IN CONFIDENCE

Office of the Minister of Health
Cabinet Legislation Committee

Medicines Amendment Regulations 2022

Proposal

1 This paper seeks authorisation for submission to the Executive Council of the Medicines Amendment Regulations 2022.

Executive Summary

2 Under the Medicines Act 1981, no one may administer a prescription medicine without a prescription unless they are authorised to do so by the Act or the Regulations.

3 These amendments to the Medicines Regulations enable a diverse range of people to administer vaccinations. This allows vulnerable populations to be vaccinated by people they already know and trust in locations that are convenient to them.

4 The amendments are to enable:

4.0 people to be authorised as Vaccinating Health Workers on the same basis as COVID-19 vaccinators

4.1 pharmacists and other authorised vaccinators to administer the influenza vaccine to people of all ages, rather than only to people aged 13 years and over.

5 The amendments also increase the maximum fees set under the Medicines Regulations. These increases implement the outcome of a fees review and address long standing cost recovery inequities.

Policy

6 The regulations do not require any new policy decisions from the Legislation Cabinet Committee.

Regulations are needed to improve access to vaccines and increase vaccine workforce capacity

7 On 6 April 2022, the Cabinet Social Wellbeing Committee agreed to regulations to amend the Medicines Regulations [SWC-22-MIN-0059 refers]. The agreed regulations enable the Director-General or a Medical Officer of

Health to authorise a person who meets certain criteria to prepare and/or administer vaccines without a prescription (Vaccinating Health Worker).

8 The criteria that must be met are:

8.0 That the person has successfully completed training as approved by the Director-General for either or both:

8.0.0 preparing vaccines

8.0.1 administering vaccines without a prescription

8.1 That the person has the following competencies

8.1.0 the person can carry out basic emergency techniques, including resuscitation and the treatment of anaphylaxis; and

8.1.1 the person has knowledge of the safe and effective handling of immunisation products and equipment.

9 The amendment regulations provide that the authorisation may:

9.0 specify the vaccines that may be prepared or administered

9.1 be subject to conditions

9.2 be amended by the Director-General or a Medical Officer of Health to specify new vaccines, remove vaccines, or amend conditions.

10 The amendment regulations also enable pharmacists and other authorised vaccinators to administer the influenza vaccine to all age groups.

Amendment to fees

11 On 26 October 2021 Cabinet agreed to the amendment of the maximum fees set in regulation 61 and Schedule 5A of the Medicines Regulations 1984 [CAB-21-MIN-0430 refers].

12 It was also agreed that a new regulation would be included to allow significant changed medicine notifications to be charged as new medicines. However, during the drafting process Parliamentary Counsel Office advised that the result intended by Cabinet was better achieved by further increasing the maximum fee for all changed medicine notifications under regulation 61(7) rather than including a new regulation.

13 The maximum fee for a changed medicine notification under regulation 61(7) will be aligned with the maximum fee for a new medicine application under regulation 61(4). This will enable an appropriate fee to be charged when a changed medicine notification requires significant evaluation.

14 The changes to the fees were based on a scheduled fee review on all fees set in regulation 61 and Schedule 5A of the Medicines Regulations 1984.

15 The proposed fee changes are required to provide for cost recovery for Medsafe processes and to address longstanding cost recovery inequities.

16 The following table shows the proposed fee changes:

Regulation 61	Fee Type description	Old fee (maximum – inc GST)	New fee (maximum – inc GST)
(1)	Schedule 5A licences	See below	
(4)	Fee for any other application made under section 21 for the consent of the Minister under section 20 of the Act (new medicines other than new novel medicines)	$43,875	$79,877
(5)	New related products	$5,500	$5,731
(6)	Provisional consent under section 23	$8,437	$85,202
(7)	Changed medicine notifications	$3,200	$79,877
Schedule 5A	Licence application fees		
	Licence to manufacture medicines	$13,750	$14,328
	Licence to pack medicines	$845	$880
	Licence to sell medicines by retails	$845	$880
	Licence to sell medicines by wholesale	$1,054	$1,123
	Licence to hawk medicines	$845	$880
	Combined licence to pack and sell by retail	$300	$313
	Licence to operate a pharmacy	$1,030	$1,097

17 Regulation 61(4) equates to an 82 percent increase while regulation 61(6) equates to a 910 percent increase. Regulation 61(7) has been increased to a level to allow for significant changed medicine notifications to be charged as new medicines. These are maximums and fee waivers can (and are intended to) be applied according to the amount of evaluation effort that is required. All other fee increases are set at 4.2 percent, in line with the calculated Consumer Price Index movement since the last fees review in 2017.

Timing

18 The regulations will be notified in the *New Zealand Gazette* as soon as possible after officials are informed of the Executive Council's agreement. The regulations will come into force 28 days after they are notified in the *Gazette*.

Compliance

19 The regulations comply with:

19.0 the principles of the Treaty of Waitangi;

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

19.2 the principles and guidelines set out in the Privacy Act 2020;

19.3 relevant international standards and obligations;

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

20 The regulations will be made under section 105 of the Medicines Act. This section requires that I must be satisfied that consultation has occurred with 'such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations.' I am satisfied that the Ministry has consulted with the appropriate organisations and bodies on my behalf.

Regulations Review Committee

21 I am not aware of any grounds for the Regulations Review Committee to draw these regulations to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

22 The draft regulations have been certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

Impact Analysis

23 Treasury's Regulatory Impact Analysis team has determined that the Medicines Amendment Regulations 2022 proposal to authorise a person who meets certain criteria to prepare and/or administer a vaccine without a prescription 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.

24 A Regulatory Impact Statement (RIS) for the fees increase was prepared in accordance with Cabinet's impact analysis requirements and was submitted at the time that Cabinet approval was sought for the policy relating to the relevant regulations. The Ministry of Health QA panel has reviewed the RIS and considered it met the quality assurance criteria.

Publicity

25 Once the regulations are notified in the *Gazette*, officials will update the Medsafe website with respect to the fees changes and will communicate directly with stakeholders. Officials will also publicise the changes to the vaccinator workforce via appropriate workforce channels.

Proactive release

26 In accordance with Cabinet Office circular CO(18)(4), I intend to proactively release this paper, and the previous paper on regulations, within 30 business days of Cabinet agreeing the regulations, subject to redactions under the Official Information Act 1982.

Consultation

27 The following agencies have been consulted on the regulations and this paper: the Department of the Prime Minister and Cabinet, the Accident Compensation Corporation, Treasury, Pharmac and Te Puni Kōkiri.

Recommendations

I recommend that the Cabinet Legislative Committee:

1 note that on 26 October 2021 Cabinet agreed to the amendment of the maximum fees set in regulation 61 and Schedule 5A of the Medicines Regulations 1984 [CAB-21-MIN-0430 refers];

2 note that on 6 April 2022 the Cabinet Social Wellbeing Committee agreed to amend the Medicines Regulations 1984 to enable the Director-General or a Medical Officer of Health to authorise a person who meets certain criteria to prepare and/or administer vaccines without a prescription [SWC-22-MIN-0059];

3 note that the Cabinet Social Wellbeing Committee also agreed to amend the Medicines Regulations 1984 to allow pharmacists and authorised vaccinators to administer the influenza vaccine to people of all ages;

4 authorise the submission to the Executive Council of the Medicines Amendment Regulations 2022;

5 note that the Medicines Amendment Regulations 2022 will be notified in the *New Zealand Gazette* as soon as possible after officials have been informed of the Executive Council's approval and will come into force 28 days after they are notified in the *Gazette*.

Authorised for lodgement

Hon Andrew Little
Minister of Health

Medicines Amendment Regulations 2022

Order in Council

At Wellington this day of 2022

Present:
in Council

These regulations are made under section 105 of the Medicines Act 1981—

(a) on the advice and with the consent of the Executive Council; and

(b) on the advice of the Minister of Health given after consultation with the organisations or bodies that appeared to the Minister to be representative of persons likely to be substantially affected by the regulations.

Contents

Regulations

1 Title

These regulations are the Medicines Amendment Regulations 2022.

2 Commencement

(1) Regulations 6 and 8 come into force on 1 July 2022.

(2) The rest of these regulations come into force on 19 May 2022.

3 Principal regulations

These regulations amend the Medicines Regulations 1984.

4 New regulation 44AA inserted (Alternative authorisation of vaccinators)

After regulation 44A, insert:

44AA Alternative authorisation of vaccinators

(1) The Director-General or a Medical Officer of Health may authorise a person who meets the requirements of this regulation to—

(a) prepare a vaccine:

(b) administer a vaccine without a prescription.

(2) An authorised person must, at all times while performing the tasks authorised under these regulations, work under the clinical supervision and direction of a suitably qualified health practitioner.

Application for authorisation

(3) In applying for authorisation, a person must provide evidence to satisfy the Director-General or the Medical Officer of Health, as the case may be,—

(a) that the person has successfully completed training as approved by the Director-General for either or both of the following:

(i) preparing for administration the 1 or more vaccines for which the person has applied for authorisation:

(ii) administering those vaccines; and

(b) that the person also has the following competencies:

(i) the person can carry out basic emergency techniques, including resuscitation and the treatment of anaphylaxis; and

(ii) the person has knowledge of the safe and effective handling of immunisation products and equipment.

Conditions, etc, of authorisation

(4) The Director-General or the Medical Officer of Health, as the case may be,—

(a) must specify in the authorisation the 1 or more vaccines that the authorised person may prepare or administer (or both):

(b) may, on application by the authorised person, amend the authorisation by adding or removing any vaccine.

(5) An application to add a vaccine must be made in accordance with subclause (3)(a).

(6) The Director-General or the Medical Officer of Health, as the case may be, may—

(a) impose conditions on an authorisation as they think fit:

(b) amend or revoke any condition by written notice to the authorised person.

(7) An authorisation is valid for a period of 2 years, unless it is revoked earlier under subclause (8).

(8) The Director-General or the Medical Officer of Health, as the case may be, may revoke an authorisation by written notice to the authorised person if satisfied that the authorised person has failed to comply with any condition on their authorisation.

5 Regulation 44AB amended (Authorisation of vaccinators)

(1) In the heading to regulation 44AB, replace "**vaccinators**" with "**COVID-19 vaccinators**".

(2) After regulation 44AB(3), insert:

(4) This regulation applies to the authorisation of COVID-19 vaccinators instead of regulation 44AA.

(5) This regulation is revoked on 1 June 2023.

6 Regulation 61 amended (Fees)

(1) In regulation 61(4), replace "$43,875" with "$79,877".

(2) In regulation 61(5), replace "$5,500" with "$5,731".

(3) In regulation 61(6), replace "$8,437" with "$85,202".

(4) In regulation 61(7), replace "$3,200" with "$79,877".

7 Schedule 1 amended

In Schedule 1, Part 1, item 1090, delete "to a person 13 years of age or over".

8 Schedule 5A amended

In Schedule 5A, third column, replace each figure in the first column of the following table with the corresponding figure in the second column:

13,750	14,328
845	880
845	880
1,054	1,123
845	880

300	313
1,030	1,097

Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations amend the Medicines Regulations 1984 (the **principal regulations**). They make 2 sets of amendments.

The first set of amendments comes into force on 19 May 2022. It relates to vaccinations and the authorisation of people to prepare and administer them. The amendments—

- insert *new regulation 44AA* into the principal regulations to enable the Director-General of Health or a Medical Officer of Health to authorise people to prepare or administer vaccines under the clinical supervision and direction of a suitably qualified health practitioner (*see regulation 4*):
- amend regulation 44AB of the principal regulations so that a similar power to authorise people to prepare or administer a COVID-19 vaccine is revoked on 1 June 2023 (*see regulation 5*):
- amend Schedule 1 of the principal regulations so that the influenza vaccine is not classed as a prescription medicine in certain cases, regardless of the recipient's age (*see regulation 7*).

The second set of amendments (*see regulations 6 and 8*) comes into force on 1 July 2022. It increases the fees payable for—

- a licence application specified in Schedule 5A of the principal regulations:
- an application for the Minister of Health's consent to sell, distribute, or advertise a new medicine (other than a new medicine that contains a novel active ingredient):
- an application for the Minister's consent to sell, distribute, or advertise a new related product:
- an application for the Minister's provisional consent to sell, supply, or use a new medicine:
- a notification to the Director-General of Health of a material change made by the manufacturer of a medicine.

Regulatory impact statement

The Ministry of Health produced a regulatory impact statement on 28 July 2021 to help inform the decisions taken by the Government relating to the contents of this instrument.

A copy of this regulatory impact statement can be found at—

- https://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements
- https://treasury.govt.nz/publications/informationreleases/ris

Issued under the authority of the Legislation Act 2019.
Date of notification in *Gazette*:
These regulations are administered by the Ministry of Health.