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

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

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).

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).

10 Notification of authorisations and exemptions

Notification of authorisations

(1) An authorisation under clause 8 for a specified person must be notified in writing to the applicant and the authorised person.

(2) An authorisation under clause 8 for a class of persons must be—

(a) published on a publicly accessible Internet site maintained by or on behalf of the New Zealand Government; and

(b) notified in the *Gazette*.

Notification of exemptions

(3) An exemption under clause 9 for a specified point-of-care test must be notified in writing to the applicant.

(4) An exemption under clause 9 for a class of point-of-care tests must be—

(a) published on a publicly accessible Internet site maintained by or on behalf of the New Zealand Government; and

(b) notified in the *Gazette*.

Schedule 1
Transitional, savings, and related provisions

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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.

Explanatory note

This note is not part of the order, but is intended to indicate its general effect.

This order prohibits a person from importing, manufacturing, supplying, selling, packing, or using a point-of-care test for SARS-CoV-2 or COVID-19 unless the Director-General of Health has—

- authorised the person's activity; or
- exempted the point-of-care test from the prohibition.

This order comes into force on 22 April 2021. It replaces the Notice Under Section 37 of the Medicines Act 1981 (*Gazette* 2020-go1737).

Approval by resolution required

This order must be approved by a resolution of the House of Representatives before the expiry of the period described in section 16(2) of the COVID-19 Public Health Response Act 2020. If this does not happen, the order is revoked on the expiry of that period.

Issued under the authority of the Legislation Act 2012.
Date of notification in *Gazette*: 14 April 2021.
This order is administered by the Ministry of Health.

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