

Food and Drugs

BELIZE:

**FOOD AND DRUGS (REGISTRATION, LICENSING AND
INSPECTION) REGULATIONS**

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BELIZE:

STATUTORY INSTRUMENT

No. 54 of 2017

REGULATIONS made by the Minister responsible for health in exercise of the powers conferred upon him by section 55 of the Food and Drugs Act, Chapter 291 of the Substantive Laws of Belize, Revised Edition 2011 and all other powers thereunto him enabling.

(Gazetted 29th July, 2017.)

PART 1

Preliminary

1. These Regulations may be cited as the

Citation.

**FOOD AND DRUGS(REGISTRATION, LICENSING
AND INSPECTION) REGULATIONS, 2017**

2. In these Regulations, unless the context otherwise requires,

Interpretation.

“the Act” means the Food and Drugs Act;

“authorized officer” means an officer that has been authorized in writing by the Minister to exercise any of the powers conferred in these Regulations;

“commercialize” means to make available on the market, and “commercialization” shall be construed accordingly;

“competent authority” means the Director of Health Services or his nominee in the Ministry;

“drug” means any substance or mixture of substances, whether for internal or external use, manufactured, sold or represented for use in,

- (a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical state, of the symptoms thereof, in man; or
- (b) restoring, correcting of modifying organic functions in man;

“finished drug” means the final dosage form of a drug that has gone through all manufacturing stages, including packaging into the container and final packaging;

“facility licence” means a facility licence granted by the competent authority, under regulation 10;

“import authorization” means a written authorization issued by the competent authority authorizing the commercialization of an orphan drug;

“inspector” means an inspector appointed under this Regulation;

“ministry” means the Ministry responsible for health;

“orphan drug” means a drug intended for use in a rare disease;

“public health standards” means standards developed to promote and protect the health of people and the communities where they live, learn, work and play;

“pharmaceutical facility” means any premises from which any drugs are stored, manufactured, sold, dispensed or otherwise supplied directly to the public by retail or wholesale;

“product licence” means the legal document granted by the competent authority, under regulation 5, authorizing the commercialization of a product;

“manufacturing plant” means a facility that carries out operations involved in the preparation of a drug, from receipt

of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished drug.

PART 2

Registration of Drugs

3.-(1) A person shall not commercialize any drug, unless that person has obtained registration of, and receives a product licence for, that drug from the competent authority.

Prohibition of sale, etc. of unregistered drug.

(2) The Minister may, in his discretion, exempt any person or any drug from the requirements of sub-regulation (1).

(3) Any person who contravenes sub-regulation (1) commits an offence and is liable on summary conviction to a fine not exceeding \$10,000.00.

4.-(1) An application for registration of a drug shall be made in the form set out as Form 1 in Schedule 1, and shall be accompanied by the following,

Application for registration.

- (a) a valid GMP certificate;
- (b) a valid certificate of Pharmaceutical Product (CPP) based on the model established by World Health Organization or a Certificate of Free Sales (CFS) if the country of origin is not a member of the World Health Organization certification scheme;
- (c) a valid certificate from the competent health authority in the country of origin;
- (d) a valid certificate of analysis of finished drug submitted by the manufacturer's quality control lab, original;

- (e) the drug's technical information, namely,
 - (i) a summary of product characteristics, including information in support of its contents; and
 - (ii) samples of the final marketing package, which should include the labels, primary packaging, secondary packaging and any external packaging for all dosage forms and presentations of the medicine to be marketed, the package insert, accessories if applicable, and samples of the finished product;
- (f) pharmacological information of finished drug;
- (g) environmental risk assessment for medicines such as hormones antineoplastic agents, radiopharmaceuticals, and any other deemed necessary by the competent authority; and
- (h) a fee of one hundred dollars for each drug per importer.

(2) All documents required under this regulation for the registration of a drug shall be in the English language and if not in the English language, the applicant shall provide the competent authority with an English translation of the document attached to the original.

Orphan
drugs.

5.-(1) Notwithstanding regulation 4, a person shall not be required to register or obtain a product licence for an orphan drug.

(2) Notwithstanding sub-regulation (1), a person shall not import into Belize or commercialize an orphan drug unless that person receives import authorization from the

competent authority, given having regard to such qualifying criteria for commercialization as the competent authority has determined.

(3) An application for importation authorization shall be made in writing to the competent authority.

(4) A person who contravenes sub-regulation (2) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars.

6.-(1) The competent authority may grant a product licence for any drug if the person seeking the product licence has applied in writing to the competent authority, and satisfies the requirements for drug registration under this regulation.

