External User Guide

Local Factory License Issuance

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1. Brief Overview

This manual is prepared to help applicants Apply for granting a Local Factory License Issuance.

After completing this manual, the applicant should be able to perform all activities related to Local Factory License Issuance on EDE Portal.

Please note: This service is only available to the **Local Manufacturers** Applicants.

2. Apply for Service

Portal users who have logged in successfully to EDE portal will be directed to Dashboard screen where they can apply to EDE's e-services.

For applicants to apply to their available services, they must go through the following process:

1. Create a new application
2. Complete application
3. Review application

The sections below will help user through the step-by-step process of applying to an application.

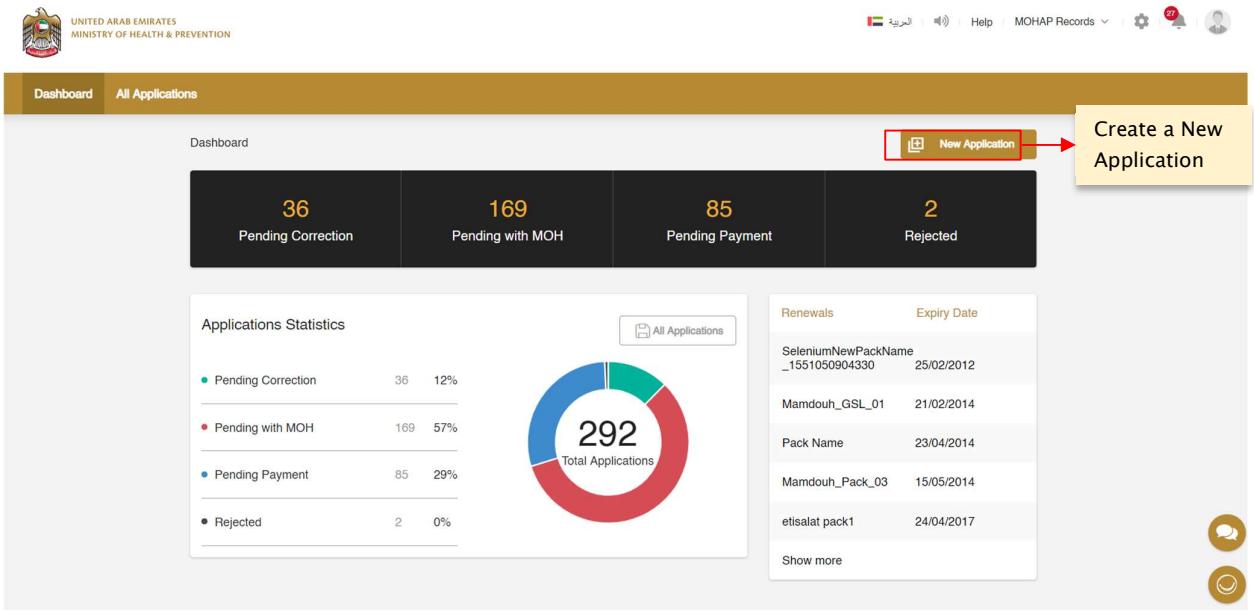


FIGURE A: DASHBOARD SCREEN

2.1 Create a New Application

To create a new application from the Applicant Portal, the user must do the following:

a. Click on the **New Application**
b. Select **Local Medical Factory** ⇨ **Registration** ⇨ **Local Factory License Issuance.**
c. Click Create Application button

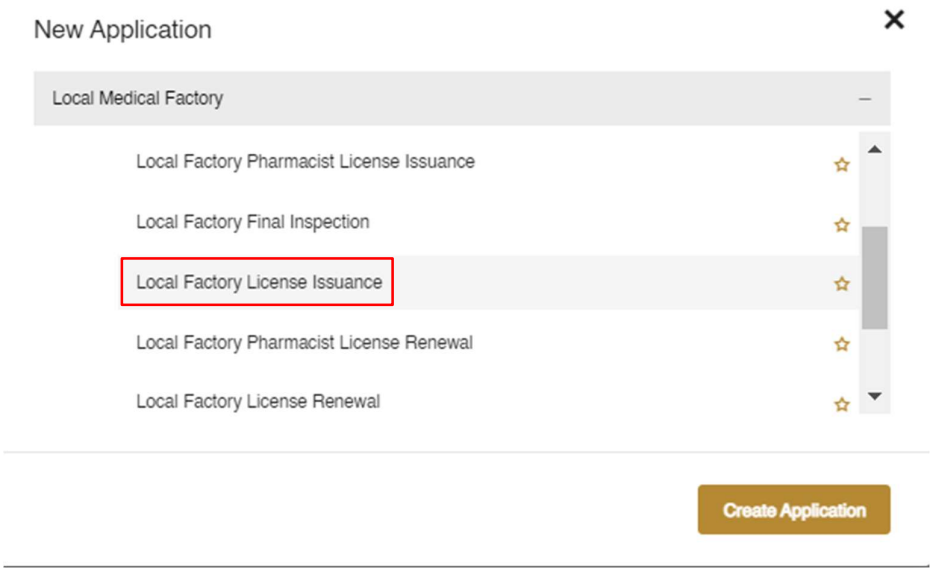


FIGURE B: NEW APPLICATION SCREEN

To complete a Local Factory License Issuance application, the applicant must fill the following sections:

