Briefing

Regulation of COVID-19 Point of Care Testing under COVID-19 Act

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To:	Hon Chris Hipkins, Minister for COVID-19 Response		
Copy to:	Hon Andrew Little, Minister of Health Hon Meka Whaitiri, Minister of Customs		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

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Security level:	IN CONFIDENCE	**Date:**	28 January 2021
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This report provides advice on regulating COVID-19 Point of Care testing kits/materials (POC tests). Specifically, we seek your agreement to:
   - continue to prohibit the importation, manufacture, supply, sale or use of antigen and antibody POC tests under the COVID-19 Public Health Response Act 2020 (the COVID-19 Act);
   - prohibit the importation, manufacture, supply, sale or use of molecular and other types of POC tests under the COVID-19 Act;
   - ensure acceptable POC tests (including antigen, antibody and molecular) can be approved in certain circumstances (e.g. labs).

Summary

2. Reliable and accurate COVID-19 testing, alongside other public health measures, remains a core part of our Elimination Strategy.
3. New Zealand relies on highly sensitive nasopharyngeal RT-PCR (Reverse Transcription Polymerase Chain Reaction) testing (PCR) to detect and stamp out COVID-19 when a person is symptomatic. PCR testing is considered to be the "gold standard" in New Zealand because it is highly accurate, reliable and provides fairly rapid results (within 24-48 hours).
4. POC tests are administered at or near the point of care and use samples to measure antibodies or antigens to test if a patient had a past or recent infection of COVID-19. Molecular COVID-19 POC tests are also available.
5. POC test kits are "medical devices" under the Medicines Act 1981 (the Medicines Act) but there are significant known regulatory gaps in this Act. The Medicines Act does not require medical devices to be assessed or approved so there is no scrutiny of these POC tests in New Zealand. This leads to a heightened risk of low-quality, inaccurate or counterfeit POC kits entering New Zealand to be used by New Zealanders or on-sold to other countries (such as the Pacific).
6. In April 2020, the Ministry was notified that companies were importing and selling POC tests. The regulator, MedSafe - under delegation from the Minister of Health - issued a Notice under section 37 of the Act (the Notice) due to concerns over the accuracy and

reliability of these POC tests. The Notice restricts the importation, manufacture, sale, supply and use of POC COVID-19 tests. The Notice expires on 21 April 2021. The prohibition cannot be renewed under the Medicines Act, which makes the prohibition of COVID-19 POC tests time limited.

7. 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. Officials understand ESR has not approved any POC tests yet.

8. The Notice explicitly covers POC tests using an antigen or antibody detection system. Molecular POC tests are not specified in the Notice. Molecular tests are becoming increasingly more accurate and reliable. However, similar risks exist with molecular POC tests as the antibody or antigen POC tests.

9. POC tests that can 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 of COVID-19 infection;
   - the potential **misuse and misinterpretation** by the patient/public leading to risky behaviours and an outbreak or spread of COVID-19;
   - POC tests being **substituted for quality-assured and highly accurate PCR tests** and 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.

10. Overreliance on inaccurate POC tests is of particular concern given the emergence of new, highly, transmissible variants of COVID-19.

11. Officials recommend extending the prohibition on the importation, manufacture, supply, sale or use of COVID-19 POC tests through an Order issued under section 11 of the COVID-19 Act. The types of POC tests to be prohibited should include antigen, antibody and molecular.

12. POC tests may become more accurate with technology advancements. It is recognised this could allow for more rapid testing and surveillance therefore we recommend the Order to provide a mechanism to approve particular POC tests in certain circumstances (users, types and environments).

Recommendations

We recommend you:

a) **Note** that a Notice under the Medicines Act 1981 is in force until 21 April 2021 to prohibit the importation, manufacture, supply, sale or use of POC COVID-19 tests (unless exempt) and that this Notice cannot be renewed. **Yes/No**

b) **Note** scientific experts still consider available COVID-19 POC tests have quality and reliability issues that are likely to hamper COVID-19 control efforts. **Yes/No**

c) **Agree** to extend the prohibition of importing, manufacturing, supply, sale or use of all POC tests (including molecular) through a section 11 Order under the COVID-19 Public Health Response Act 2020 unless exempt or authorised. **Yes/No**

Dr Ashley Bloomfield
Director-General of Health
Date: 27/01/2021

Hon Chris Hipkins
Minister for COVID-19 Response
Date: 6/2/2021

Regulation of COVID-19 Point of Care Testing under COVID-19 Act

Background

1. Reliable and accurate COVID-19 testing, alongside other public health measures, remains a core part of our Elimination Strategy by:

    a. detecting symptomatic and asymptomatic individuals with COVID-19 at the border so they can be appropriately managed and COVID-19 kept out and stamped out; and

    b. monitoring and surveillance of COVID-19 in the community through symptomatic testing and contact tracing to prevent transmission of the virus to the wider community.

Point of Care testing

2. Point of care (POC) testing is defined as the analysis of clinical specimens outside the traditional laboratory, near to or at the site of patient care. POC tests use samples to measure antibodies or antigens for COVID-19 without the need to transfer the sample to a laboratory. Other POC tests can be molecular.

3. New Zealand relies on highly sensitive PCR tests to detect and stamp out COVID-19 when a person is symptomatic. POC tests that detect viral antigens or antibodies are less sensitive than PCR tests. The use of unauthorised POC tests may undermine highly sensitive and more accurate PCR testing.

4. The benefits of POC testing include rapid diagnosis of COVID-19 within minutes of being administered. It may support more rapid contact tracing through early detection and immediate self-isolation while waiting for the results of a PCR test. Other POC testing (e.g. molecular) has the potential in future to provide more accurate testing for COVID-19.

5. POC tests are most useful in countries with high prevalence of COVID-19 cases for surveillance purposes. In countries with few cases and no shortage of laboratory-based testing capacity, like New Zealand, the *quality* of testing is important. The Institute of Environmental Science and Research (ESR) considers PCR testing is of a high quality and well understood. PCR testing is also integrated in the wider public health system network enabling an orderly and co-ordinated testing regime.

6. In light of the ever-evolving nature of the virus (including the new highly transmissible variants) and the international context, officials are keeping a watching brief on developments mindful of the potential benefits of POC tests (particularly molecular testing) if there is high prevalence of COVID-19 in New Zealand.

7. As POC tests are less reliable than PCR tests, it is more likely patients with active infection will be falsely categorised as not having the disease when they do. This is likely to hamper disease control efforts.

Existing regulation of POC tests

Regulation of "medical devices" in New Zealand

8. Gaps exist in the regulation of medical devices under the Act. POC tests are considered medical devices (classified as In-Vitro Diagnostic devices) under the Medicines Act 1981 (the Medicines Act). MedSafe is responsible for regulation under the Medicines Act – MedSafe regulates medicines in New Zealand but medical devices do not need to be assessed or approved and these devices are not required to be entered into MedSafe's medical devices notification database (WAND).

9. The Act does not provide a mechanism to allow for effective scrutiny around the quality and accuracy of POC tests. This creates a heightened risk of low-quality or counterfeit POC tests entering New Zealand, being used by untrained New Zealanders who could misinterpret the results, and potentially being sold on to other countries (e.g. in the Pacific).

10. The Therapeutic Products Bill is being progressed and aims to address some of these regulatory gaps. The Bill will provide a modern regulatory framework and ensure the quality and efficacy of such products (including medical devices) but will not be enacted for a few years.

Notice to prohibit the import, manufacture, supply, sale and use of certain POC tests

11. On 22 April 2020, a Notice was issued under section 37 of the Medicines Act to prohibit the importation, manufacture, packing, sale, supply or use of antigen or antibody COVID-19 POC tests.

12. Under the Medicines Act, the Minister of Health has the power to issue a Notice of up to one year prohibiting the sale and import of a specified medical device. It is an offence to contravene the Notice. This Notice cannot be renewed.

13. The Notice provides for an exemption if a POC test has been approved by MedSafe and those kits/materials are imported, manufactured, packaged, sold, supplied or used with the intention they are only to be used for testing by specified categories of approved registered health care professionals.

14. ESR provides advice to MedSafe on the quality of any new POC test to diagnose for COVID-19 and stays abreast of international developments in this area.

