Briefing

COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 for consultation

Date due to MO:	19 March 2021	**Action required by:**	25 March 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20210652
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Steve Waldegrave	Group Manager, System Strategy and Policy	s 9(2)(a)

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 for consultation

Security level:	IN CONFIDENCE	**Date:**	19 March 2021
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This report recommends that you consult with the Prime Minister, the Minister of Justice and the Minister of Health on the attached draft COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 (the Order).

Summary

2. On 6 February 2021 you agreed to extend the prohibition of importing, manufacturing, supply, sale or use of all Point-of-Care (POC) tests (including molecular) through a section 11 Order under the COVID-19 Public Health Response Act 2020 (the Act) unless exempted or authorised [HR 20210098 refers]. This is required as the current mechanism prohibiting POC tests in this way expires on 21 April 2021 and is unable to be renewed.

3. The proposed draft Order contains measures to further prevent the spread or outbreak of COVID-19, including by ensuring that the public have ready access to quality testing and new test types as the science supports, and authorised individuals can be exempted.

4. A POC test is any kit or other material that is intended to:

   a. be used to test for SARS-CoV-2 or COVID-19 infection[1] or immunity (whether current or historical) in an individual; and

   b. produce a result without analysis at a laboratory.

5. The attached draft Order prohibits a person from importing, manufacturing, supplying, selling, packing, or using a POC test unless the Director-General of Health (Director-General) has:

   a. authorised the person's activity; or

   b. exempted the point-of-care test from the prohibition.

6. To make or amend an Order under section 11 of the Act you must:

   a. receive advice from the Director-General about –

      i. the risks of the outbreak or spread of COVID-19; and

      ii. the nature and extent of measures that are appropriate to address those risks; and

[1] **Making the distinction between the virus and the disease.**

b. have regard to any decision by the Government on how to respond to those risks and avoid, mitigate or remedy the effects of the outbreak or spread of COVID-19 (including taking into account any social, economic or other factors); and

c. be satisfied that the proposed Order does not limit or is a justified limit on the rights and freedoms in the New Zealand Bill of Rights Act 1990; and

d. consult with the Prime Minister, the Minister of Justice, the Minister of Health and any other Ministers you think necessary; and

e. be satisfied that the Order is appropriate to achieve the purpose of the Act.

7. Officials have worked closely with the New Zealand Customs Service, the Ministry for Primary Industries, the Ministry of Business Innovation and Employment, and other stakeholders to develop the proposed Order and will continue to work to ensure the Order is implemented promptly.

8. Following Ministerial consultation, officials will finalise the Order, and provide you with a version for signing on or before 19 April 2021.

Recommendations

We recommend you:

a)	**Note** the attached draft COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 gives effect to the policy previously agreed in HR20210098 i.e. by extending the existing prohibition of importing, manufacturing, supply, sale or use of all Point-of-Care tests to mitigate risk.	**Noted**
b)	**Note** that advice from the Director-General of Health is that the COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 is in line with the purposes of the COVID-19 Public Health Response Act 2020, to prevent, and limit the risk of, the outbreak or spread of COVID-19.	**Noted**
c)	**Agree** to consult with the Prime Minister and Minister of Justice on the attached draft COVID-19 Public Health Response (Point-of-Care Tests) Order 2021.	**Yes/No**

Maree Roberts
Deputy Director-General,
System Strategy and Policy
Date:

Hon Chris Hipkins
Minister for COVID-19 Response

Date: 25/3/21

COVID-19 Public Health Response (Point-of-Care Tests) Order 2021 for consultation

Background

1. In April 2020, the Ministry was notified that companies were importing and selling POC tests. POC tests are 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.

2. The Group Manager, MedSafe – acting with delegated authority from the Minister of Health – issued a Notice on 22 April 2020 under section 37 of the Medicines Act 1981 (the Notice), due to concerns over the accuracy and reliability of POC tests. The Notice restricts the importation, manufacture, sale, supply and use of POC tests. The Notice expires on 21 April 2021. The prohibition cannot be renewed under the Medicines Act, which makes the current prohibition of POC tests time limited.

3. The Notice allows an exemption for antigen and antibody POC tests if, for instance, a satisfactory standard of accuracy is reached. MedSafe relies on the expert knowledge of New Zealand's Crown Research Institute of Environmental Science and Research (ESR) to determine if an antigen or antibody POC test should be exempt.

4. Unauthorised POC tests that may be imported, manufactured, supplied, sold or used in New Zealand carry the following risks:

    - concerns from scientific experts over the **accuracy** of POC tests and their potential to provide patients with a misleading result regarding their COVID-19 infection or immunity status;
    - the potential **misuse and misinterpretation** by the patient or public leading to risky behaviours and the risk of an outbreak or spread of COVID-19;
    - POC tests being **used instead of quality-assured and highly accurate PCR tests**, thereby undermining the effectiveness of the PCR testing system; and
    - a **lack of integration** into the test results repository and wider contact tracing process, which could make detection and management of positive cases difficult in the public health system.

5. Officials recommended extending the prohibition on the importation, manufacture, supply, sale or use of POC tests through an Order issued under section 11 of the Act. The types of POC tests to be prohibited should include antigen, antibody and molecular.

6. The Order as drafted would effectively continue the prohibition to give effect to previously agreed policy decisions [HR 20210098 refers] including:

    a. continue to prohibit the importation, manufacture, supply, sale, or use of antigen and antibody POC tests under the Act;

b. prohibit the importation, manufacture, supply, sale, or use of molecular and other types of POC tests under the Act;

c. create a pathway for the Director-General to authorise certain persons (or organisations e.g. ESR) to import, manufacture, supply, sell or use certain COVID-19 POC tests if satisfied it would be consistent with the purpose of the Act and not cause any significant risk to the public health response.

d. create an exemptions framework to ensure acceptable POC tests (including antigen, antibody and molecular) can be exempt in certain circumstances for legitimate uses and purposes, and to accommodate future technological or scientific advancements in POC tests.

