ECONOMIC DEVELOPMENT BOARD MAURITIUS

GUIDELINES

SETTING UP A PHARMACEUTICAL MANUFACTURING UNIT

September 2021

www.edbmauritius.org

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1 Introduction

The development of the pharmaceutical industry constitutes an integral component of government's economic agenda to diversify into new sectors of activity targeting high value-added products.

This publication provides guidance to promoters interested to set up a pharmaceutical manufacturing unit in Mauritius. The guidelines are designed to provide information and assist in decision making. The manufacturing of pharmaceutical products is governed by the Pharmacy Act 1983

2 Incentives

The table below lists the incentives applicable to companies engaged in pharmaceutical, medical devices, cosmeceutical/dermatological products and R & D/ Research Laboratories:

Activity	Incentives
(i) **Pharmaceutical products** (ii) **Medical Devices, Instruments and products** (iii) **Cosmeceutical / Dermatological products**	• 8-year corporate tax holiday • No registration duty or Land Transfer tax on purchase or lease of land or building • 3 % corporate tax *(after 8-year corporate tax holiday)* • No import duties on equipment & raw material • No export duties in Mauritius • VAT on raw materials is payable at customs clearance but reimbursable on exports • Accelerated depreciation of 50% on machinery, equipment and construction of industrial premises dedicated to manufacturing activities • Waiver on Building and Land Use Permit fees for construction of pharmaceutical manufacturing factory • 30% margin of preference • Refund of 60% on Air Freight Cost for export to Africa (including Madagascar), Australia, Canada, Europe, Japan, Middle East Countries and USA (until June 2022) • Refund of 25% on Basic Freight Cost (the maximum of USD 300 per 20T-feet container and USD 600 per 40T –feet container) 49 ports in 20 countries in Africa
iv) **Pharmaceutical and Medical Devices manufacturing**	• **Eligible for the Premium Investor Scheme and can benefit from:** (i) rebates, exemptions and preferential rates, in relation to taxes, duties, fees, charges and levies under any enactment (ii) facilities, grants and exemptions in relation to : • land and buildings / infrastructure and public facilities/ utilities; and labour requirements, including foreign labour

	Activity	Incentives
i)	**R & D and Research Laboratories**	• VAT exemption on construction of medical R&D centers • VAT exemption on plants and equipment • Accelerated depreciation of 50% in respect of capital expenditure incurred on R&D, that is the investment cost is fully amortised in 2 years • Exemption of registration duty on acquisition of immovable property • Double deduction in respect of qualifying expenditure on R&D directly related to the entity's trade or business and provided the R&D is carried out in Mauritius.
ii)	**Support Services**	• Any other activities in relation to provision of support services to the development of the pharmaceutical industry. • Applicable taxes as defined in the existing legislations.

3 Land Availability

Amongst other land options available for the establishment of a pharmaceutical manufacturing facility in Mauritius, Government has earmarked an area of 66.5 acres of land for the development of the Pharmaceutical industry in the forthcoming Pharmaceutical and Life Sciences Park located in Rose Belle.