Proposal to extend the regulation of POC tests

New Zealand context: The Elimination Strategy, the Testing Strategy and no community transmission

15. New Zealand currently has one community case of COVID-19. However, highly transmissible COVID-19 variants have recently been identified around the globe. These

variants are resulting in higher numbers of COVID-19 infected individuals and related deaths. To reduce residual risk and further protect New Zealanders, arrivals from all countries to New Zealand (except Australia, Antarctica and some Pacific Islands) are required to show evidence of a negative COVID-19 test prior to departure.

16. Our Elimination Strategy aims to keep COVID-19 out and stamp it out. The strategy relies on robust case detection and surveillance to identify new cases quickly and take appropriate action. PCR laboratory testing can be rapid - approximately 24-48 hours but can be completed in a much shorter timeframe - and is also highly accurate and reliable.

17. The Ministry of Health supports its COVID-19 response through its Testing Strategy. The Testing Strategy does not focus on widespread asymptomatic testing of communities unless as part of an outbreak or case investigation.

Risks associated with the import, manufacture, supply, sale or use of certain POC tests

18. As highlighted, there are risks associated with the import, manufacture, supply, sale and use of POC tests that could undermine our response to COVID-19. These risks provide compelling reasons to regulate, and include:

    a. concerns about the accuracy of POC tests and their potential to provide a misleading result. New Zealand's ESR and the WHO have advised that existing POC tests remain inaccurate and unreliable. Patients with an active infection may be missed or may be falsely categorised as having the virus when they do not, further hampering disease control efforts

    b. the potential misuse and misinterpretation of results by the public that could lead to risky behaviours contributing to the risk of an outbreak or spread of COVID-19. Untrained individuals are likely to not properly use, administer or interpret tests. A November 2020 UK study found individuals misinterpreted the results of POC tests and relied on inaccurate findings. Further, ESR advises that, if unregulated, POC tests could be used by untrained persons who do not understand the conditions or time limitations of particular tests (e.g. antigen tests generally must be used in symptomatic persons suspected of COVID-19 within five days otherwise the false negative rate is unacceptably high)

    c. POC tests are substituted for quality-assured PCR tests therefore undermining the effectiveness of the system; and

    d. a lack of integration with the test results repository and wider contact tracing process making detection and management of positive cases difficult.

Section 11 Order to prohibit POC tests

Section 11 Order to prohibit the import, manufacture, supply, sale or use of POC tests

19. Officials recommend extending the prohibition on importing, manufacture, supply, sale or use of certain POC tests through the use of an Order issued under section 11 of the COVID-19 Act.

20. Other options were assessed (see Appendix 1). However, we recommend an Order made under the COVID-19 Act in that it:

a. maintains confidence in the reliability and accuracy of New Zealand's COVID-19 test results

b. retains the ability to approve POC tests as the technology improves

c. is not time-bound but, as an Order under the COVID-19 Act, it will need to be regularly reviewed, which ensures officials maintain a watching brief over scientific and technological POC test advancements

d. can be easily integrated into the overarching national public health system for a co-ordinated, orderly response; and

e. is consistent with New Zealand's Bill of Rights Act 1990 (BORA).

21. POC tests may become more accurate with scientific and technological advancements allowing for more rapid testing and surveillance. In light of this, we recommend that the Order provide a mechanism for the Minister for the COVID-19 Response and / or Director-General of Health to authorise or approve certain COVID-19 POC tests. This approval of certain POC tests will be based on expert advice (e.g. ESR or equivalent) similar to the current Notice.

22. Further, in certain circumstances, the import of POC tests and immediate re-export overseas has been allowed if those tests have been required for use in another country that cannot access other forms of COVID-19 tests (eg donor to an international development project in Africa). It may be appropriate to continue this practice under the proposed section 11 Order.

Enforcement powers to stop POC tests entering New Zealand

23. The Order under section 11 of the COVID-19 Act will enable inaccurate or unreliable POC tests to be unlawful. Nonetheless enforcement powers will be required to seize or detain unreliable or counterfeit POC tests at the border.

24. We will work with our colleagues at Customs and the Ministry of Primary Industries to ensure officers from these agencies can seize or detain POC COVID-19 tests at the border if deemed necessary. Regulation may be required under the Customs and Excise Act 2018. If so, Cabinet approval will be sought to instruct PCO to prepare the necessary regulatory instruments.

Equity

25. An objective of the COVID-19 Testing Strategy is to ensure access to testing is effective and equitable for all groups, in particular Māori.

