Medicines Amendment Bill 2011 (2012 No 345-2)

<table>
<thead>
<tr>
<th>Date of Introduction:</th>
<th>13 October 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portfolio:</td>
<td>Health</td>
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<td>Select Committee:</td>
<td>Health</td>
</tr>
<tr>
<td>Date report presented:</td>
<td>3 August 2012</td>
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</tbody>
</table>

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by John McSoriley BA LL.B, Barrister
Legislative Analyst
P: (04) 817-9626 (Ext. 9626)

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Purpose

The main aim of the Bill is to amend the Medicines Act 1981 (the Act) to:

- "modernise the definitions of medicine, medical device, and therapeutic purpose to align the boundary between medicines and medical devices with international norms;

- "amend the approval process for new medicines;

- "align the prescribing framework for nurse practitioners and optometrists with medical practitioners, dentists, and midwives;

- "establish a new category of delegated prescriber, whose members will be allowed to prescribe under an authorisation (a delegated prescribing order) issued by an authorised prescriber;
“establish a mechanism to allow time-limited demonstration sites of extended prescribing rights to new groups of health practitioners;

“make minor and technical amendments to update and clarify the provisions for granting licences to manufacture, pack, and sell medicines and to operate a pharmacy;

expand the regulation-making powers in the Act to provide for new standards and innovative practice, such as electronic prescribing”1.

The Bill as introduced is described in Bills Digest No 1946.

Main changes

Delegated prescriber

The bar-2 Bill amends the regulation-making provision relating to delegated prescribers in order that delegated prescribing rights may be made. The amendments provide detail as to how delegated prescribing orders are issued. The bar-2 Bill also sets out the supervisory responsibilities of authorised prescribers, and imposes other requirements on delegated prescribers. The prescription medicines that may be prescribed under a delegated prescribing order are to be specified by the Director-General of Health by notice in the Gazette after consulting with the relevant organisations or bodies that are considered representative of persons likely to be substantially affected (Part 1, Clause 36, amending New Section 105D of the Act).

Minister’s consent

The Bill, as introduced, sets out the criteria to be applied when the Minister determines whether to give consent, or provisional consent, to the distribution of a new medicine.

The bar-2 Bill provides that the applicant for consent be a person or company in New Zealand. A similar amendment is made in respect of ministerial consent for distribution of changed medicines (Part 1, Clause 12, amending New Sections 21(1) and 23(1); Clause 14, amending New Section 24(3)).

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1 Medicines Amendment Bill, 2011 No 345-1, Explanatory note, General policy statement, pp. 1 and 2
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