

Hon Andrew Little

Minister of Health

Minister Responsible for the GCSB

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Lead Coordination Minister for the Government's Response to the Royal Commission's Report into the Terrorist Attack on the Christchurch Mosques



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Legislative Statement for the Medicines Amendment Bill

The Medicines Amendment Bill (the Bill) amends Part 2 of the Medicines Act 1981 (the Act) and revokes the Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022.

The Bill inserts new section 34A into the Act. The new section enables the Director-General of Health (the Director-General) to authorise by notice the administration of a consented COVID-19 vaccine. The Director-General must be satisfied that administration of the vaccine is an appropriate measure to manage the risks associated with the outbreak or spread of COVID-19.

The Director-General will only be able to use this power in relation to COVID-19 vaccines that already have consent, or provisional consent, under section 20 or 23 of the Act. The Director-General must also have regard to the likely therapeutic value of the COVID-19 vaccine, and its risk (if any) of injuriously affecting the health of any person.

The Director-General can specify in the notice who may receive the vaccine, the recommended number and frequency of doses, the manner of administration; and any other circumstances in which the vaccine may be administered.

The amendments are needed to provide a permanent and future-proofed solution to meet ongoing COVID-19 vaccine requirements, such as additional doses, changes to dose intervals, or targeting different population groups, should the scientific evidence support this.

We know that immunity gained from COVID-19 vaccination wanes over time and can wane within a matter of months. This means the COVID-19 vaccination programme is on-going. Further doses are now required for certain groups, and Pfizer New Zealand have indicated they do not intend to apply for approval of further doses of the Pfizer/BioNTech COVID-19 vaccine in New Zealand. Therefore, the amendment will enable new doses to be efficiently and permanently added to the COVID-19 vaccine schedule.

To ensure the new power does not undermine the usual medicines consenting process under the Act, the new provision is deliberately narrow and applies only to already consented COVID-19 vaccines.

Following the Act coming into force, the Director-General may, by notice, authorise the administration of a consented COVID-19 vaccine other than in accordance with any data sheet for the vaccine. Ministers will be informed of the COVID-19 vaccination options based on the latest scientific and technical advice, prior to the Director-General's decision.

It is anticipated that the new provision will initially be utilised by the Director-General to enable fourth doses of the Pfizer/BioNTech COVID-19 vaccine to be administered to

recommended groups without a prescription. However, that will be a decision for the Director-General once the amendment comes into force.

The Bill will also revoke the Epidemic Preparedness (Medicines Act 1981—COVID-19) Immediate Modification Order 2022 (IMO), which made provision for third (booster) doses of the Pfizer/BioNTech COVID-19 vaccine to be administered at a reduced dose interval of three months since previous dose (instead of the approved six months). The IMO is a temporary measure, and once the Epidemic Preparedness Notice expires or is revoked, the IMO will automatically be revoked. It is intended that the IMO will be revoked with the enactment of the Bill and that the ongoing availability of the third (booster) dose at the reduced dose interval will be authorised by the Director-General via the new provision.