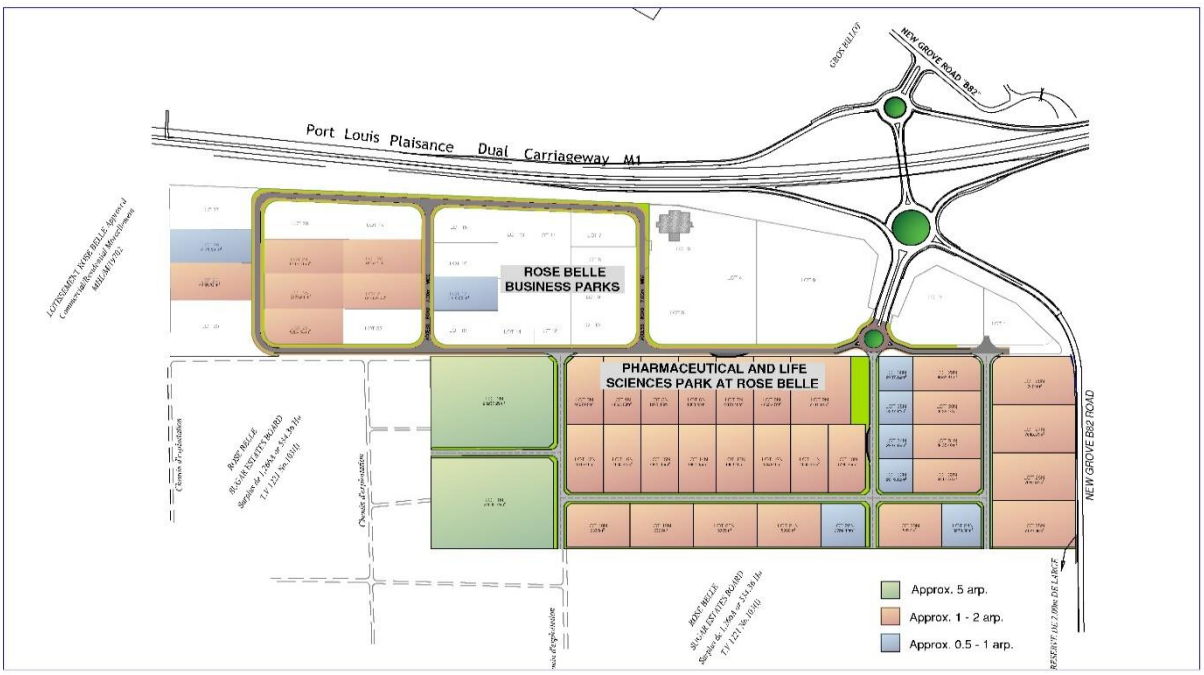


Figure 1: Proposed masterplan of the Pharmaceutical and Life Sciences Park in Rose Belle

4 Proposed activities and products

The proposed activities which can be conducted in the Pharmaceutical and Life Sciences Park are as follows:

i) Manufacture of pharmaceutical products
ii) Manufacture of Medical Devices, Instruments and products
iii) Manufacture of Cosmeceutical products
iv) R & D and Research Laboratories
v) Support services related to the development of the pharmaceutical industry

The proposed products that can be manufactured are as follows:

i) Solid unit dosage forms (e.g. tablets, suppositories etc)
ii) Semi-solid dosage forms (e.g.creams & ointment)
iii) Liquid dosage forms (e.g. syrups)
iv) Parenterals including Total Parenteral Nutrition (TPN) (e.g. vaccines & sera)
v) Ophthalmic eye/ear/nasal drops
vi) Powders (e.g. dusting powders for wound management)
vii) Aerosols (inhalers & sprays)
viii) Dermatological / Cosmeceutical products
ix) Other pharmaceutical dosage forms
x) Medical Devices, Instruments and products

5 Licences

5.1 Pharmaceutical Manufacturing Unit

Figure 2 below lists the licenses/clearances required to set up a pharmaceutical manufacturing facility in Mauritius:

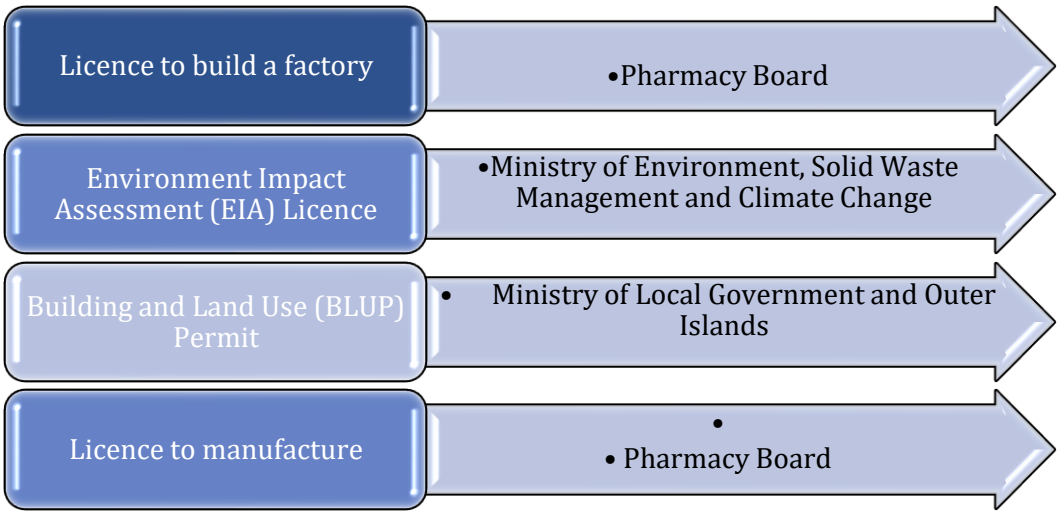


Figure 2: Main Licences required to set up a pharmaceutical manufacturing plant

6 Procedures

6.1 Licence to build a factory (for pharmaceutical manufacturing)

The promoter is required to submit a written application and a copy of his Business Plan to the Pharmacy Board and the Economic Development Board.

The **Business Plan duly validated by a WHO consultant** should encompass the following information, amongst others:

1. Background and experience of promoters / shareholders
2. A clear description of business activity including details about the different production process stages and process flow.
3. Details of the type of pharmaceutical products to be manufactured
4. Site Plan and location
5. Factory layout
6. Plans of all installations to be made
7. Details of the type of machinery to be used and the sources of energy
8. Profile of team of experts
9. Sourcing country for raw materials
10. Projected investment
11. Employment creation
12. Project financing details
13. Financial forecast
14. Target Market including exporting countries

Technical details are provided by the Pharmacy Board in the **Guidelines for Manufacturing of Pharmaceutical Products.**

6.1.1 Evaluation

i. A Technical Evaluation is conducted by the Planning Committee and the recommendations are submitted to the Pharmacy Board for consideration.

ii. Applications which are approved by the Board are issued with the relevant documentation pertaining to the licence to build a factory upon payment of the prescribed fee.

6.1.2 Application fees

Licence to build a factory	• MUR 2,100

6.2 Environmental clearance

Upon issue of a Licence to build the factory by the Pharmacy Board, the promoter can submit an application to the Ministry of Environment, Solid Waste Management and Climate Change for an Environment Impact Assessment as prescribed in Fifth Schedule of the Environment Protection Act. More details can be assessed through the following link below:
https://environment.govmu.org/Pages/Environmental-Assessment-Division.aspx
It should also be noted that:

a) Environmental clearances in relation to projects involved in the manufacturing of medical devices and cosmeceutical products may require a simple clearance, or a PER Approval or an EIA licence, depending on the scope and scale of the project. (*For example, a medical device manufacturing unit may require a PER if the devices are made of plastic products*).

b) Similarly, a cosmeceutical manufacturing company may be subject to EIA licence, if the medical component of the product is manufactured on site and will depend on the scale of production and activity.

6.3 Building and Land Use permit (BLUP)

An online application for a Building and Land Use Permit should be submitted to the Ministry of Local Government and Outer Islands. Additional information can be assessed through the following link: https://dcgp.mu/land-use-and-planning-department/

6.4 Licence to manufacture

After commissioning of the factory, the promoter should submit a written application for a license to manufacture to the Pharmacy Board and provide information in support of his application as follows:

a) the formula of each pharmaceutical product to be manufactured.
b) the technical description of the production process
c) details of all quality control
d) other information or documents as the Board may require.

The license to manufacture will be considered in compliance with Good Manufacturing Practices (GMP) requirements and any other conditions stipulated by the Pharmacy Board.

