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Council for Trade-Related Aspects of Intellectual Property Rights

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MAIN DEDICATED INTELLECTUAL PROPERTY LAWS AND REGULATIONS NOTIFIED UNDER ARTICLE 63.2 OF THE AGREEMENT

New Zealand

Protection of Undisclosed Information

The present document reproduces[1] the following laws and regulations, as notified by New Zealand under Article 63.2 of the Agreement (see document IP/N/1/NZL/1):

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[1] In English only

ANALYSIS

Title
1. Short Title and commencement
2. New Part inserted

PART IIA
PROTECTION OF CERTAIN CONFIDENTIAL INFORMATION ABOUT INNOVATIVE ANIMAL REMEDIES

35A. Interpretation
35B. Protection of confidential supporting information about innovative animal remedies
35C. Circumstances where protection under section 35B does not apply
3. Publication of results of analyses and details of animal remedies
4. Regulations

1994, No. 126

An Act to amend the Animal Remedies Act 1967

[*9 December 1994*

BE IT ENACTED by the Parliament of New Zealand as follows:

1. Short Title and commencement—(1) This Act may be cited as the Animal Remedies Amendment Act 1994, and shall be read together with and deemed part of the Animal Remedies Act 1967 (hereinafter referred to as the principal Act).

(2) This Act shall come into force on a date to be appointed by the Governor-General by Order in Council; and one or more orders may be made bringing different provisions into force on different dates.

2. New Part inserted—The principal Act is hereby amended by inserting, after section 35, the following Part:

"PART IIA

"PROTECTION OF CERTAIN CONFIDENTIAL INFORMATION ABOUT INNOVATIVE ANIMAL REMEDIES

"35A. **Interpretation**—In this Part of this Act, unless the context otherwise requires,—

" 'Applicant' means—

"(a) A person who makes or has made, as the case may be, an application; and

"(b) A person on whose behalf an application is, or has been, made, as the case may be:

" 'Application' means an application for the issue under section 21 of this Act of a licence or a provisional licence to manufacture or import, as the case may be, an animal remedy:

" 'Commencement date' means the date on which this Part of this Act comes into force:

" 'Confidential information' includes—

"(a) Trade secrets; and

"(b) Information that has commercial value that would be, or would be likely to be, diminished by disclosure:

" 'Confidential supporting information' means confidential information given—

"(a) In, or in relation to, an innovative animal remedy application; and

"(b) About the animal remedy that is or was, as the case may be, the subject of that application:

" 'Ingredient' includes a chemical or biological entity:

" 'Innovative animal remedy application' means,—

"(a) In relation to an application made after the commencement date, an application that refers to an active ingredient—

"(i) That is an active ingredient of the animal remedy to which the application relates; and

"(ii) That has not, before that application is received by the Board, been referred to in any other application (except in an application by the applicant for a provisional licence for that animal remedy) as an active ingredient of an animal remedy; and

"(b) In relation to an application made before the commencement date, an application that referred to an active ingredient—

"(i) That is or was, as the case may be, an active ingredient of the animal remedy to which the application related; and

"(ii) That had not, before that application was received by the Board, been referred to in any other application (except in an

application by the applicant for a provisional licence for that animal remedy) as an active ingredient of an animal remedy:

" 'Protected period' means,—

"(a) In relation to confidential supporting information, relating to an innovative animal remedy application, received by the Board after the commencement date, a period commencing on the date that information is received by the Board and ending,—

"(i) Where—

"(A) The Board has either issued a licence, not being a provisional licence, under section 21 of this Act, or refused to grant such licence, in relation to the animal remedy that is the subject of the innovative animal remedy application; and

"(B) The date of that issue or refusal is not more than 5 years after the Board received an application in relation to that animal remedy,—

on the date 5 years after the date of that issue or refusal; or

"(ii) In any other case, on the date 5 years after the innovative animal remedy application to which that information relates is or was, as the case may be, received by the Board:

