



Islamic Republic of Afghanistan
Ministry of Public Health
General Directorate of Pharmaceutical Affairs

FOREIGN PHARMACEUTICAL MANUFACTURING COMPANY REGISTRATION GUIDELINE FOR AFGHANISTAN



2015



Islamic Republic of Afghanistan
Ministry of Public Health
General Directorate of Pharmaceutical Affairs

Foreign Pharmaceutical Manufacturing Company Registration Guideline for Afghanistan

2015

This publication is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of General Directorate of Pharmaceutical Affairs (GDPA)-Ministry of Public (MoPH) of the Islamic Republic of Afghanistan with the technical support of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to the most efficacious, safe and cost-effective medicines and appropriate use of medicines.

Strengthening Pharmaceutical Systems
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: sps@msh.org
Web: www.msh.org/sps

CONTENTS

Abbreviations and Acronyms	iv
Foreword.....	v
Acknowledgments.....	vi
Introduction.....	1
Objectives and Scope	2
Requirements for Registration of Foreign Pharmaceutical Manufacturing Companies	3
1.1. Cover Letter.....	3
1.2. Completed and Signed Application Form.....	3
1.3. Letter of Authorization.....	3
1.4. Manufacturing License.....	3
1.5. Company Profile	4
1.6. Good Manufacturing Practice Certificate	4
1.7. International Organization for Standardization Certificate.....	4
1.8. List of Products on Sale	4
1.9. Total Sale Turnover.....	4
1.10. Regulatory Situation of the Company in the Country of Origin and in Other Countries.....	5
1.11. Site Master File	5
Annex 1. Application Form for the Registration of a Foreign Pharmaceutical Manufacturing Company.....	9
Annex 2. Guide on How to Complete the Application Form for the Registration of a Foreign Pharmaceutical Manufacturing Company.....	12
Annex 3. Checklist for Submission of Documents for the Registration of a Foreign Pharmaceutical Manufacturing Company.....	16
Annex 4. Flowchart of the Application Procedure for Registration of a Foreign Pharmaceutical Manufacturing Company.....	19
Annex 5. Appeal Form.....	20

ABBREVIATIONS AND ACRONYMS

BP	British Pharmacopoeia
FPMC	foreign pharmaceutical manufacturing company
GDPA	General Directorate of Pharmaceutical Affairs
GMP	Good Manufacturing Practices
IP	International Pharmacopoeia
ISO	International Organization for Standardization
MoPH	Ministry of Public Health
SMF	site master file
SPS	Strengthening Pharmaceutical Systems
USAID	US Agency for International Development

FOREWORD

The General Directorate of Pharmaceutical Affairs (GDPA) in Afghanistan was established under the Ministry of Public Health (MoPH) in 2006, with the mission of leading, initiating, and managing all programs and systems relevant to pharmaceuticals at the country level.

The Regulation on Manufacturing and Importing Medicine and Medical Appliances, issue number 916, dated February 24, 2007, requires that a foreign pharmaceutical manufacturing company (FPMC) that intends to market their products in Afghanistan be register with the GDPA.

This document has been developed by the GDPA to provide direction to applicants on the format and contents required in a company dossier and other general requirements to be submitted to the GDPA when registering an FPMC.

Adherence to this guideline by submitting all required data in the correct format will facilitate efficient and effective evaluation as well as expedite the approval process.

I wish to commend the Strengthening Pharmaceutical Systems (SPS) Project funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health for the tremendous technical support. I also thank the members of the Foreign Pharmaceutical Manufacturing Company Registration Guideline Development Task Force and all those who contributed to the development of this document.

Dr. Ahmad Jan Naim
Acting Minister of Public Health

ACKNOWLEDGMENTS

The GDPA in the MoPH wishes to acknowledge the individual members of the Task Force for their contributions to the development of these guidelines. The acknowledgment is extended to the following people in particular:

- Pharmacist Mohammad Omar Mansory, GDPA, Registration and License Issuing Manager
- Pharmacist Nematullah Nawrozian, MoPH/National Medicines and Food Board Medicines Affairs Technical Advisor
- Pharmacist Latefa Qaomi, GDPA, Pharmaceutical Products and Companies Registration Manager
- Pharmacist Abdul Hadi, GDPA, Foreign Companies Registration Officer
- Pharmacist Khan Aqa Osmani, GDPA
- Pharmacist Mohammad Basir, SPS Supply Chain Systems Advisor in Afghanistan
- Pharmacist Mohammad Zafar Omari, SPS Afghanistan Chief of Party
- Mr. Mahmud Azimi, SPS Pharmaceutical Management Information Systems Officer in Afghanistan

I would also like to acknowledge comments received from the Medicines Committee and the National Medicines and Food Board members.

The GDPA further expresses its gratitude to the SPS Project for providing technical support in the development of this guidance document, with the financial assistance of USAID.

Pharmacist Abdul Hafiz Quraishi
General Director of Pharmaceutical Affairs

INTRODUCTION

The Ministry of Public Health (MoPH) of the Islamic Republic of Afghanistan, through the General Directorate of Pharmaceutical Affairs (GDPA), administers the registration system for all FPMCs that wish to market their products in Afghanistan. Registration of FPMCs in Afghanistan shall be made by the provisions of article 16 (clause 2) and under the conditions of article 18 (clause 1) of the Regulation on Manufacturing and Importing Medicine and Medical Appliances, dated 24 February, 2007, issue number 916.

The safety, efficacy, and quality of pharmaceutical products can be highly affected by the lack of adequate controls on importation. It is therefore imperative that the importation of pharmaceutical products conforms to certain set standards. In this context, the importation of pharmaceutical products should not be treated in the same way as ordinary commodities.

To strengthen the control of imported pharmaceutical products, the GDPA has revised and upgraded the current Registration Rules for Foreign Companies to a guideline will assist those in the field to adhere to Afghanistan laws and regulations during importation activities.

The use of this guideline will help the country move closer to the noble goal of making safe, efficacious, and good- quality pharmaceutical products available to the people of Afghanistan.

The GDPA in the MoPH is responsible for compliance and enforcement of this guidance document.

This document replaces the Registration Rules for Foreign Companies for registration of FPMCs. A separate guideline for registering products, called the Medicines Registration Guideline, can be obtained from the GDPA.

OBJECTIVES AND SCOPE

Objectives

The primary objectives of this guidance document are to provide transparent and clear guidelines and procedures for the registration of FPMCs and to ensure that all products imported and distributed in Afghanistan conform to acceptable standards of quality, safety, and efficacy.

Scope

The guideline is intended to promote effective and efficient processes for the development and submission of applications to register FPMCs and subsequent evaluation by the GDPA.

REQUIREMENTS FOR REGISTRATION OF FOREIGN PHARMACEUTICAL MANUFACTURING COMPANIES

Applicants must submit the following information/documents to the GDPA to register an FPMC.

1.1. Cover Letter

- 1) A cover letter on the applicant company's letterhead must be submitted with the application for registration.
- 2) The letter should be dated and signed by the responsible person in the applicant company, who may be the president or deputy for the company or organization.

1.2. Completed and Signed Application Form

- 1) A completed, signed, and dated application form should be submitted for each company. A copy of the form may be obtained from the GDPA website (www.gdpa.gov.af).
- 2) A competent qualified person shall complete all application forms. He/she shall ensure that all information provided to the GDPA is true and correct to the best of his/her knowledge. The applicant should be aware that if he/she makes any false statements, representations, or declarations in connection with an application to the GDPA, he/she will have committed an offence.
- 3) The submission should include hard and electronic copies in PDF format and in Microsoft Word on DVDs/CDs.

1.3. Letter of Authorization

- 1) The applicant should provide a copy of the letter of authorization from the manufacturing company for the application of the company registration (not applicable if the applicant is the manufacturing company).
- 2) The letter of authorization should be on company letterhead and dated and signed by the president or deputy for the company or organization.

1.4. Manufacturing License

- 1) Provide a valid copy of the manufacturing license of the company issued by MoPH and/or drug regulatory authority of the country of origin. If there is more than one manufacturing site, provide the manufacturing license for each site. Copies of the licenses must be duly endorsed by three agencies (Ministry of Health, Ministry of Commerce, and Ministry of Foreign Affairs or equivalents) in the country of origin and

the Afghanistan embassy. In the absence of the Afghanistan embassy in that country, the non-resident embassy may endorse the licenses.

- 2) Provide information on the nature of the company, whether individual, partnership, or a corporation and the name of the owner or operator. In the case of a partnership, the name of each partner must be provided. In the case of a corporation, the name and title of each corporate officer and director and the state of incorporation must be provided.

1.5. Company Profile

- 1) Provide an updated copy of the manufacturing company's profile.

1.6. Good Manufacturing Practice Certificate

- 1) Provide a valid copy of the Good Manufacturing Practice (GMP) certificate issued by an authoritative body. If there is more than one manufacturing site, provide the GMP certificate for each site. Copies of the certificate must be duly endorsed by three agencies (Ministry of Health, Ministry of Commerce, and Ministry of Foreign Affairs or equivalents in the country of origin and the Afghanistan embassy. In the absence of the Afghanistan embassy in that country, the non-resident embassy may endorse the certificates.
- 2) Provide additional information, such as certificates from the US Food and Drug Administration, other stringent regulatory authority countries, etc., if applicable.

1.7. International Organization for Standardization Certificate

- 1) Provide a copy of valid International Organization for Standardization (ISO) or any other competent organization certificate on quality management.

1.8. List of Products on Sale

- 1) Provide the list of the manufacturing company's products on sale in the country of origin and in other countries; this list should include trade name, generic name, packaging size, dosage form, shelf life, and registration date and number. This list should be signed and stamped by the company and competent authority of the country of origin on each page.

1.9. Total Sale Turnover

- 1) Provide the total sales turnover for the previous three years, each year separately. The numbers should be split between export and domestic sales. (Proof documents for export and domestic sales should be provided.)

1.10. Regulatory Situation of the Company in the Country of Origin and in Other Countries

- 1) Provide information on the registration status of the company's products in the country of origin and in other countries where the products are authorized, pending, rejected, withdrawn (by applicant after authorization), or suspended (by competent authority)

Note: *Please enclose at least three certified copies of the product registration certificate issued by the relevant authority. Copies of the certificate must be duly endorsed by three agencies (Ministry of Health, Ministry of Commerce, and Ministry of Foreign Affairs or equivalents) in the country of origin and the Afghanistan embassy. In the absence of the Afghanistan embassy in that country, the non-resident embassy may endorse the certificates.*

1.11. Site Master File

Provide a copy of site master file (SMF), if there is more than one site; provide the SMF for each site, which should include:

1.11.1. General Information on the Manufacturer

- 1) Contact Information on the Manufacturer
 - a) Name and official address of the manufacturer
 - b) Names and street addresses of the sites, buildings, and production units located on the site
 - c) Contact information for the manufacturer, including 24 hours-a-day telephone numbers in case of product defects or recalls
 - d) Identification number of the site, e.g. GPS details
- 2) Authorized Pharmaceutical Manufacturing Activities of the Site
 - a) Brief description of manufacture, import, export, distribution, and other activities as authorized by the relevant competent authorities
 - b) Types of products currently manufactured on-site (attach the list)
 - c) List of GMP inspections of the sites within the last five years; include dates and names/countries of the competent authorities that performed the inspections. A copy of GMP certificate should be included, if available.
- 3) Any Other Manufacturing Activities Carried Out on the Site
 - a) Description of non-pharmaceutical activities carried out on the site, if any.

1.11.2. Quality Management

1. Quality Management System of the Manufacturer

- a) Brief description of the quality management systems run by the company.

2. Release Procedure of Finished Products

- a) Detailed description of qualification requirements (education and work experience) of the authorized/qualified person(s) responsible for batch certification and releasing procedures
- b) General description of batch certification and releasing procedure
- c) Role of authorized/qualified person(s) responsible for quarantine and release of finished products and assessment of compliance with the marketing authorization
- d) General description of procedure for release of finished products

1.11.3. Personnel

1) Company Organization Chart

- a) Include qualifications, skills, and experience of the staff responsible for quality management, production, quality control, packing, warehousing, and distribution of drugs (pharmacists and others)

2) Number of Employees

- a) Include the number of employees engaged in quality management, production, quality control, packing, warehousing, and distribution

3) Employee training policy and outline of arrangement of training programs

4) Health requirement for personnel engaged in production

5) Personnel hygiene requirement including clothing

1.11.4. Premises and Equipment

1) Premises

- a) Short description of plant, size of the site, and list of buildings
- b) Layouts of warehouses and storage areas, with special areas for storage and handling of highly toxic, hazardous, and sensitive materials, if applicable
- c) Brief description of specific storage conditions if applicable, but not indicated on the layouts
- d) Brief description of heating, ventilation, and air conditioning systems, including principles for defining the air supply, temperature, humidity, pressure differentials and air change rates, and policy of air recirculation (%)
- e) Brief description of water systems (schematic drawings of the systems)

2) Equipment

- a) Brief description and list of equipment and machineries used in production (maintenance, calibration, and validation)
- b) List of equipment and machineries used in laboratory (maintenance, calibration and validation)
- c) Brief description of the cleaning and sanitation methods or procedures for manufacturing areas, equipment, and machines

Note: above details to be authorized by designated qualified responsible person.

