



## In Executive Council

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*His Excellency the Governor-General is recommended to*

Sign the attached Order in Council making the  
Medicines Amendment Regulations 2011

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

Hon Tony Ryall  
Minister of Health

*Approved in Council*

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*Clerk of the Executive Council*



## Office of Hon Tony Ryall

Minister of Health  
Minister of State Services

4 JUL 2011

His Excellency, the Honourable Sir Anand Satyanand, GNZM, QSO  
Governor-General  
Government House  
Wellington

Your Excellency

### **MEDICINES AMENDMENT REGULATIONS 2011**

These regulations are made under sections 62 and 105 of the Medicines Act 1981 ("the Act") and amend the Medicines Regulations 1984 ("the principal regulations").

Several of the regulations require statutory prerequisites to have been met.

Section 62(1)(a) of the Act, allows for the making of regulations to regulate the insertion in medical advertisements of information or warnings concerning any unwanted, incidental or untoward effects of medicines and statements of the precautions to be taken by the user of the medicine.

Section 62(2) of the Act requires that regulations may only be made under section 62(1)(a):

- on the recommendation of the Minister after consultation with such organisations or bodies as the Minister considers likely to be substantially affected by the regulations (s 62(2)(a)); and
- if the regulations are designed to achieve a fair and balanced indication of the potential effects of the medicine (s 62(2)(b)); and
- if the regulations do not require the disclosure of information that may reasonably be regarded as confidential, or that cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published or the inclusion of which in the advertisement is otherwise impractical (s 62(2)(c)).

I have carried out the consultation required. I am also satisfied that the regulations, as amended, achieve a fair and balanced indication of the potential effects of the relevant medicines and do not require the disclosure of information that is prohibited.

Section 61(c) of the Act requires that, before advising you to make any regulations under that regulation, I consult with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations. I have carried out such consultation.

Section 105 of the Act requires that, before advising you to make any regulations under that regulation, I consult with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations. I have carried out such consultation.

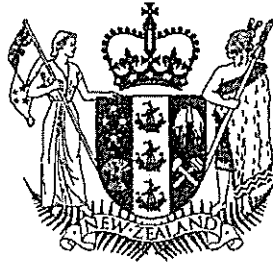
The requirements have therefore been met.

Yours sincerely



Hon Tony Ryall  
Minister of Health

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT

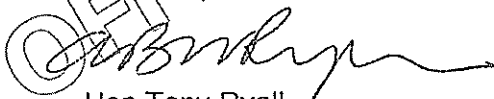


## In Executive Council

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*His Excellency the Governor-General is recommended to*

Sign the attached Order in Council making the  
Medicines (Standing Order)  
Amendment Regulations 2011



Hon Tony Ryall  
Minister of Health

*Approved in Council*

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*Clerk of the Executive Council*

# MINISTRY OF HEALTH – AUDIT TRAIL

DUE DATE: 30/6/11 URGENT (24 hours)  SEMI-URGENT (3 DAYS)  ROUTINE (1 WEEK)

Title <u>LEG paper for Medicines Regulatory changes</u>		Doctrak / Health Report / OIA / Ministerial # <u>20110362</u>	
File Reference <u>HC18-02-9-2</u>	Lotus Notes Database <u>Pharmaceuticals Health Reports</u>	Lotus Notes Drawer <u>Medicines Act 1981/9 Regulations</u>	Lotus Notes Folder <u>Regulatory changes 2010/11 Cabinet Papers &amp; RIS</u>

**RESPONSIBILITIES - CHECKED AND APPROVED BY (clearly print name and initial):**

Author/Person & Business Unit (content/quality) Date: <u>3/4/11</u> Ext: <u>2-28</u> <u>S. Wainwright</u>	Peer Review (content/quality) Date: <u>21/4/11</u> Ext: <u>2966</u> <u>J. Kelly</u> <u>H. Laker</u>
Accountable Manager or Chief Advisor Date: <u>1/1</u> Ext: <u>2158</u> <u>Michael Hempel</u>	Admin/EANPA (formatting / quality) Date: <u>3/4/11</u> Ext: <u>2154</u> <u>ASMETO.</u>

7-16 CC 24/8 (Michael Hempel) 12/5/11 2468

**\*\*PLEASE ENSURE YOU CLEARLY PRINT YOUR NAME AND SIGN\*\***

BUSINESS UNIT SIGN OFF (if required, print sign and date)	CORPORATE SIGN OFF (if required, print sign and date)
DIRECTOR GENERAL <b>SIGNED OUT</b> DIRECTOR-GENERAL'S OFFICE Date: <u>1/1</u>	CHIEF FINANCIAL OFFICER/FINANCE Date: <u>1/1</u>
POLICY Date: <u>1/1</u>	COMMUNICATIONS Date: <u>1/1</u>
MAORI HEALTH Date: <u>1/1</u>	HEALTH LEGAL <u>B. SUTTON</u> Date: <u>16/5/11</u>
CLINICAL LEADERSHIP, PROTECTION & REGULATION Date: <u>1/1</u>	IT Date: <u>1/1</u>
NATIONAL HEALTH BOARD Date: <u>1/1</u>	OTHER Date: <u>1/1</u>
SECTOR CAPABILITY AND IMPLEMENTATION Date: <u>1/1</u>	COMMENTS <u>Went through ICPC 13/5/11</u> <u>(had only formatting issues which have been incorporated).</u>
CORPORATE SERVICES Date: <u>1/1</u>	
CHIEF NURSE Date: <u>1/1</u>	

**IMPORTANT NOTE:** Documents with "financial implications" must be approved by the Chief Financial Officer and the DD-G Corporate Services. Documents with IT implications must be approved by relevant Director Information Strategy or Information Delivery & Op's



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Minister of Health  
Minister of State Services

4 JUL 2011

His Excellency, the Honourable Sir Anand Satyanand, GNZM, QSO  
Governor-General  
Government House  
Wellington

Your Excellency

### MEDICINES (STANDING ORDER) AMENDMENT REGULATIONS 2011

These regulations are made under section 105 of the Medicines Act 1981 ("the Act") and amend the Medicines (Standing Order) Regulations 2002 ("the principal regulations").

The regulations amend the requirements for counter-signing of standing orders issued under the principal regulations.

Section 105 of the Act requires that, before advising you to make any regulations under that section, I consult with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations. I have carried out such consultation.

The requirement has therefore been met.

Yours sincerely

Hon Tony Ryall  
Minister of Health