1990 - No. 363

STOCK MEDICINES ACT 1989 - REGULATION

(Stock Medicines Regulation 1990)

NEW SOUTH WALES

[Published in Gazette No. 80 of 22 June 1990]

HIS Excellency the Governor, with the advice of the Executive Council, and in pursuance of the Stock Medicines Act 1989, has been pleased to make the Regulation set forth hereunder.

IAN ARMSTRONG
Minister for Agriculture and Rural Affairs.

Citation

1. This Regulation may be cited as the Stock Medicines Regulation 1990.

Commencement

2. This Regulation commences on 1 July 1990.

Definitions

3. In this Regulation:

"approved name", in relation to a substance, means:

(a) the name specified as the Australian Approved Name of the substance in the Fifth Edition, Revised March 1989, of the publication entitled "Australian Approved Names and Other Names for Therapeutic Substances" published by the Australian Government Publishing Service; or

(b) if no name is so specified for the substance, the accepted scientific name or the name descriptive of the true nature and origin of the substance; or

(c) if the substance is in the form of a salt or ester of a substance the Australian Approved Name of which is specified in the publication referred to in paragraph (a), but the Australian Approved Name of the salt or ester is not so specified, the Australian Approved Name of the substance specified as referred to in paragraph (a) followed by the name recommended for the radical or group forming the salt or ester in the publication entitled "Definitive Rules for Nomenclature of Organic Chemistry - 1957 Rules" published under the direction of the International Union of Pure and Applied Chemistry as in force on 1 July 1990;

"batch number" means any combination of letters or figures or of both which is given by a manufacturer to a batch and by which that batch can be traced in manufacture and identified in distribution;

"container", in relation to a stock medicine, means the vessel, bottle, syringe, tube, ampoule, vial, sachet, strip pack, blister pack, wrapper, cover or like receptacle or envelope which immediately covers the stock medicine but does not include anything intended for ingestion;

"drug of addiction" means any substance specified in Schedule Eight of the Poisons List proclaimed under section 8 of the Poisons Act 1966;

"expiry date", in relation to a stock medicine, means the date (month and year) after which the stock medicine should not be used, being a date occurring not later than 5 years after the date of its manufacture or such other date as is approved by the Director-General;

"poison" means any substance specified in Schedule One, Two, Three, Five, Six or Seven of the Poisons List proclaimed under section 8 of the Poisons Act 1966;

"primary pack", in relation to the supply at any one time of any substance, material, body or thing referred to in this Regulation, means the complete package in addition to the container as presented to the person supplied, excluding any wrapping, bag, carton or similar article in which the container is placed at the rime of supply;

"principal label" means:

(a) if there are 2 or more labels, the label which shows the name of the product more plainly than any other label primarily designed to attract attention or, if there are 2 or more such labels, each of the labels; or

(b) if the matter or writing contained on a label is divided into portions, the portion of that label on which the name of the product is most prominently shown or, if there are 2 or more such portions, each of the portions;

"product" means the stock medicine contained in the package concerned;

"restricted substance" means any substance specified in Schedule Four of the Poisons List proclaimed under section 8 of the Poisons Act 1966;

"the Act" means the Stock Medicines Act 1989;

"withholding period", in relation to a stock medicine, means the minimum period which should elapse between last administration of the stock medicine, or feed treated with the stock medicine, and:

(a) the slaughter for human consumption of animals to which the stock medicine has been administered; or

(b) the harvesting of wool, fibre, milk or eggs or the release of honey for human consumption from an animal to which the stock medicine has been administered.

Withholding periods

4. For the purposes of clause 5 (1), the withholding periods for a stock medicine are:

(a) as set out in the publication of the Australian Government Printing Service entitled "MRL STANDARD - Standard for maximum residue limits of pesticides, agricultural chemicals, feed additives, veterinary medicines and noxious substances in foods - Up to and including 78th PACC, November 1987"; or

(b) if there is not any withholding period so set out for the stock medicine or the class of stock medicines concerned, but there is such a withholding period set out in a notice published in the Commonwealth Gazette by the Australian Agricultural and Veterinary Chemicals Council under section 15 (6) of the

Agricultural and Veterinary Chemicals Act 1988 of the Commonwealth – as set out in the notice; or

(c) if there is not any such withholding period ascertainable under paragraph (a) or (b), the period determined by the Director-General for the stock medicine or the class of stock medicines concerned.

Application for registration: additional particulars

5. For the purposes of section 7 (2) of the Act, the following particulars may be required by the Director-General to be contained in an application for registration of a stock medicine:

(a) the approved name of each of the ingredients contained in the stock medicine, accompanied by the applicable pharmacopoeia1 standard or manufacturer's specification;

(b) the composition of the technical material which contains the active constituent used in the formulation of the stock medicine, the chemical and physical properties of that material, the range of content of each active constituent and the names and content of any substances present as impurities;

(c) the quantity or proportion of each ingredient, which must be expressed:

(i) in respect of a tablet, capsule, pessary, suppository or single dose of powder or granules, as the quantity of the ingredient per unit of the stock medicine; or

(ii) in respect of any other form of preparation, as the proportion that each ingredient bears to the whole of the stock medicine (expressed as a weight/weight, weight/volume or volume/volume ratio, as appropriate);

(d) in respect of a preparation in which potency units are used as a measure of activity, the number of such units. (The potency unit to be used must be the International Unit approved by the World Health Organisation or, if no potency unit has been approved, the potency unit to be used must be that approved by the Director-General.);

(e) the potency of liquid biological stock medicines, and of biological stock medicines (whether liquid or not) which are required to be prepared before use, must be expressed as potency units or weight of active substance per dose, per unit volume or per container;

(f) in the case of sterile, pyrogen-free stock medicines, the methods used to achieve sterility and freedom from pyrogens and particulate matter;

(g) the methods for analysis of the ingredients in the formulation of the stock medicine;

(h) a medicinal claim for the stock medicine that includes a description of the species of stock on which the stock medicine is intended for use and information on the efficacy of the stock medicine for the purposes proposed when used in accordance with the instructions that must appear on the label;

(i) directions for use that include dose rate, route of administration, frequency and duration of treatment and, where applicable, a dose/volume table;

(j) directions for storage of the product to ensure that the product conforms to its specifications until the expiry date;

(k) data on which the expiry date for each batch of product was determined;

(l) in the case of a stock medicine for administration or application to any food producing species, the withholding period in relation to that stock medicine;

(m) procedures for dealing with spillage and decontamination of the stock medicine and disposal of unwanted stock medicine;

(n) all toxicology and toxicity data available to the applicant in respect of the stock medicine, each of its active constituents and each other ingredient of the stock medicine must be supplied and is to include, if applicable, each of the following:

(i) acute dermal toxicity;

(ii) acute inhalation toxicity;

(iii) sub-acute (short term) toxicity studies in not less than 2 species, one of which is the rat;

(iv) at least one 2 year toxicity study (in a species considered appropriate by the Director-General);

(v) any other data which the Director-General considers to be relevant;

(o) data on the mode of action, absorption, distribution, metabolism and elimination of the stock medicine;

(p) data on the persistence and distribution in soil and water and the breakdown mechanisms of the stock medicine;

(q) data on any other known hazards of the stock medicine or its ingredients;

(r) the net count, weight or volume of the contents of all containers or primary packs of the medicine the applicant proposes to market;

(s) 2 copies of the draft label incorporating the particulars required by clause 12.

Changes in a stock medicine or in a label

6. If, after the registration of any stock medicine pursuant to an application, a person proposes to vary the formulation or any other aspect of the stock medicine described in the application, the person must, before commencing to sell the stock medicine with the varied formulation or aspect, reapply to the Director-General, using the form approved by the Director-General for applications for registration of the stock medicine concerned.

Maximum penalty: 50 penalty units.

Application for renewal of registration

7. (1) For the purposes of section 8 (4) of the Act, the Director-General may approve, as the form for an application for renewal of registration of a stock medicine, the same form as that approved for an application for registration of the stock medicine.

(2) In such a case, the application for renewal of registration must be accompanied by the particulars specified in section 7 (2) of the Act and, subject to the Director-General's discretion, clause 5.

(3) In the case of biological stock medicines, an application for renewal of registration must, if the Director-General requests, include evidence that the stock medicine has been satisfactorily tested in the previous 3 years by the Commonwealth Therapeutic Goods Administration Laboratory or any other laboratory approved by the Director-General.

Fees for applications

8. (1) For the purposes of section 7 (3) (a) of the Act, the prescribed application fee is $100.

(2) For the purposes of section 7 (3) (b) of the Act, the prescribed fee is $300 to be paid at the time of lodgment of printed labels and prior to the registration certificate being issued.

Packages

9. (1) A package for a stock medicine must:

(a) be impervious to, and incapable of, chemical reaction with the stock medicine; and

(b) have sufficient strength to prevent leakage of the stock medicine arising from ordinary handling, storage and transport; and

(c) be fitted with a device capable of securely closing and readily re-closing the package, unless the contents are intended to be used on one occasion only, and

(d) have sufficient excess capacity to prevent the package from breaking if its contents were to expand during handling, storage or transport; and

(e) be of such a nature as to enable all of its contents to be removed in a manner that, with the exercise of no more than reasonable care by a person removing the contents, will not cause the stock medicine to harm any person or damage the environment.

(2) A person must not sell a stock medicine contained in a package unless, when the stock medicine is sold:

(a) the package complies with subclause (1); and

(b) the package is securely closed.

Maximum penalty: 50 penalty units.

(3) A person is exempt from compliance with any or all of the requirements of this clause if the person has been so exempted by a written instrument issued by the Director-General.

Size of label

10. (1) A person must not sell a package containing a stock medicine that has a label attached to it displaying the particulars required by section 44 of the Act unless the label complies with this clause.

Maximum penalty: 50 penalty units.

(2) The label must have an area of not less than:

(a) 12 square centimetres, if the intended capacity of the package is not more than 100 millilitres of the stock medicine; or

(b) 25 square centimetres, if the intended capacity of the package is more than 100 millilitres but not more than 500 millilitres of the stock medicine; or

(c) 50 square centimetres, if the intended capacity of the package is more than 500 millilitres of the stock medicine; or

(d) any other area of which the Director-General may approve.

(3) For the purposes of obtaining the approval of the Director-General under subclause (2) (d), an application must be made in writing to the Director-General setting out:

(a) the size of the label for which approval is sought; and

(b) the stock medicine to which the label refers; and

(c) the size of the package to which it is intended to attach the label; and

(d) the reason why the applicant wishes to use a label of that particular size.

Packages: manner of stating particulars

11. For the purposes of section 44 of the Act, the manner in which particulars must appear on a package or on a label attached to a package is:

(a) in the case of words, in writing in the English language; and

(b) on the face of the package or label so that the particulars can be read easily by a person holding the package; and

(c) in durable characters on material of appropriate durability for the expiry date of the particular stock medicine; and

(d) unless otherwise approved by the Director-General, in letters and figures not less than 1.5 millimetres high; and

(e) parallel to the main text, whether or not between printed parallel lines; and

(f) in a colour which affords a distinct contrast to the background colour or colours of the package and the package or, if written on a label, the colour or colours of the label.

Packages: particulars required

12. (1) For the purposes of section 44 (1) (d) of the Act, the required particulars in respect of primary packs are:

(a) the distinctive name of the product, as stated in the application for registration; and

(b) the approved name, and the quantity or proportion of the active constituent substance or substances, which must be expressed:

(i) in respect of a tablet, capsule, pessary, suppository or single dose of powder or granules, as the quantity of the active constituent in the product unit; or

(ii) in respect of a product intended for extemporaneous preparation prior to administration or application, as the volume of the normal dose and the quantity of the active constituent that will be contained in that volume after preparation; or

(iii) in respect of any other product, as the proportion that each active constituent bears to the whole of the product (expressed as a weight/weight, weight/volume or volume/volume ratio in metric units of measure); and

(c) in respect of a preparation in which potency units are used as a measure of activity, the number of such units per unit weight, volume or solid dosage unit; and

(d) unless otherwise approved by the Director-General, directions for use, including dose rates, in metric terms, for each species and class of animal, frequency, duration and manner of administration or application and any other information necessary for the proper mixing and administration or application of the product; and

(e) in the case of a stock medicine for administration or application to a food producing species, the withholding period or periods required in relation to the product, as stated in the application for registration, or renewal of registration, of the product preceded by a heading **"WITHHOLDING PERIOD"** in boldface sans serif capital letters or, if no withholding period is required for a food producing species, the words **"WITHHOLDING PERIOD NIL"** or **"WITHHOLDING PERIOD NOT REQUIRED"** in boldface sans serif capital letters; and

(f) claims or statements made as to the efficacy of the product for use for any purpose, being claims or statements made in the application for registration, or renewal of registration, of the product; and

(g) the expiry date of the product immediately preceded by the words "expiry date" or the word "expiry" or the abbreviation "exp"; and

(h) directions for storage stated in the application for registration, or renewal of registration, of the product which must include, except as provided by subclause (2), one of the following directions concerning storage conditions:

(i) Store below minus 18°C (Deep freeze);

(ii) Store below minus 5°C (Freeze);

