Minister of Health

Cabinet material: Transitioning of Labelling Requirements for Medicines Newly Scheduled as Controlled Drugs under the Misuse of Drugs Act 1975

29 August 2023

These documents have been proactively released by the Ministry of Health on behalf of the Minister of Health, Hon Dr Ayesha Verrall.

Titles of Cabinet papers:

Transitioning of labelling requirements for medicines newly scheduled as controlled drugs under the Misuse of Drugs Act 1975 (Cabinet Legislation Committee)

Transitioning of labelling requirements for medicines newly scheduled as controlled drugs under the Misuse of Drugs Act 1975 (Cabinet Social Wellbeing Committee)

Titles of minutes:

Cabinet Social Wellbeing Committee: Minute of Decision (SWC-23-MIN-0031)

Report of the Cabinet Legislation Committee: Period Ended 9 June 2023 (CAB-23-MIN-0235)

Report of the Cabinet Social Wellbeing Committee: Period Ended 6 April 2023 (23-MIN-0122)

Cabinet Legislation Committee: Minute of Decision (LEG-23-MIN-0087)

Key to redaction codes:

Out of scope: material that is out of scope to this proactive release.

SWC-23-MIN-0031

Cabinet Social Wellbeing Committee

Minute of Decision

Transitioning of Labelling Requirements for Medicines Newly Scheduled as Controlled Drugs under the Misuse of Drugs Act 1975

Portfolio **Health**

On 5 April 2023, the Cabinet Social Wellbeing Committee:

1 **noted** that in November 2022, the Cabinet Legislation Committee authorised submission to Executive Council of a commencement Order (approved 14 November 2022) to bring into effect new controlled drug classifications for fentanyl, zopiclone and zolpidem on 1 July 2023 and for tramadol on 1 October 2023 [LEG-22-MIN 0192];

2 **noted** that the regulations do not permit suppliers to transition their labelling to the new requirements;

3 **noted** that it will be expensive and difficult for pharmaceutical companies to legally comply with the labelling requirements without disrupting supply of these medicines, which would impact adversely on patients;

4 **noted** there is unlikely to be any public interest in taking any enforcement action against breaches of the labelling requirement, however a mechanism is required for suppliers of these medicines and controlled drugs to transition their labelling lawfully in a manner that is compliant with the regulations;

5 **noted** there is precedent for labelling transitions in the Medicines Regulations 1984 to assist with classification changes;

6 **agreed** to adding a general transition provision for labelling requirements of 6 months at wholesale level and 9 months at retail level to the Misuse of Drugs Regulations 1977 to assist suppliers to comply with the requirements when medicines are newly scheduled into, or are rescheduled within, the Misuse of Drugs Act 1975;

7 **agreed** to add a targeted transition provision to the Misuse of Drugs Regulations 1977 and Medicines Regulations 1984 to allow fentanyl, zopiclone, zolpidem and tramadol to be supplied with the updated labelling before the commencement date;

8 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the above decisions.

Rachel Clarke
Committee Secretary

Attendance (see over)

Present:
Rt Hon Chris Hipkins
Hon Carmel Sepuloni (Chair)
Hon Kelvin Davis
Hon Grant Robertson
Hon Dr Megan Woods
Hon Jan Tinetti
Hon Dr Ayesha Verrall
Hon Willie Jackson
Hon Kiri Allan
Hon Peeni Henare
Hon Priyanca Radhakrishnan
Hon Kieran McAnulty
Hon Ginny Andersen
Hon Barbara Edmonds
Hon Willow-Jean Prime
Hon Rino Tirikatene
Jo Luxton, MP

Officials present from:
Office of the Prime Minister
Office of the Chair
Officials' Committee for SWC

CAB-23-MIN-0235

Cabinet

Minute of Decision

Report of the Cabinet Legislation Committee: Period Ended 9 June 2023

On 12 June 2023, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 9 June 2023:

Out of scope	[redacted]	
[redacted]	[redacted]	
LEG-23-MIN-0087	**Transitioning of Labelling Requirements for Medicines Newly Scheduled as Controlled Drugs Under the Misuse of Drugs Act 1975** Portfolio: Health	CONFIRMED
Out of scope	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

Out of scope

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Rachel Hayward
Secretary of the Cabinet

CAB-23-MIN-0122

Cabinet

Minute of Decision

Report of the Cabinet Social Wellbeing Committee: Period Ended 6 April 2023

On 11 April 2023, Cabinet made the following decisions on the work of the Cabinet Social Wellbeing Committee for the period ended 6 April 2023:

Out of scope [redacted]

SWC-23-MIN-0031	**Transitioning of Labelling Requirements for Medicines Newly Scheduled as Controlled Drugs under the Misuse of Drugs Act 1975** Portfolio: Health	CONFIRMED

Out of scope [redacted]

Rachel Hayward
Secretary of the Cabinet

LEG-23-MIN-0087

Cabinet Legislation Committee

Minute of Decision

Transitioning of labelling requirements for medicines newly scheduled as controlled drugs under the Misuse of Drugs Act 1975

Portfolio **Health**

On 8 June 2023, the Cabinet Legislation Committee:

1 **noted** that on 5 April 2023, the Cabinet Social Wellbeing Committee agreed to:

1.1 add a general transition period (6 months at wholesale level and 9 months at retail level) for labelling requirements in the Misuse of Drugs Regulations 1977;

1.2 add a targeted transition provision to allow suppliers of fentanyl, tramadol, zopiclone and zolpidem to supply products with the updated labelling ahead of the commencement date;

[SWC-23-MIN-0031]

2 **noted** that the Misuse of Drugs Amendment Regulations 2023 and the Medicines Amendment Regulations 2023 give effect to the decisions referred to in paragraphs 1.1 and 1.2 above;

3 **noted** that section 105(1) of the Medicines Act 1981 requires consultation with organisations or bodies likely to be affected by the amendment regulations;

4 **noted** that Medsafe, Pharmac, the pharmacy sector and pharmaceutical industry representa ives were consulted in the development of these proposals;

5 **noted** the advice of the Minister of Health that the requirement in the Medicines Act 1981 has been met;

6 **noted** that a waiver of the 28-day rule is sought:

6.1 in order to ensure the amendments occur as soon as possible to prevent disruption of supply of important medicines;

6.2 on the grounds that the regulation has little or no effect on the public and confers only benefits to actors in the medicines supply chain;

7 **agreed** to waive the 28-day rule so the Misuse of Drugs Amendment Regulations 2023 and the Medicines Amendment Regulations 2023 can come into force on 16 June 2023;

8 **authorised** the submission to the Executive Council of the:

8.1 Misuse of Drugs Amendment Regulations 2023 [PCO 25548/4.0];

8.2 Medicines Amendment Regulations 2023 [PCO 25553/2.0].

Rebecca Davies
Committee Secretary

Present:
Hon Kelvin Davis
Hon Dr Ayesha Verrall
Hon Michael Wood
Hon Andrew Little
Hon Kieran McAnulty (Chair)
Hon Willow-Jean Prime
Hon Dr Duncan Webb
Hon Dr Deborah Russell
Tangi Utikere, MP (Chief Government Whip)

Officials present from:
Office of the Prime Minister
Officials Committee for LEG

In Confidence

Office of the Minister of Health

Cabinet Legislation Committee

Transitioning of labelling requirements for medicines newly scheduled as controlled drugs under the Misuse of Drugs Act 1975

Proposal

1 This paper proposes the Cabinet Legislation Committee authorise the submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2023 and the Medicines Amendment Regulations 2023.

2 These amendments will allow a lawful mechanism for suppliers to transition their labelling during controlled drug classification changes.

Policy

3 On 14 November 2022 [CAB-22-MIN-0507], Cab net authorised a commencement Order to bring the new controlled drug classifications into effect for the following medicines: fentanyl, zopiclone and zolpid m on 1 July 2023 and tramadol on 1 October 2023.

4 Once scheduled, or rescheduled, th se medicines will require specific labelling to comply with the Misuse of Drugs Regulations 1977 to be supplied lawfully.

5 The current regulations do not allow for a transition period for labelling requirements when medicines are scheduled, or rescheduled, as controlled drugs. Therefore, suppliers would need to transition the labelling of their products throughout the supply chain in a single day. This is impractical and attempting compliance would likely disrupt supply of important medicines.

6 To address these concerns, Cabinet agreed on 5 April 2023 [SWC-23-MIN-0031] to:

6.1 add a general transition period (6 months at wholesale level and 9 months at retail level) for labelling requirements in the Misuse of Drugs Regulations 1977;

6.2 add a targeted transition provision to allow suppliers of fentanyl, tramadol, zopiclone and zolpidem to supply products with the updated labelling ahead of the commencement date.

7 The Misuse of Drugs Amendment Regulations 2023 and the Medicines Amendment Regulations 2023 will give effect to these decisions.

Timing and 28-day rule

8 A waiver of the 28-day rule is sought to ensure that the transition provisions come into effect as soon as possible to provide a lawful mechanism for suppliers affected by upcoming classification changes on 1 July 2023.

9 A waiver is justified as the regulatory change has little or no effect on the public and confers only benefits to actors in the medicines supply chain. In addition, a waiver will ensure the supply of essential medicines is not interrupted.

Compliance

10 These amendment regulations comply with:

10.1 the principles of the Te Tiriti o Waitangi;

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

10.3 the principles and guidelines set out in the Privacy A t 2020;

10.4 relevant international standards and obligations;

10.5 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

11 Section 105(1) of the Medicines Act 1981 requires consultation with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations. This statutory requirement has been met. The Ministry of Heal h consulted with Medsafe, Pharmac, the pharmacy sector and pharmaceutical industry representatives in the development of these proposals.

Regulations Review Committee

12 There are no grounds for the Regulations Review Committee to draw these regulation to the attention of the House of Representative under Standing Order 327.

Certification by Parliamentary Counsel

13 The Parliamentary Counsel Office has certified these regulations as being in order for submission to Cabinet.

Impact analysis

14 The Treasury's Regulatory Impact Analysis team has determined that the proposal to add transitional labelling provisions to the Medicines Regulations 1984 and the Misuse of Drugs Regulations 1977 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.

Publicity

15 The Ministry of Health and Medsafe will inform affected stakeholders of the changes once agreed to by Cabinet.

Proactive release

16 I intend to proactively release this paper subject to any necessary redactions under the Official Information Act 1982 and in accordance with Cabinet circular CO(18)4 on e the amendment regulations come into effect.

Consultation

17 The following agencies were consulted: New Zealand Police, New Zealand Customs Service, National Drug Intelligence Bureau, Te Whatu Ora and Te Whai Aka Ora and Department of Prime Minister and Cabinet.

Recommendations

I recommend that the Cabinet Legislation Committee:

1 note that on 5 April 2023 [SWC-23-MIN-0031], Cabinet agreed to:

1.1 add a general transition period (6 months at wholesale level and 9 months at retail level) for labelling requirements in the Misuse of Drugs Regulations 1977;

1.2 add a targeted transition provision to allow suppliers of fentanyl, tramadol, zopiclone and zolpidem to supply products with the updated labelling ahead of the commencement d te;

2 note that the Misuse of Drugs Amendment Regulations 2023 and the Medicines Amendment Regulations 2023 will give effect to the decisions referred to in recommendations 1.1 and 1.2 above;

3 note that section 105(1) of the Medicines Act 1981 requires consultation with organisations or bodies likely to be affected by the amendment regulations;

4 note that Medsafe, Pharmac, the pharmacy sector and pharmaceutical industry representatives were consulted in the development of these proposals;

5 note the advice of the Minister of Health that this requirement has been met;

6 note a waiver of the 28-day rule is sought in order to ensure these amendments occur as soon as possible to prevent disruption of supply of important medicines. A waiver is justified as the regulation has little or no effect on the public and confers only benefits to actors in the medicines supply chain;

7 agree to waive the 28-day rule so these amendment regulations can come into force on 16 June 2023;

8 authorise the submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2023 and the Medicines Amendment Regulations 2023.

Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health

Misuse of Drugs Amendment Regulations 2023

Order in Council

At Wellington this day of 2023

Presen :
in Council

These regulations are made under section 37 of the Misuse of Drugs Act 1975 on the advice and with the consent of the Executive Council.

