1980/145

THE ANIMAL REMEDIES REGULATIONS 1980

KEITH HOLYOAKE, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington this 14th day of July 1980

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to the Animal Remedies Act 1967, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

ANALYSIS

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Animal Remedies Regulations 1980.

(2) These regulations shall come into force on the 1st day of August 1980.

2. Interpretation—In these regulations, unless the context otherwise requires,—

"The Act" means the Animal Remedies Act 1967:

"Equipment" includes all apparatus, containers, instruments, machinery, piping, receptacles, thermometers, utensils, and other articles used in the preparation, testing, handling, manufacture, container filling, or storage of biochemical substances:

"Licence" means a principal technician's licence issued under regulation 5 of these regulations or, as the case may require, a licence issued under regulation 13 of these regulations in respect of any premises used for the manufacture of any biochemical substance:

"Principal technician", in relation to the manufacture of a biochemical substance, means the person who has the immediate direction, supervision, and control of the actual process of manufacturing that substance in premises licensed under these regulations; and includes the licensee of the substance if he himself exercises immediate direction, supervision, and control over manufacture:

"Proprietor", in relation to a biochemical substance manufactured in any premises in New Zealand, means the holder of the licence issued under these regulations in respect of those premises, and, in relation to a biochemical substance not manufactured in New Zealand, means the importer of the substance.

PART I—LICENSING OF PRINCIPAL TECHNICIANS

3. Principal technicians to be licensed—(1) No person shall engage in the manufacture of any biochemical substance unless he is the holder of a principal technician's licence issued under these regulations in respect of the manufacture of that substance.

(2) Every person who acts in contravention of subclause (1) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

4. Applications for principal technicians' licences—Every person desiring to obtain a principal technician's licence in respect of the manufacture of any biocnemical substance shall make application in writing to the Animal Remedies Board in the form provided by the Board for the purpose, and shall set out in his application the particular biochemical substance or substances in respect of which he seeks a licence, and such further information or particulars as may be required by the said form.

5. Issue of principal technician's licences—(1) The Board shall issue a principal technician's licence to the applicant if it satisfied that, by virtue of his qualifications, training, skill, and experience, he is a fit and proper person to be granted a licence.

(2) Every principal technician's licence shall be issued in Form 1 in the First Schedule to these regulations.

6. Effect of principal technicians' licences—Every principal technician's licence shall authorise the licensee to engage, or be employed, in the manufacture only of the biochemical substance or substances specified in the licence.

7. Duration of principal technicians' licences—(1) Every principal technician's licence, unless sooner revoked or renewed in accordance with these regulations, shall expire on the expiry date next following the date of the issue of the licence.

(2) In subclause (1) of this regulation, the term "expiry date" means the 31st day of March in the year 1984, and in every fifth year thereafter.

8. Renewal of principal technician's licences—(1) On the application of a licensee, the Board may from time to time renew his licence for a period of 5 years commencing with the day after the date of expiry of the licence.

(2) All the provisions of these regulations relating to the issue of a principal technician's licence shall apply, with the necessary modifications, to the renewal of such a licence.

(3) On the renewal of a principal technician's licence, the Board shall issue to the licensee a certificate of renewal in Form 2 in the First Schedule to these regulations.

9. Revocation of principal technicians' licences—(1) Any principal technician's licence may be revoked by the Board—

(a) If the licensee so requests; or

(b) If any biochemical substance manufactured under his supervision is found by the Board—

(i) To have deteriorated before the expiry date of the lot or batch concerned; or

(ii) To be dangerous; or

(iii) To be ineffective for its purpose; or

(iv) Not to comply with any standard prescribed by the Board; or

(c) If the holder of the licence becomes, in the opinion of the Board or of the proprietor, incompetent in the performance of the duties or operations authorised by the terms of his licence.

(2) The revocation of any principal technician's licence shall be effected by a declaration of revocation in writing by the Board served upon the licensee or sent to the licensee by post in a registered letter addressed to him at his usual or last known place of abode.

Licensing of Premises

10. Biochemical substances to be manufactured only in licensed premises—(1) No person shall carry on the manufacture of any biochemical substance in any premises unless he holds a licence issued under these regulations in respect of those premises.

PART II—LICENSING OF PREMISES

(2) Every person who contravenes subclause (1) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

11. Conditions for licensing of premises—The Board shall not grant a licence under these regulations unless it is satisfied—

(a) That the premises have been erected in compliance with regulation 21 of these regulations; and

(b) That the premises comply with the requirements of regulation 22 of these regulations; and

(c) The person who is to perform the duties of principal technician in respect of the manufacture of biochemical substances in the premises holds a principal technician's licence issued under these regulations.

12. Applications for premises licences—Every person who proposes to use any premises for the manufacture of any biochemical substance shall make application to the Board, on a form provided by the registrar, for a licence authorising the manufacture on those premises of the biochemical substance or substances specified in the application.

13. Inspection of premises—On receipt of an application for a licence in respect of any premises, the Board shall cause the premises described in the application to be inspected and reported on by a person appointed by the Board for the purpose.

14. Issue of premises licences—On receipt of the report referred to in regulation 13 of these regulations, and on being satisfied that—

(a) The requirements of these regulations in respect of the premises and its equipment have been complied with; and

(b) A licensed principal technician has been appointed in respect of the premises,—

the Board shall issue to the applicant a licence in respect of the premises in Form 3 in the First Schedule to these regulations.

15. Effect of premises licences—Every licence issued under regulation 14 of these regulations shall authorise the licensee to manufacture on the premises described in the licence only the biochemical substance or substances specified in the licence.

16. Duration of premises licences—(1) Every licence issued under regulation 14 of these regulations, unless sooner revoked or renewed in accordance with these regulations, shall expire on the expiry date next following the date of the issue of the licence.

(2) In subclause (1) of this regulation, the term "expiry date" means the 31st day of March in the year 1984, and in every fifth year thereafter.

17. Renewal of premises licences—(1) On the application of a licensee, the Board may from time to time renew the licence held by him in respect of any premises for a period of 5 years commencing with the day after the date of expiry of the licence.

(2) All the provisions of these regulations relating to the issue of a licence in respect of any premises shall apply, with the necessary modifications, to the renewal of such a licence.

(3) On the renewal of a licence in respect of any premises, the Board shall issue to the licensee a certificate of renewal in Form 4 in the First Schedule to these regulations.

18. Amendment of premises licences—(1) On the application of the licensee of any premises, the Board may, by notice in writing given to the licensee, amend or vary the licence in respect of his premises by authorising the licensee to manufacture on the premises a biochemical substance or biochemical substances not already specified in his licence.

(2) The Board may at any time, of its own motion, by notice in writing given to a licensee, amend the licence in respect of his premises by striking out the name of any biochemical substance specified in the licence if, after analysis or biological testing conducted under the auspices of the Board, the Board is satisfied that the substance manufactured by the licensee pursuant to the licence has, after manufacture but before sale by the licensee,—

(a) Become dangerous; or

(b) Become ineffective for its purpose.

19. Revocation of premises licences—(1) Any licence in respect of any premises may be revoked by the Board—

(a) If the licensee so requests; or

(b) If, during the period of 12 months immediately preceding the revocation, the licensee has been convicted of any offence against the Act or against these regulations or any other regulations made under the Act; or

(c) If the premises cease to comply in all respects with the requirements of regulation 21 of these regulations, or the licensee fails to maintain the premises as required by regulation 22 of these regulations; or

(d) If the licensee fails to comply with a requisition served on him in respect of the premises under regulation 23 of these regulations; or

(e) If there is no longer a licensed principal technician employed on the premises.

(2) The revocation of a licence in respect of any premises shall be effected by a declaration of revocation in writing by the Board served upon the licensee or delivered at his licensed premises to some person appearing to be the manager of the premises, or sent to the licensee by post in a registered letter addressed to the licensee at his licensed premises.

Miscellaneous Provisions

20. Construction or alteration of premises—(1) Every person intending to construct any premises for use in the manufacture of any biochemical substance may submit to the Board for its approval an adequate plan and description of the intended premises, together with the prescribed fee.

(k) They shall have hand basins conveniently adjacent to any toilet accommodation, which basins shall be furnished with waste pipes and serviced with pipes to supply hot and cold water, and shall not be used for any other purpose than personal ablutions.

(2) If, in such a case, the Board approves the plan and description, it may, subject to the other requirements of this Part of these regulations, notify the applicant in writing that, on completion of the premises in accordance with the plan and description, it will issue to the applicant a licence in respect of the premises.

(3) Every licensee intending to alter any existing premises used in the manufacture of any biochemical substance shall submit to the Board for its approval an adequate plan and description of the intended premises, together with the prescribed fee.

(4) The licensee shall not commence any such alterations until the Board notifies him in writing that it approves of the proposed alterations.

(5) No person, either before, during, or after the construction or alteration of the premises, shall, without prior permission in writing from the Board, in any material way depart from the description and plan approved by the Board.

(6) Every person who fails to comply with or contravenes any of the provisions of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

21. Requirements as to premises—(1) All premises used or intended for use in the manufacture of any biochemical substance shall comply in all respects with the following requirements:

(a) They shall be suitably constructed and subdivided to prevent the spread of disease:

(b) They shall be equipped with adequate and suitable equipment for quality control and the safe and hygienic preparation, manufacture, handling, container filling, and storage of biochemical substances:

(c) They shall be provided with a conveniently located and adequate supply of clean water, both hot and cold, and be well and properly drained in accordance with the Drainage and Plumbing Regulations 1978:

(d) They shall have adequate and suitable hygienic accommodation for the proper management and effective control of animals used in the preparation, manufacture, or testing of biochemical substances:

(e) They shall have adequate and suitable incinerators or other means for the destruction of carcasses of animals and contaminated material of a dangerous character:

(f) All floors shall be constructed of impervious and easily cleaned materials finished to a smooth, plane surface:

(g) All interior walls shall be of impervious material finished to a smooth, plane surface:

(h) All ceilings of rooms shall be of a smooth, impervious surface capable of being cleaned without damage to the surface:

(i) All rooms shall be provided with adequate ventilation and with adequate natural or artificial lighting:

(j) They shall have adequate toilet accommodation, none of which shall open directly into any room in which biochemical substances are prepared, manufactured, handled, or stored:

(2) Notwithstanding paragraph (b) of subclause (1) of this regulation, the Board may in any particular case waive the requirements of that paragraph so far as it relates to quality control if—

(a) The licensee has made arrangements for quality control measures to be undertaken on his behalf on other premises; and

(b) The Board is satisfied that those other premises are equipped with adequate and suitable equipment for quality control.

22. Licensee to maintain premises and equipment—The licensee of every licensed premises shall at all times during the currency of his licence maintain his premises and all equipment used in connection with the manufacture of biochemical substances in his licensed premises in a clean condition and in good order and repair.

23. Inspector may require defects in premises to be remedied—(1) Where any inspector appointed under the Act is satisfied that any premises in respect of which a licence is in force under these regulations no longer comply in all respects with the provisions of these regulations relating to such premises, he may give written notice to the licensee of the defects and of the alterations or repairs required to remedy the defects.

(2) Where notice is given to him under subclause (1) of this regulation, the licensee shall take all necessary steps to remedy every defect specified in the notice within such period as may be agreed upon between the licensee and the inspector or, failing such agreement, within such period as the Board may stipulate.

24. Manufacturing methods—(1) The licensee of any licensed premises shall—

(a) Adopt such methods and precautions as are necessary to prevent contamination during the course of the manufacture and container filling, or deterioration during the storage, of every biochemical substance manufactured in the premises:

(b) Properly isolate and keep isolated all animals affected with/or exposed to any infectious or contagious disease in the course of the preparation of any biochemical substance:

(c) Effectively destroy forthwith the carcasses of all animals and all contaminated waste material of a dangerous character used in the manufacture or testing of any biochemical substance in the premises.

(2) Every licensee who fails to comply with any requirement of subclause (1) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

25. Licensees to keep records—(1) Every licensee shall keep on the licensed premises an accurate record of the following particulars in respect of each biochemical substance manufactured on the premises:

(a) The date of manufacture of each lot or batch of the biochemical substance:

(b) The serial number by which each lot or batch of the biochemical substance may be identified:

(c) The tests made for potency, sterility, safety, abnormal toxicity, or other properties of the biochemical substance in relation to each relevant standard (if any) established and published by the Board from time to time.

(2) Every licensee shall keep on the licensed premises a sample of every lot or batch of any biochemical substance manufactured by him on those premises, and shall retain the sample until the expiry date of the lot or batch.

(3) Every licensee who fails to comply with any requirement of subclause (1) or subclause (2) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

PART III—SPECIAL PROVISIONS RELATING TO SELENIUM REMEDIES

26. Interpretation—In this Part of these regulations, unless the context otherwise requires,—

"Medical practitioner" means a person for the time being registered as a medical practitioner under the Medical Practitioners Act 1968:

"Pharmacist" means a person for the time being registered as a pharmacist under the Pharmacy Act 1970:

"Selenium" includes every compound of selenium and every article, substance, or preparation that contains more than 3 parts per million of selenium:

"Selenium remedy" means an animal remedy that contains selenium:

"Veterinary prescription" means a prescription or order issued by a veterinary surgeon:

"Veterinary surgeon" means a person for the time being registered as a veterinary surgeon under the Veterinary Surgeons Act 1956; and includes a person authorised by section 33 (3) of that Act to continue to use the description of veterinary practitioner.

27. Storage of selenium remedies—(1) No person shall store any selenium remedy unless—

(a) He is the holder of a wholesaler's poison licence for the time being in force under the Poisons Act 1960; or

(b) He is a medical practitioner; or

(c) He is a pharmacist; or

(d) He is a veterinary surgeon; or

(e) The remedy was supplied to him for the treatment of an animal pursuant to a written order or prescription signed by a veterinary surgeon.

(2) Every person who stores any selenium remedy in contravention of subclause (1) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

28. Use or supply of selenium remedies—(1) Subject to the succeeding provisions of this regulation, no person shall use or supply any selenium remedy except—

(a) Pursuant to a written order or prescription signed by a veterinary surgeon; or

(b) Pursuant to regulation 36 of these regulations and in accordance with the relevant requirements of the Second Schedule to these regulations.

(2) The Board may from time to time authorise any person in writing to use any specified selenium remedy for the purpose of field trials.

(3) Nothing in subclause (1) of this regulation applies in respect of the use or supply of any selenium remedy by a veterinary surgeon in the practice of his profession and for the treatment of animals under his care.

(4) Every person who uses or supplies any selenium remedy in contravention of subclause (1) of this regulation, except pursuant to and in accordance with the terms of any written authority given by the Board in accordance with subclause (2) of this regulation, commits an offence and is liable on summary conviction to a fine not exceeding $200.

29. Prescribing or ordering selenium remedies—(1) No veterinary surgeon shall prescribe or order any selenium remedy except in the practice of his profession and for the treatment of animals under his care.

(2) Every veterinary surgeon who prescribes or orders any selenium remedy in contravention of subclause (1) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

30. Effect of veterinary prescriptions for selenium remedies—(1) Every veterinary prescription for selenium remedy shall, unless otherwise stated in the prescription, authorise the supply of that remedy on one occasion only.

(2) No veterinary prescription for a selenium remedy shall authorise the supply of that remedy more than 6 months after the date of the prescription.

(3) No person shall supply any selenium remedy on more than one occasion pursuant to a veterinary prescription unless the veterinary surgeon has stated in the prescription the number of times on which or the intervals at which the remedy may be supplied pursuant to the prescription.

(4) Where the veterinary surgeon has stated in the prescription the number of times on which or the intervals at which the selenium remedy may be supplied pursuant to the prescription, no person shall supply the remedy more often or at a lesser interval than stated in the prescription.

(5) No person shall supply any selenium remedy pursuant to a veterinary prescription more than 6 months after the date of the prescription.

(6) Every person who supplies any selenium remedy in contravention of subclause (3) or subclause (4) or subclause (5) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

31. Endorsement and retention of veterinary prescriptions—(1) Every person who supplies any animal remedy pursuant to a veterinary prescription shall comply with the following requirements:

(a) On each occasion on which he supplies the remedy pursuant to the prescription, he shall endorse on the prescription the date of supply, and the nature of the selenium remedy supplied:

(b) He shall retain each such prescription at his business premises, in such a manner as to be readily available for inspection, for a period of at least 3 years from the date of the last supply pursuant to that prescription.

(2) Every person to whom subclause (1) of this regulation applies shall allow any member of the Police or any Inspector appointed under the Act to inspect and make copies of any prescription held by that person under that subclause.

(3) Every person who fails to comply with any of the requirements of subclause (1) or subclause (2) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

32. Dispensing of selenium remedies—(1) Selenium intended to be administered orally, and not to be mixed with any other animal remedy, shall be dispensed in liquid form in one of the following 3 concentrations only, and each such concentration shall be coloured as follows:

Concentration in milligrams per millilitre	Colour
1 ± 5.0%	Red
2 ± 5.0%	Green
5 ± 5.0%	Yellow

(2) A solution of any selenium remedy intended to be administered by injection shall comply with the following requirements:

(a) It shall be within the range pH 6.5 to 7.5:

(b) It shall be sterile, and contain a preservative to ensure that it remains sterile:

(c) It shall be free of any colouring material.

(3) Every person who dispenses any selenium remedy that contravenes any of the provisions of subclause (1) or subclause (2) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

33. Labelling of selenium remedies—(1) No person shall supply any selenium remedy other than in a bottle or other suitable container that complies with the relevant requirements of the Poisons Act 1960 and to which is attached a label that states—

(a) That the contents include selenium; and

(b) In the case of a selenium remedy to which regulation 32 (1) of these regulations applies, the concentration of selenium in the remedy.

(2) Every person who supplies any selenium remedy otherwise than in compliance with subclause (1) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

34. Restrictions on supply and use of selenium remedies above certain strength—(1) No person shall supply a selenium remedy of a concentration greater than 5 milligrams per millilitre to any other person who is not a veterinary surgeon or a pharmacist.

(2) No person other than a veterinary surgeon shall use for any purpose a selenium remedy of a concentration greater than 5 milligrams per millilitre.

(3) Every person who supplies or uses any selenium remedy in contravention of subclause (1) or subclause (2) of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

Part IV—Miscellaneous Provisions

35. Board may prescribe Code of Standards—(1) The Board may from time to time establish a Code of Standards (not inconsistent with any of the requirements of the Act or these regulations), and thereafter amend any such Code, relating to all or any of the following matters:

(a) Standards of quality, purity, safety, and potency for any animal remedy, or any ingredient of any animal remedy:

(b) The colouring of any animal remedy:

(c) The general tests to be carried out on biochemical substances and the appropriate special tests to be carried out on specific biochemical substances or specific classes of biochemical substances before sale:

(d) The construction, design, layout, sanitation, and condition of premises in which any animal remedy is manufactured, stored, or tested, the structural alteration of any such premises, and the plant and equipment that may be used in the manufacture of any animal remedy.

(2) The Board may promulgate any such Code of Standards in such manner as it thinks fit to persons engaged in the manufacture, importation, or sale of animal remedies.

36. Restrictions on supply and use of specified animal remedies—(1) No person shall supply or use any animal remedy that contains a prescription poison (within the meaning of the Poisons Act 1960), or any biochemical substance the use of which is for the time being restricted under Part VI of the Act, except—

(a) Pursuant to a prescription from a veterinary surgeon; or

(b) In the case of a prescription poison or biochemical substance specified in the first column of the Second Schedule to these regulations, where the poison or substance is administered to the type of animal, within the maximum dosage, during the period, for the purpose, and subject to the limitations, specified in the second, third, fourth, fifth, and sixth columns of that Schedule.

(2) No veterinary surgeon shall prescribe an antibiotic or hormone for the purpose of growth promotion, except an antibiotic or hormone specified in the first column of the Second Schedule to these regulations.

(3) Every person who supplies or uses any animal remedy in contravention of subclause (1) of this regulation, and every veterinary surgeon who prescribes any antibiotic or hormone in contravention of subclause (2) of this regulation, commits an offence and is liable on summary conviction to a fine not exceeding $200.

(4) The provisions of this regulation shall apply notwithstanding anything in the Poisons Regulations 1964.

37. Appeals from Board—Any person affected by a decision of the Board—

(a) Refusing an application by him for a licence under these regulations; or

(b) Refusing an application by him for the renewal of any such licence; or

(c) Refusing to approve the issue or renewal of any such licence except subject to conditions; or

(d) Revoking or suspending any such licence—

may appeal to the Supreme Court in accordance with section 34 of the Act.

38. Fees—(1) Every application for a licence for an animal remedy made pursuant to—

(a) Section 17 of the Act for a full licence; or

(b) Section 22 of the Act for a provisional licence; or

(c) Section 23 of the Act for the renewal of a licence—

shall be accompanied by a fee of $30; but no fee shall be payable for an application made pursuant to subsections (3) and (4) of section 22 of the Act for the purpose of converting a provisional licence into a full licence.