The licence to manufacture is valid for a period of one year as from the date specified in the licence and is renewed annually upon payment of the prescribed fee. Thereafter, inspections with regard to the GMP Certification are carried out at defined intervals.

6.5 Applicable fees

Licence to manufacture (one time fee)	• MUR 5,100
Renewal	• MUR 5,100

7 Registration of locally manufactured Pharmaceutical Product

Pursuant to section 36C registration of locally manufactured pharmaceutical product should be made on the prescribed form and accompanied by a non-refundable processing fee. The application is examined by the Trade and Therapeutics Committee and recommendations are submitted to the Board.

Where the Board grants an application, it shall upon payment of the prescribed fee register the locally manufactured pharmaceutical product. A Certificate of registration is issued by the Board to the applicant for a period of **one year** as from the date specified on the certificate of registration and is **renewed** annually upon payment of the prescribed fee.

7.1 Applicable fees per product **

Application	•MUR 2,500 (non-refundable)
Registration and marketing authorisation	• MUR 5,000
Renewal	• MUR 2,000 (per year)

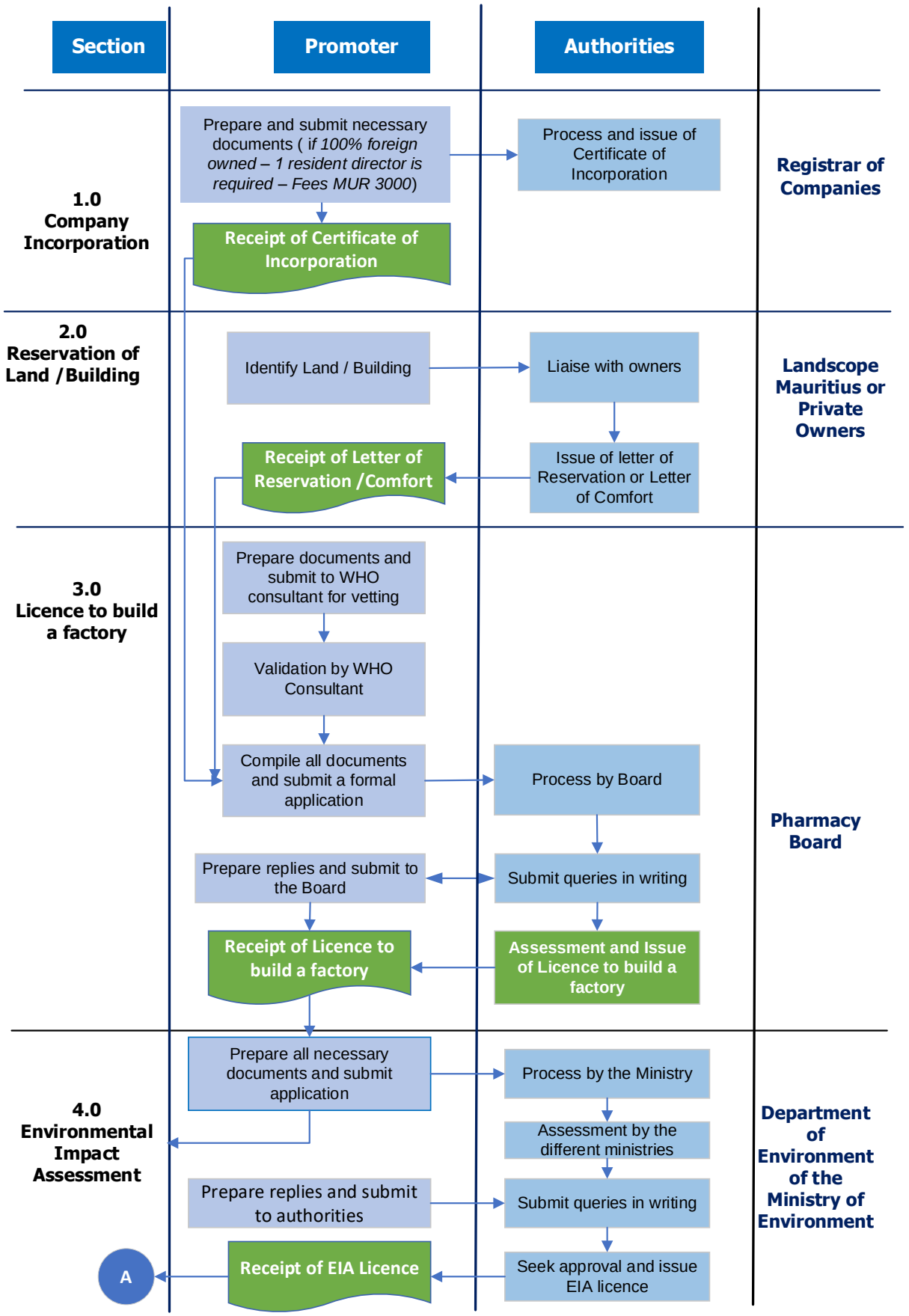
**** Note: Applicable fees are subject to revision by the Pharmacy Board and same can be adjusted accordingly.**