Grant or
refusal of
product
licence.

(2) Where the competent authority grants a product licence, the competent authority shall provide the applicant with a registration code for the drug.

(3) The competent authority shall allow an applicant six months to satisfy the requirements for the registration of a drug.

(4) The competent authority shall refuse to grant a product licence if,

- (a) an applicant fails to satisfy the requirements within the time stated under sub-regulation (3);
- (b) the risk benefit analysis is unfavourable;
- (c) there is insufficient justification for the therapeutic efficacy;
- (d) the drug does not have the quali-quantitative composition declared or its quality is compromised;

- (e) the information submitted during the request is erroneous or does not comply with the Act or the provisions of the Antibiotics Act, Chemists and Druggists Act and Misuse of Drugs Act, or
- (f) the applicant does not comply with the requirements of any Act specified in paragraph (e).

Application for amendment of product licence, upon change of circumstances.

7.-(1) If, after a product licence is granted, a change has occurred in relation to any required information or documents supplied upon application for the product licence, the licensee shall make an application to the competent authority for approval of amended registration of the drug concerned using the modified information or documents, in the form set out as Form 1 in Schedule 1, and accompanied by,

- (a) the fee of fifty dollars; and
- (b) the relevant documents with the amendments.

(2) The competent authority may grant an amended product licence if the applicant satisfies the requirements for the registration of a drug under this regulation.

(3) Where the competent authority grants an amended product licence, the competent authority shall provide the applicant with an amended registration code.

(4) A licensee who fails to notify of a change under paragraph (1), or notwithstanding such a change, operates under without an amended product licence commits an offence and shall be liable on summary conviction to a fine not exceeding ten thousand dollars.

Duration and renewal of product licence.

8.-(1) A product licence shall be valid until the expiration date of the GMP certificate or the Certificate of Pharmaceutical Product, whichever expires first, and may be renewed on

application by the holder of the product licence in the form set out as Form 1 and on payment of the renewal fee of fifty dollars.

(2) The application for renewal of a product licence shall be made six months prior to the expiration of the product licence.

(3) The competent authority shall cancel the registration of a drug if the holder of the product licence fails to submit an application for renewal within the time under sub-regulation (2).

9.-(1) The holder of a product licensee shall ensure that the labelling and packaging insert for the drug is legible at all times and should be the same as submitted in the application for registration.

Labelling and
packaging
insert of drug.

(2) A person who contravenes this regulation commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars.

PART 3

Facility Licence

10.-(1) A person who owns a pharmaceutical facility shall apply to the competent authority for a facility licence therefor.

Application for
facility licence.

(2) An application for a facility licence shall be made in the form set out as Form 2 of Schedule 1.

(3) An application for a facility licence shall be accompanied by the appropriate documents specified in the application form and the application fee prescribed in Schedule 2.

(4) Any person who contravenes sub-regulation (1) commits an offence and is liable on summary conviction to a fine not exceeding ten thousand dollars

Grant of
facility licence.

11.-(1) The competent authority shall inspect every pharmaceutical facility before granting a facility licence under regulation 10.

(2) The competent authority may grant a facility licence, if the facility meets the public health standards established by the competent authority.

(3) A facility licence shall only apply to the nature of the business offered by the pharmaceutical facility at the time the licence is granted.

Duration and
renewal of
facility licence.

12. A facility licence granted under regulation 10 (1) shall be valid for a period of one year and may be renewed on application by the holder of the facility licence.

Non-
transferability
of facility
licence.

13. A facility licence shall not be transferred to any other person or facility.

Notification of
changes.

14. The owner of a pharmaceutical facility shall notify the competent authority in writing if there are any changes in,

(a) location of the pharmaceutical facility; or

(b) the name of the pharmaceutical facility.

Procedure on
notification.

15.-(1) The competent authority shall issue a new licence if there is a change in the name of the pharmaceutical facility.

(2) The competent authority shall inspect a new pharmaceutical facility when notified by the owner of a change in location of the pharmaceutical facility and determine whether to re-issue a facility licence for the new pharmaceutical facility.

16.-(1) The owner of a pharmaceutical facility shall apply in writing to the competent authority for approval if the owner of the pharmaceutical facility intends to expand or discontinue the nature of business to which the facility licence applies.

Procedure
on change of
the nature of
business and
change in
ownership.

(2) The competent authority may require the owner of a pharmaceutical facility to submit a new application if the competent authority considers the change in the nature of business to be substantial.

(3) The new owner of a pharmaceutical facility shall apply for a new facility licence if there is a change in ownership of a licensed pharmaceutical facility.

(4) For the purposes of this regulation, a change in ownership occurs when,

- (a) ownership and responsibility for the operation of the assets constituting the licensed pharmaceutical facility are transferred from the holder of the licence to another person;
- (b) there is a material change in a partnership that is caused by the removal, addition, or substitution of a partner;
- (c) in the case of ownership by a corporate body,
 - (i) the holder of the licence merges into another corporate body; or
 - (ii) there is the consolidation of two or more corporate bodies, one of which is the holder of the licence, resulting in the creation of a new corporate body; or
- (d) there is the leasing of all the pharmaceutical facility's operations to another person.

Display of
facility licence.

17.-(1) The holder of a facility licence shall prominently display the facility licence at the pharmaceutical facility.

(2) Any person who contravenes sub-regulation (1) commits an offence and is liable on summary conviction to a fine not exceeding one thousand dollars.

Notification
of closure
pharmaceutical
facility.

18.-(1) The holder of a facility licence shall notify the competent authority in writing of the closure of a pharmaceutical facility

(2) A notification under sub-regulation (1) shall be given to the competent authority sixty days prior to the close of the pharmaceutical facility.

PART 4

Miscellaneous

Powers of
competent
authority.

19.-(1) The competent authority shall have the powers to do all things necessary to carry out its functions under these Regulations.

(2) In particular and without limiting the generality of sub-regulation (1), the competent authority may,

(a) vet the applications for product licences;

(b) supervise the operation of any person granted a product licence under these regulations to ensure compliance with,

(i) the terms and conditions of the product licence;

(ii) the provisions of these regulations and other legislation; or

- (iii) any directives issued by the competent authority;
- (c) set annual fees including the commercialization fee, which is set by the end of the third month of each year;
- (d) set guidelines and forms regarding the registration, post registration process, and quality evaluation of drugs;
- (e) seize, confiscate or destroy any unregistered drug, and
- (f) appoint inspectors to carry out drug inspections.

20. An inspector appointed by the competent authority under these Regulations shall have the power to,

Powers of
inspectors.

- (a) enter to inspect any place where on reasonable grounds he believes any drug is manufactured, produced, prepared, preserved, packaged, stored or sold to examine such article and take samples thereof and examine anything that the inspector reasonably believes is used or capable of being used for such manufacturing, production, preparation, preservation, packaging or storing of a drug;
- (b) open and examine any receptacle or package that on reasonable grounds, the inspector believes contains any drugs;
- (c) examine any books, documents or other records found in any place which the inspector reasonably believes contains any information relevant to the enforcement of the provisions of the Act or these Regulations;

- (e) monitor the sale of drugs, and oversee the management, storage, distribution, disposal and record keeping at any place where drugs are manufactured, stored or distributed, to ensure proper drug management;
- (f) seize, remove and detain for such time as may be necessary, any drug which the inspector reasonably believes contravenes any provision of the Act or these Regulations;
- (g) seize, remove and detain for such time as may be necessary, any item that is found in a pharmacy which the inspector reasonably believes contravenes any provision of the Act of these Regulations;
- (h) destroy as may be necessary, any expired drug with the authorization of the competent authority; and
- (i) temporarily close any establishment which the inspector reasonably believes contravenes any provision of this Act or these Regulations or any other any relevant with the permission of the competent authority.

Duties of
inspector.

21. An inspector shall,

- (a) supervise the research, development, manufacture and trade of pharmaceuticals, as well as the medical organization's use of pharmaceuticals;
- (b) not divulge technological, business and any other information gained from such inspection;
- (c) regularly promulgate the results of sampling examinations and inspections on the quality of pharmaceuticals;

- (d) follow up on the inspections of any pharmaceutical manufacturer, pharmaceutical importer or pharmaceutical wholesaler, that the inspector has certified in conformity with relevant standards as established by the competent authority;
- (e) not participate in pharmaceutical manufacturing and trade, and shall not endorse or supervise the manufacture and sale of pharmaceuticals in the name of the inspector or that of any of his relatives;
- (f) receive operational guidance regarding the inspection of any pharmaceutical manufacturer, pharmaceutical importer or pharmaceutical wholesaler and medical organizations from the competent authority;
- (g) supply a letter of confidentiality to the competent authority prior to his conduct of any inspections.

22. An inspector shall present his or her credentials to any person appearing to be an occupant or person in charge of any place before conducting any supervision or inspection at that place.

Procedure on
inspection.

23.-(1) Wherever a quantity of a regulated or unauthorized drug is scheduled to be confiscated, or destroyed by an inspector, the holder of the product licensee or a representative of the holder of the product licence shall be present at such confiscation or destruction.

Procedure on
confiscation or
destruction.

(2) Any person who is not present as required under paragraph (1) commits an offence and is liable on summary conviction to a fine not exceeding five thousand dollars, and shall be responsible for all costs of the action taken by the authorized officer from the Ministry.

24. A person who is aggrieved by a decision of an inspector may, within seven days of the decision, apply to the competent authority for re-inspection.

Application for
re-inspection.

Revocation and
cancellation of
licence.

25.-(1) The competent authority may revoke any licence issued under this Regulation if the competent authority is satisfied that the holder of the licence is not in compliance with any requirement under the Act or these Regulations.

(2) Before the revocation of any licence issued under this Regulations, the competent authority shall give written notice to the licence holder and allow the licence holder an opportunity to make representation in relation to the revocation.

(3) The holder of a licence may request that the competent authority cancels a licence.

Application for
review.

26.-(1) A person who is aggrieved by a decision of the competent authority may, within twenty-one days of the decision, apply to a Judge in Chambers of the Supreme Court for review of the decision.

(2) Notwithstanding section 112 of the Supreme Court of Judicature Act, an application for review shall not itself result in the suspension of the decision in relation to which the application is made, but the applicant may, within the time prescribed under the Supreme Court of Judicature Act, for making such application, apply to the Supreme Court for stay of execution of the decision, pending the determination of the application.

(3) Upon hearing an application, the Supreme Court may,

(a) dismiss the application; or

(b) remit the matter back to the competent authority for further consideration with such directions as it considers fit.

27. Any person that, prior to and at the date of commencement of these Regulations, is engaged in commercialization of any drug or owns a pharmaceutical facility, is, notwithstanding the provision of these Regulations, not requires to hold a product licence or facility licence, at any time prior to the 31st October, 2017.

Transitional
provision.

SCHEDULE I

FORM 1

(Regulation 5 (1))

MINISTRY OF HEALTH
DRUG REGISTRATION APPLICATION FORM

Completion of this form is necessary for consideration for drug registration.
 Type or print legibly.

Application Date		Application No. <i>(for official use only)</i>	
Product Name		Product Registration No. <i>(for official use only)</i>	
Generic Name or International Non- proprietary (INN) name			
TYPE OF APPLICATION			
New	<input type="checkbox"/>		
Renewal	<input type="checkbox"/>		
Modification	<input type="checkbox"/>		

PRODUCT LICENSEE INFORMATION			
Social Security No.			
Full name			
Date of Birth		Country of birth	
Permanent Address	Street	Town	District
Telephone number			
Email address			

COMPANY'S INFORMATION	
Business Name	
Trade License No.	
Date of issue	

Place of issue	
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MANUFACTURER INFORMATION	
Name of Manufacturer	
Country of Manufacture	

DOCUMENTS TO BE SUBMITTED WITH APPLICATION FORM		
No.	Document	Received (for official use only)
1	Ministry of Health Pharmaceutical Wholesaler/Importer Licence	
2	Good Manufacturing Practice Certificate	
3	Manufacturer's Sanitary Licence	
4	Certificate of Pharmaceutical Product (when applicable)	
5	Free Sale Certificate (when applicable)	
6	Certificate of analysis	
7	Product sample	
8	Additional scientific technical information (optional)	

AFFIDAVIT		
<p>I, _____ (licence holder) declare that the information detailed in this document is truthful and complies with the legal requirements; on the other hand, _____ (registered chemist and druggist) acting as the professional responsible for the product _____ (product name), declare under oath that the information concerning the name of the product, formulation and therapeutic indications are truthful and guarantee the good quality of the product. Consequently, we declare that this file meets the requirements for registration, so that the data contained in this application, are expression of truth and assume administrative and criminal liabilities.</p>		
Name and signature of product licensee	Name and Signature of Chemist and Druggist	Date

FOR OFFICIAL USE ONLY

FORM 2

(Regulation 10 (2))



