Version
as at 28 October 2021

COVID-19 Public Health Response (Point-of-care Tests) Order 2021

(LI 2021/66)

This order is made by the Minister for COVID-19 Response under section 11 of the COVID-19 Public Health Response Act 2020 in accordance with section 9 of that Act.

Contents

Note

The Parliamentary Counsel Office has made editorial and format changes to this version using the powers under subpart 2 of Part 3 of the Legislation Act 2019.

Note 4 at the end of this version provides a list of the amendments included in it.

This order is administered by the Ministry of Health.

Order

1 Title

This order is the COVID-19 Public Health Response (Point-of-care Tests) Order 2021.

2 Commencement

This order comes into force on 22 April 2021.

Preliminary provisions

3 Purpose

The purpose of this order is to prevent, and limit the risk of, the outbreak or spread of COVID-19 and to otherwise support the purposes of the Act.

4 Interpretation

In this order, unless the context otherwise requires,—

Act means the COVID-19 Public Health Response Act 2020

manufacture has the meaning given by section 2(1) of the Medicines Act 1981

pack has the meaning given by section 2(1) of the Medicines Act 1981

point-of-care test means any kit or other material that is intended to—

(a) be used to test for SARS-CoV-2 or COVID-19 infection or immunity (whether current or historical) in an individual; and

(b) produce a result without analysis at a laboratory

sell has the meaning given by section 2(1) of the Medicines Act 1981.

5 Transitional, savings, and related provisions

The transitional, savings, and related provisions (if any) set out in Schedule 1 have effect according to their terms.

6 Application of order

This order applies to the whole of New Zealand.

Prohibitions

7 Prohibitions on point-of-care tests

A person must not import, manufacture, supply, sell, pack, or use a point-of-care test unless—

(a) the person's activity is authorised under clause 8; or

(b) the point-of-care test is exempt from the prohibition under clause 9.

Authorisations and exemptions

8 Director-General may authorise persons to deal with point-of-care tests

(1) The Director-General may authorise any person or class of persons to do any or all of the activities that are prohibited by clause 7 if the Director-General is satisfied that—

(a) the activity will not pose a material risk to the public health response to COVID-19; and

(b) the authorisation is not inconsistent with the purpose of the Act; and

(c) the authorisation is no broader than is reasonably necessary to address the matters giving rise to it.

(2) An authorisation may apply to a person or class of persons in respect of—

(a) all point-of-care tests; or

(b) 1 or more classes of point-of-care tests; or

(c) a specified point-of-care test.

(3) The Director-General may impose conditions on the authorisation as the Director-General considers necessary.

(4) An applicant for an authorisation must, at their own cost, provide any evidence or other information that the Director-General reasonably requires to be satisfied of the matters set out in subclause (1).

(5) An authorisation for a person must be notified in writing to the applicant and the authorised person.

(6) An authorisation for a class of persons is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this clause		
Publication	The maker must: • notify it in the *Gazette* • publish it on a publicly accessible Internet site maintained by, or on behalf of, the New Zealand Government	LA19 ss 73, 74(1)(a), Sch 1 cl 14
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the secondary legislation.

Clause 8(5): inserted, on 28 October 2021, by regulation 116 of the Legislation Act (Sub-delegated Secondary Legislation) Regulations 2021 (LI 2021/248).

Clause 8(6): inserted, on 28 October 2021, by regulation 116 of the Legislation Act (Sub-delegated Secondary Legislation) Regulations 2021 (LI 2021/248).

9 Director-General may exempt point-of-care tests from prohibitions

(1) The Director-General may exempt any point-of-care test or class of point-of-care tests from the application of any or all of the prohibitions in clause 7 if the Director-General is satisfied that—

(a) the point-of-care test or class of point-of-care tests is sufficiently accurate and reliable so as not to pose a material risk to the public health response to COVID-19; and

(b) the exemption is not inconsistent with the purpose of the Act; and

(c) the exemption is no broader than is reasonably necessary to address the matters giving rise to it.

(2) The Director-General may impose conditions on the exemption as the Director-General considers necessary.

(3) An applicant for an exemption must, at their own cost, provide any evidence or other information that the Director-General reasonably requires to be satisfied of the matters set out in subclause (1).

(4) An exemption for a point-of-care test must be notified in writing to the applicant.

(5) An exemption for a class of point-of-care tests is secondary legislation (*see* Part 3 of the Legislation Act 2019 for publication requirements).

Legislation Act 2019 requirements for secondary legislation made under this clause		
Publication	The maker must: • notify it in the *Gazette* • publish it on a publicly accessible Internet site maintained by, or on behalf of, the New Zealand Government	LA19 ss 73, 74(1)(a), Sch 1 cl 14
Presentation	It is not required to be presented to the House of Representatives because a transitional exemption applies under Schedule 1 of the Legislation Act 2019	LA19 s 114, Sch 1 cl 32(1)(a)
Disallowance	It may be disallowed by the House of Representatives	LA19 ss 115, 116

This note is not part of the secondary legislation.

Clause 9(4): inserted, on 28 October 2021, by regulation 117 of the Legislation Act (Sub-delegated Secondary Legislation) Regulations 2021 (LI 2021/248).

Clause 9(5): inserted, on 28 October 2021, by regulation 117 of the Legislation Act (Sub-delegated Secondary Legislation) Regulations 2021 (LI 2021/248).

10 Notification of authorisations and exemptions

[Revoked]

Clause 10: revoked, on 28 October 2021, by regulation 118 of the Legislation Act (Sub-delegated Secondary Legislation) Regulations 2021 (LI 2021/248).

Schedule 1
Transitional, savings, and related provisions

cl 5

Part 1
Provisions relating to this order as made

There are no transitional, savings, or related provisions relating to this order as made.

Dated at Wellington this 9th day of April 2021.

Hon Chris Hipkins,
Minister for COVID-19 Response.

Issued under the authority of the Legislation Act 2019.
Date of notification in *Gazette*: 14 April 2021.

Notes

1 General

This is a consolidation of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 that incorporates the amendments made to the legislation so that it shows the law as at its stated date.

2 Legal status

A consolidation is taken to correctly state, as at its stated date, the law enacted or made by the legislation consolidated and by the amendments. This presumption applies unless the contrary is shown.

Section 78 of the Legislation Act 2019 provides that this consolidation, published as an electronic version, is an official version. A printed version of legislation that is produced directly from this official electronic version is also an official version.

3 Editorial and format changes

The Parliamentary Counsel Office makes editorial and format changes to consolidations using the powers under subpart 2 of Part 3 of the Legislation Act 2019. See also PCO editorial conventions for consolidations.

4 Amendments incorporated in this consolidation

Legislation Act (Sub-delegated Secondary Legislation) Regulations 2021 (LI 2021/248): regulations 116–118

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