"(b) In relation to confidential supporting information, relating to an innovative animal remedy application, received by the Board not more than 5 years before the commencement date, a period commencing on the commencement date and ending,—

"(i) Where—

"(A) The Board has either issued or issues a licence, not being a provisional licence, under section 21 of this Act, or refused or refuses to grant such licence, in relation to the animal remedy that was the subject of the innovative animal remedy application; and

"(B) The date of that issue or refusal is or was, as the case may be, not more than 5 years after the Board received an

application in relation to that animal remedy,—

on the date 5 years after the date of that issue or refusal; or

"(ii) In any other case, on the date 5 years after the innovative animal remedy application to which that information related was received by the Board:

" 'WTO Country' means a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on the 15th day of April 1994.

"35B. **Protection of confidential supporting information about innovative animal remedies**—Where the Board receives, or received not more than 5 years before the commencement date, an innovative animal remedy application and confidential supporting information, the Board, during the protected period in relation to that confidential supporting information,—

"(a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Board; and

"(b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

"35C. **Circumstances where protection under section 35B does not apply**—(1) Notwithstanding section 35B of this Act, the Board may, during the protected period in relation to confidential supporting information,—

"(a) Disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,—

"(i) With the consent of the applicant who made the application to which the confidential supporting information relates or related; or

"(ii) If that disclosure or use is, in the opinion of the Board, necessary to protect the health or safety of members of the public; or

"(b) Disclose that confidential supporting information to—

"(i) A Government department or statutory body for the purposes of that Government department or statutory body:

"(ii) An adviser for the purposes of obtaining advice about the animal remedy to which the information relates,—

if, in the opinion of the Board, the Government department, statutory body, or adviser, as the case may be, will take reasonable steps to ensure the information is kept confidential; or

"(c) Disclose that confidential supporting information to any one or more of the following:

"(i) The World Health Organisation:

"(ii) The Food and Agriculture Organisation:

"(iii) The Office International des Epizooties:

"(iv) A regulatory agency of a WTO country:

"(v) A person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act.

"(2) The power to grant consent under subsection (1) (a) (i) of this section may be exercised by a person other than the applicant referred to in that subsection if—

"(a) That applicant—

"(i) Has notified the Board in writing that that other person may grant that consent; and

"(ii) Has not notified the Board in writing that that person's authority to grant that consent has been withdrawn; or

"(b) That applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that person has notified the Board of the transfer."

3. Publication of results of analyses and details of animal remedies—Section 55 of the principal Act is hereby amended by omitting the word "The", and substituting the words "Subject to Part IIA of this Act, the".

4. Regulations—Section 65 of the principal Act is hereby amended by inserting, after paragraph (g), the following paragraph:

"(ga) Approving persons or organisations, or classes of persons or organisations, for the purposes of section 35C (1) (c) (v) of this Act:".

This Act is administered in the Ministry of Agriculture and Fisheries.

WELLINGTON, NEW ZEALAND: Published under the authority of the New Zealand Government—1994

59516D—94/NS

ANALYSIS

Title
1. Short Title and commencement
2. New Part inserted

PART IIIA
PROTECTION OF CERTAIN CONFIDENTIAL INFORMATION ABOUT INNOVATIVE PESTICIDES

35A. Interpretation
35B. Protection of confidential supporting information about innovative pesticides
35C. Circumstances where protection under section 35B does not apply
35D. Protection of information about agricultural chemicals

3. Regulations

1994, No. 127

An Act to amend the Pesticides Act 1979

[*9 December 1994*

BE IT ENACTED by the Parliament of New Zealand as follows:

1. Short Title and commencement—(1) This Act may be cited as the Pesticides Amendment Act 1994, and shall be read together with and deemed part of the Pesticides Act 1979 (hereinafter referred to as the principal Act).

(2) This Act shall come into force on a date to be appointed by the Governor-General by Order in Council; and one or more orders may be made bringing different provisions into force on different dates.

2. New Part inserted—The principal Act is hereby amended by inserting, after section 35, the following Part:

"PART IIIA

"PROTECTION OF CERTAIN CONFIDENTIAL INFORMATION ABOUT INNOVATIVE PESTICIDES

"35A. **Interpretation**—In this Part of this Act, unless the context otherwise requires,—

" 'Applicant' means—

"(a) A person who makes or has made, as the case may be, an application; and

"(b) A person on whose behalf an application is, or has been, made, as the case may be:

" 'Application' means an application for registration of a pesticide under section 22 of this Act or for an experimental use permit under section 25 of this Act:

" 'Commencement date' means the date on which this Part of this Act comes into force:

" 'Confidential information' includes—

"(a) Trade secrets; and

"(b) Information that has commercial value that would be, or would be likely to be, diminished by disclosure:

" 'Confidential supporting information' means confidential information given—

"(a) In, or in relation to, an innovative pesticide application; and

"(b) About the pesticide that is or was, as the case may be, the subject of that application:

" 'Ingredient' includes a chemical or biological entity:

" 'Innovative pesticide application' means—

"(a) In relation to an application made after the commencement date, an application that refers to an active ingredient—

"(i) That is an active ingredient of the pesticide to which the application relates; and

"(ii) That has not, before that application is received by the Board, been referred to in any other application (except in an application by the applicant for an experimental use permit for that pesticide) as an active ingredient of a pesticide; and

"(b) In relation to an application made before the commencement date, an application that referred to an active ingredient—

"(i) That is or was, as the case may be, an active ingredient of the pesticide to which the application related; and

"(ii) That had not, before that application was received by the Board, been referred to in any other application (except in an application by the applicant for an experimental use permit for that pesticide) as an active ingredient of a pesticide:

" 'Protected period' means,—

"(a) In relation to confidential supporting information, relating to an innovative pesticide application, received by the Board after the commencement date, a period commencing on the date that information is received by the Board and ending,—

"(i) Where—

"(A) The Board has either issued a certificate of registration under section 26 of this Act, or refused to grant such certificate of registration, in relation to the pesticide that is the subject of the innovative pesticide application; and

"(B) The date of that issue or refusal is not more than 5 years after the Board received an application in relation to that pesticide,—

on the date 5 years after the date of that issue or refusal; or

"(ii) In any other case, on the date 5 years after the innovative pesticide application to which that information relates is or was, as the case may be, received by the Board:

"(b) In relation to confidential supporting information, relating to an innovative pesticide application, received by the Board not more than 15 years before the commencement date, a period commencing on the commencement date and ending,—

"(i) Where the Board has issued or issues a certificate of registration under section 26 of this Act, or refused or refuses to grant such certificate of registration, in relation to the pesticide that was the subject of the innovative pesticide application, on the earlier of the 2 following dates:

"(A) The date 15 years after the date of that issue or refusal:

"(B) The date 5 years after the commencement date; or

"(ii) In any other case, on the earlier of the 2 following dates:

"(A) The date 15 years after the innovative pesticide application to which

that information related was received by the Board:

"(B) The date 5 years after the commencement date:

" 'WTO Country' means a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on the 15th day of April 1994.

"35B. **Protection of confidential supporting information about innovative pesticides**—Where the Board receives, or received not more than 15 years before the commencement date, an innovative pesticide application and confidential supporting information, the Board, during the protected period in relation to that confidential supporting information,—

"(a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Board; and

"(b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

"35C. **Circumstances where protection under section 35B does not apply**—(1) Notwithstanding section 35B of this Act, the Board may, during the protected period in relation to confidential supporting information,—

"(a) Disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,—

"(i) With the consent of the applicant who made the application to which the confidential supporting information relates or related; or

"(ii) If that disclosure or use is, in the opinion of the Board, necessary to protect the health or safety of members of the public; or

"(b) Disclose that confidential supporting information to—

"(i) A Government department or statutory body for the purposes of that Government department or statutory body:

"(ii) An adviser for the purposes of obtaining advice about the pesticide to which the information relates,—

if, in the opinion of the Board, the Government

department, statutory body, or adviser, as the case may be, will take reasonable steps to ensure that information is kept confidential; or

"(c) Disclose that confidential supporting information to—

"(i) The World Health Organisation:

"(ii) The Food and Agriculture Organisation:

"(iii) A regulatory agency of a WTO country:

"(iv) A person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act.