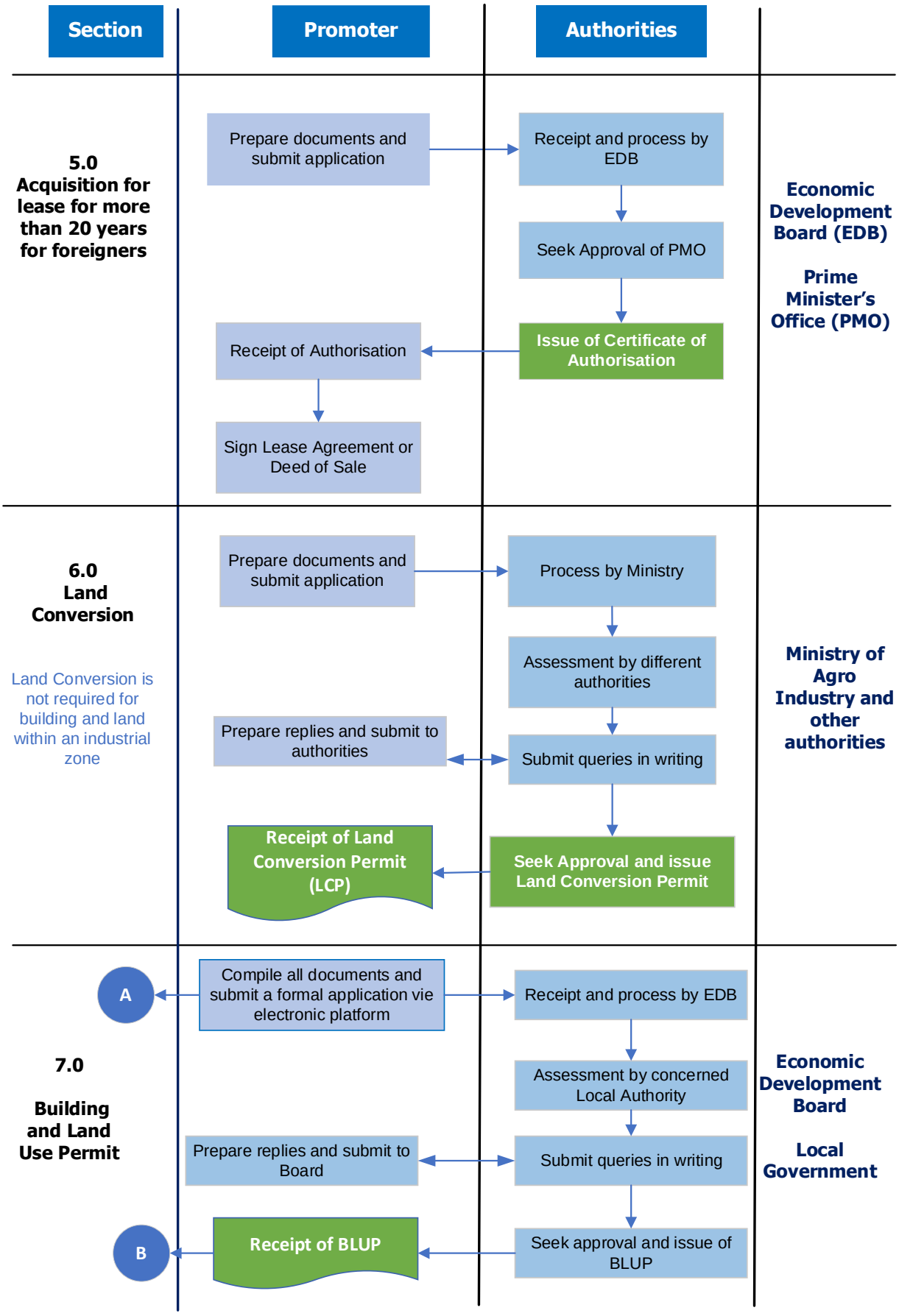
8 Sale of locally manufactured pharmaceutical products on local market