(iii) Store below 8°C (Refrigerate);

(iv) Store at 2°C to 8°C (Refrigerate. Do not freeze);

(v) Store below 25°C (Air conditioning);

(vi) Store below 30°C; and

(i) the batch number of the batch in which the product was manufactured, immediately preceded by the words "Batch number" or the symbol "B" or "[B]"; and

(j) precautionary statements, if required by the Director-General, in a form approved, and having the content determined, by the Director-General; and

(k) the net contents of the product contained in the package, which must be expressed:

(i) in the case of a product presented in individual dosage units, as the number of units in the container or primary pack; or

(ii) in the case of any other product, as the net weight or volume of the contents of the container or primary pack; and

(l) the name and complete Australian address of the place of business (not being a post office or cable, telegraphic or code address) of the manufacturer or distributor; and

(m) if required by the Director-General, and if not included in the name of the product, the product grouping of the product as specified by the Director-General; and

(n) if required by the Director-General, in the case of a stock medicine containing a poison, restricted substance or drug of addiction, the words "READ SAFETY DIRECTIONS BEFORE OPENING" in capital letters immediately below the words "KEEP OUT OF REACH OF CHILDREN"; and

(o) in the case of a stock medicine intended to be marketed for undiluted application in an aerosol container, the words "READ SAFETY DIRECTIONS BEFORE USING" in capital letters below the words "KEEP OUT OF REACH OF CHILDREN" (if appearing); and

(p) in the case of a product containing Diethylcarbamazine or its salts intended for use for the prevention of heartworm (Dirofilariasis) in dogs, the words "WARNING: Consult a veterinary surgeon before use. Adverse reactions may occur when administering this product to dogs for the prevention of heartworm."; and

(q) the statement "FOR ANIMAL TREATMENT ONLY" shown at the top centre of the principal label above the product name. (If the product contains a poison, restricted substance or drug of addiction, that statement must appear immediately below the words "KEEP OUT OF REACH OF CHILDREN", unless determined otherwise by the Director-General.); and

(r) for any internal parasiticide:

(i) the scientific name and the common name of the parasites to be treated by the product; and

(ii) a resistance statement, if the Director-General determines that such a statement is necessary.

(2) A package containing a registered stock medicine is not required to have on it, or on a label attached to it, any of the directions concerning storage conditions specified in subclause (1) (h) (i)–(vi) if:

(a) the Director-General exempts packages of the stock medicine from that requirement; and

(b) the package has on it, or on a label securely and conspicuously attached to it, such other directions, if any, concerning the temperature at which the stock medicine must be stored as the Director-General specifies or approves when exempting the packages.

(3) For the purposes of section 44 (1) (d) of the Act, the required particulars in respect of single-use syringes, unless otherwise

determined by the Director-General, are the particulars specified in subclause (1) (a), (b), (c), (e), (g), (h), (i) and (q).

(4) For the purposes of section 44 (1) (d) of the Act, the required particulars in respect of any container (other than a single-use syringe) which has a capacity of 10 millilitres or less, unless otherwise determined by the Director-General, are the particulars specified in subclause (1) (a), (b), (c), (d), (e), (f), (g), (h), (i), (k), (l) and (q).

(5) For the purposes of section 44 (1) (d) of the Act, the required particulars in respect of individually wrapped stock medicines, unless otherwise determined by the Director-General, are the particulars specified in subclause (1) (a), (b), (g), (i) and (q).

(6) For the purposes of section 44 (1) of the Act, a person must not state on a package containing a stock medicine or on a label fixed to a package containing a stock medicine:

(a) words which imply excessive efficacy, or

(b) words implying or making a comparison with another product; or

(c) when occurring in the name of the stock medicine, the word "safe", "harmless", "non-toxic", "non-poisonous" or "non-injurious"'.

Maximum penalty 50 penalty units.

Requirement to notify certain deficiencies

13. (1) For the purposes of section 29 (1) (a) of the Act, any deficiency in the formulation of a stock medicine includes both subpotency and superpotency of constituents.

(2) For the purposes of section 29 (1) (a), (b) and (c) of the Act, initial notification, if not in writing, must be followed by written notification within 7 days of the person becoming aware of the information required to be notified.

Advertising

14. (1) For the purposes of section 43 of the Act, a person must not advertise a stock medicine which contains a substance included in Schedule One, Three, Four or Eight of the Poisons List proclaimed under section 8 of the Poisons Act 1966 except:

(a) in a journal, the circulation of which is intended to be limited to persons who are veterinary surgeons, pharmacists or persons

who are engaged in the business of selling wholesale stock medicines; or

(b) in any other document that is intended to be published exclusively to or among the persons referred to in paragraph (a).

