In Confidence

Office of the Minister of Health

Cabinet

Proposed amendment to the Medicines Act 1981 – Provisional Approvals

Proposal

1 This paper seeks agreement to amend the Medicines Act 1981 to ensure that the Minister of Health is able to give provisional consent to sell and use medicines where it is desirable to meet clinical and public health need and to validate existing provisional consents that have been granted by Medsafe.

Executive Summary

2 Responding to the pandemic has highlighted an urgent need for amendments to the Medicines Act, including through the judicial review brought by Ngā Kaitiaki Tuku Iho Medical Society Inc seeking a declaration that the current provisional consent of the COVID-19 Pfizer vaccine is unlawful.

3 There is a lack of clarity in how section 23(1) is drafted which creates a possible barrier for accessing safe and effective medicines.

4 I am seeking to make legislative changes to clarify the policy intent for provisional approval and to ensure New Zealanders continue to have access to safe and effective medicines. I propose to do this by:

4.1 validating a number of existing provisional consents that have been granted by Medsafe under section 23 of the Medicines Act; and

4.2 amending the Medicines Act to ensure that there is a sustainable approach for future provisional consent decisions and to remove doubt as to its application.

Background

The Medicines Act 1981

5 The Medicines Act aims to ensure that the medicines and products used in New Zealand meet acceptable standards of safety, quality and efficacy and that the benefits outweigh the risks. It requires all medicines and vaccines imported, supplied, sold and administered in New Zealand to be approved, under either section 20 or 23.

6 The Medicines Act, which currently regulates medicines and vaccines, is outdated. It is out of step with international regulatory practice, consumer expectations, and has

not kept pace with significant technological changes in medicines, advanced therapies and medical devices[1].

7 I am progressing the Therapeutic Products Bill which will repeal and replace the Medicines Act. The Bill will provide modern, comprehensive regulation of medicines and medical devices consistent with modern international regulatory best practice.

8 Section 20 of the Medicines Act provides for the Minister of Health to grant full consent of medicines following assessment by Medsafe. Section 23 of the Act provides for the Minister of Health to grant provisional consent where they consider it is desirable for the medicine to be "sold, supplied, or used on a restricted basis for the treatment of a limited number of patients". These decisions are delegated to Medsafe.

9 The policy intent of section 23 is to enable early access to medicines and vaccines that meet a significant clinical and public health need following assessment by Medsafe. It is intended to provide time limited consent where the benefits are found to outweigh the risks of the medicines or vaccines, which is consistent with international regulatory practice.

10 Examples of when provisional consent is used, include where there is an innovative new medicine, to respond to an urgent clinical or public health need, and to provide for urgent approval of medicines particularly where there are imminent supply disruptions. Section 23 provides flexibility to allow access to important medicines while providing a good measure of protection.

11 Provisional consent provided by section 23 is a robust process and provides a greater degree of assurance (based on a more detailed assessment of data) than emergency authorisation provisions that are available and applied in other jurisdictions.

Judicial Review

12 Ngā Kaitiaki Tuku Iho Medical Society Inc (Ngā Kaitiaki) has brought judicial review proceedings challenging the decision to grant provisional consent of the COVID-19 Pfizer vaccine under section 23(1) of the Medicines Act and the government's rollout of the Pfizer vaccine.

13 In large part, Ngā Kaitiaki's claim turns on the interpretation of section 23(1) of the Medicines Act. Ngā Kaitiaki's position is that the potential treatment of everyone aged 16 and over with the COVID-19 Pfizer vaccine is not a "limited number of people" and therefore the decision to grant provisional consent was unlawful.

14 On 12 May 2021, the High Court heard an application for interim orders seeking declarations to stop the Pfizer vaccine rollout until the substantive case can be heard. The Court reserved its decision and Crown Law expects the interim judgment will be handed down this week.

15 At the interim hearing, the High Court made comments along the lines that it appeared the provisional consent power was intended to be available only where the

[1]Examples of new and emerging technologies include immunotherapies, personalised medicines, nanotechnology, gene therapies, insulin pumps, computer assisted and robotic surgery, machine learning and Artificial Intelligence as part of integrated software and the increased use of 3D printing.

medicine would be used by a small group of people, and that everyone aged 16 and older may not be a sufficiently small enough group.

Implications

16 If the Court delivered a judgment aligned with those comments, the implications would be that the:

16.1 rollout of the COVID-19 Pfizer vaccine will be suspended or limited to a small group of people (on an interim or permanent basis); and

16.2 the ability to provisionally consent other COVID-19 vaccines (and other medicines) will be seriously hindered.

17 Therefore, there is a current need and opportunity to amend or modify the Medicines Act to address these risks and to update section 23 to ensure that it reflects the policy intent and modern practices. I am satisfied that Medsafe followed a robust and appropriate decision-making process in regard to assessing the safety, quality and efficacy of the Pfizer COVID-19 vaccine as per standard practice, and where the evidence has been found to show the benefits of the Pfizer COVID-19 vaccine outweigh any potential risks.

Options

18 I propose to address any uncertainty that has been highlighted by the judicial review proceedings. The proceedings seek a judgment on the legality of the decision to grant provisional consent to the COVID-19 Pfizer vaccine under section 23 of the Medicines Act. The uncertainty relates to section 23(1) which the Minister may, by notice in the *Gazette*, in accordance with this section, give his provisional consent to the sale or supply or use of a new medicine where they are of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

19 I propose to amend the Medicines Act to clarify that section 23 enables New Zealanders to gain early access to medicines and vaccines that have been assessed for safety, quality and efficacy by Medsafe, and where the evidence has been found to show the benefits of the medicines outweigh the risks. This approach allows for access for all New Zealanders (not limited to a restricted number of patients) should there be a significant clinical and public health need, which is in line with the policy intent of section 23.

20 The key difference between a provisional consent (under section 23) and a full consent (under section 20) is that a provisional consent can only be granted for a maximum of two years (although the Minister has the power to renew a provisional consent). It is also easier for Medsafe to impose conditions and monitor compliance with those conditions for provisional consents.

21 In order to clarify and confirm previous and future decisions that have been legitimately and appropriately made applying section 23 of the Medicines Act, there are two issues that need to be addressed:

21.1 validating existing decisions that have provided provisional consent, including the COVID-19 Pfizer vaccine, to confirm those decisions; and

21.2 providing a suitable option for future decisions that will address the current limitations of the Medicines Act under section 23.

22 This is an interim measure until the Therapeutic Products Bill is progressed through Parliament. The Bill is scheduled to be introduced in 2022.

Validating existing provisional consents

23 Validation relates to decisions that have already been made and validates decisions with retrospective effect. Options to address validation of such decisions include:

23.1 only validating the COVID-19 Pfizer vaccine provisional approval addressed in detail below; or

23.2 specifying a list of existing provisional approvals that have been made and remain current (recommended); or

23.3 a wide validation that would seek to generally cover all provisional consents.

24 There are currently 30 active provisional consents, including the provisional consent for the COVID-19 Pfizer vaccine. Of that, the current view is that five of these active provisional consents may create the same issue as the COVID-19 Pfizer vaccine. That is, the use of those medicines is arguably not restricted to a "limited number of patients". It is recommended that we address the five active provisional consents.

25 Below is a brief overview of those five provisional consents:

25.1 Two of the provisional consents are for different influenza vaccines for use in the event of an influenza pandemic. Much like the COVID-19 Pfizer vaccine, we anticipate in an influenza pandemic that the desire will be for these vaccines to be administered to the majority of the New Zealand population.

25.2 Two of the provisional consents are for contraceptive medicines which could arguably be given to any female in New Zealand.

25.3 A medicine used as a source of water and electrolytes in hospital. Although not included as a condition this medicine was given provisional consent specifically to create a stockpile to protect against shortages during the COVID-19 pandemic.

