Medicines Amendment Act (No 2) 2003

Public Act 2003 No 56
Date of assent 17 October 2003
Commencement see section 2

Contents

The Parliament of New Zealand enacts as follows:

1 Title

(1) This Act is the Medicines Amendment Act (No 2) 2003.

(2) In this Act, the Medicines Act 1981 is called "the principal Act".

2 Commencement

This Act comes into force on 30 October 2003.

3 Interpretation

Section 2(1) of the principal Act is amended by inserting, in their appropriate alphabetical order, the following definitions:

"**ERMA** means the Environmental Risk Management Authority established under the Hazardous Substances and New Organisms Act 1996

"**new organism** has the same meaning as in section 2A of the Hazardous Substances and New Organisms Act 1996

"**qualifying new medicine** means a new medicine that—

"(a) is or contains a new organism; and

"(b) meets the criteria set out in section 38I(3) of the Hazardous Substances and New Organisms Act 1996

"**qualifying organism** means a new organism that is or is contained in a qualifying new medicine".

4 New section 5A inserted

The principal Act is amended by inserting, after section 5, the following section:

"5A **Relationship with Hazardous Substances and New Organisms Act 1996**

In relation to medicines that are or contain hazardous substances or new organisms, the requirements of this Act are additional to the requirements of the Hazardous Substances and New Organisms Act 1996."

5 New sections 24A to 24G inserted

The principal Act is amended by inserting, after section 24, the following headings and sections:

"*Qualifying new medicines*

"24A **Assessment of qualifying new medicines**

The Director-General may grant an approval under section 38I of the Hazardous Substances and New Organisms Act 1996 for the release of a qualifying new medicine if he or she—

"(a) has the consent of the Minister to do so; and

"(b) is acting under a delegation from ERMA given under section 19 of that Act.

"24B **Procedure if Director-General declines to grant approval**

If the Director-General declines to grant an approval because the new organism is not a qualifying new medicine, then—

"(a) the Director-General must—

"(i) inform ERMA that the new medicine is not a qualifying new medicine; and

"(ii) provide ERMA with a copy of all information (from assessing the safety, quality, and efficacy of the new medicine) that the Director-General considers may assist ERMA in deciding whether to approve or decline the application under the Hazardous Substances and New Organisms Act 1996; and

"(b) the Minister must not consent under section 20 or give provisional consent under section 23 to the distribution, sale, or advertising of the medicine unless the Minister receives written advice from ERMA that the medicine has been approved for release under the Hazardous Substances and New Organisms Act 1996.

"Approval of medicines required for use in special emergency

"24C **Interpretation**

In sections 24D to 24G, unless the context otherwise requires,—

"**hazardous substance** has the same meaning as in section 2(1) of the Hazardous Substances and New Organisms Act 1996

"**responsible Minister** has the same meaning as in section 49A of the Hazardous Substances and New Organisms Act 1996

"**special emergency** has the same meaning as in section 49A of the Hazardous Substances and New Organisms Act 1996.

"24D **Approval of medicines required for use in special emergency**

"(1) An application may be made to the Minister for approval to distribute, sell, or advertise in a special emergency a medicine that is or contains a hazardous substance or new organism.

"(2) The Minister may approve an application under subsection (1) with or without conditions, as long as the Minister is satisfied that—

"(a) the special emergency has been declared and has not come to an end; and

"(b) the medicine is required for the special emergency; and

"(c) the application complies with subsection (3).

"(3) An application under subsection (1) must—

"(a) be accompanied by the prescribed application fee (if any); and

"(b) be in a form approved by the Director-General; and

"(c) be accompanied by any information that the Minister considers is necessary for determining whether or not to approve the application.

"24E **Notification or publication of approval**

The approval of an application under section 24D must be notified in the *Gazette*.

"24F **Duration of approval**

An approval of an application under section 24D takes effect on the day specified in the approval, and expires on the earlier of—

"(a) the date of expiry (if any) of the special emergency specified by the responsible Minister in—

"(i) the declaration declaring the special emergency; or

"(ii) a later declaration declaring that the special emergency has ceased; or

"(b) the date of expiry (if any) specified by the responsible Minister in the approval, which must not be later than the date of expiry of the special emergency; or

"(c) if paragraph (a) or paragraph (b) does not apply, 2 years after the date on which the approval is granted.

"24G **Consequences of expiry of approval**

On the expiry of an approval of an application under section 24D, the medicine to which the approval applies must not be distributed or used unless authorised by or under any other provision of this Act."

Legislative history

9 October 2003	Divided from New Organisms and Other Matters Bill (Bill 47–2) as Bill 47–3C
14 October 2003	Third reading
17 October 2003	Royal assent

This Act is administered in the Ministry of Health.