"(2) The power to grant consent under subsection (1) (a) (i) of this section may be exercised by a person other than the applicant referred to in that subsection if—

"(a) That applicant—

"(i) Has notified the Board in writing that that other person may grant that consent; and

"(ii) Has not notified the Board in writing that that person's authority to grant that consent has been withdrawn; or

"(b) That applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that person has notified the Board in writing of the transfer.

"35D. **Protection of information about agricultural chemicals**—Where the Board has information—

"(a) That related to an application to register a substance as an agricultural chemical under section 14 of the Agricultural Chemicals Act 1959; and

"(b) That would have been confidential supporting information in respect of which the Board would have had obligations under section 35B of this Act had it been given in relation to an application,—

this Part of this Act shall apply, with such modifications as may be necessary, as if it were confidential supporting information."

3. Regulations—Section 76 of the principal Act is hereby amended by inserting, after paragraph (d), the following paragraph:

"(da) Approving persons or organisations, or classes of persons or organisations, for the purposes of section 35C (1) (c) (iv) of this Act:".

This Act is administered in the Ministry of Agriculture and Fisheries.

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ANALYSIS

Title
1. Short Title and commencement
2. New sections inserted
23A. Interpretation
23B. Protection of confidential supporting information about innovative medicines
23C. Circumstances where protection under section 23B does not apply
3. Regulations

1994, No. 128

An Act to amend the Medicines Act 1981

[*9 December 1994*

BE IT ENACTED by the Parliament of New Zealand as follows:

1. Short Title and commencement—(1) This Act may be cited as the Medicines Amendment Act 1994, and shall be read together with and deemed part of the Medicines Act 1981 (hereinafter referred to as the principal Act).

(2) This Act shall come into force on a date to be appointed by the Governor-General by Order in Council; and one or more orders may be made bringing different provisions into force on different dates.

2. New sections inserted—The principal Act is hereby amended by inserting, after section 23, the following sections:

"23A. **Interpretation**—In this section, and in sections 23B and 23C of this Act, unless the context otherwise requires,—

" 'Applicant' means—

"(a) A person who makes or has made, as the case may be, an application; and

"(b) A person on whose behalf an application is, or has been, made, as the case may be:

" 'Application' means an application for the consent of the Minister under section 20 of this Act, or for the provisional consent of the Minister under section 23 of this Act, in relation to a medicine:

" 'Commencement date' means the date this section, and sections 23B, and 23C of this Act come into force:
" 'Confidential information' includes—
"(a) Trade secrets; and
"(b) Information that has commercial value that would be, or would be likely to be, diminished by disclosure:
" 'Confidential supporting information' means confidential information given—
"(a) In, or in relation to, an innovative medicine application; and
"(b) About the medicine that is or was, as the case may be, the subject of that application:
" 'Ingredient' includes a chemical or biological entity:
" 'Innovative medicine application' means,—
"(a) In relation to an application made after the commencement date, an application that refers to an active ingredient—
"(i) That is an active ingredient of the medicine to which the application relates; and
"(ii) That has not, before that application is received by the Minister, been referred to in any other application (except in an application by the applicant for provisional consent for that medicine) as an active ingredient of a medicine; and
"(b) In relation to an application made before the commencement date, an application that referred to an active ingredient—
"(i) That is or was, as the case may be, an active ingredient of the medicine to which the application related; and
"(ii) That had not, before that application was received by the Minister, been referred to in any other application (except in an application by the applicant for provisional consent for that medicine) as an active ingredient of a medicine:
" 'Protected period' means—
"(a) In relation to confidential supporting information, relating to an innovative medicine application, received by the Minister after the commencement date, a period commencing on the date that information is received by the Minister and ending,—