1. Search by Final Inspection Application Number
2. Attachments.

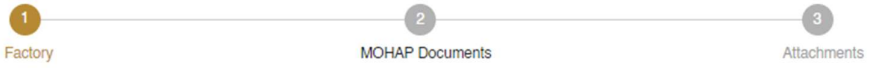


FIGURE C: PROGRESS BAR

2.1.1 Search Completed Final Inspection Application Number

Applicants should search by the Local Factory Final Inspection Application Number.

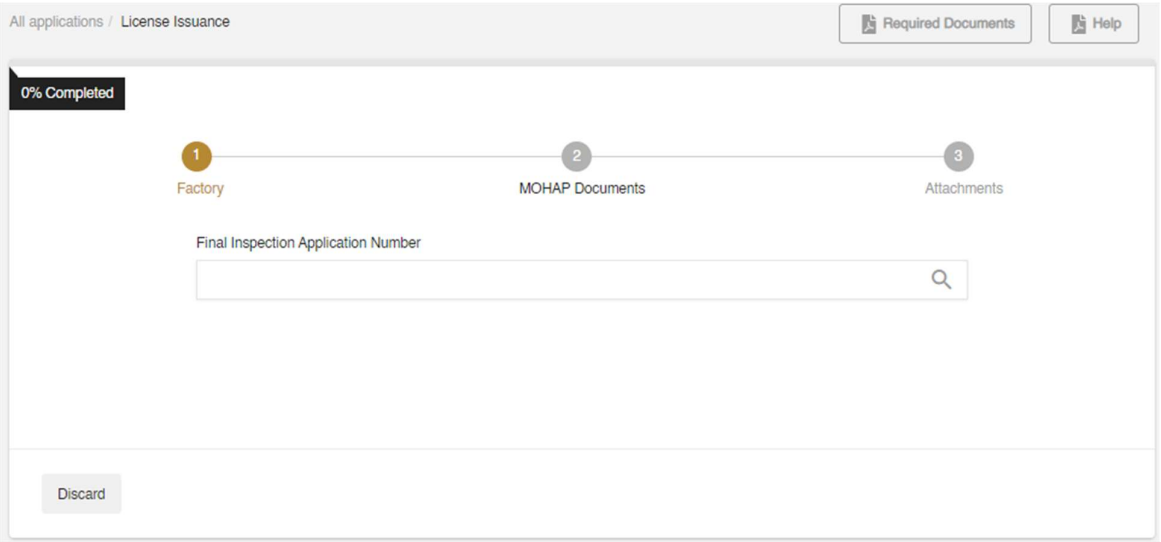


FIGURE D: SEACRCH FINAL INSPECTION APPLICATION SCREEN

The below Local Factory details will be auto-populated:

- Factory Name(English)
- Factory Name(Arabic)
- Emirate
- City(English)
- City(Arabic)
-Address / Location(English)
- Address / Location(Arabic)
- Building/Location Owned By
- P.O.Box (Optional)
- Telephone (Optional)
- Fax (Optional)
- Website (Optional)
-Categories
- Remarks (Optional)