26 I intend to take a subsequent paper to the Cabinet Social Wellbeing Committee on 19 May 2021 which will address the appropriate legislative vehicle (refer to paragraphs 50-53). As the nature of the approach will vary depending on the more substantive decisions related to the proposed amendments to the Medicines Act.

Providing a suitable option for future decisions that will remove any doubt about section 23 of the Medicines Act

27 Three options have been considered to remove any doubt about section 23 for future decisions that are made by Medsafe:

27.1 validate the provisional consent of the COVID-19 Pfizer vaccine; or

27.2 amend the Act to enable provisional consent for COVID-19 related medicines only; or

27.3 (Recommended approach) amend the Medicines Act to clarify the circumstances for the granting of provisional consent to enable early access to medicines in New Zealand and remove the reference in section 23(1) to "on a restricted basis for the treatment of a limited number of patients".

28 Officials have considered the following factors in developing the options in this paper:

28.1 the minimum amendment necessary to address the lack of clarity in the drafting of section 23(1);

28.2 the potential impact on the COVID-19 Vaccine and Immunisation Programme;

28.3 providing an interim approach that supports the sustainability of New Zealand's medicine supply until the Therapeutic Products Bill comes into force;

28.4 ensuring that we maintain a robust approach for the assessment of new medicines for safe and effective use in New Zealand; and

28.5 ensuring that we maintain public trust and confidence of the assessment process for provisional consent and ensure that we maintain integrity of the independent process conducted by Medsafe.

Option 1: only validate the current provisional consent provided for the COVID-19 Pfizer vaccine

29 This option will validate the provisional consent that has been granted for the COVID-19 Pfizer vaccine only, using an appropriate statutory instrument such as a current COVID-related Validation Amendment Bill.

30 This approach would remove any doubt over the provisional consent for the COVID-19 Pfizer vaccine which has undergone robust assessment of safety, quality and efficacy by Medsafe. The COVID-19 Pfizer vaccine is currently being rolled out across New Zealand.

31 This approach would not address the likely need for further decisions relating to the use of the COVID-19 Pfizer vaccine for example to extend approval to a wider age cohort. This would also not address the likely need to approve any other COVID-19 vaccine, subject to any other vaccine meeting any assessment criteria set by Medsafe.

32 New Zealand has additional Advance Purchase Agreements with other COVID-19 vaccine suppliers, as part of a vaccine portfolio approach. Purchasing multiple vaccines manages significant risks associated with uncertainty around supply, vaccine failure during development, the potential need for booster or annual COVID-19 vaccinations, and updated vaccines to manage new COVID-19 variants of concern.

33 Medsafe has received and is assessing three applications for other COVID-19 vaccines and may receive further applications for consideration. It would potentially be required to revisit provisional consent for these vaccines and other COVID-19 related medicines.

34 The problem that has been identified is a legal question as to whether the drafting of the provisional consent power meets the policy intent. An approach solely focused on the Pfizer COVID-19 vaccine might be misunderstood as reflecting on the safety and quality of the vaccine and the robustness of Medsafe's assessment and process (which is not in question).

35 This option may also impact on New Zealand's role in supporting the Pacific and global efforts to reduce the impact of COVID-19, given that donation of COVID-19 vaccines to other countries from New Zealand requires regulatory approval.

Option 2: Amend the Medicines Act to specifically provide for provisional consent for COVID-19 related medicines and vaccines

36 The Medicines Act could be amended to specifically provide for provisional consent for COVID-19 related medicines and vaccines that could be used for the purpose of managing the risk of COVID-19.

37 This approach would provide a robust and clear pathway for the regulatory approval of the COVID-19 Immunisation Programme and potential need for other COVID-19 medicines, including other COVID-19 vaccines purchased as part of our vaccine portfolio.

38 As noted above, the problem that has been identified is a legal question as to whether the drafting of the provisional consent power meets the policy intent. The evaluative process is not in question.

