

Has the Crown really demonstrated that the limitation on the *Right to Decline Medical Treatment* was reasonable and demonstrably justified?



Part 2: Significance of Provisional vs Full Consent

Under the [Medicines Act 1981](#), before a medicine can be distributed in New Zealand the Minister of Health must grant either 'Consent' or 'Provisional Consent'. These are not the same ... in fact they are very different.

1. **Consent.** To gain full 'Consent', under [Section 21](#) particulars about the safety and efficacy are required to be supplied, and then under [Section 22\(1\)\(b\)](#) the Minister must, ***"weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person."***
2. **Provisional Consent.** The legal requirement to gain 'Provisional Consent' is a very much lower bar than that required for full 'consent'. Under [Section 23](#), the minister may grant provisional consent if he, ***"is of the opinion that it is desirable that the medicine be sold, supplied, or used."***

Pfizer applied for 'Consent' to distribute their Comirnaty vaccine in New Zealand in November 2020.

Medsafe, acting on behalf of the Minister, evaluated their application. Medsafe's Clinical Evaluation Report was published in January 2021. The 'Summary' stated:

"The benefit risk balance of Comirnaty (COVID-19 mRNA Vaccine) for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older, is not clear. At this stage, there is evidence only for short-term protection, and longer-term safety data are lacking. However, experience with the vaccine is accumulating rapidly.

Notwithstanding uncertainties, in the light of high clinical need and the expectation of further data (including regarding duration of protection) around April 2021, a provisional consent under section 23 of the Medicines Act 1981 may be appropriate."

Medsafe's final recommendation states:

"Due to the unresolved concerns and additional quality, safety and efficacy data to be provided at the time of completion of the evaluation, Medsafe is unable to recommend that this product be granted consent. It is therefore recommended that the application be referred to the Medicines Assessment Advisory Committee (MAAC) under section 22(2) of the Medicines Act 1981 for their consideration."

In other words, the 'likely therapeutic value' had been weighed against the risk of it 'injuriously affecting the health of any person', and the application for 'Consent' was declined.

Medsafe referred the application to the Medicines Assessment Advisory Committee (MAAC) for their consideration for 'Provisional Consent' and recommended 56 conditions if 'Provisional Consent' was deemed appropriate.

MAAC met on 2 February 2021 to consider the application and recommended that 'Provisional Consent' be given under Section 23, with amended conditions.

'Provisional Consent' for the distribution of a new medicine was gazetted on 3 Feb 2021 with 58 conditions, valid until 3 November 2021. When this expired, 'Provisional Consent' was again gazetted on 8 November with just 8 conditions, valid until 3 November 2023.

The Minister has now twice refused to give his consent, and this is the critical point. To be clear, the evaluation process may have been a thorough process, but it is **the outcome of the evaluation** that is important. Having examined the data provided by Pfizer, having weighed the therapeutic value, having weighed the risk, the Minister has now twice declined to give his 'Consent'.

The repeated refusal of the Minister to give consent can only mean that Medsafe was not properly satisfied as to either its therapeutic value and/or the risk of vaccine injury, which are the two requirements for consent. There is no other legal basis for declining 'Consent'.

Our Courts to date have not been fully informed of the significance of this. Medsafe has successfully confused the Courts, by stressing the thoroughness of the evaluation, rather than the outcome of the evaluation. The judges have been wrongly convinced that because the evaluation process was so thorough, there was no need for concern. They have mistakenly relied upon 'approval' as giving an assurance that there were no concerns about the vaccine's safety and efficacy, without seeming to realise that 'Consent' was declined because there were concerns about safety and efficacy!

In his affidavit in the NZDSOS/NZTSOS case, Dr Town (the Chief Science Advisor) continued to confuse the Court with his statement:

"Medsafe has provisionally approved several COVID-19 vaccines for use in New Zealand. In granting provisional approval, data from clinical trials was considered in a risk-benefit matrix, and it was recommended that the benefits the vaccines provide from COVID-19 outweigh any risks." (Dr Town's affidavit, NZTSOS/NZDOS, 16 February 2022, paragraph 18)

If the benefits had outweighed the risks, full 'Consent' could have been granted under Section 20. It was not.

A fitting analogy might be getting a Warrant of Fitness for your car. The inspection was very thorough and found that there was a hole in your muffler, the brakes were leaking fluid, the right rear tyre had no tread, and the front-left headlamp wasn't working. You continue driving your car and when stopped by the Police for driving a dangerous vehicle, you protest that they should have no concerns because the inspection was 'very thorough' and 'robust'.

The important point is that application for full 'Consent' under Section 20 was made, and application for full 'Consent' was declined. The reason for the application being declined is the real issue and must not be obfuscated with proclamations as to the thoroughness or robustness of the 'Provisional Consent' process. It is not the thoroughness of the 'Provisional Consent' process that is important - it is the outcome of the full 'Consent' process. The application for Consent was declined because there were, among other things, outstanding issues concerning safety and efficacy. And there still are!

Was Justice Cooke aware of this?