MINISTRY OF HEALTH
APPLICATION FORM FOR PHARMACEUTICAL ESTABLISHMENTS
LICENSING AND ACCREDITATION UNIT



Application #: 000000

A: DEMOGRAPHIC (For the applicant)		
Name of Facility:		Application Date: DD MM/YYYY
Name of Owner: First	Second	SSB #: 00000000
Date of Birth: 00 00 00	Age: 00	Country of Birth:
Applicant Permanent Address:		Citizenship:
Establishment Address:		District:
e-mail address:		Telephone Number(s): 00000000 00000000
B: FACILITY INFORMATION		
FACILITY TYPE (Please tick below) <input type="checkbox"/> Retail <input type="checkbox"/> Wholesale <input type="checkbox"/> Manufacturing <input type="checkbox"/> Other (Specify: _____)	NATURE OF BUSINESS (Please tick below) <input type="checkbox"/> Retail Sale <input type="checkbox"/> Wholesale <input type="checkbox"/> Import <input type="checkbox"/> Health food Store <input type="checkbox"/> Other (Specify: _____)	APPLICATION IS FOR (Please tick below) <input type="checkbox"/> New License <input type="checkbox"/> Change of Ownership <input type="checkbox"/> Renewal <input type="checkbox"/> Expansion of Services
TYPE OF MEDICATION(S) TO BE SOLD OR IMPORTED: (Please tick below ALL that applicable) <input type="checkbox"/> General OTC <input type="checkbox"/> Pharmacy OTC <input type="checkbox"/> Prescription Medications <input type="checkbox"/> Antibiotics <input type="checkbox"/> Drugs - Controlled <input type="checkbox"/> All of the Above Drugs Type		
C: PRIMARY CONTACT INFORMATION (The following requirements are to be submitted with each application if Owner of Establishment is a Pharmacist)		
Means of Verification		Comments and relevant information
Full name of certified Pharmacist (s)		
Pharmacist Registration number		
Permanent Address		
District of Residence		
D: SECONDARY CONTACT INFORMATION (The following requirements are required for the owner of the facility, if not a Pharmacist)		
Business Registration Number		
Tax Identification Number		
E: INFORMATION RELATING TO PHARMACEUTICAL		
Certificate of verification regarding origin of pharmaceuticals (whether imported or registered in country)		
List of medications to trade along with name of manufacturer		
List of Over the Counter Drug (OTC) and name of manufacturer		
List of Prescription Drugs and name of manufacturer		
List of Controlled Pharmaceuticals and name of manufacturer		
F: AFFIDAVIT		
I, _____ (Applicant Owner) hereby affirm that the statement in this application is true and correct. Application is hereby made to operate a health facility in Belize.		
Applicant - Print Name and Sign		Date (dd/mm/yyyy)
(SEE REQUIREMENTS OVERLEAF)		

OFFICIAL USE ONLY:

Date Received: _____
 Inspection date: _____
 Approved/Denied: A D
 Date Approved/Denied: _____

Inspection Report #: _____
 Certificate Report #: _____
 Certifying Officer Name: _____
 Signature: _____

PLEASE NOTE THE FOLLOWING REQUIREMENTS TO BE SUBMITTED WITH APPLICATION FORM (NEW APPLICANTS):

- i. Facility floor plan for the business.
- ii. Business certificate of registration.
- iii. Proof of citizenship of applicant (s) and pharmacist (s) to be employed (notarized birth certificate or passport).
- iv. Photo Identification of applicant(s) and pharmacist (s) to be employed (notarized social security or drivers permit).
- v. Notarized and authenticated original degree, diploma or certificate for all pharmacist (s) to be employed. The final signature of authentication must be that of the Embassy of Belize or British High Commission in that country.
- vi. Notarized and Authenticated copy of Chemist and Druggist Certificate (for each pharmacist employed).
- vii. Official translation of all documents to English Language, if documents are in any other language.
- viii. Letter of employment verification between owner and Pharmacist (s) (if owner of the facility is not the pharmacist).
- ix. Proof that applicant is able to read and write English (for those from non-English speaking country).
- x. For each pharmacist (s) and the owner, provide a most recent police record from the Belize Police Department (not older than six months). For foreign applicants: Police Record from country of citizenship(s) and from Belize, if living in the country for less than six (6) months.
- xi. For each manufacturer the following authenticated and notarized documents must be submitted GMP certificate, CPP or free sale certificate, national health authority certificate from the competent authority of the country where the manufacturing plant is, and certificate of analysis.

PLEASE NOTE THE FOLLOWING REQUIREMENTS TO BE SUBMITTED WITH APPLICATION FORM (RENEWAL):

- i. Copy of most recent approved license from the Director of Health Services, Ministry of Health.
- ii. For the applicant, their most recent police record from the Belize Police Department (not older than six months).
- iii. If any new pharmacist (s) will be recruited at the time of renewal, then, step (iii) to step (ix) above will be applicable.

SCHEDULE 2
APPLICATION FEES

(Regulations 10(3))

APPLICATION FEES

Retail Facility	\$250.00
Wholesale Facility	\$550.00
Importer of Drugs Facility	\$550.00
Manufacturing plant	\$5,000.00

MADE by the Minister responsible for health this 25th day of July, 2017.



(Hon. Pablo Marin)
Minister of Health