39 A COVID-19 specific provision may also introduce inconsistences in the ability to assess and approve COVID-19 related medicines and vaccines and those for other conditions. As noted previously, the current judicial review proceedings highlight a lack of clarity with the technical drafting of section 23(1).

Option 3 (Recommended): Amend the Medicines Act to clarify the purpose and scope of provisional consent consistent with modern international regulatory practice for medicines.

40 The Medicines Act could be amended to clarify the circumstances for the granting of provisional consent to enable early access where there is a significant clinical and public health need and benefits outweigh the risks and remove the reference in section 23(1) to "on a restricted basis for the treatment of a limited number of patients".

41 Removing reference to "on a restricted basis for the treatment of a limited number of patients" is required to allow for access for all New Zealanders should there be a

significant clinical and public health need, which is in line with the policy intent of section 23.

42 Any amended section should ensure that provisional consent can be provided:

42.1 on a time limited basis;

42.2 where Medsafe is satisfied on the basis of the data available the medicine is sufficiently more likely than not to be safe to use;

42.3 where the benefits outweigh the risks;

42.4 for conditions to be made relating to the product sponsor and/ or to any aspects of the consent; and

42.5 in a manner that remains consistent with sections 20, 21 and 22 of the Medicines Act.

43 This approach would allow for Medsafe on behalf of the Minister to grant provisional consent for all medicines where justified due to the nature of a public health situation and the information necessary for a full consent under section 20 is not reasonably feasible. Section 23(2) specifies the application for provisional consent must meet existing requirements relating to the safety, quality and efficacy of the medicine and an assessment of the benefits and risks as set out in sections 21 and 22 of the Medicines Act.

44 This approach would provide a consistent approach across all medicines and certainty for suppliers and the health sector and help maintain public trust and confidence in the process. It is the minimum amendment necessary to address the lack of clarity in the drafting of section 23(1).

The Therapeutic Products Bill will replace the Medicines Act

45 Work to review the Medicines Act has been ongoing for a number of years. This work is reflected in the Therapeutic Products Bill which the Ministry of Health is currently finalising ahead of introduction to Parliament in 2022. The Therapeutic Products Bill will repeal and replace the Medicines Act. The purpose of the new legislation is to provide a modern and comprehensive regulatory scheme which will provide assurance of the safety, quality, and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare [SOC-15-MIN-0049; SOC-15-MIN-50; SOC-16-MIN-0025; SWC-18-MIN-0176 refers].

46 The Therapeutic Products Bill will provide for different product approval pathways appropriate to the specific circumstance and proportionate to the risk of the products. It will specifically require that the benefits outweigh the risks and enables conditions to be imposed as part of any product approval. The Bill will address wider issues with the relevance and application of the Medicines Act. The Bill will retain and further refine the original policy intent of the Medicines Act which is to ensure timely access to safe medicines.

47 Following consultation on a draft Therapeutic Products Bill in early 2019, the Ministry of Health received 442 submissions. These submissions are informing

ongoing work on the Bill. There was broad support from across the stakeholder groups for updating New Zealand's therapeutic product regulation and for a range of approval pathways that are proportionate to the risks of the products and their use.

48 The next opportunity for public consultation on the Bill will be at the Select Committee stage. Further consultation will be undertaken during the development of Regulations.

Financial Implications

49 There are no financial implications from the proposed amendments to the Medicines Act.

Legislative Implications

50 A Bill amending the Medicines Act 1981 will be required to give effect to Cabinet's decisions.

51 Legislation reflecting those decisions will be prepared for consideration by the Cabinet Social Wellbeing Committee on 19 May 2021 and introduced in time for passage on 20 May 2021.

52 The specific legislative vehicle to validate any existing provisional consents and amend provisional consent authority in the Medicines Act is subject the specific option Cabinet agrees to. If Cabinet agrees to amend the Medicines Act to clarify the original intent of the provisional consent pathway, this will likely be addressed in a stand-alone Bill that amends the Medicines Act.