Contents

Regulations

1 Title

These regulations are the Misuse of Drugs Amendment Regulations 2023.

2 Commencement

These regulations come into force on 16 June 2023.

3 Principal regulations

These regulations amend the Misuse of Drugs Regulations 1977.

4 New regulation 2A inserted (Transitional, savings, and related provisions)

After regulation 2, insert:

2A Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in Schedule 1AAA have effect according to their terms.

5 Regulation 25 amended (Labelling of containers)

Replace regulation 25(6) and (7) with:

(6) In any proceedings in respect of an alleged contravention of subclause (1) in which regulation 25A is pleaded in defence, the burden of proving that defence lies on the person charged

6 New regulation 25A inserted (Exemptions from regulation 25)

After regulation 25 insert:

25A Exemptions from regulation 25

(1) The requirement in regulation 25(1) for a label to display the appropriate designation does not apply in respect of a controlled drug supplied by a manufacturer or wholesaler,—

(a) if the appropriate designation of the controlled drug described in regulation 25(2) has changed, for the period of 6 months immediately following the date on which the designation changed; and

(b) if the designation as a controlled drug is new, for the period of 6 months immediately following the date on which the substance was added to Schedule 1, 2, or 3 of the Act.

(2) The requirement in regulation 25(1) for a label to display the appropriate designation does not apply in respect of a controlled drug supplied by a retailer,—

(a) if the appropriate designation of the controlled drug described in regulation 25(2) has changed, for the period of 9 months immediately following the date on which the designation changed; and

(b) if the designation as a controlled drug is new, for the period of 9 months immediately following the date on which the substance was added to Schedule 1, 2, or 3 of the Act.

7 Regulation 53 revoked (Transitional)

Revoke regulation 53.

8 New Schedule 1AAA inserted

Insert the Schedule 1AAA set out in the Schedule of these regulations as the first schedule to appear after the last regulation of the principal regulati ns

Schedule
New Schedule 1AAA inserted

r 8

Schedule 1AAA
Transitional, savings, and related provisions

r 2A

Part 1
Provision relating to Misuse of Drugs Amendment Regulations 2023

1 Exemption from requirement in regulation 25(1) for fentanyl supplied before 1 July 2023

The requirement in regulation 25(1) for a label to di play the appropriate designation does not apply in respect of fentanyl supplied by a retailer, manufacturer, or wholesaler before 1 July 2023.

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, which come into force on 16 June 2023, amend the Misuse of Drugs Regulations 1977. The amendments include a transitional provision (*new regulation 25A*) relating to labelling requirements for—

- contro led drugs, where the appropriate designation for the drug described in regulation 25(2) changes:
- substances that become controlled drugs under the Misuse of Drugs Act 1975 (the **Act**) for the first time.

The effect of the transitional provision is to provide an exemption in relation to the controlled drug from the requirement to display the appropriate designation described in regulation 25(2)—

- if the drug is supplied by a manufacturer or wholesaler, for a period of 6 months from the date of the change of status under the Act:
- if the drug is supplied by a retailer, for a period of 9 months from the date of the change of status under the Act.

An exemption is also provided from the designation labelling requirement in respect of fentanyl supplied by a retailer, manufacturer, or wholesaler before 1 July 2023. The designation of fentanyl under the Act changes on 1 July 2023 from class B3 to class

B1 (*see* the Misuse of Drugs (Classification and Presumption of Supply) Order 2022). The exemption permits a retailer, manufacturer, or wholesaler to supply fentanyl with labelling updated to reflect its new designation in advance of 1 July 2023.

Regulatory impact statement

A regulatory impact statement is not required for these regulations.

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

Medicines Amendment Regulations 2023

Order in Council

At Wellington this day of 2023

Presen :
in Council

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

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

(b) on the advice of the Minister of Health given after complying with that section.

Contents

Regulations

1 Title

These regulations are the Medicines Amendment Regulations 2023.

2 Commencement

These regulations come into force on 16 June 2023.

3 Principal regulations

These regulations amend the Medicines Regulations 1984.

