Office of the Minister of Health

Cabinet Social Policy Committee

Approval to implement changes to several regulations under the Medicines Act 1981

Proposal

1. Agreement is sought to issue drafting instructions to the Parliamentary Counsel Office to implement proposals discussed in the recent *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981*.

Executive Summary

2. The regulatory framework for medicines is in need of updating. Earlier this year, the Government agreed to consult on a suite of amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002, 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 were recommended to labelling, advertising, dispensing, and prescribing requirements.

3. Having considered the submissions received, it is proposed to proceed with the original proposals (as set out in the *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981),* and in some cases, make some further amendments arising out of submitter feedback. The Minister of Health will issue drafting instructions to the Parliamentary Counsel Office to give effect to these changes. These drafting instructions will also include the next periodic update of Schedule 1 of the Medicines Regulations 1984.

Background

4. In New Zealand, medicines and medical devices are regulated by the Medicines Act 1981 and associated regulations, most notably the Medicines Regulations 1984. This legislative framework is in need of updating, to ensure it safeguards consumers while not creating unnecessary barriers to innovation.

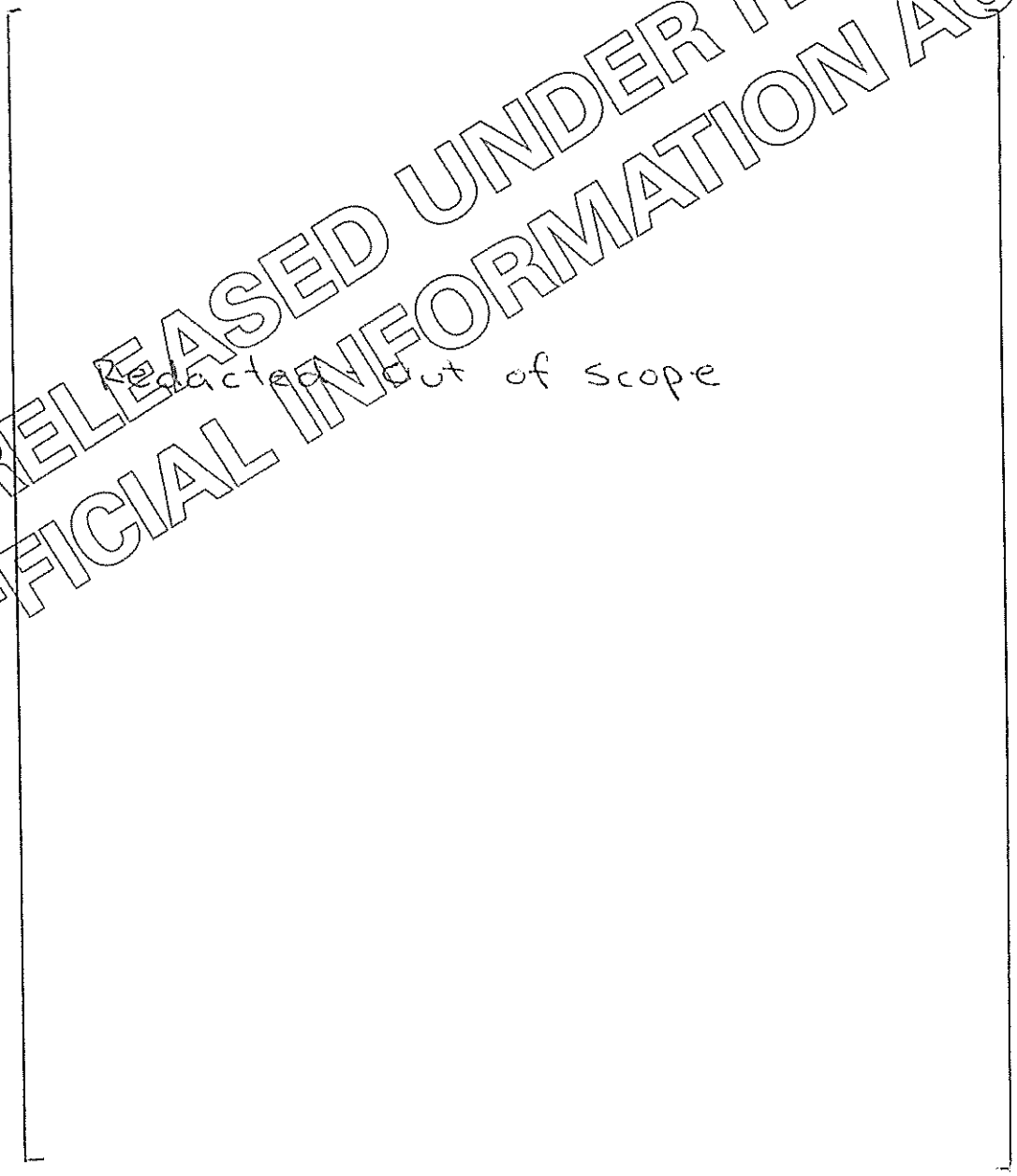
5. Many of the problems in the current medicines legislative framework can only be addressed through changes to the Medicines Act itself. While this is likely to happen during the current parliamentary term, it is likely to take some time to implement a new Act, and some improvements can be made in the mean time through amendments to regulations.

