In Confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Medicines Amendment Bill: Approval for Introduction

Proposal

1. This paper seeks authorisation to introduce amendments to the Medicines Act (1981) – Provisional Approvals (section 23 (1)) related to provisional consents granted by Medsafe.

2. It is proposed the Bill is introduced and progressed through all stages under urgency on Wednesday 19 May 2021.

Policy

3. The Medicines Act, which currently regulates medicines and vaccines, is outdated.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.

4. 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. It is scheduled to be introduced in 2022.

5. Responding to the COVID-19 pandemic has highlighted an urgent need for amendments to the Medicines Act 1981 in the interim.

6. The Medicines Act (the 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.

7. 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". Section 20 of the Act provides for the Minister of Health to grant full consent of medicines following assessment by Medsafe.

8. The policy intent of section 23 is to enable early access to medicines and vaccines that meet a significant clinical and public health need. 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.

9. 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.

10. However, there is a lack of clarity in how section 23 as drafted which creates a possible barrier for accessing safe and effective medicines. The proposed change to section 23 to remove 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, as agreed by Cabinet [CAB-21-MIN-0170].

11. As agreed by Cabinet [CAB-21-MIN-0170], this Bill will:

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

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

Impact analysis

12. Treasury's Regulatory Impact Analysis team has determined that this proposal is exempt from the requirement to provide a Regulatory Impact Statement on the grounds that it has no or only minor impacts on businesses, individuals, and not-for-profit entities.

Compliance

13. The proposed changes comply with:

    13.1 the principles of the Treaty of Waitangi

    13.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993

    13.3 the principles and guidelines set out in the Privacy Act 2020

    13.4 relevant international standards and obligations

    13.5 the Legislation Guidelines (2018 edition), which are maintained by the Legislation Design and Advisory Committee.

14. This proposal would have retrospective effect and relates to matters that are subject to legal proceedings. On 18 May 2021, the High Court released a judgment commenting on the reference to a "limited number of patients" in section 23(1) and urging the Crown to consider this matter carefully.

15. The Legislation Guidelines note that legislation with retrospective effect 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 in the public interest because of the need to access medicines subject to a provisional consent and, in the case of the provisional consent granted for the Pfizer COVID-19 vaccine, are essential to public health because of the potential impact on the rollout of the vaccine .

16. The proposal may limit rights under section 27 NZBORA. However, I consider the limit to be justifiable under section 5 NZBORA as the proposal is essential in allowing access to safe and effective medicines for New Zealanders where there is an urgent clinical or public health need.

Climate implications

17. This proposal is exempt from the requirement to provide a Climate Implications of Policy Assessment (CIPA).

Consultation

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

Binding on the Crown

19. This proposal does bind the Crown, in accordance with section 6 of the Act.

Associated regulations

20. Regulations will not be required to support the implementation of the Bill.

Other instruments

21. The Bill does not include any new provisions empowering the making of other instruments that are deemed to be legislative instruments or disallowable instruments (or both).

Commencement of legislation

22. The amendments will come into force on the day after it receives Royal assent.

Parliamentary stages

23. The attached amendment is proposed to be introduced to the House under urgency and progressed through all stages on Wednesday 19 May 2021.

24. I consider this is appropriate because there is an urgent need to ensure that New Zealanders are able to continue to access safe and effective medicines, and to clarify the validity of the Pfizer COVID-19 vaccine and other medicines that are provisionally consented under Section 23 of the Medicines Act.

25. The High Court released an interim judgment on 18 May 2021 finding that it was reasonably arguable that the provisional consent granted for the Pfizer COVID-19 vaccine was ultra vires section 23 of the Medicines Act, given the reference to a

"limited number of patients". The Court urged the Crown now to consider this question carefully and noted that the provisions of the Medicines Act at issue are inapt. In light of the Court's judgment, I consider that this amendment should be progressed urgently.

Proactive Release

26. I intend to proactively release this Cabinet paper subject to any redactions consistent with the Official Information Act 1982 and Cabinet Office agreement, no later than 30 days after Cabinet consideration.

Recommendations

I recommend that the Social Wellbeing Committee:

1. **Note** the amendment to section 23 of the Medicines Act 1981 will clarify the circumstances for granting provisional consent for medicines to be made by the Minister of Health:

    1.1 on a time limited basis

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

    1.3 where the benefits outweigh the risks

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

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

2. **Note** that the amendment to the Medicines Act 1981 will validate a number of existing provisional consents that have been granted by Medsafe 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, including the provisional consent of the COVID-19 Pfizer vaccine

3. **Note** the intention that the amendments to the Medicines Act 1981 be introduced under urgency and passed through all stages on Budget Night, 20 May 2021

4. **Note** that the amendments to the Medicines Act 1981 will come into force on the day after Royal Assent

5. **Authorise** the introduction of the Medicines Amendment Bill.

Authorised for lodgement

Hon Andrew Little
Minister of Health