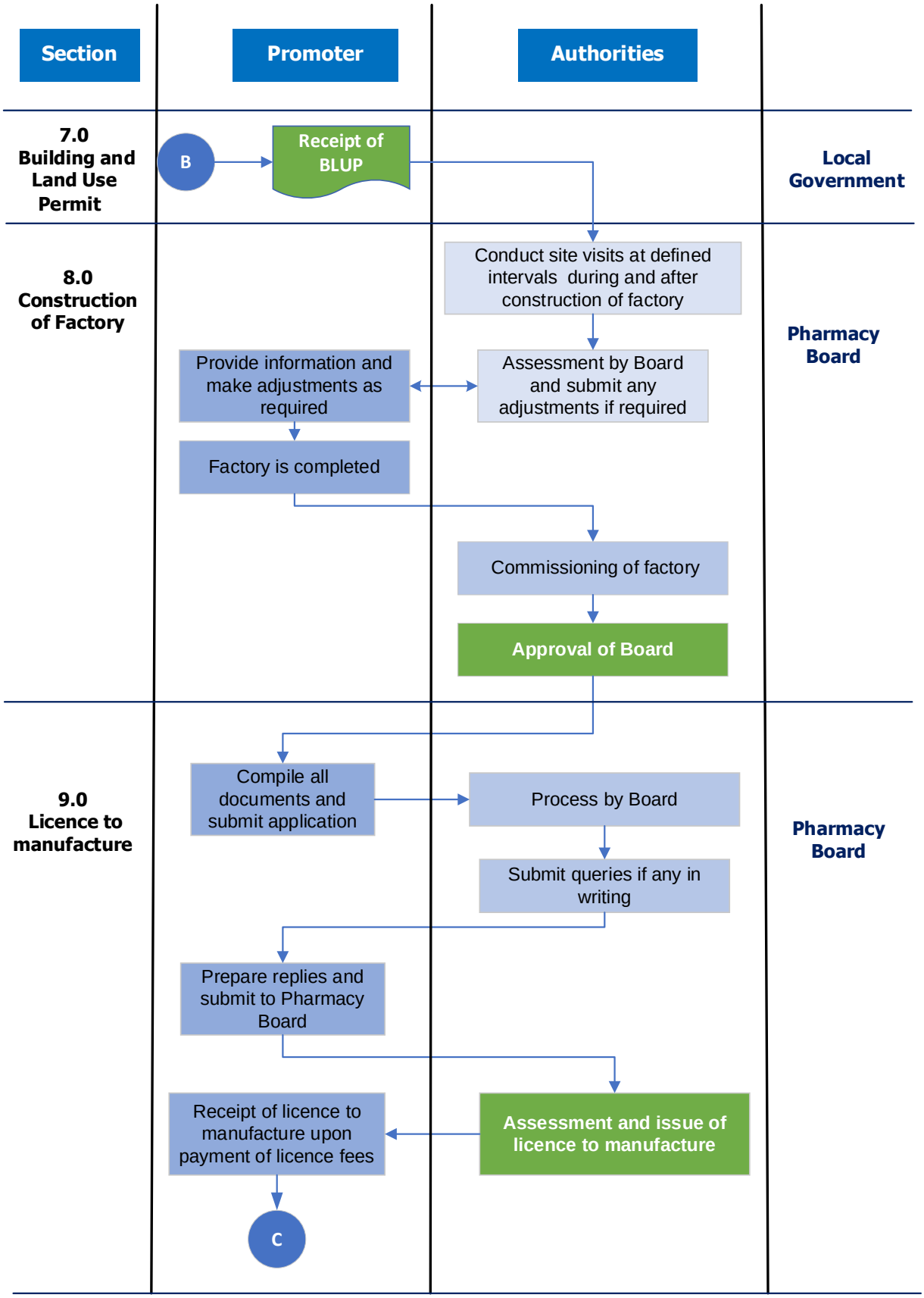
The sale of a locally manufactured pharmaceutical product on the local market is prohibited unless

