In investigating the dynamics behind the Pfizer-Australia relationship, here are some points to ponder: In order for the Australian Government to comply with its obligations under the Pfizer Agreement, did it covertly amend its legislation to make clear its position on experimental vaccines?<sup>i</sup> Did it negotiate aspects of foreign debt, put up Commonwealth assets as surety or create a Guarantee Fund by depositing fiat in a foreign bank account? Let's do a little digging.

## Pfizer said:

## Australian Government response:



'...[W]e don't have answers to questions such as whether it gives you one, two or five years of protection'.

Dr. John Skerritt Senate Select Committee, 21/06/2021

This section grants approval for use of therapeutic goods for special and **experimental uses** that are not included in the Register.

Effective 19 February 2021; TGA Act; s. 41HB



We know that we've got more than enough Pfizer... for **population-wide coverage**...'

Dr. Brendan Murphy Senate Select Committee, 21/06/2021

In order to manage a listed human disease, an individual may be required to receive a specified vaccination at a specified medical facility.

Biosecurity Act 2015 (Cth); s. 92(a) and (b)



Notwithstanding non-compliance with the requirement to include registration data on product labels (which would ordinarily subject the Sponsor to a fine), civil penalties have been **amended** and conditions **removed** in respect of the importation and supply of COVID-19 vaccines.

Effective 19 February 2021; TGA Act; s. 19D(4)(ba)



'We don't disclose where our vaccines come from'.

Dr. Brendan Murphy Senate Select Committee, 21/06/2021

This clause on 'restricted information' essentially amounts to a 'market exclusivity' and anti-competition provision. It upholds Pfizer's demand for

confidentiality by protecting data generated by the Sponsor for 5 years and precludes the public accessing information.

Effective 19 February 2021; TGA Act

Commercial-in-confidence is information that, if released, would cause **competitive detriment.** The individual must demonstrate that the information is not in the public domain; not legally required to be disclosed; and is not readily discoverable.

s.5(a)-(d), AI Register Act Biosecurity Act 2015 (Cth); s. 15

'I think they all understand that we're all working in a constrained supply arrangement'.

Dr. Brendan Murphy Senate Select Committee, 21/06/2021

An existing TGA provision on the duty to report medicinal shortages is complemented by the introduction of a new clause which imbues the Minister with power to **declare a serious scarcity** of specified medicine across the whole, or part, of Australia.

Effective 19 February 2021; TGA Act; s. 30EK

The Secretary can give such consent in relation to a vaccine for COVID-19 and avoid the risk that the civil penalties in the Act could delay the availability of COVID-19 vaccines in Australia.

Effective 19 February 2021; TGA Act; s. 19D(4)(ba)

An Immunisation Register electronically records and stores vaccination data.

The Australian Immunisation Register Act

The TGA confirms a Clinical Trial Registry will be made accessible free-of-charge to the public. It may be established within or outside Australia.

Effective 19 February 2021; TGA Act; s. 26AF(3)

The TGA introduced s.52G sets out exemptions, approvals and prohibitions on the movement of drugs.

Effective 19 February 2021; TGA Act; s. 52G





In total, 97 alterations were made to the TGA legislation in the current 2020–2021 Pandemic Period. Of course, the TGA states that legislative amendments are aimed at implementing a level of preparedness. This could be why, as of 9 August 2021; children aged between 12 and 15 years became eligible for the Pfizer vaccine. Minors with specified underlying medical conditions, children who are Aboriginal and Torres Strait Islanders and children living in remote communities are encouraged to submit to immunisation. On one hand, we don't want our historically-underrepresented, vulnerable and marginalised indigenous population absorbing a disproportionate share of the risk; yet you'd think living in a remote community would present the safest and lowest-risk environment for transmissibility.

<sup>i</sup> The external affairs power enshrined in s. 51(xxix) of the *Commonwealth Constitution* provides the basis for, and gives effect to, international agreements. International agreements are generally construed to be conventions and treaties

ii Therapeutic Goods Amendment (2020 Measures No. 2) Bill 2020, Explanatory Memoranda

<sup>&</sup>lt;a href="https://www.aph.gov.au/Parliamentary\_Business/Bills\_Legislation/Bills\_Search\_Results/Result?bId=r6651">https://www.aph.gov.au/Parliamentary\_Business/Bills\_Legislation/Bills\_Search\_Results/Result?bId=r6651</a>.

\*\*Australian Government – Department of Health, \*\*ATAGI statement regarding vaccination of adolescents aged\*\*

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<sup>12–15</sup> years: A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding vaccination of adolescents aged 12-15 years;, 2 August 2021 <a href="https://www.health.gov.au/news/atagi-statement-regarding-vaccination-of-adolescents-aged-12-15-years">https://www.health.gov.au/news/atagi-statement-regarding-vaccination-of-adolescents-aged-12-15-years</a>.

<sup>&</sup>lt;sup>iv</sup> This is not to discount the threat posed by FIFO medical and police personnel who could inadvertently import the virus.