Tonga

THERAPEUTIC GOODS REGULATIONS 2011

Chapter 28.34.32

2016 Revised Edition

Tonga

THERAPEUTIC GOODS REGULATIONS 2011

Arrangement of Sections

Regulation

Tonga

THERAPEUTIC GOODS REGULATIONS 2011

2016 Revised Edition

THERAPEUTIC GOODS ACT 2001

IN EXERCISE of the powers conferred by section 35 of the Therapeutic Goods Act 2001, the Minister of Health with the consent of Cabinet has made the following Regulations -

Commencement [16th June, 2011][1]

1 Short Title

This Regulation may be cited as the Therapeutic Goods Regulations 2011.

2 Interpretation

In these Regulations, unless the context otherwise requires –

"Act" means the Therapeutic Goods Act 2001;

"Ministry" means the Ministry of Health; and

"Secretary" means the secretary to the National Drugs and Medical Supplies Committee established under the Act.

3 Import

An application for a licence to import therapeutic goods shall be –

(a) made in Form 1 of Schedule 1; and

(b) accompanied by the prescribed fees.

4 Supply other than by wholesale

An application for a licence to supply medicinal drugs other than by wholesale shall be –

(a) made in Form 2 of Schedule 1; and

(b) accompanied by the prescribed fee.

5 Supply by wholesale

An application for a licence to supply therapeutic goods by wholesale shall be –

(a) made in Form 3 of Schedule 1; and

(b) accompanied by the prescribed fee.

6 Manufacture

An application for a licence to manufacture therapeutic goods shall be –

(a) made in Form 4 of Schedule 1; and

(b) accompanied by the prescribed fee.

7 Inclusion in registered list

An application for inclusion of a medicinal drug in the registered list shall be –

(a) made in Form 5 of Schedule 1; and

(b) accompanied by the prescribed fee.

8 Licensed activities

A licence may authorise one or more of the activities provided in regulations 3, 4, 5, or 6, provided that the prescribed fee shall be paid for each activity.

9 Fees

For the purposes of the Act and these Regulations the fees shall be those prescribed in Schedule 2.

10 Granting and issuance of licence

For the purposes of the Act and these Regulations a licence shall be granted and issued in the form prescribed in Schedule 3, upon payment of the prescribed fee.

11 Authorised Officers

(1) The Secretary shall provide an authorised officer with an identity document that verifies his designation.

(2) An authorised officer shall return the identity document to the Secretary where he is no longer acting as an authorised officer.

12 Exemptions

Pursuant to section 35(c) of the Act, traditional Tongan healers are exempted from the provisions of the Act and these Regulations, where they supply traditional herbal materials of local origin that are not processed beyond either drying or simple extraction and that do not fall into the classes of medicinal drugs in the registered list.

SCHEDULE 1

FORM 1

(Regulation 3)

APPLICATION FOR LICENCE TO IMPORT THERAPEUTIC GOODS

Name of applicant:

Applicants Qualification:

Applicant's business address:

Applicant's postal address:

Classes of medicinal drugs for which a licence is sought:

(pursuant to section 5(2) of the Act)

Names and addresses of premises at which the therapeutic goods may be stored at any stage, including point(s) of sale:

Name	Address

Declaration:

I declare that the above is a complete list of premises at which goods subject to import under this licence may be stored before they are disposed of by this applicant, and that each of these premises is available for inspection by an authorised officer. Access to any of these premises pursuant to the Act may be obtained by contacting the person whose signature appears below.

Signature of applicant:

(Where the applicant is a company - a Director or the Secretary)

Signatory's position in company:

Date of signature:

Contact details for the signatory:

Tel No:

Fax No:

Email:

FORM 2

(Regulation 4)

APPLICATION FOR LICENCE TO SUPPLY MEDICINAL DRUGS (OTHER THAN BY WHOLESALE)

Name of applicant:

Applicants Qualification:

Applicant's business address:

Applicant's postal address:

Classes of medicinal drugs for which a licence is sought:

(pursuant to section 5(2) of the Act)

Is the applicant a pharmacist, veterinary practitioner or retailer?

(If yes, specify which.)

Names and addresses of premises at which the drugs may be stored at any stage, including the point(s) of sale by this applicant:

(Attach extra pages if necessary)

Name	Address

Declaration:

I declare that the above is a complete list of premises at which drugs subject to wholesale under this licence may be stored before they are disposed of by this applicant, and that each of these premises is available for inspection by an authorised officer. Access to any of these premises pursuant to the Act may be obtained by contacting the person whose signature appears below.

Signature of applicant:

(Where the applicant is a company - a Director or the Secretary)

Signatory's position in company:

Date of signature:

Contact details for the signatory:

Tel No:

Fax No:

Email:

FORM 3

(Regulation 5)

APPLICATION FOR LICENCE TO SUPPLY THERAPEUTIC GOODS (WHOLESALE)

Name of applicant:

Applicants Qualification:

Applicant's business address:

Applicant's postal address:

Classes of therapeutic goods for which a licence is sought:

(pursuant to section 5(2) of the Act)

Is the applicant a pharmacist, veterinary practitioner or wholesaler?

(If yes, specify which.)

Names and addresses of premises at which the goods may be stored at any stage, including the point(s) of sale by this applicant:

(Attach extra pages if necessary)

Name	Address

Declaration:

I declare that the above is a complete list of premises at which goods subject to wholesale under this licence may be stored before they are disposed of by this applicant, and that each of these premises is available for inspection by an authorised officer. Access to any of these premises pursuant to the Act may be obtained by contacting the person whose signature appears below.

Signature of applicant:

(Where the applicant is a company - a Director or the Secretary)

Signatory's position in company:

Date of signature:

Contact details for the signatory:

Tel No:

Fax No:

Email:

FORM 4

(Regulation 6)

APPLICATION FOR LICENCE TO MANUFACTURE THERAPEUTIC GOODS

Name of applicant:

Applicants Qualification:

Applicant's business address:

Applicant's postal address:

Premises/buildings at which any step in manufacture occurs, including the premises/buildings of any contract manufacturers: (Attach extra pages if necessary)

Name of site	Street address	Class of therapeutic goods

Persons who are to have control of the production of the goods and of the quality control measures that are to be employed:

(Attach additional pages if necessary)

Name of person	Name of site(s)	Responsibility	Qualification and experience

Declaration:

I declare that:

(a) Standards at each of these premises conform with the Ministry of Health, standards in Good Manufacturing Practices.

(b) All of these premises are available for inspection by an authorised officer.

(c) Access to any of these premises under the terms of those Acts may be obtained by contacting the person whose signature appears below.

Signature of applicant:

(Where the applicant is a company - a Director or the Secretary)

Signatory's position in company:

Date of signature:

Contact details for the signatory:

Tel No:

Fax No:

Email:

FORM 5

(Regulation 7)

APPLICATION FOR INCLUSION OF MEDICINAL DRUGS IN THE REGISTERED LIST

Name of applicant:

(May be the name of a registered company in Tonga or of a Tongan resident)

Applicant's business address:

Applicant's postal address:

Medicinal Drug

Brand name:

Non-propriety Name (INN):

Place of Manufacture:

Is it of United States Pharmacopoeia or British Pharmacopoeia standard or proven equivalent standard?

Is it registered in any of the countries listed in the schedule to the Therapeutic Goods Act 2001?

Would it be appropriate for use in Tonga?

What class in the registered list is it likely to be included in?

Attach a World Health Organization Certificate for a Pharmaceutical Product Moving in International Commerce signed by the government regulatory authority in a country which is a signatory to the World Health Organisation Certification Scheme.

Declaration:

I declare that the above information is accurate and correct to the best of my knowledge and all attached information has been obtained from the government regulatory authority of the manufacturing country who is a signatory to the World Health Organisation Certification Scheme.

Signature of applicant:

Date of signature:

Contact details for the signatory:

Tel No:

Fax No:

Email:

SCHEDULE 2

(Regulation 9)

FEES

Item	Activities	Fees
1	Inclusion of a new medicinal drug in the Registered List	$10.00
	Import	
2	Application for an import licence	$20.00
3	Inspection fee relating to an import licence	$50.00
4	Issuance fee for an import licence	$200.00
	Manufacturing	
5	Application fee for a manufacturing licence	$20.00
6	Inspection fee relating to a manufacturing licence	$200.00
7	Issuance fee for a manufacturing licence	$500.00
	Supply other than by Wholesale	
8	Application by retail stores selling Class 1 medicinal drugs only, for licence to supply medicinal drugs other than by wholesale	NIL
9	Application by persons other than retail stores selling Class 1 medicinal drugs only, for licence to supply medicinal drugs other than by wholesale	$20.00
10	Issuance fee to persons other than retail stores selling Class 1 medicinal drugs only, for licence to supply medicinal drugs other than by wholesale	$100.00
	Supply by Wholesale	
11	Application fee for licence to supply therapeutic goods by wholesale	$20.00
12	Issuance fee for licence to supply therapeutic goods by wholesale	$200.00

SCHEDULE 3

(Regulation 10)

LICENCE

(Therapeutic Goods Act)

National Drugs and Medical Supplies Committee

This is to certify that ..... who operates a premises located at ..... and owned by ..... who is the registered owner, has been granted a licence pursuant to the Therapeutic Goods Act 2001 and the Therapeutic Goods Regulations 2011 allowing the following activities:

.....

.....

.....

.....

The licence is issued this ..... day of ..... 20.....

Licence No: .....

.....

Chairman

This Licence must be retained and displayed upon the premises at all times

ENDNOTES

[1] Gazette 16 June 2011