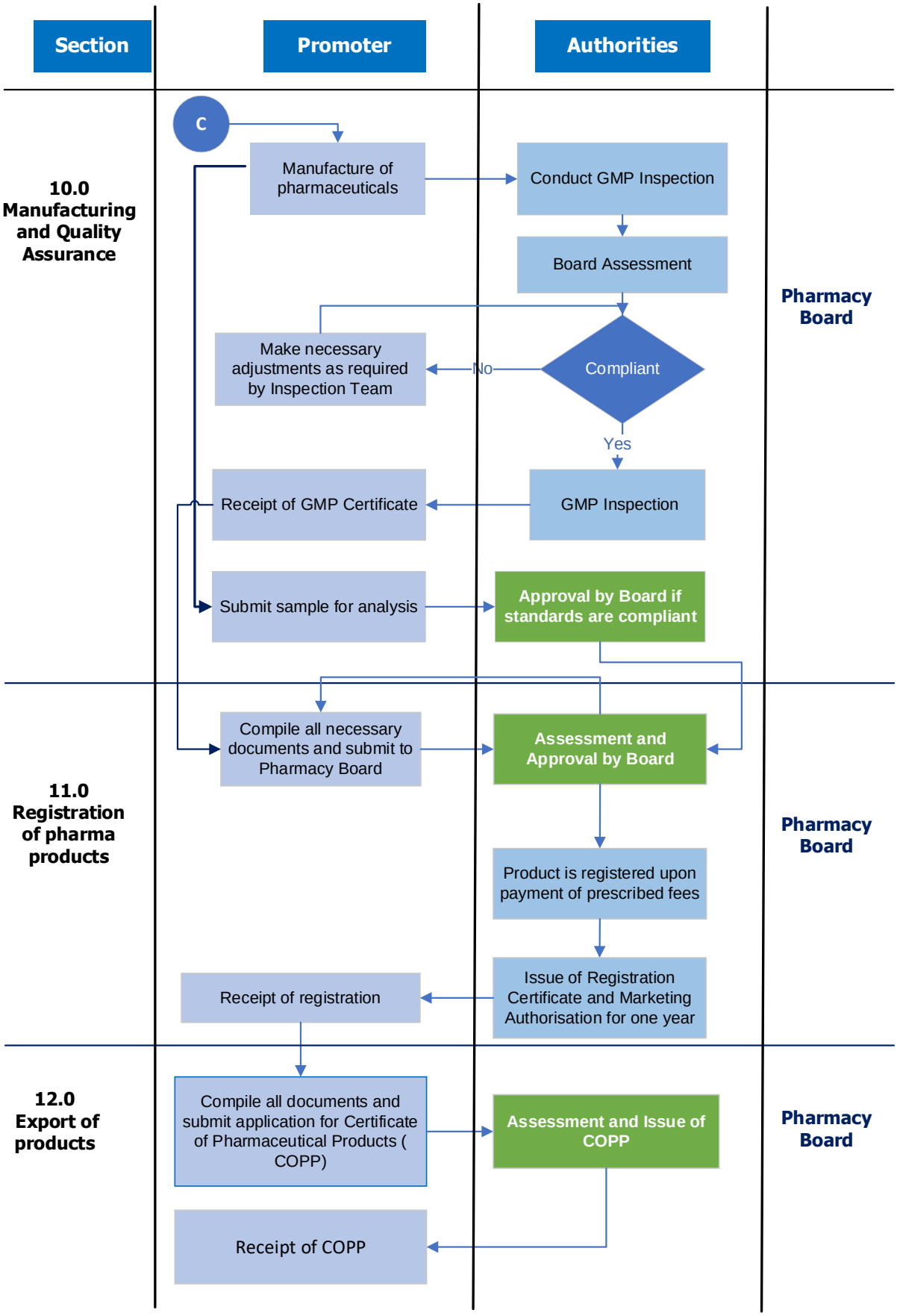
1) the licensee registered as a manufacturer under section 36 of the Pharmacy Act and
2) the pharmaceutical product is registered with the Board under section 36C.