"(i) Where—

"(A) The Minister has either notified consent, not being provisional consent, in the *Gazette* under section 20 of this Act, or refused to grant such consent, in relation to the medicine that is the subject of the innovative medicine application; and

"(B) The date of that notification or refusal is not more than 5 years after the Minister received an application in relation to that medicine,—

on the date 5 years after the date of that notification or refusal; or

"(ii) In any other case, on the date 5 years after the innovative medicine application to which that information relates is or was, as the case may be, received by the Minister:

"(b) In relation to confidential supporting information, relating to an innovative medicine application, received by the Minister not more than 5 years before the commencement date, a period commencing on the commencement date and ending,—

"(i) Where—

"(A) The Minister has notified or notifies consent, not being provisional consent, in the *Gazette* under section 20 of this Act, or refused or refuses to grant such consent, in relation to the medicine that was the subject of the innovative medicine application; and

"(B) The date of that notification or refusal is or was, as the case may be, not more than 5 years after the Minister received an application in relation to that medicine,—

on the date 5 years after the date of that notification or refusal; or

"(ii) In any other case, on the date 5 years after the innovative medicine application to which that information related was received by the Minister:

" 'WTO Country' means a country that is a party to the Agreement establishing the World Trade

Organization adopted at Marrakesh on the 15th day of April 1994.

"23B. **Protection of confidential supporting information about innovative medicines**—Where the Minister receives, or received not more than 5 years before the commencement date, an innovative medicine application and confidential supporting information, the Minister, during the protected period in relation to that confidential supporting information,—

"(a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Minister; and

"(b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

"23C. **Circumstances where protection under section 23B does not apply**—(1) Notwithstanding section 23B of this Act, the Minister may, during the protected period in relation to confidential supporting information,—

"(a) Disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,—

"(i) With the consent of the applicant who made the application to which the confidential supporting information relates or related; or

"(ii) If that disclosure or use is, in the opinion of the Minister, necessary to protect the health or safety of members of the public; or

"(b) If, in the opinion of the Minister, the relevant committee, adviser, Government department, statutory body, or person will take reasonable steps to ensure the confidential supporting information is kept confidential, disclose that confidential supporting information to—

"(i) An advisory or technical committee appointed under section 8 of this Act; or

"(ii) The Medicines Classifications Committee appointed under section 9 of this Act; or

"(iii) The Medicines Review Committee established under section 10 of this Act; or

"(iv) Any adviser for the purpose of obtaining advice about the medicine to which the confidential supporting information relates; or

"(v) A Government department or statutory body for the purposes of the Government department or statutory body; or

"(c) Disclose that confidential supporting information to any one or more of the following—

"(i) The World Health Organisation:

"(ii) The Food and Agriculture Organisation:

"(iii) Any regulatory agency of a WTO Country:

"(iv) Any person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act.

"(2) The power to grant consent under subsection (1) (a) (i) of this section may be exercised by a person other than the applicant referred to in that subsection if—

"(a) That applicant—

"(i) Has notified the Minister in writing that that other person may grant that consent; and

"(ii) Has not notified the Minister in writing that that person's authority to grant that consent has been withdrawn; or

"(b) That applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that other person has notified the Minister in writing of the transfer."

3. Regulations—Section 105 of the principal Act is hereby amended by inserting, after paragraph (a), the following paragraph:

"(aa) Approving persons or organisations, or classes of persons or organisations, for the purposes of section 23c (1) (c) (iv) of this Act:".

This Act is administered in the Ministry of Health.

WELLINGTON, NEW ZEALAND: Published under the authority of the New Zealand Government—1994

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