26. We understand the actual cost of a PCR test is approximately $200 per individual. However, PCR testing is available and accessible to anyone at no cost irrespective of age or region.

Te Tiriti o Waitangi consideration

27. POC tests could be seen to support the principle of Tino Rangatiratanga – Māori self-determination – by providing Māori with autonomy to test themselves or their communities as they deem appropriate.

28. However, POC tests are not yet at an acceptable standard deemed by the regulator, MedSafe, for New Zealanders to rely on. It is considered all New Zealanders need access to high quality healthcare. If the position on POC tests change then the Ministry will consult with Iwi/Māori groups.

Next steps

29. If you agree to our recommendation to make a section 11 Order under the COVID-19 Act to prohibit the import, manufacture, supply, sale or use of POC tests then we will work with the Parliamentary Counsel Office (PCO) to provide you with a draft Order by April 2021.

30. We will also provide you with further advice and a proposed policy position on private PCR testing for COVID-19 in February 2021.

31. If you agree to regulate through an Order under section 11 of the COVID-19 Act, we will also work with Customs and MPI colleagues to enable the appropriate enforcement for POC tests at the border.

ENDS.

Appendix 1: Options for regulation of POC tests in New Zealand

Appendix 1: Possible ways to regulate POC testing kits/materials in New Zealand

Legislation	Benefit/Reason to consider option	Reason for discounting option
Section 11 Order under the COVID-19 Public Health Response Act 2020	The Minister of Health has the power to make a binding, enforceable Order under section 11 of the Act to require people to take specific actions, or comply with specified measures, that contribute to or are likely to contribute to preventing the risk of the outbreak or spread of COVID-19.	Not discounted (preferred option).
COVID-19 Public Health Response Amendment Bill 2021	The COVID-19 Act is tailored to respond to the needs of the pandemic in New Zealand. The Amendment Act may need to be relied upon when made if a section 11 Order is inappropriate.	A regulatory gap would occur because the Notice expires in April 2021 and this Amendment Bill is expected to be passed mid-late 2021.
Section 96 of the Customs and Excise Act 2018 (C & E Act)	The C & E Act is existing legislation and allows the making of Orders which prohibit the importation of goods or classes of goods providing such a prohibition is considered necessary in the public interest. The prohibition can be absolute or conditional, which would facilitate a permit or consent type regime, which can be administered by any agency specified in the Order. An advantage of this option is that Customs, which will be enforcing the prohibition, is familiar with the drafting and enforcement of Customs Import Prohibition Orders.	The C & E Act would only prohibit importation of testing kits/materials and no other important parts of the supply chain that are problematic (e.g. manufacture, supply, sale, use, etc). Nevertheless, we will look to develop a Customs Importation Notice to ensure POC tests can be seized or detained.
Consumer protection laws: Consumer Guarantees Act (CGA) and Fair-Trading Act (FTA)	If used in tandem with the C & E Act, consumer protection laws could provide additional protection to consumers/patients against unsafe goods or products in those parts of the supply chain not covered by the C & E Act.	Health Legal advise it is unlikely the CGA or FTA could adequately achieve the intended regulatory objective. The CGA largely relies on individuals self-identifying the product they have purchased is not fit for the purpose it was bought. Most consumers are unlikely to be able to identify if a test is counterfeit/meets the scientific claims made about the product. Remedies are likely to be difficult for

		consumers to enforce, especially against overseas sellers. The FTA prevents misrepresentations being made about products. Part 3 also enables controls to be placed on unsafe products that could cause harm to the user. However, POC tests could still cause harm in the absence of misrepresentations, and the Part 3 provisions are unlikely to assist, as the tests themselves are unlikely to cause injury.
Section 38 of the Medicines Act 1981	This Act currently regulates therapeutics in New Zealand so could be an appropriate regulatory tool.	Section 38 of the Act provides *post*-market regulation only i.e. once the kits are already in New Zealand. It is therefore not considered the most viable option to prevent the issue.
Therapeutic Products Bill	This Bill provides comprehensive regulation of these types of medical devices across the product lifecycle, including premarket approval, supply chain and use controls, and post-market monitoring.	A regulatory gap may arise because the Notice expires in April 2021 and the Bill is yet to be introduced to parliament. A new regulatory scheme for therapeutic products (medicines and medical devices) is still some years away.