1.11.5. Documentation

- 1) Description of documentation system (i.e., electronic, manual)
- 2) If documents and records are stored or archived off-site (including pharmacovigilance data, when applicable), include an inventory
 - a) The inventory should list of types of documents/records; names and addresses of storage sites; and an estimate of the time required to retrieve documents from the off-site archive

1.11.6. Production

- 1) Type of Products
 - a) Type of actual product manufactured (attach product list with product capacity)
 - b) Information about especially toxic or hazardous substances handled
- 2) Process Validation
 - a) Brief description of general policy for process validation
 - b) Policy for reprocessing or reworking
- 3) Materials Management and Warehousing
 - a) Arrangements for the handling of starting materials, packaging materials, bulk and finish products, including sampling, quarantine, release, and storage
 - b) Arrangements for handling rejected materials and products

Note: above details to be authorized by designated qualified responsible person in production.

1.11.7. Quality Control and Assurance

- 1) Number of staff specializing in quality control and quality assurance (pharmacists, chemists, others)

- 2) Names and addresses of quality control laboratories used in addition to the company's own laboratory
- 3) Description of quality control activities performed on-site in terms of physical, chemical, microbiological, and biological testing
- 4) Whole copy of the quality and safety system manual and copy of certificates held, if any
- 5) Which standards are used in quality control (BP, USP, IP, etc.)?
- 6) Procedures in place for handling quality failures

Note: *above details to be authorized by designated qualified responsible person in quality control and assurance.*

1.11.8. Distribution, Complaints, Product Defects, and Recalls

- 1) Distribution
 - a) Types and locations of the companies to which the products are shipped from the site
 - b) Brief description of the system to ensure appropriate environmental conditions during transit, e.g., temperature monitoring/control
 - c) Arrangement for product distribution and methods by which product traceability is maintained
- 2) Complaints, Product Defects, and Recalls
 - a) Brief description of the system for handling complaints and product recalls
- 3) Self-Inspection
 - a) Short description of the self-inspection system of the company with focus on criteria used for selection of the areas to be covered during planned inspections, and follow-up activities

ANNEX 1. APPLICATION FORM FOR THE REGISTRATION OF A FOREIGN PHARMACEUTICAL MANUFACTURING COMPANY

(This form has been modified slightly to fit on the pages. Actual forms may differ.)

**Islamic Republic of Afghanistan
Ministry of Public Health
General Directorate of Pharmaceutical Affair
Registration and License Issuing Department
Application for Registration of Foreign Pharmaceutical Manufacturing Company**

1. Application Number (for GDPA use only):		
Instruction:		
<ol style="list-style-type: none"> 1. Applicants are advised to refer to the GDPA’s <i>Foreign Pharmaceutical Manufacturing Company Registration Guideline in Afghanistan</i> and the GDPA’s <i>Guide on How to Complete the Application Form for the Registration of a Foreign Pharmaceutical Manufacturing Company</i> (Annex 2) for guidance before completing this application form. 2. The application submission should include duplicate hard copies and electronic copies in PDF format and Microsoft Word on DVD/CDs for each company. The form <u>MUST</u> be typed. 3. The completed, signed, and dated application form should be submitted to the Registration and License Issuing Department of the GDPA. 		
2. Applicant Company Particulars		
2.1.	Name of Company (in capital letters)	
2.2.	Business Registration Number	
2.3. Company Address and Contact Information		
2.3.1.	Country	2.3.6. Fax Number
2.3.2.	Province	2.3.7. Official E-Mail
2.3.3.	City	2.3.8. Telephone Number
2.3.4.	Mailing Address	2.3.9. Company Website
2.3.5.	Postal Code	
Note:		
<ol style="list-style-type: none"> a. Please enclose a copy of the Letter of Authorization from the manufacturing company. b. Please attach a copy of the Business Registration Certificate of the applicant company. 		
3. Applicant Particulars (Person authorized to submit and handle application on behalf of the company)		
3.1.	First Name	
3.2.	Family Name	

3.3.	Designation		
3.4.	ID Card or Passport Number		
3.5.	Official E-mail		
3.6.	Telephone Number		
3.7.	Fax Number		
3.8.	Applicant Address		
3.8.1.	Country		3.8.4. Address Line – 1
3.8.2.	Province		3.8.5. Address Line – 2
3.8.3.	City		3.8.6. Address Line – 3
4. Foreign Pharmaceutical Manufacturing Company Particulars			
4.1	Name of Company (in capital letters)		
4.2	Year of Establishment		
4.3	Website Address		
4.4	Head Office Address		4.5 Manufacturing Site Address 1
4.4.1.	Country		4.5.1. Province
4.4.2.	Province		4.5.2. City
4.4.3.	City		4.5.3. Mailing Address
4.4.4.	Mailing Address		4.5.4. Postal Code
4.4.5.	Postal Code		4.5.5. Fax Number
4.4.6.	Fax Number		4.5.6. Official E-mail
4.4.7.	Official E-mail		4.5.7. Telephone Number
4.4.8.	Telephone Number		4.5.8. Manufacturing License Number
			4.5.9. GMP Certificate Number
4.6	Manufacturing Site Address 2		4.7 Manufacturing Site Address 3
4.6.1.	Province		4.7.1. Province
4.6.2.	City		4.7.2. City
4.6.3.	Mailing Address		4.7.3. Mailing Address
4.6.4.	Postal Code		4.7.4. Postal Code
4.6.5.	Fax Number		4.7.5. Fax Number
4.6.6.	Official E-mail		4.7.6. Official E-mail
4.6.7.	Telephone Number		4.7.7. Telephone Number
4.6.8.	Manufacturing License Number		4.7.8. Manufacturing License Number

4.6.9. GMP Certificate Number		4.7.9. GMP Certificate Number	
4.8 Manufacturing Site Address 4		4.9 Manufacturing Site Address 5	
4.8.1. Province		4.9.1. Province	
4.8.2. City		4.9.2. City	
4.8.3. Mailing Address		4.9.3. Mailing Address	
4.8.4. Postal Code		4.9.4. Postal Code	
4.8.5. Fax Number		4.9.5. Fax Number	
4.8.6. Official E-mail		4.9.6. Official E-mail	
4.8.7. Telephone Number		4.9.7. Telephone Number	
4.8.8. Manufacturing License Number		4.9.8. Manufacturing License Number	
4.8.9. GMP Certificate Number		4.9.9. GMP Certificate Number	

5. Certification by a Responsible Person in the Applicant Company

On behalf of [insert the name of the company], I hereby declare that:

- All of the information in this application is true.
- Information in all of the annexes attached to this application is true and complete. All available data, reports, and information relevant to the company have been provided.
- [Insert the name of the company] agrees to abide by the Afghanistan Medicines Law and Manufacturing and Importing Medicine and Medical Appliances Regulation.
- [Insert the name of the company] agrees to notify the General Directorate of Pharmaceutical Affairs, Ministry of Public Health, of any change in the information submitted in this application and of any new information during the course of the evaluation of this application.

I understand that any false statement is an offence under the laws of Afghanistan and that all documents submitted for evaluation will not be returned.

Submitted by:

Name: (in capital letters)

Position in the Applicant Company: (in capital letters)

Date:

Signature:

Company Stamp

Received by: (GDPA)

Name: (in capital letters)

Position: (in capital letters)

Date:

Signature:

Note: all pages of the application form must be signed and stamped.

ANNEX 2. GUIDE ON HOW TO COMPLETE THE APPLICATION FORM FOR THE REGISTRATION OF A FOREIGN PHARMACEUTICAL MANUFACTURING COMPANY

Notes

1. All sections of the application form MUST be completed. Please indicate N.A. (not applicable) in those areas that are not relevant to the application.
2. All information and documents must be prepared in English or Dari/Pashto.
3. If additional sheets are required, use A4-size paper, cross-reference the relevant section of the application, and attach the page(s) immediately behind the application form.

1. Application Number

This section will be completed by the GDPA. Do not fill in this part.

2. Applicant Company Particulars

2.1. Name of Company

The company named in this section, the local importer, should be based and registered in Afghanistan. The company making an application is called the applicant company. For every successful application for registration, a Company Registration Certificate will be issued in the name of the foreign pharmaceutical manufacturing company. (Attach the letter of authorization.)

2.2. Business Registration Number

Type the business registration number of the applicant company that has been issued by the Ministry of Commerce and Industries (MoCI) and registered in the MoPH-GDPA. (Attach the business registration certificate.)

2.3. Company Address and Contact Information

- 2.3.1. Country: Put “Afghanistan”; see section 2.1 above.
- 2.3.2. Province: Provide the applicant company’s state in Afghanistan.
- 2.3.3. City: Provide the applicant company’s city in Afghanistan.
- 2.3.4. Mailing Address: Type the detail mailing address of the applicant company in Afghanistan.
- 2.3.5. Postal Code: Provide the postal code of the applicant company in Afghanistan.
- 2.3.6. Fax Number: Type the fax number of the applicant company in Afghanistan (if applicable).
- 2.3.7. Official E-Mail: Provide the official e-mail address of the applicant company in Afghanistan. An official email address is the one that is officially assigned by the

company and that is used for official communication. It is NOT a personal email address.

2.3.8. Telephone Number: Type the telephone number of the applicant company in Afghanistan that has been assigned for official communication.

2.3.9. Company Website: Provide the website address of the applicant company (if applicable).

3. Applicant Particulars

Provide information on the **person** who is authorized to submit the application and manage it on behalf of the company. The person named in this section should be available to be contacted at all times. During the initial evaluation process and after a company is registered in Afghanistan, the GDPA will liaise only with this person. It should be noted that the applicant bears full responsibility for ensuring that all available and relevant information is submitted to support the application.

3.1. First Name

Provide the first name of the applicant (as it appears on his/her ID card or passport)

3.2. Family Name

Type the family name of the applicant (as it appears on his/her ID card or passport)

3.3. Designation

Provide the designation or job title of the applicant in the applicant company.

3.4. ID Card or Passport Number

Provide the Tazkira number or passport number of the applicant.

3.5. Official Email

Type the official e-mail address of the applicant. The official e-mail address is the one officially assigned by the company, which is used for official communications. It is NOT a personal e-mail address.

3.6. Telephone Number

Provide the telephone number of the applicant in Afghanistan, which is assigned for official communications.

3.7. Fax Number

Provide the fax number of the applicant (if applicable).

3.8. Applicant Address

- 3.8.1. Country: Put “Afghanistan”; see section 2.1 above
- 3.8.2. Province: Type the applicant’s province in Afghanistan
- 3.8.3. City: Provide the applicant’s city in Afghanistan
- 3.8.4. Address: Provide the applicant’s mailing address in Afghanistan

4. Foreign Pharmaceutical Manufacturing Company Particulars

4.1. Name of Company

Provide the name of the foreign pharmaceutical manufacturing company.

4.2. Year of Establishment

Provide year of the establishment of the company, as it appear on license certificate issued by the competent authority in the country of origin.

4.3. Website Address

Provide the web site address of the manufacturer (if applicable).

4.4. Head Office Address

- 4.4.1. Country: Provide the country where the manufacturing company is located.
- 4.4.2. Province: Provide the state where the head office of the manufacturing company is located.
- 4.4.3. City: Provide the city where the head office of the manufacturing company is located.
- 4.4.4. Mailing address: Provide the mailing address of the manufacturing company’s head office.
- 4.4.5. Postal code: Provide the postal code of the manufacturing company’s head office.
- 4.4.6. Fax number: Provide the fax number of the manufacturing company’s head office (if applicable).
- 4.4.7. Official E-mail: Provide the official e-mail address of the manufacturing company’s head office. An official e-mail address is the one that has been assigned by the company and is used for official communication. It is NOT a personal e-mail address.
- 4.4.8. Telephone number: Provide the telephone number of the manufacturing company’s head office that has been assigned for official communication.

4.5. Manufacturing Site Address 1:

- 4.5.1. Province: Provide the state in where the manufacturing site is located.
- 4.5.2. City: Provide the city where the manufacturing site is located.
- 4.5.3. Mailing address: Provide the mailing address of the manufacturing site.
- 4.5.4. Postal code: Provide the postal code of the manufacturing site.

- 4.5.5. Fax number: Provide the fax number of the manufacturing site (if applicable).
- 4.5.6. Official e-mail: Provide the official e-mail address of the manufacturing site. An official e-mail address is the one that has been assigned by the company and is used for official communication. It is NOT a personal e-mail address.
- 4.5.7. Telephone Number: Provide the telephone number of the manufacturing site that has been assigned for official communication.
- 4.5.8. Manufacturing License Number: Provide the manufacturing license number of the manufacturing site that has been assigned by the MoPH and or drug regulatory authority of the country of origin.
- 4.5.9. GMP Certificate Number: Provide the GMP certificate number of the manufacturing site issued by a competent authority.

If there is more than one manufacturing site, provide the above information for each site in sections 4.6., 4.7, 4.8, and 4.9.

5. Certification by a Responsible Person in the Applicant Company

The application form for registration of a foreign pharmaceutical manufacturing company MUST be duly completed and signed.

Submitted by:

Name: Type the name of the person who is authorized to submit and manage the application on behalf of the company

Position in the applicant company: Provide the title of the position of the person in the applicant company.

Date: Note the date that the company's authorized person is submitting the application to the GDPA.

Signature: Signature of the president or deputy of the applicant company.

Company Stamp: Place the applicant company's stamp in the space provided.

This next section will be completed by the responsible person in the GDPA; the applicant should not fill in this section.

Received by:

Name: Name of the authorized person in the GDPA who has received the application.

Position: Title of the position of the person who has received the application in the GDPA.

Date: Date that the GDPA's authorized person has received this application.

Note: *All pages of the application form must be signed and stamped.*

ANNEX 3. CHECKLIST FOR SUBMISSION OF DOCUMENTS FOR THE REGISTRATION OF A FOREIGN PHARMACEUTICAL MANUFACTURING COMPANY

(This form has been modified slightly to fit on the pages. Actual forms may differ.)

Application Number	
Name of the Applicant Company	
Applicant Name	
Name of Foreign Pharmaceutical Manufacturing Company	
Date	

S/No	Documents Required	Applicant (√)	GDPA (√)	GDPA Remarks
1	Cover Letter			
	➤ Cover letter is available.			
2	Application Form			
	➤ A completed and signed application form and hard and electronic copies on CD/DVD are available.			
3	Letter of Authorization			
	➤ Letter of authorization from the manufacturing company is available. <i>Note: Not applicable if the applicant is the manufacturing company.</i>			
4	Business Registration Certificate			
	➤ Business registration certificate is available.			
5	Manufacturing License			
	➤ Copy of manufacturing license (issued by the competent authority in the country of origin) is available. <i>Note: Copies of the license must be duly endorsed by the authorized agencies in the country of origin and the Afghanistan Embassy; in the absence of the Afghanistan Embassy in that country, the non-resident embassy may endorse the licenses.</i>			
6	Company Profile			
	➤ Company profile is available.			

Annex 3. Checklist for Submission of Documents for Registration of an FPMC

S/No	Documents Required	Applicant (√)	GDPA (√)	GDPA Remarks
7	GMP Certificate			
	<p>➤ Copy of the GMP Certificate is available.</p> <p>Note: <i>Copies of the certificate must be duly endorsed by the authorized agencies in the country of origin and the Afghanistan Embassy; in the absence of the Afghanistan Embassy in that country, the non-resident embassy may endorse the certificate.</i></p>			
8	ISO Certificate			
	<p>➤ Copy of the ISO Certificate is available.</p>			
9	List of Products on Sale			
	<p>➤ List of products on sale in the country of origin and other countries is available.</p> <p>Note: <i>This list should be signed by the company and competent authority of the country of origin on each page.</i></p>			
10	Total Sales Turnover			
	<p>➤ Total sales turnover in the previous three years is available.</p> <p>Note: <i>Proof documents for export and domestic sales must be provided.</i></p>			
11	Regulatory Situation of the Company in the Country of Origin and Other Countries			
	<p>➤ Information on the registration status of the products in the country of origin and in other countries is available.</p> <p>Note: <i>Enclose at least 3 certified copies of the product registration certificate issued by the relevant authority.</i></p>			
12	SMF (if there is more than one manufacturing site; provide the SMF for each site)			
	<p>➤ General information on the manufacturer</p> <ul style="list-style-type: none"> - Contact information on the manufacturer - Authorized pharmaceutical manufacturing activities of the site - Any other manufacturing activities carried out on the site 			
	<p>➤ Quality management</p> <ul style="list-style-type: none"> - Quality management system of the manufacturer - Release procedure for finished products 			

S/No	Documents Required	Applicant (√)	GDPA (√)	GDPA Remarks
	<ul style="list-style-type: none"> ➤ Personnel <ul style="list-style-type: none"> - Organization chart of the company - Number of employees - Employee training policy - Personnel health and hygiene requirement 			
	<ul style="list-style-type: none"> ➤ Premises and equipment <ul style="list-style-type: none"> - Premises - Equipment 			
	<ul style="list-style-type: none"> ➤ Documentation <ul style="list-style-type: none"> - Documentation system 			
	<ul style="list-style-type: none"> ➤ Production <ul style="list-style-type: none"> - Types of products - Process validation policy - Materials management and warehousing 			
	<ul style="list-style-type: none"> ➤ Quality control and quality assurance <ul style="list-style-type: none"> - Number of staff on quality control and quality assurance - Quality and safety system manual 			
	<ul style="list-style-type: none"> ➤ Distribution, Complain, Product Defects and Recall <ul style="list-style-type: none"> - Distribution - Complains, product defects and recalls - Self-inspection 			
13	Additional information, if any			

Submitted by:

Name: (in capital letters)

Position in the Applicant Company: (in capital letters)

Date:

Signature:

Company Stamp

Received by: (GDPA)

Name: (in capital letters)

