In Confidence

Office of the Minister of Health

Cabinet Legislation Committee

Approval to implement changes to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002

Proposal

1 This paper seeks authorisation to submit the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 to the Executive Council.

Policy

2 The purpose of the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 is to update aspects of the regulatory framework for medicines in order to: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters. Changes include exclusion of certain low risk products from regulation under the medicines legislation and amendments to labelling, advertising, dispensing and prescribing requirements.

3 In line with previous Cabinet decisions [SOC Min (10) 23/1], the Medicines Amendment Regulations 2011 and Medicines (Standing Order) Amendment Regulations 2011 will:

Redacted - Out of Scope

Redacted - out of scope

o) Update Schedule 1 of the Medicines Regulations 1984, which lists all classified medicines.

[Redacted - Out of Scope]

Regulatory impact analysis

5. A Regulatory Impact Statement was submitted to Cabinet with the original policy proposals [SOC Min (10) 23/1].

Timing and 28-day rule

6. Regulations 14, 15 and 18 will come into force on 1 December 2011. This will allow time for the necessary changes to be made to software systems. A waiver to the 28-day rule is sought to allow the remainder of the regulations to come into force on 1 August 2011. The amendments will confer only benefits to the public.

Compliance

7. The Regulations comply with:

   a) the principles of the Treaty of Waitangi
   b) the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993
   c) the Privacy Act 1993
   d) relevant international standards and obligations
   e) *Legislative Advisory Committee Guidelines: Guidelines on Process and Content.*

Regulations Review Committee

8. There are no grounds for the Regulations Review Committee to draw the regulations to the attention of the House under Standing Order 310.

Certification by Parliamentary Counsel

9. The draft regulations were certified by parliamentary counsel as being in order for submission to Cabinet.

Publicity

10. The *Report of the analysis of submissions and final decisions on proposed amendments to Regulations under the Medicines Act 1981* was published on the Ministry of Health website in November 2010. In addition, the Ministry of Health included information about the key changes to the regulations in the March edition of its publication *Prescriber Update*. The Ministry of Health will also write to responsible authorities and other organisations with an interest in

the changes to update them on the changes, including the decision not to proceed with the change to the period of supply for prescription medicines. Medsafe will also publish information about the changes affecting industry on its website and in its regular communications with industry groups.

Consultation

11. The following Government agencies were consulted on the development of the policy: The Treasury; the Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; the Ministry for the Environment; the Environmental Risk Management Authority, the Accident Compensation Corporation; and PHARMAC. The Department of Prime Minister and Cabinet was informed.

12. In addition, the Ministry of Health received 84 submissions on its consultation document, *Consultation on Proposed Amendments to Regulations under the Medicines Act 1981,* from a wide cross-section of affected stakeholders. Feedback from this consultation was incorporated into the final policy proposals.

Recommendations

13. The Minister of Health recommends that the Cabinet Legislation Committee

    1 **Note** that Cabinet agreed to make a number of changes to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002 that sit under the Medicines Act 1981 to exclude certain low risk products from regulation under the Medicines legislation and to amend labelling, advertising, dispensing and prescribing requirements [SOC Min (10) 23/1]

    [Redacted – Out of Scope]

    3 **Note** that the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 give effect to the decision referred to in recommendation 1 above.

[Redacted – Out of Scope]

6. **Authorise** the submission to the Executive Council of the Medicines (Standing order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011

Tony Ryall

Hon Tony Ryall
Minister of Health

Date: 30 June 2011

Consultation on Cabinet and Cabinet Committee Submissions

Certification by Department:

Guidance on consultation requirements for Cabinet/Cabinet committee papers is provided in the CabGuide (see Procedures: Consultation): http://www.cabguide.cabinetoffice.govt.nz/procedures/consultation

Departments/agencies consulted: The attached submission has implications for the following departments/agencies whose views have been sought and are accurately reflected in the submission:

The following Government agencies were consulted on the development of the policy: The Treasury; the Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; the Ministry for the Environment; the Environmental Risk Management Authority, the Accident Compensation Corporation; and PHARMAC.

Departments/agencies informed: In addition to those listed above, the following departments/agencies have an interest in the submission and have been informed:

The Department of Prime Minister and Cabinet was informed.

Others consulted: Other interested groups have been consulted as follows:

The NZ Medical Association, GP Leaders Forum and the Royal College of GPs were consulted on the change to the period of supply for prescription medicines.

Name, Title, Department: Barbara Phillips, Deputy Director-General (Acting), Ministry of Health

Date: 29/6/11 **Signature**

Certification by Minister:

Ministers should be prepared to update and amplify the advice below when the submission is discussed at Cabinet/Cabinet committee.

The attached proposal:

Consultation at Ministerial level	☐ **has been** consulted with the Minister of Finance *[required for all submissions seeking new funding]* ☐ **has been** consulted with the following portfolio Ministers: ☑ **did not need** consultation with other Ministers
Discussion with National caucus	☐ **has been** or ☐ **will be** discussed with the government caucus ☑ **does not need** discussion with the government caucus
Discussion with other parties	☐ **has been** discussed with the following other parties represented in Parliament: ☐ Act Party ☐ Maori Party ☐ United Future Party ☐ Other [specify] ☐ **will be** discussed with the following other parties represented in Parliament: ☐ Act Party ☐ Maori Party ☐ United Future Party ☐ Other [specify] ☑ **does not need** discussion with other parties represented in Parliament

Portfolio	Date	Signature
Health	30/6/11	Ryall