4 New regulation 2A inserted (Transitional, savings, and related provisions)

After regulation 2, insert:

2A Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in Schedule 1AA have effect according to their terms.

5 Regulation 65A revoked (Transitional provision arising from enactment of Medicines Amendment Regulations 2011)

Revoke regulation 65A.

6 New Schedule 1AA inserted

Insert the Schedule 1AA set out in the Schedule of these regulations as the first schedule to appear after the last regulation of the principal regulations.

Schedule
New Schedule 1AA inserted

r 6

Schedule 1AA
Transitional, savings, and related provisions

r 2A

Part 1
Provisions relating to Medicines Amendment Regulations 2023

1 Exemption from requirement in regulation 13(1)(f) for zopiclone and zolpidem supplied before 1 July 2023

The requirement in regulation 13(1)(f) does not apply in respect of zopiclone or zolpidem supplied by a retailer, manufacturer or wholesaler before 1 July 2023.

2 Exemption from requirement in regulation 13(1)(f) for tramadol supplied before 1 October 2023

The requirement in regulation 13(1)(f) does not apply in respect of tramadol supplied by a retailer, manufacturer or wholesaler before 1 October 2023.

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, which come into force on 16 June 2023, amend the Medicines Regulations 1984 to provide exemptions from labelling requirements in respect of specified prescribed medicines.

On 1 July 2023, the prescribed medicines zopiclone and zolpidem become class C5 controlled drugs. On 1 October 2023, the prescribed medicine tramadol becomes a class C2 controlled drug (*see* the Misuse of Drugs (Classification and Presumption of Supply) Order 2022). The exemptions in *new Schedule 1AA* permit a retailer, manufacturer, or wholesaler to supply those prescribed medicines with labelling updated to reflect their new designations in advance of 1 July and 1 October 2023 respectively.

Regulatory impact statement

A regulatory impact statement is not required for these regulations.

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

In confidence

Office of the Minister of Health

Cabinet Social Wellbeing Committee

Transitioning of labelling requirements for medicines newly scheduled as controlled drugs under the Misuse of Drugs Act 1975

Proposal

1 This paper seeks agreement to add transition provisions for labelling requirements into the Medicines Regulations 1984 and Misuse of Drugs Regulations 1977. Having a transition period permanently included in the regulations provides a lawful mechanism to allow for labelling to transition during classification changes.

2 There is some time sensitivity to this as an agreement needs to be reached in time for changes to be implemented for new controlled drug classifications due to take effect from 1 July 2023.

Relation to government priorities

3 This is an operational adjustment that requires Cabinet approval.

Executive summary

4 In November 2022, a commencement Order was made that will apply new controlled drug classifications to prescription medicines fentanyl, zopiclone and zolpidem from 1 July 2023, and to tramadol from 1 October 2023.

5 The commencement dates were advised on the basis that the updated stock with the new labelling requirements would be able to be phased into the supply chain ahead of the commencement date. However, it has since become clear that the labelling regulations mean products labelled with the updated classification statement cannot be lawfully supplied to wholesalers and pharmacies before the commencement date.

6 In order to comply with the law, products with the updated labelling will have to be introduced to the entire supply chain, and product with the previous labelling removed (and destroyed), all in a single day. This is impractical and attempting compliance will cause disruption to supply.

7 There is unlikely to be any public interest in taking any enforcement action against breaches of the labelling requirement. However, a mechanism is required for suppliers of these medicines and controlled drugs to transition their labelling lawfully in a manner that is compliant with the regulations.

8 There is a precedent for labelling transitions for medicines under regulation 15 of the Medicines Regulations 1984 during periods of classification changes for prescription medicines, restricted medicines, and pharmacy-only medicines (refer paragraph 23).

9 There is minimal risk from having both new and old labelling in the supply chain for a limited time as the Ministry of Health can communicate with suppliers on any new regulatory requirements despite the label classification. Medicines dispensed to patients are not required to include the classification of a medicine or controlled drug on the label (refer paragraph 26).

10 To address this labelling issue, I propose that labelling transition provisions be added to the Medicines Regulations 1984 and Misuse of Drugs Regulations 1977 to ensure continuity of supply of important medicines.