9 Overview of relevant Permits and Licences




Section
Promoter
Authorities
5.0 Acquisition for lease for more than 20 years for foreigners
Prepare documents and submit application
Receipt and process by EDB
Seek Approval of PMO
Issue of Certificate of Authorisation
Receipt of Authorisation
Sign Lease Agreement or Deed of Sale
Economic Development Board (EDB)
Prime Minister's Office (PMO)
6.0 Land Conversion
Land Conversion is not required for building and land within an industrial zone
Prepare documents and submit application
Process by Ministry
Assessment by different authorities
Prepare replies and submit to authorities
Submit queries in writing
Receipt of Land Conversion Permit (LCP)
Seek Approval and issue Land Conversion Permit
Ministry of Agro Industry and other authorities
A
Compile all documents and submit a formal application vie electronic platform
Receipt and process by EDB
7.0 Building and Land Use Permit
Assessment by concerned Local Authority
Prepare replies and submit to Board
Submit queries in writing
B
Receipt of BLUP
Seek approval and issue of BLUP
Economic Development Board
Local Government


Section
Promoter
Authorities
7.0 Building and Land Use Permit
B
Receipt of BLUP
Local Government
8.0 Construction of Factory
Conduct site visits at defined intervals during and after construction of factory
Pharmacy Board
Provide information and make adjustments as required
Assessment by Board and submit any adjustments if required
Factory is completed
Commissioning of factory
Approval of Board
9.0 Licence to manufacture
Compile all documents and submit application
Process by Board
Pharmacy Board
Submit queries if any in writing
Prepare replies and submit to Pharmacy Board
Receipt of licence to manufacture upon payment of licence fees
Assessment and issue of licence to manufacture
C


Section
Promoter
Authorities
C
Manufacture of pharmaceuticals
Conduct GMP Inspection
Board Assessment
10.0 Manufacturing and Quality Assurance
Pharmacy Board
Make necessary adjustments as required by Inspection Team
No
Compliant
Yes
Receipt of GMP Certificate
GMP Inspection
Submit sample for analysis
Approval by Board if standards are compliant
Compile all necessary documents and submit to Pharmacy Board
Assessment and Approval by Board
11.0 Registration of pharma products
Pharmacy Board
Product is registered upon payment of prescribed fees
Issue of Registration Certificate and Marketing Authorisation for one year
Receipt of registration
12.0 Export of products
Compile all documents and submit application for Certificate of Pharmaceutical Products (COPP)
Assessment and Issue of COPP
Pharmacy Board
Receipt of COPP

Contacts:

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For any additional information kindly address your queries to the Pharmacy Board through the following email address: moh-pharm@govmu.org

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