53 This approach would clarify the Medicines Act provisional consent as an interim measure ahead of the commencement of the new Therapeutic Products Bill which is underway and is expected to be introduced into Parliament in 2022. The Therapeutic Products Bill will provide a comprehensive modern regulatory scheme for medicines, advanced therapies, and medical devices.

Impact Analysis

54 An exemption for a Regulatory Impact Statement will need to be sought from Treasury and further advice will be provided on this as part of the legislation paper to be considered by the Social Wellbeing Committee on 19 May 2021.

Human Rights

55 This proposal would have retrospective effect and relates to matters that are subject to a prospective court decision. The Legislation Guidelines note that such legislation needs to be justified as being in the public interest and should impair the rights of litigants no more than is reasonably necessary to serve that interest. They also note that retrospective legislation may be appropriate if it is essential to public safety. The validations proposed are essential to public safety because of the potential impact on the rollout of the COVID-19 Pfizer vaccine and are in the public interest. It is not possible to preserve the position of the litigants without compromising that public interest.

Consultation

56 The following departments and agencies were consulted in the development of this paper: the Department of the Prime Minister and Cabinet, Ministry of Justice, Crown Law and the Parliamentary Counsel Office.

Communications

57 The Ministry will prepare supporting communication materials for the Parliamentary process and will work with Crown Law on appropriate communications with the Court. The Court and the other parties to the judicial review will need to be advised if Cabinet decides to make any legislative amendment.

58 The Ministry does not anticipate the need for proactive communications over and above those that usually accompany a change in legislation.

Proactive Release

59 This paper will be proactively released as soon as practicable following Cabinet's decisions. Release will be subject to redactions as appropriate under the Official Information Act 1982.

Recommendations:

The Minister of Health recommends that the Committee:

1. **Note** that aspects of the Medicines Act are outdated
2. **Note** that a particular lack of clarity has been highlighted in relation to section 23 of that Act which provides for provisional consent of medicines
3. **Note** the Therapeutic Products Bill is being progressed which will repeal and replace the Medicines Act. The Bill will provide modern, comprehensive regulation of medicines and medical devices consistent with modern international regulatory best practice
4. **Note** that the Therapeutic Products Bill is intended to be introduced to Parliament in 2022
5. **Agree** to amend the Medicines Act to further clarify and enable the provisional consent for medicines to be made by the Minister of Health:
    - 5.1. on a time limited basis
    - 5.2. where Medsafe is satisfied on the basis of the data available the medicine is sufficiently more likely than not to be safe to use
    - 5.3. where the benefits outweigh the risks
    - 5.4. for conditions to be made relating to the product sponsor and/ or to any aspects of the consent, and
    - 5.5. in a manner that remains consistent with sections 20, 21 and 22 of the Medicines Act

6. **Note** that the proposed amendment to the Medicines Act is consistent with the policy intent of section 23 and also consistent with the policy decisions informing the Therapeutic Products Bill [SOC-15-MIN-0049; SOC-15-MIN-50; SOC-16-MIN-0025; SWC-18-MIN-0176 refers]

7. **Agree** to amend the Medicines Act to:

   7.1. Option 1: validate the provisional consent of the COVID-19 Pfizer vaccine

   OR

   7.2. Option 2: validate the provisional consent of the COVID-19 Pfizer vaccine and specifically provide for provisional consent for COVID-19 related medicines and vaccines

   OR

   7.3. Option 3 (Recommended): validate the provisional consent of the COVID-19 Pfizer vaccine and clarify the purpose and scope of provisional consent consistent with modern international regulatory practice for medicines

8. **Agree**, if option 3 is chosen, to also validate other existing provisional consents that have been made where a question may be raised as to whether they are intended to be sold to, supplied to or used by more than a limited number of patients

9. **Authorise** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the agreed options set out in recommendations (5), (7) and (8) above

10. **Authorise** the Minister of Health to approve any matters of detail that may arise during the drafting of the amendment bill, in consultation with the Attorney-General if necessary.

Authorised for lodgement

Hon Andrew Little

Minister for Health