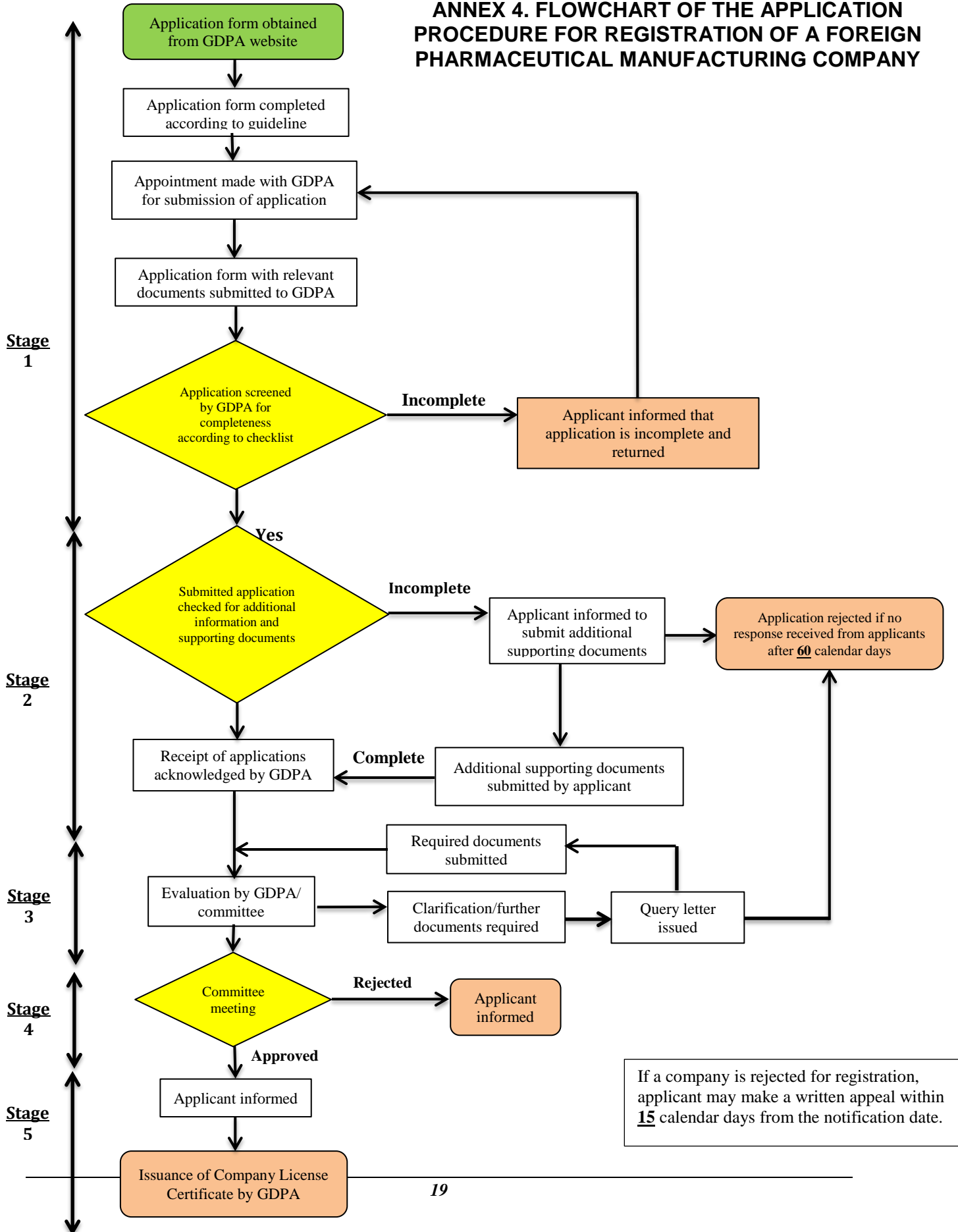
Position: (in capital letters)

Date:

Signature:

Note: all pages of the checklist must be signed and stamped.

ANNEX 4. FLOWCHART OF THE APPLICATION PROCEDURE FOR REGISTRATION OF A FOREIGN PHARMACEUTICAL MANUFACTURING COMPANY



ANNEX 5. APPEAL FORM

**Islamic Republic of Afghanistan
Ministry of Public Health
General Directorate of Pharmaceutical Affairs
Registration and License Issuing Department
Appeal Form**

Date: dd/mm/yy

To: National Medicines and Food Board, Ministry of Public Health

From: (Name of Company Appealing)

Particulars of Appeler: (name of the person who is fully authorized to submit and process the appeal on behalf of the company)	Designation	Address	Phone Number

I wish to appeal for registration of the below foreign pharmaceutical manufacturing company in Afghanistan.

Details of the Rejected Company

Application Number:	
Date of Rejection:	
Name of Manufacturing Company:	
Reasons for Appeal	
Documents Submitted to Support Appeal	

Note:

Only appeals accompanied by relevant new information or supporting documents NOT previously submitted will be considered. The appeal must be submitted within fifteen (15) calendar days from date of rejection; otherwise a new application is required to be submitted according to the Foreign Pharmaceutical Manufacturing Company Registration Guideline.

Name and Address of the Company:

Contact Number:

Signature and Stamp of the Company:



