

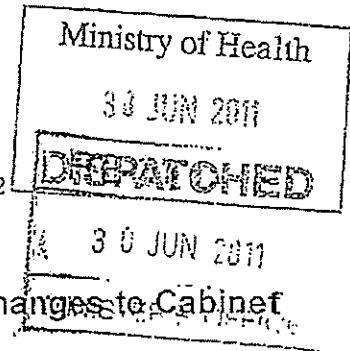


Action required by: urgent

Date sent to Minister:

Minister's reference: not applicable

File number: HC18-02-9-2



To: ~~Hon Tony Ryall (Minister of Health)~~

Title: ~~Approval to Submit Medicines Regulations Changes to Cabinet~~
Legislation Committee

Advice

1. In October 2010, Cabinet agreed to changes to the Medicines (Standing Order) Regulations 2002 and the Medicines Regulations 1984 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.

Redacted ~~copy~~ ^{of} ~~scope~~

RELEASED UNDER THE OFFICIAL INFORMATION ACT

4. The Ministry has drafted the attached Cabinet paper for consideration at Cabinet Legislation Committee (LEG). The Cabinet paper seeks authorisation for the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 to be submitted to the Executive Council. A copy of the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 are attached to the Cabinet paper for your information. The final certified copies of the Regulations will be submitted directly to Cabinet Office by the Parliamentary Counsel Office.
5. If the LEG paper and attached Order in Council are submitted to the Cabinet Office by 10.00am on Monday 4 July 2011 they can be considered by LEG on Thursday, 7 July and Cabinet and the Executive Council on Monday, 11 July. To allow the majority of the amended Regulations to come into force on 1 August 2011, a waiver to the 28 day rule is sought. The LEG paper seeks a waiver to the 28 day Rule on the grounds that the changes confer only benefits on the public. The amended provisions of the Regulations that require changes to advertising and labelling of medicines have transition provisions until 1 February 2012 and 1 September 2012 respectively. Note that Regulations 14, 15 and 18 require changes to software systems and will come into force on 1 December 2011.

The Ministry recommends that you:

- a) **Sign:** the attached Cabinet Legislation Committee paper seeking the Committee's authorisation to submit the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 to Executive Council Yes / No
- b) **Sign:** the Order in Council recommending that the Governor-General make the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 Yes / No
- c) **Forward:** the Cabinet Legislation paper and the Order in Council to the Cabinet Office by 10.00am Monday, 4 July 2011. Yes / No



Barbara Phillips
Deputy Director-General (Acting)
Policy Business Unit

Minister's Signature

Date:

Ministry of Health Contacts:

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Minister's feedback

	Very poor	Poor	Neutral	Good	Very Good
Quality of advice	1	2	3	4	5
Writing style	1	2	3	4	5
Quality of analysis	1	2	3	4	5
Completeness of information	1	2	3	4	5

Comments: