

**In Confidence**

Office of the Minister of Health  
Chair, Cabinet Legislation Committee

**Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations (No 2) 2022**

**Proposal**

- 1 This paper seeks authorisation for submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations (No 2) 2022.

**Policy**

*Improvements to electronic prescribing*

- 2 The New Zealand ePrescription Service (NZePS) is a fast, secure system for the transmission and authentication of electronic prescriptions. It enables a prescription to be generated by the prescriber on an approved system, transmitted to the NZePS health information exchange broker and downloaded electronically at a community pharmacy.
- 3 The use of electronic prescriptions, instead of traditional hard-copy prescriptions, reduces costs for practices, provides flexibility for practitioners and improves the patient experience with fewer delays and less chance of prescriber error.
- 4 Transitioning prescriptions onto the NZePS will also enable regulators to more efficiently monitor and audit prescribing behaviour.
- 5 On 15 August 2022, Cabinet agreed to amend regulations to remove regulatory barriers to electronic prescribing and improve patient access to medicines by:
  - 5.1 enabling controlled drugs to be prescribed electronically
  - 5.2 reducing the frequency prescribers need to issue prescriptions for certain controlled drugs, when issued through the NZePS
  - 5.3 codifying the waiver issued by the Director-General that enables electronic prescribing
  - 5.4 ensuring designated pharmacist prescribers and designated prescriber nurses can continue to prescribe certain medicines when they become controlled drugs [CAB-22-MIN-0316].

## IN CONFIDENCE

### *Minor correction to Misuse of Drugs Regulations*

- 6 A minor printing error within regulation 48(1) of the Misuse of Drugs Regulations has also been identified. Correcting the error requires changing a reference from a “2” to a “1”.
- 7 Parliamentary Counsel Office have recommended using this opportunity to correct the error.

### **Timing and 28-day rule**

- 8 I am not seeking a waiver of the 28-day rule.
- 9 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**

- 10 The regulations comply with:
- 10.1 the principles of the Treaty of Waitangi;
  - 10.2 advice from the Treaty Provisions Officials Group on any Treaty of Waitangi provisions;
  - 10.3 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;
  - 10.4 the principles and guidelines set out in the Privacy Act 2020;
  - 10.5 relevant international standards and obligations;
  - 10.6 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.
- 11 The Misuse of Drugs Amendment Regulations 2022 will be made under section 37 of the Misuse of Drugs Act 1975.
- 12 The Medicines Amendment Regulations (No 2) 2022 will be made under section 105 of the Medicines Act 1981. This section contains a statutory prerequisite 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 consultation has taken place with the appropriate organisations and that this prerequisite has been met.

### **Regulations Review Committee**

- 13 The Parliamentary Counsel Office does not consider there are grounds for the Regulations Review Committee to draw this instrument or regulations to the attention of the House of Representatives under Standing Order 327.

IN CONFIDENCE

### **Certification by Parliamentary Counsel**

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

### **Impact Analysis**

- 15 The Treasury's Regulatory Impact Analysis team has determined that the proposals in this paper are exempt from the requirement to provide a Regulatory Impact Statement on the grounds that they have no or only minor impacts on businesses, individuals, and not-for-profit entities.

### **Publicity**

- 16 My office will issue a press release about these changes once they have been authorised by the Executive Council.
- 17 Once the regulations are notified in the *Gazette*, officials from Manatū Hauora and Te Whatu Ora will communicate directly with the impacted health practitioners to ensure they are aware of the new regulations and the implications.

### **Proactive release**

- 18 This paper will be proactively released according to standard processes under the Cabinet Office circular CO (18) 4, subject to redactions as appropriate under the Official Information Act 1982.

### **Consultation**

- 19 The following agencies have been consulted on this paper: Pharmac, New Zealand Police, New Zealand Customs Service, Ministry of Justice, Te Whatu Ora, Te Aka Whai Ora, the Department of the Prime Minister and Cabinet and the Treasury.

### **Recommendations**

I recommend that the Cabinet Legislation Committee:

- 1 note that on 15 August 2022 Cabinet agreed to:
- 1.1 enable controlled drug medicines to be prescribed electronically
  - 1.2 reduce the frequency prescribers need to issue prescriptions for certain controlled drugs, when issued through the NZePS
  - 1.3 codify the waiver issued by the Director-General that enables electronic prescribing
  - 1.4 ensure designated pharmacist prescribers and designated prescriber nurses can continue to prescribe certain medicines when they become controlled drugs [CAB-22-MIN-0316 refers];

**IN CONFIDENCE**

- 2 note that the Misuse of Drugs Amendment Regulations 2022 will give effect to the decision referred to in recommendation 1.1, 1.2 and 1.4 above;
- 3 note that the Medicines Amendment Regulations (No 2) 2022 will give effect to the decision referred to in recommendation 1.3 above;
- 4 note that the Misuse of Drugs Amendment Regulations 2022 will also correct a minor printing error in regulation 48(1);
- 5 note that section 105 of the Medicines Act requires that I be satisfied that consultation has occurred with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations;
- 6 note my advice as Minister of Health that these requirements have been met;
- 7 authorise the submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations (No 2) 2022;
- 8 note that the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations (No 2) 2022 will come into force on 22 December 2022.

Authorised for lodgement

Hon Andrew Little

Minister of Health

**IN CONFIDENCE**