(2) For the purposes of section 43 of the Act, a person must not publish, circulate or distribute, or cause to be published, circulated or distributed, any written or printed matter containing any claim, statement or representation, or make or cause to be made any verbal claim, statement or representation, as to the efficacy or any other property of an unregistered stock medicine for a use for any purpose.

Intramammary products to contain dyemarker

15. (1) For the purposes of section 41 (1) (c) of the Act, it is a standard for a stock medicine for bovine intramammary infusion which contains any antibiotic substance that the preparation must contain, in the quantity prescribed by this clause, the dyemarker Brilliant Blue FCF (Index Number 42090 in the Third Edition, 1971, of the Society of Dyers and Colourists Colour Index) or any other dyemarker approved by the Director-General.

(2) The quantity of dyemarker must be:

(a) in products containing 100 mg or less of total antibiotic substance, 125 mg dyemarker; or

(b) in products containing more than 100 mg of total antibiotic substance, 250 mg of dyemarker.

(3) In this clause, **"total antibiotic substance"** includes sulphonamides, trimethoprim, nitrofurans and other chemical substances but does not include immunobiological substances.

(4) The quantity of dyernarker may be less than that otherwise required by this clause if data is provided to the Director-General which proves that, at the visual end-point, 95 percent of the antibiotic has been excreted and the Director-General had approved of the proposed lower level of dyemarker.

Storage and expiry date of stock medicines

16. A person must not sell a stock medicine to another person if:

(a) the seller has stored and kept the stock medicine contrary to any directions on the package or the label or on the package in which it is contained; or

(b) the expiry date shown on the label has passed.

Maximum penalty 50 penalty units.

Directions for use etc.

17. A person who supplies feed to another person knowing that the feed has been treated with a stock medicine must:

(a) ensure that the other person is aware that the feed has been so treated; and

(b) provide the other person with such written details concerning the use of the stock medicine (including the withholding period) as were obtained by the person who supplies the feed when that person obtained the feed or when that person obtained the stock medicine with which the feed has been treated.

Maximum penalty 50 penalty units.

Sampling

18. (1) For the purposes of section 50 (5) of the Act, the inspector who took the sample concerned may deliver the sample of stock medicine to an analyst by the use of any form of conveyance in or on which an inspector or an officer of the Department has possession of the sample.

(2) For the purposes of section 50 (6) of the Act, the package required to be kept by an inspector must be kept by the inspector concerned in his or her possession or in a place to which only the inspector or a person authorised by the inspector has access, until the Director-General directs the inspector as to the manner in which the inspector is to dispose of the stock medicine.

Fees and allowances for assessors

19. (1) An assessor is entitled to be paid a fee of $534 for every day, or the appropriate proportion of that fee for each part of a day, during which the assessor is involved in an appeal under Division 4 of Part 2 of the Act.

(2) An assessor is also entitled to be paid such travelling and subsistence allowances as the Minister may from time to time determine in respect of the assessor.

Standards of manufacture

20. A person who manufactures a biological stock medicine must not manufacture the biological stock medicine in contravention of any standard included in the following orders made under the Therapeutic Goods Act 1966 of the Commonwealth:

Therapeutic Goods Order No. 11

Standard for Sterile Therapeutic Goods

Therapeutic Goods Order No. 18

Infectious Laryngotracheitis Vaccine, Live Virus

Therapeutic Goods Order No. 21

General Standard for Live Avian Vaccines

Therapeutic Goods Order No. 30

Standards adopted from the British Pharmacopoeia (Veterinary) 1985 - Addendum 1988
The British Pharmacopoeia (Veterinary) 1977
The British Veterinary Codex 1965, Supplement 1970

Maximum penalty 50 penalty units.

TABLE OF PROVISIONS

EXPLANATORY NOTE

The object of this Regulation is to provide administrative detail for the purposes of the Stock Medicines Act 1989.

The Regulation contains provisions concerning applications for registration, and renewal of registration, of stock medicines, including details of the particulars that may be required to be provided in support of an application for registration or renewal of registration and of the fees payable.

Provisions are also made relating to the packaging and labelling of stock medicines, and for a range of other matters arising under the Stock Medicines Act 1989 concerning certain aspects of the manufacture, advertising, sampling, sale and use of stock medicines.