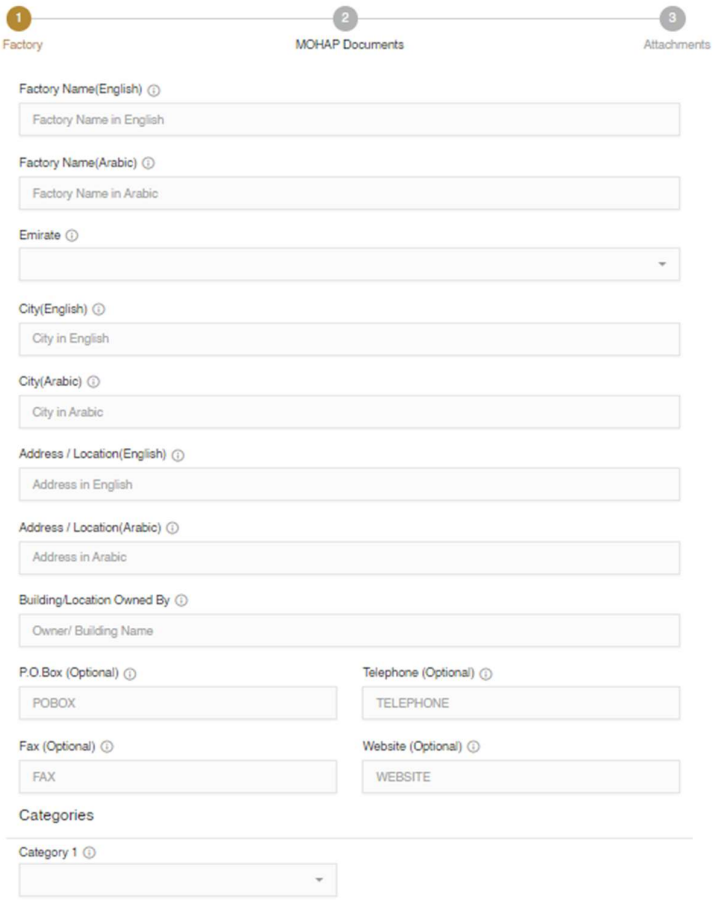


FIGURE E: FACTORY DETAILS SCREEN

2.1.2 EDE Documents

It is not required from the applicant to take any action on this screen, EDE Documents will be uploaded by EDE officers.

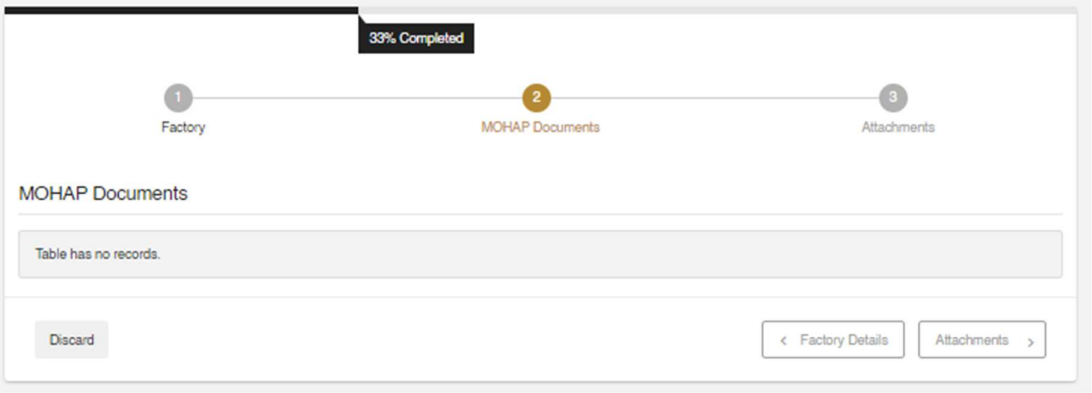


FIGURE F: EDE DOCUMENTS SCREEN

Applicants can move to the next section by clicking Attachments button.

2.1.3 Attachments Screen

Below are the attachments the applicant must submit before moving to the next section.

a. Site Master File
b. Technical Manager Appointment Letter
c. Technical Manager EDE License
d. Production Manager Appointment Letter
e. Production Manager EDE License
f. Quality Assurance Manager Appointment Letter
g. Quality Assurance Manager EDE License (Optional)
h. Quality Control Manager Appointment Letter (Optional)
i. Quality Control Manager EDE License (Optional)
j. Pharmacists' Licenses EDE License (Optional)
k. GMP Certificate (Optional)
l. List Of Employees In Each Department And The Responsibility (Optional)