6. Accordingly, the Ministry of Health was directed to progress amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. The proposed amendments: 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.

7. In February 2010, Cabinet noted the release of the *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981* [SOC Min (10) 1/1, recommendation 6 refers]. The Consultation Paper was released on 26 February 2010 and submissions closed on 26 March 2010. Eighty-four submissions were received. The Ministry has now summarised the submissions and provided advice on the issues they raise. A *Report of the Analysis of Submissions and Final Decisions* is attached as Appendix One.

Comment

8. Most of the original proposals amendments were widely supported by submitters, and should proceed. Some submitters suggested additional useful amendments, and it proposed that these also proceed. The following sections briefly describe the proposals and main areas of submitter comment. The submission summary in Appendix One provides a more detailed analysis.



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42. The Ministry of Health also proposes to include drafting instructions for the next update to Schedule 1 along with the other proposals set out in this paper, for the sake of efficiency. Schedule 1 of the Medicines Regulations comprises a list of individual medicines that are classified as Prescription Medicines, Restricted Medicines or Pharmacy Only Medicines. Classifications for new medicines and changes to the classification of existing medicines are given immediate effect through a time-limited notice in the *New Zealand Gazette*. Typically, Schedule 1 is updated every 12-18 months to include recent additions and changes. This is a technical change that does not require policy approval from Cabinet, as consultation has already occurred, and the changes notified in the *New Zealand Gazette*.

Consultation

43. The following Government agencies were consulted in the development of this Cabinet paper: 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. Their comments have been noted in the paper. The Department of Prime Minister and Cabinet were provided with a copy of the paper.

44. The Ministry of Health received 84 submissions on the proposals from a wide cross-section of affected stakeholders, including: District Health Boards; government agencies; companies involved in the manufacture or supply of medicines, related products or cosmetics; organisations representing those suppliers; the advertising sector; groups representing or regulating health professionals; individual health professionals; organisations delivering healthcare services; and consumer groups. There was also a final brief round of consultation with organisations representing pharmacists (eg, Pharmacy Guild, Pharmaceutical Society) and prescribers (eg, Medical Council, College of General Practitioners, Midwifery Council).

Financial Implications

45. Costs associated with drafting and implementing the new regulations will be met from within Vote Health baselines.

Legislative Implications

46. Drafting instructions will be issued to the Parliamentary Counsel Office to give effect to the changes through amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002.

Human Rights and Gender Implications and Disability Perspective

47. The proposed changes have no human rights, gender or disability implications.

Regulatory Impact Analysis

Regulatory Impact Analysis Requirements

48. The Regulatory Impact Analysis Requirements apply in this case, and a Regulatory Impact Statement (RIS) is attached.

Quality of the Impact Analysis

49. The Ministry of Health's Internal Cabinet Paper Committee has reviewed the RIS prepared by the Ministry of Health, and considers that the information and analysis summarised in the RIS meets quality assurance criteria.

Consistency with Government Statement of Regulation

50. I have considered the analysis and advice of my officials, as summarised in the attached RIS and I am satisfied that, aside from the risks, uncertainties and caveats already noted in this Cabinet paper, the regulatory proposals recommended in this paper: are required in the public interest; will deliver the highest net benefits of the practical options available; and are consistent with the commitments in the Government Statement on Regulation.

Publicity

51. Once Cabinet has made decisions on these proposals, the Ministry of Health will publicly release a *Report of the Analysis of Submissions and Final Decisions on Proposed Amendments to Regulations under the Medicines Act 1981* (attached as Appendix One), subject to any amendments to reflect Cabinet's final decisions.

Recommendations

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3. **Agree** to amend the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002 to:

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t) include an update to Schedule 1, which lists all classified medicines, in the planned amendment to the Medicines Regulations.

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Hon Tony Ryall
Minister of Health

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Date: