.au/resources/publications/covid-19-vaccination.

For further information about the Covid Vaccine Claims Scheme including Frequently Asked Questions, an overview of the Scheme and the Scheme Policy, please visit www.health.gov.au/initiatives-and-programs/covid-19-vaccine-claims-scheme.

Medical Indemnity Insurance for health practitioners

The Commonwealth's medical indemnity schemes provide financial protection to both privately practising health practitioners and patients in circumstances where a patient sustains an injury (or adverse outcome) caused by medical misadventure, malpractice, negligence or an otherwise unlawful act. In Australia, it is compulsory for all registered health professionals to hold medical indemnity insurance under the <u>Health Practitioner Regulation National Law Act 2009</u> (National Law). Subsection 129(1) of the National Law provides:

A registered health practitioner must not practise the health profession in which the practitioner is registered unless appropriate professional indemnity insurance arrangements are in force in relation to the practitioner's practice of the profession.

The objective of the Commonwealth's medical indemnity schemes are to:

- promote stability in the medical indemnity insurance industry
- keep premiums affordable for doctors and allied health professionals; and
- ensure availability of professional indemnity insurance for eligible midwives.

Thank you for writing on this matter.

Yours sincerely

Nigel Murray

Assistant Secretary

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MBS Policy and Specialist Services Branch

17 November 2022