Background

11 On 5 May 2022, the House of Representatives approved the Misuse of Drug (Classification and Presumption of Supply) Order 2022 (the Order), which schedules or up-schedules 49 substances (including some prescription medicines) into or within the Misuse of Drugs Act 1975 (the Act).

12 Of the 49 substances affected, 3 prescription medicines (tramadol, zopiclone and zolpidem) will be scheduled in the Act and fentanyl will be up-scheduled to a higher controlled drug classification within the Act.

13 A commencement Order made on 14 November 2022 will bring the controlled drug classifications for fentanyl, zopiclone and zolpidem into effect on 1 July 2023 and for tramadol on 1 October 2023 [CAB-22-MIN-0507]

Operational issue with labelling requirement

14 The commencement Order timeline was developed with the intention of balancing the need to classify these medicines in a timely manner while ensuring uninterrupted supply to New Zealanders. The Misuse of Drugs Regulations 1977 do not provide for a labelling transition period. Therefore, the updated labelling requirements (regulation 25(1) of Misuse of Drugs Regulations 1977) for the supply of all newly scheduled controlled drugs (to reflect the new classification) must be met on the commencement date.

15 To account for the time needed for companies to meet these labelling requirements, the commencement dates were set at 1 July 2023 for fentanyl, zopiclone and zolpidem, and 1 October 2023 for tramadol.

16 However, it has since become clear that the lack of a transition arrangement in the regulations creates a technical issue for the pharmaceutical supply chain in New Zealand because all parties (companies, wholesalers, and pharmacies) would legally need to transition their labelling across the entire supply chain within a single day. This would impact the supply of these important medicines within New Zealand around the time the new classifications take effect.

17 Medsafe has advised that this is impractical and would likely put the supply chain of important medicines under significant pressure. This may result in supply issues of essential medicines for New Zealanders. Discussions with affected pharmaceutical companies indicate that it would be difficult and expensive to comply with the requirements without disrupting supply of these important medicines.

18 From the commencement date, stock not bearing the updated classification statements will need to be destroyed. Whilst recalling products already in the supply chain to be over-labelled could occur, it is not considered to be a viable option as this introduces safety risks (for example, companies could not be sure that the medicine had been stored appropriately). Destruction of stock not bearing the updated classification statement would likely result in an unnecessary cost to the health care system.

19 There is unlikely to be any public interest in taking any enforcement action against breaches of the labelling requirement, due to its impracticality and the impact it would have on the supply of essential medicines. However, a mechanism is required for suppliers of these medicines and controlled drugs to transition their labelling lawfully in a manner that is compliant with the regulations.

Proposed general transition arrangement for controlled drug labelling requirements

20 The lack of a labelling transition period in the Misuse of Drugs Regulations 1977 is a problem for affected medicines currently and will likely be an issue in the future when there is a new classification of a controlled drug that is also a medicine (although these do not occur often).

21 During the reclassification process for the fentanyl tramadol, zopiclone and zolpidem, the commencement dates were chosen to account for labelling changes to occur and this delayed other enforcement powers under the Misuse of Drugs Act 1975 from coming into effect. In the future, there may be times where enforcement powers are required to take effect sooner than the timeframe for labelling updates to occur.

22 To address this, I propose that a transition period for labelling requirements be included in the Misuse of Drugs Regulations 1977.

23 Transitional arrangements are commonplace for labelling changes on medicines during classification changes. A precedent has been set in regulation 15 of the Medicines Regulations 1984. This regulation allows for a labelling transition period of 3 months at wholesale level and 6 months at retail level after the date on which a medicine is classified as either prescription medicine, restricted medicine or pharmacy-only. During this period, the new labelling requirements do not apply.

24 A similar approach is recommended to be adopted with respect to labelling for new controlled drug classifications. This proposal would allow suppliers a period of 6 months at wholesale level and 9 months at retail level to transition their labelling in the supply chain and remove the need to further delay the commencement of any future new controlled drug classifications to accommodate for labelling changes. The proposed length of the transition period is longer than a similar provision of the Medicines Regulations 1984 to better reflect modern manufacturing lead times whilst balancing the need for this regulatory change efficiently.