(2) Every advertisement for an animal remedy submitted for approval pursuant to section 39 (1) of the Act after the lodging of an application for a licence in respect of the remedy shall be accompanied by a fee of $5.

(3) Any request by a buyer for an analysis of an animal remedy, made pursuant to section 43 (1) of the Act, shall be accompanied by a fee of $100.

(4) Every application for the Board's approval in respect of the construction or alteration of any premises in which any animal remedy is manufactured, stored, or tested, made pursuant to regulation 22 of these regulations, shall be accompanied by a fee of $20.

39. Revocations and savings—(1) The regulations specified in the Third Schedule to these regulations are hereby consequentially revoked.

(2) All applications, approvals, licences, registers, certificates and generally all aspects of authority and all other documents, matters, acts and things, and all periods of time which originated or had effect under the regulations hereby revoked and are of continuing effect at the time of coming into force of these regulations, shall enure for the purposes of these regulations, as fully and effectually as if they had originated under these regulations and shall, when necessary, be deemed to have so originated.

(3) Without limiting subclause (2) of this regulation, for the purposes of these regulations,—

(a) Every licence issued to a principal technician under the Stock Remedies (Biological Products) Regulations 1951* and in force immediately before the commencement of these regulations shall be deemed to have been issued under regulation 5 of these regulations:

(b) Every licence issued in respect of any premises under those regulations and in force immediately before the commencement of these regulations shall be deemed to have been issued under regulation 14 of these regulations.

*S.R. 1951/202: Reprinted (with Amendments Nos. 1 to 9) S.R. 1967/81

SCHEDULES

Regs. 5 (2), 8 (3), 14, 17 (3)

FIRST SCHEDULE

PRESCRIBED FORMS

Form 1

Licence No. .....

PRINCIPAL TECHNICIAN'S LICENCE

(Regulation 5 (2), Animal Remedies Regulations 1980)

PURSUANT to the application of [*Full name*], of [*Address*], dated the ..... day of ..... 19....., the said [*Full name*] is hereby licensed under the Animal Remedies Regulations 1980 as a principal technician for the purposes of the said regulations in respect of the manufacture of the following biochemical substances, namely ..... . This licence is subject to the provisions of the said regulations and shall continue in force until the 31st day of March 19...., unless sooner revoked or surrendered.

Dated at Wellington this ..... day of ..... 19..... .

..... Registrar
Animal Remedies Board.

Form 2

CERTIFICATE OF RENEWAL OF PRINCIPAL TECHNICIAN'S LICENCE

(Regulation 8 (3), Animal Remedies Regulations 1980)

PURSUANT to the application of [*Full name*], of [*Address*], dated the ..... day of ..... 19....., the principal technician's licence held by the said [*Full name*] and numbered ..... is hereby renewed, subject to the provisions of the Animal Remedies Regulations 1980, until the 31st day of March 19....., or until the licence is sooner revoked or surrendered.

....., Registrar,
Animal Remedies Board.

Form 3

Licence No. .....

LICENCE IN RESPECT OF PREMISES

(Regulation 14, Animal Remedies Regulations 1980)

THE premises of [*Name of owner or occupier*], of [*Address*], situated at ..... and described in application dated the ..... day of ..... 19....., are hereby licensed under the Animal Remedies Regulations 1980 for the manufacture in the said premises of the following biological products, namely, ... This licence is subject to the provisions of the said regulations and shall continue in force until the 31st day of March 19....., unless sooner revoked or surrendered.

Dated at Wellington this ..... day of ..... 19..... .

.....,
Registrar,
Animal Remedies Board.

Form 4

CERTIFICATE OF RENEWAL OF LICENCE IN RESPECT OF PREMISES

(Regulation 17 (3), Animal Remedies Regulations 1980)

PURSUANT to the application of [*Name of owner or occupier*], of [*Address*], dated the ..... day of ..... 19....., the licence numbered ..... issued to the said [*Name of owner or occupier*] in respect of premises situate at ..... is hereby renewed, subject to the provisions of the Animal Remedies Regulations 1980, until the 31st day of March 19..... or until the licence is sooner revoked or surrendered.

Dated at Wellington this ..... day of ..... 19..... .

.....,
Registrar,
Animal Remedies Board.

SECOND SCHEDULE

Substances to Which Restrictions on Dispensing and Prescribing Apply

All antibiotics are available only on veterinary prescription except the following:

Antibiotic	Animal Species	Use level	Direction of Medication	Claim	Limitations to be shown on the label
Bacitracin Zn. and Bacitracin	Domestic fowl and turkeys	Up to 20 ppm	Throughout life	Growth promotion	
	Domestic fowl and turkeys	Up to 100 ppm	Up to 10 days under "stress" conditions	Treatment of "stress"	
	Pigs	Up to 20 ppm	All ages	Growth promotion and feed conversion	
	Pigs	Up to 100 ppm	First 8 weeks	Periods of "stress"	
	Calves	Up to 100 ppm	Up to 12 weeks	Growth promotion and feed conversion	
Flavomycin	Domestic fowl and turkeys	Up to 50 ppm	Throughout life	Growth promotion and improve feed conversion	
	Pigs	Up to 75 ppm	Throughout life	Growth promotion and improve feed conversion	
	Calves	Up to 75 ppm	Up to 12 weeks of age		
Hygromycin B	Pigs	8–12 ppm	Continuously	Control of large round worms, nodule worms, and whip worms in pigs (*Ascaris, Oesophogostomum, and Trichuris*)	Medication to be withdrawn 48 hours before slaughter.

	Domestic fowl	8–12 ppm	Continuously	Control of large, round worms, caecal worms and capillary worms in chickens (*Ascaridia galli, Heterakis gallinae,* and *Capillaris spp*)	Medication to be withdrawn 48 hours before slaughter.
Kitasamycin	Chickens	55–110 ppm in feed	Continuously	Growth promotion	
		250–1000 ppm in drinking water	Continuously for 1–5 days	Prevention of CRD	
	Pigs	55–100 ppm in feed	Continuously	Growth promotion	
		50–100 ppm in drinking water	Continuously for 1–5 days	Prevention of swine dysentery	
Monensin	Chickens	120 ppm	Continuously	As an aid in the prevention of coccidiosis caused by *E. Necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Not to be fed to laying domestic fowl.
Nifursol	Domestic fowls and turkeys	Up to 75 ppm	Continuously	Prevention of Blackhead. Growth promotion	Medication to be withdrawn 48 hours before slaughter.
Nihydrazone	Domestic fowls and turkeys	100 ppm	Up to 14 weeks	Prevention of Coccidiosis	Do not feed to chickens over 14 weeks.

Antibiotic	Animal Species	Use level	Direction of Medication	Claim	Limitations to be shown on the label
Nitrovin	Chickens and turkey poults	Up to 20 ppm	Up to 10 weeks	Growth promotion and improve feed conversion	Medication to be withdrawn 48 hours before slaughter.
	Pigs	Up to 20 ppm	To market weight	Growth promotion and improve feed conversion	As above
Penicillin in any base which is biologically eliminated	Sheep	Up to 1 000 000 units	1–3 days	For the treatment of animal disease	Treated animals not to be slaughtered for human consumption within 30 days of the last injection.
	Cattle	Up to 5 000 000 units	1–3 days	For the treatment of animal disease	As above.
Penicillin mastitis preparations in cerate or other form	Cattle	Up to 100 000 units	Up to 3 days	For the treatment of mastitis	Milk to be withheld from main supply for a period of 96 hours or 8 milkings unless satisfactory evidence can be produced to show that milk contains less than 0.05 units/ml in less than this time.
Sodium salinomycin	Chickens	60 p.p.m	Continuously	Prevention of coccidiosis	Withdraw 24 hours before slaughter. Not to be used in conjunction with Tiamulin or other anticoccidials.

Sodium sulphadimidine	Domestic fowls and turkeys	Up to 0.05% in the drinking water	As set out in the label or packing slip	Treatment of Coccidiosis	
Sodium sulphaquinoxaline	Domestic fowls, turkeys, and game birds	Up to a final concentration in the water of 0.05% approximately	As set out on the label or packing slip 3:2:3 schedule	Prevention and treatment of Coccidiosis	Medication to be withdrawn 10 days before slaughter. Not to be fed to laying birds.
Tiamulin hydrogen fumarate	Chickens	125–250 ppm in drinking water	Continuously for 3–5 days	Treatment of CRD	Withdraw 3 days before slaughter. Not for use with monensin or salinomycin.
	Pigs	45–60 ppm	Continuously for 3–5 days	Prevention of swine dysentery	Withdraw 5 days before slaughter.
Tylosin	Chickens and turkey poults	800–1000 ppm	For 5 days after hatching Repeat for 2 days at 3–5 weeks of age	Aid in the control of CRD	
	Chickens	0.5g of Tylosin base per litre of water	First 3 days of life and for 24 hours at 4 weeks of age Two days at 9 weeks, 2 days at 16 weeks, 2 days at 20 weeks, 2 days at 24 weeks, or when birds are housed Up to 5 days at above levels for treatment	Aid in the prevention and treatment of CRD	

Antibiotic	Animal Species	Use level	Direction of Medication	Claim	Limitations to be shown on the label
Tylosin	Turkey poults	0.5g of Tylosin base per litre of water	First 5 days of life and for 24 hours at 4 weeks. Treatment as for chickens		
	Pigs	10–110 ppm	Continuously	Growth promotion and feed conversion	
	Calves	40 ppm	Continuously up to 12 weeks	For use in milk replacers	
Tylosin (tartrate injectable)	Chickens	6.25–12.5 mg per bird	Once and repeat if necessary within 1 week	For the treatment of CRD in chickens	
	Turkey poults	6.25–12.5 mg per bird	Directly into each sinus. Repeat in 10 days if necessary	For treatment of sinusitis	
Virginiamycin	Domestic fowl, turkeys, and pigs	Up to 20 ppm	From day old until marketing	Growth promotion and improve feed conversion	Not to be fed to laying birds or adult pigs.

2. Preparations containing not more than 1 percent of selenium sulphide, used in the treatment of dogs.

3. Pig, horse, and poultry feed supplements containing not more than 300 ppm of selenium.

THIRD SCHEDULE

Reg. 39 (1)

REGULATIONS REVOKED

Regulations	Serial Number
The Stock Remedies Regulations 1947	S.R. 1947/138 (Reprinted with Amendments Nos. 1 to 3) S.R. 1962/45
The Stock Remedies Regulations 1947, Amendment No. 1	S.R. 1948/86
The Stock Remedies (Biological Products) Regulations 1951	S.R. 1951/202 (Reprinted with Amendments Nos. 1 to 9) S.R. 1967/81
The Stock Remedies Regulations 1947, Amendment No. 2	S.R. 1953/42
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 1	S.R. 1953/119
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 2	S.R. 1958/28
The Stock Remedies Regulations 1947, Amendment No. 3	S.R. 1959/65
The Selenium Control Regulations 1959	S.R. 1959/202
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 3	S.R. 1961/27
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 4	S.R. 1962/94
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 5	S.R. 1964/7
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 6	S.R. 1964/56
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 7	S.R. 1964/142
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 8	S.R. 1965/36
The Stock Remedies (Biological Products) Regulations 1951, Amendment No. 9	S.R. 1965/193
The Selenium Control Regulations 1959, Amendment No. 2	S.R. 1966/42
The Animal Remedies (Fees) Regulations 1968	S.R. 1968/11
The Animal Remedies (Fees) Regulations 1968, Amendment No. 1	S.R. 1976/167
The Selenium Control Regulations 1959, Amendment No. 3	S.R. 1978/128

A. C. MACLEOD,
Acting for the Clerk of Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations are made pursuant to the Animal Remedies Act 1967. They consolidate, amend, and replace the Stock Remedies Regulations 1947, the Stock Remedies (Biological Products) Regulations 1951, and the Selenium Control Regulations 1959.

Part I provides for the licensing by the Animal Remedies Board of persons (termed principal technicians) who will be in charge of premises in which animal remedies are to be manufactured.

Similarly, Part II provides for the licensing by the Board of the premises on which animal remedies are to be manufactured.

Part III makes special provisions relating to animal remedies containing selenium. In broad terms, these may be handled only by or through licensees (under the Poisons Act 1960), medical practitioners, pharmacists, and veterinary surgeons.

Part IV contains miscellaneous provisions.

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These regulations are administered in the Ministry of Agriculture and Fisheries.