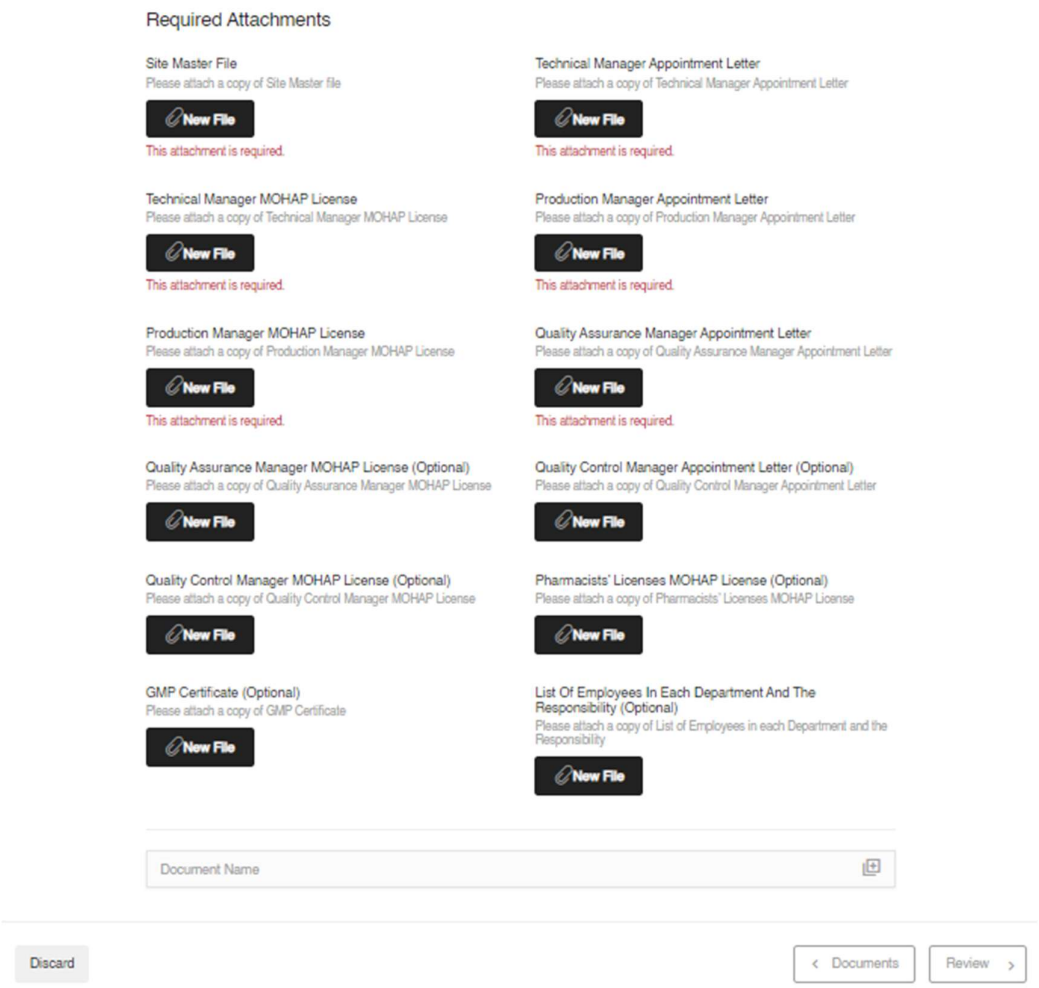


FIGURE G: ATTACHMENTS SCREEN

2.1.4 Review Application

Review Application After the applicant completes filling all application details, they must click on the Review button to proceed with application submission. Once the applicant clicks the Review button, they will be redirected to Review screen where they are able to perform the following actions:

a. Edit Application

b. Discard Application

c. Read & Accept General Terms & Conditions

d. Submit Application

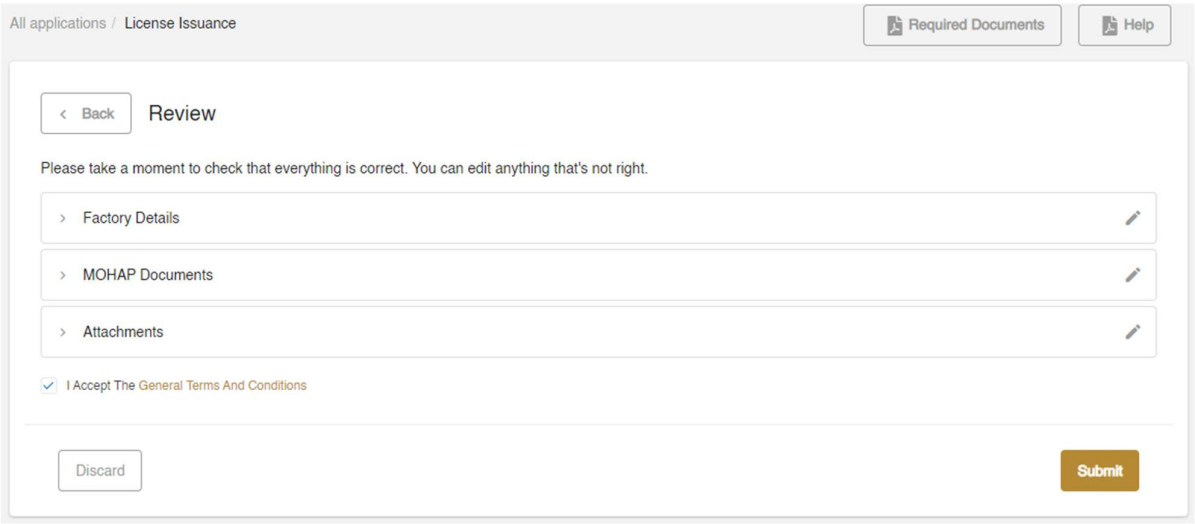


FIGURE H: REVIEW APPLICATION SCREEN

Application should be created on “All Applications” List, Applicant will receive all Officer Request and Status Update Notifications by Email.

2.2 Checkout

After an application has been submitted, EDE officer will be able to review the application and return it back for payment:

- Application Fees: AED 50,000 per Application