25 It would provide certainty to companies that they have reasonable time to lawfully transition the labelling of their products to meet the new requirements. This would also allow enforcement powers under the Misuse of Drugs Act 1975 to come into effect sooner.

26 Labelling provides information to participants in the supply chain on factors such as how these medicines should be handled, stored and recorded. There is minimal risk to patients with having both the old and new labels of these medicines in the supply chain during a transition period. When medicines are dispensed to a patient, the labelling requirements for the dispensed medicine do not require the classification of a medicine or controlled drug to be included on the label.

27 Consultation with representatives from the pharmaceutical industry and pharmacy groups supported a labelling transition period to be included into the Misuse of Drugs Regulations 1977 to assist suppliers during periods of classification changes.

28 The Ministry of Health will arrange communications to the pharmaceutical sector during the transition period, so parties are aware of any changes to the handling, storage and recording requirements of these medicines despite the classification displayed on the label.

Proposed targeted transition arrangement

29 Some suppliers of fentanyl, tramadol and zopiclone to New Zealand are making arrangements to update their labelling and would like to arrange for products with updated labelling to be supplied ahead of the commen ement date to ensure continuity of supply of these medicines.

30 I propose a transition arrangement for lab lling requirements be introduced into the regulations, specifically in relation to fentanyl, zopiclone, zolpidem and tramadol. Medsafe advises that this arrangement would allow lawful supply of these products with changed (updated) labelling before the new classifications take effect and prioritises continued access for patients

31 Section 105 of the Medicines Act 1981 requires the Minister of Health to consult with those likely to be substantially affected by the regulations. I am satisfied that this requirement has been met. Medsafe and affected companies are supportive of this proposed targeted transition arrangement.

Financial Implications

32 There are no financial implications from this proposal.

Legislative Implications

33 The proposal entails amending the Medicines Regulations 1984 and Misuse of Drugs Regulations 1977.

Impact Analysis

Regulatory Impact Statement

34 The Treasury's Regulatory Impact Analysis team has determined that the proposal to add transitional labelling provisions to the Medicines Regulations 1984 and the Misuse of Drugs Regulations 1977 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.

Climate Implications of Policy Assessment

35 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal as the threshold for significance is not met.

Human Rights

36 There are no human rights issues associated with this proposal.

Consultation

37 The Ministry of Health consulted with the following agencies on this paper: New Zealand Police, New Zealand Customs Service, National Drug Intelligence Bureau, Department of Prime Minister and Cabinet, Te Whatu Ora and Te Aka Whai Ora. No concerns were raised.

Communications

38 If Cabinet agrees to the proposal, the Ministry of Health will communicate the decision to affected suppliers.

Proactive Release

39 This paper will be proactively released on the Ministry of Health's website when the decision is communicated to stakeholders

Recommendations

The Minister of Health recommends that the Committee:

1 note that a commencement Order (made on 14 November 2022) will bring into effect new controlled drug cl ssifications for fentanyl, zopiclone and zolpidem on 1 July 2023 and for tramadol on 1 October 2023 [CAB-22-MIN-0507];

2 note that the regulations do not permit suppliers to transition their labelling to the new requirements;

3 note th t it will be expensive and difficult for pharmaceutical companies to legally comply with the labelling requirements without disrupting supply of these medicines, which would impact adversely on patients;

4 note there is unlikely to be any public interest in taking any enforcement action against breaches of the labelling requirement. However, a mechanism is required for suppliers of these medicines and controlled drugs to transition their labelling lawfully in a manner that is compliant with the regulations;

5 note there is precedent for labelling transitions in the Medicines Regulations 1984 to assist with classification changes;

6 agree to adding a general transition provision for labelling requirements of 6 months at wholesale level and 9 months at retail level to the Misuse of Drugs Regulations

1977 to assist suppliers to comply with the requirements when medicines are newly scheduled into, or are rescheduled within, the Misuse of Drugs Act 1975;

7 agree to adding a targeted transition provision to the Misuse of Drugs Regulations 1977 and Medicines Regulations 1984 to allow fentanyl, zopiclone, zolpidem and tramadol to be supplied with the updated labelling before the commencement date;

8 authorise the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the agreed recommendations.

Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health