Contents of the draft Order

General Prohibition of POC tests

7. The proposed Order defines a POC test and provides for a general prohibition of POC tests including the importation, manufacture, supply, sale, packing or use of POC tests unless pursuant to an exemption or authorisation by the Director-General.

8. The Order engages Custom's powers to seize prohibited items at the border under the Customs and Excise Act 2018.

9. The prohibition of the activity of 'packing' has also been included in the draft Order as it was considered in consultation with stakeholders to be necessary, consistent, and related to the other prohibited activities. Officials also considered adding a prohibition of 'advertising' POC tests. However, as enforcement was considered unworkable, that activity has not been prohibited.

Ability to authorise certain persons

10. The Order ensures exemptions can be achieved by providing the Director-General with the power to authorise certain persons (including organisations) to import, manufacture, supply, sell, or use POC tests if satisfied it would be consistent with the purpose of the Act and not cause any significant risk to the public health response. This power is intended to enable the Minister and Director-General to allow suitable organisations (e.g. ESR) who are subject to sufficient controls and safeguards to use certain POC tests for legitimate use and purposes (e.g. science and research).

Ability to exempt certain tests

11. The Director-General is to have the power to exempt certain POC tests from some or all of the prohibitions under the notice to accommodate for future technological or scientific advancements. The Director-General may consider a POC test has advanced to the point where it no longer poses quality or reliability concerns and should be allowed to be imported, manufactured, supplied, sold or used in New Zealand.

Director-General can set conditions

12. The Director-General should have the ability to set conditions that he or she considers necessary when authorising persons or exempting POC tests to prevent the outbreak and spread of COVID-19, or where necessary to facilitate an appropriately coordinated

public health response. These powers too are consistent with those allowed under section 12 of the Act.

13. The Director-General's power to set conditions should enable him or her to apply a broad range of controls, including specifying who can perform the test, who can be tested, where testing can be performed, and for what purpose.

14. The ability to set conditions is necessary because some tests may be appropriate for certain applications and when provided within certain contexts, such as when performed with oversight from an appropriately qualified health practitioner. However, the same test might not be appropriate for use by the general public.

Enforcement

15. The Order provides that a person who intentionally breaches the prohibition in the order is to be subject to an offence. They are to be liable on conviction to imprisonment for a term not exceeding six months or a fine not exceeding $4,000, as provided for in section 26(2) of the Act. No infringement offences are intended.

Process for making a section 11 Order

16. Under the Act, an Order may be made if either:

    a. a state of emergency has been declared (under the Civil Defence Emergency Management Act 2002);

    b. an Epidemic Notice is in force (under the Epidemic Preparedness Act 2006); or

    c. it has been authorised by the Prime Minister.

17. There is currently an Epidemic Notice in place, which allows Orders to be made under section 11 of the Act.

18. As the Minister for COVID-19 Response, you may make Orders under section 11 of the Act.

19. To make an Order under section 11 of the Act you must:

    a. have received advice from the Director-General about –

        i. the risks of the outbreak or spread of COVID-19; and

        ii. the nature and extent of measures that are appropriate to address those risks; and

    b. be satisfied that the proposed Order does not limit or is a justified limit on the rights and freedoms in the New Zealand Bill of Rights Act 1990 (NZBORA); and

    c. consult with the Prime Minister, the Minister of Justice and any other Ministers you think necessary; and

    d. be satisfied that this Order is appropriate to achieve the purposes of the Act.

20. My advice about the risks of the outbreak or spread of COVID-19 and the nature and extent of measures that are appropriate to manage those risks is set out below.

Public health rationale for the Order

21. You are receiving ongoing advice about the risks associated with COVID-19. In accordance with section 9(2) of the Act, you may have regard to that advice without it being repeated here.

22. You have previously been provided with detailed public health rationale for the proposed Order [HR 20210098 refers].

23. COVID-19 is a highly infectious disease which may be spread by people who are not competent to manage the SARS-CoV-2 virus. This supports significant measures to reduce the risk of any spread or outbreak of COVID-19 through prohibiting the use or supply of unreliable and inaccurate COVID-19 POC tests, by the general public.

New Zealand Bill of Rights Act 1990 (NZBORA)

24. A matter for you to consider each time an Order is proposed or amended under the COVID-19 Act is whether the exercise of such powers will be appropriate. The power to make an Order under section 11 of the Act must be exercised consistently with NZBORA.

25. Officials assess that no rights are engaged by the proposed Order as there are no rights associated with having or selling a commercial product.

26. It is considered that insofar as any rights are engaged and limited by the Order, any limitations would be justifiable in a free and democratic society noting that the prohibition is risk-based, and impositions on individuals' rights are directly proportionate to the level of risk of COVID-19 transmission associated with the entry and use of low-quality, inaccurate or counterfeit POC kits in New Zealand.

Implementation

27. Officials have worked closely with the New Zealand Customs Service, the Ministry for Primary Industries, the Ministry of Business Innovation and Employment, and other stakeholders to develop the proposed Order and will continue to work to ensure the Order is implemented promptly.

Next steps

28. Following Ministerial consultation finishing on 25 March, officials will finalise the Order, and provide you with a version for signing on 19 April 2021.

29. The Order will come into effect 48 hours after signing on 19 April 2021.

ENDS.