Reprint

as at 17 October 2007

Animal Remedies (Fees) Regulations 1997

(SR 1997/367)

Animal Remedies (Fees) Regulations 1997: revoked, on 17 October 2007, by section 56(b) of the Agricultural Compounds and Veterinary Medicines Amendment Act 2007 (2007 No 93)

PURSUANT to section 65 of the Animal Remedies Act 1967, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, makes the following regulations.

Contents

Note

Changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in this eprint.

A general outline of these changes is set out in the notes at the end of this eprint, together with other explanatory material about this eprint.

These regulations are administered in the Ministry of Agriculture.

1 Title and commencement

(1) These regulations may be cited as the Animal Remedies (Fees) Regulations 1997.

(2) These regulations come into force on 15 January 1998.

2 Fees

(1) The fees set out in the Schedule are payable in respect of the matters to which they relate.

(2) The fees prescribed by these regulations are inclusive of goods and services tax.

3 Revocations

The Animal Remedies (Fees) Regulations 1993[1] and the Animal Remedies (Fees) Regulations 1993, Amendment No 1[2] are consequentially revoked.

Schedule

Reg 2

Fees payable under Animal Remedies Act 1967

1

Fees payable in respect of licences to manufacture or import animal remedies

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1. On application under section 19 for a licence to manufacture or import an animal remedy—	
Pre-screening cost	364.50
Plus administration cost	2,095.88
Plus manufacturing assessment.....	455.63

[1] SR 1993/171
[2] SR 1995/103

1—*continued*

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Plus pharmacology and efficacy evaluation—	
(a) For the first named species to which the remedy is to be applicable	911.25
(b) For each additional named species to which the remedy is to be applicable	455.63
Plus safety study evaluation—	
(a) For the first named species to which the remedy is to be applicable	455.63
(b) For each additional named species to which the remedy is to be applicable	227.82
Plus toxicology evaluation—	
(a) For an application for an animal remedy with an active ingredient that is new to animal remedies or to animal remedies of that type	4,647.38
(b) For an application for an animal remedy with no active ingredient that is new to animal remedies or to animal remedies of that type, but which requires more than the basic evaluation referred to in paragraph (c)	911.25
(c) For an application which involves only minimal public or environmental exposure, which requires no assessment of data, and which requires only a basic toxicology evaluation	364.50
Plus, in the case of applications that require a residues study evaluation,—	

1—*continued*

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(a) For the first named species to which the remedy is to be applicable.....	1,093.50
(b) For each additional named species to which the remedy is to be applicable	546.75
2. On application to vary any licence, or to revoke or vary any condition imposed by the Board under section 22, or on application for approval under section 29(1) (which requires licensees to obtain the Board's approval before selling remedies whose particulars have changed)—	
(a) For minor changes (including change of licensee's name and address, change of trade name, transfer of licence, and administrative change to a label).....	364.50
(b) For substantive changes (including change in sourcing of active ingredients, change of manufacturer or method of manufacture, and change in the shelf-life)	The fee, or part of the fee, that would have been payable if the application had been made under clause 1
3. On application under section 24 for a provisional licence to manufacture or import an animal remedy—	
(a) For a provisional class I licence.....	364.50
(b) For any other provisional licence	The fee, or part of the fee, that would have been payable if the application had been made under clause 1

1—*continued*

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4. On application for reissue of a licence under section 26A(2) (which enables the reissue to the transferees of rights to animal remedies of licences surrendered by former licensees) or for reissue of a licence that has been cancelled at the request of the licence holder or revoked for failure to pay the annual fee—	
(a) In the case of an application made within 24 months of the surrender, cancellation, or revocation of the licence	A fee equivalent to the annual fees that would have been payable under clause 6 between the date of surrender, cancellation, or revocation and the date of application, if the licence had not been surrendered, cancelled, or revoked
(b) In the case of any other application ...	The fee, or part of the fee, that would have been payable if the application had been made under clause 1
5. On application under section 33 for a further licence where a licence has been lost or destroyed	364.50
6. Annual fee payable by the holder of a licence (whether full or provisional) to manufacture or import an animal remedy, payable on 1 July in each year	337.50

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Miscellaneous fees

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7. On application for a notice under section 3(1) (which empowers the Minister to exempt animal remedies from provisions of the Act).....	337.50
8. For every notice under section 45(1) (which empowers a person in possession of an animal remedy to notify an inspector that the person desires the inspector to take a sample and have it analysed)	1,125.00
9. On application for a principal technician's licence	112.50
10. On application for a licence to use premises for the manufacture of any biochemical substance.....	225.00
11. On application for approval of a plan and description of premises intended to be constructed or altered for use for the manufacture of any biochemical substance	225.00

MARIE SHROFF,
Clerk of the Executive Council.

Explanatory note

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

These regulations, which come into force on 15 January 1998, prescribe the fees payable in respect of matters under the Animal Remedies Act 1967. That Act controls the manufacture, importation, sale, and use of drugs, etc, used for treating and preventing animal diseases.

The regulations provide, among other things, for—

(a) Fees payable in respect of an application for licensing of an animal remedy:

(b) Fees payable in respect of applications for variations to licences:

(c) Fees payable in respect of applications for "provisional" class 1 licences:

(d) Fees payable in respect of the reinstatement of a licence:

(e) The annual fee for holders of licences to manufacture or import an animal remedy, payable on 1 July each year. The Board has power to revoke a licence if the licensee fails to pay any fee in respect of the licence (s 28(1)(na)).

The regulations replace the Animal Remedies (Fees) Regulations 1993 (as amended in 1995).

The regulations introduce differential fees for applications for licences to manufacture or import an animal remedy. The current fee for these applications is a flat fee of $3,150. The new fee is broken down to reflect the number of stages through which an application may need to be processed. These consist of a pre-screening stage, followed by the full processing of the application. The various stages are as follows:

Pre-screening Module

This consists of the administrative pre-screen, followed by the technical pre-screen. All applications received will be progressed through these 2 sub-modules. If there is a deficiency in the application, at the conclusion of this pre-screening section the application will be referred to the Board or its sub-delegated decision-making authority with a recommendation that the application be declined. The total amount payable at this point is $364.50.

Administrative Cost

All applications that are not declined at the end of the pre-screening module will attract a charge of $2,095.88 to cover all administration in respect of the processing of the application. This charge will make up part of the final application fee.

Manufacturing Assessment

Every application will be evaluated under this module. The cost to the applicant per application is $455.63 for costs incurred in respect of an assessment of the chemical identity, properties, formulation details and manufacturing processes, including specifications and analytical methods for all formulation ingredients, and impurities in the final product. An assessment of the stability of the final manufactured product and any use dilutions during storage is included.

Pharmacology and Efficacy Module

Every application must be evaluated under this module. The cost to the applicant for the first named species for which the remedy is to be applicable is $911.25 and for each additional species the cost will be $455.63. This module covers a review of all the data provided on the efficacy and pharmacology. This includes target animal efficacy studies, clinical, and/or field studies, and any other study to justify the claims. The scope of the review will relate to the claims being made per species.

Safety Study Module

Every application will be required to be evaluated for safety purposes for use on the species to which the application relates. The amount of the final fee will be comprised of $455.63 for the first species and $227.82 for every subsequent species. This module covers an assessment of all the data provided on the safety of the product to the target animals. It includes the safety of single and multiple doses, and where appropriate safety to hides and fleeces. The review concerns all claims being made in respect of the product as it relates to one species of animal.

Residues Study Module

Not every application will be subject to this evaluation. Those applications subject to this module will be required to pay $1,093.50 for the first species of animal to which the application relates and $546.75 for any other species to which the applicant wishes the remedy to be applicable to. This module covers an assessment of data showing the nature and level of residues and metabolites resulting from the proposed use-pattern in the target animal and the establishment of withholding periods. It reviews the analytical methods used to determine the residue in the animal products. It also includes an assessment of the effect of any major variable needed to determine the need for, and, if necessary, the establishment of, maximum residue limits.

Toxicology Module

Every application will be processed and evaluated in respect of toxicology. There are 3 different levels that the evaluation may be required to take. The first is the basic information category for which the cost will be $364.50. The next alternative is where a more thorough evaluation is required. The cost in that circumstance will be $911.25. Generally this category will apply where the active ingre-

dient is known to be the same as in other products on the market. The most challenging category is where the active ingredient is new to animal remedies or animal remedies of that type. In that case the cost will be $4,647.38 for the toxicology evaluation component of the application fee.

The most expensive, and most thorough toxicological assessment, relates to an assessment of the full range of acute studies, short term repeat dose studies, sub-chronic toxicity studies, long term toxicity studies, reproduction studies, developmental studies, genotoxicity studies, metabolism and toxicokinetical studies, human toxicological data, special toxicity data (eg neurotoxicity), first aid and safety directions and any other additional data required to make full assessment of the hazard of the product.

The next level down deals with a known active ingredient and the lowest level is the base information level.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette*: 18 December 1997.

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Notes

1 General

This is an eprint of the Animal Remedies (Fees) Regulations 1997. It incorporates all the amendments to the Animal Remedies (Fees) Regulations 1997 as at 17 October 2007. The list of amendments at the end of these notes specifies all the amendments incorporated into this eprint since 3 September 2007. Relevant provisions of any amending enactments that contain transitional, savings, or application provisions are also included, after the Principal enactment, in chronological order.

2 About this eprint

This eprint has not been officialised. For more information about officialisation, please see "Making online legislation official" under "Status of legislation on this site" in the About section of this website.

3 List of amendments incorporated in this eprint (most recent first)

Agricultural Compounds and Veterinary Medicines Amendment Act 2007 (2007 No 93): section 56(b)
