USER MANUAL

DRUG REGULATORY AUTHORITY OF PAKISTAN (DRAP)

TABLE OF CONTENTS

ABSTRACT

Welcome to the Drug Regulatory Authority of Pakistan User Manual!

Pakistan Single Window (PSW) Drug Regulatory Authority of Pakistan User Manual is your step-by-step guide on how to obtain Entity registration, Drugs Sales License, Drugs Manufacturing License, Drugs Import License, and Release Order through the PSW portal. This user manual provides background of the PSW system while describing its key features.

1. INTRODUCTION

Pakistan Single Window (PSW) is an electronic portal that allows parties involved in cross border trade and transport to lodge standardized information and documents using a single- entry point to fulfil all import, export, and transit related regulatory requirements. The information is transmitted electronically and individual data elements for clearance and regulatory approvals need only to be submitted once. Use of the PSW portal is allowed to authorized users who have completed the subscription process and in case of subscription is expired, they have initiated and concluded renewal process. Once subscribed and registered with PSW, you can access the PSW to perform cross border trade and transit related activities including online payment of taxes and OGA fees.

The PSW aims to simplify your cross-border trade and transport experience. This new platform will facilitate the trader/customs agent to apply for the Entity registration, Drugs Sales License, Drugs Manufacturing License, Drugs Import License, and Release Order from the Drug Regulatory Authority of Pakistan (DRAP). The application for the same shall be received and processed through the PSW portal. Similarly, sharing of messages and documents required for processing of regulatory approval requests shall be enabled by the PSW.

This new platform will automate all trade-related business processes of DRAP (phase-wise), including registrations. With the PSW system going live, there will be no DRAP office visits and manual submission of applications for the issuance of regulatory approvals. The processing of application will be done online, where you can have a clear visibility of the action being performed on the same.

2. BACKGROUND

As a signatory to the WTO's Trade Facilitation Agreement (2015), Pakistan has notified the establishment of a 'National Single Window' (NSW) as a 'Category C' commitment with effect from 22nd February 2017. To implement NSW the Government of Pakistan has promulgated the Pakistan Single Window Act, 2021 while declaring Pakistan Customs as the Lead Agency. Pakistan Customs has established a dedicated PSW Company (PSWC), as a not-for-profit Company under Companies Act, 2017, to implement the PSW program. The PSWC has been designated as the Operating Entity under the PSW Act for developing and maintaining the PSW portal in collaboration with 77 different public sector entities involved in regulation of cross border trade in Pakistan. The PSWC will digitize the processes of public sector entities, related to regulation of international trade. This will not only reduce the time and costs but also increase compliance and immensely benefit economic operators like importers, exporters, freight forwarders, clearing agents, shipping companies, transporters etc. The implementation of the PSW program will also enhance government controls and transparency. By creating a national electronic trade and logistics platform the PSW will help Pakistan integrate better into the regional and global single window systems. It will facilitate integration into global value chains and enable Pakistan to become hub for regional and international transit and trade.

3. SALIENT FEATURES OF DRAP MODULE

o A complete solution for online filling and processing of applications.

o It caters to all the needs of DRAP related to processing Entity registration, Drugs Sales License, Drugs Manufacturing License, Drugs Import License, and Release Order.

o A complete and comprehensive log of the activities on the trader's online request of registrations will be visible to the trader/custom agent in the system.

o The Dynamic User Management System provided to the DRAP will ensure proper performance monitoring against agreed performance benchmarks and key performance indicators.

o Communication between the officers and traders/custom agents will be done through the PSW system.

4. SYSTEM REQUIREMENTS

o To use PSW Portal on Windows®, the subscriber will require:

    a. Google Chrome Browser.

    b. Windows 7, Windows 8, Windows 8.1, Windows 10 or later

    c. An Intel Pentium 4 processor or later that's SSE3 capable.

o To use PSW Portal on Mac®, the subscriber will need:

    d. Google Chrome Browser

    e. OS X El Capitan 10.11 or later.

5. STEP BY STEP PROCESS

5.1. USER LOGIN

i. Please visit ''www.psw.gov.pk" and click on the 'Login' button.
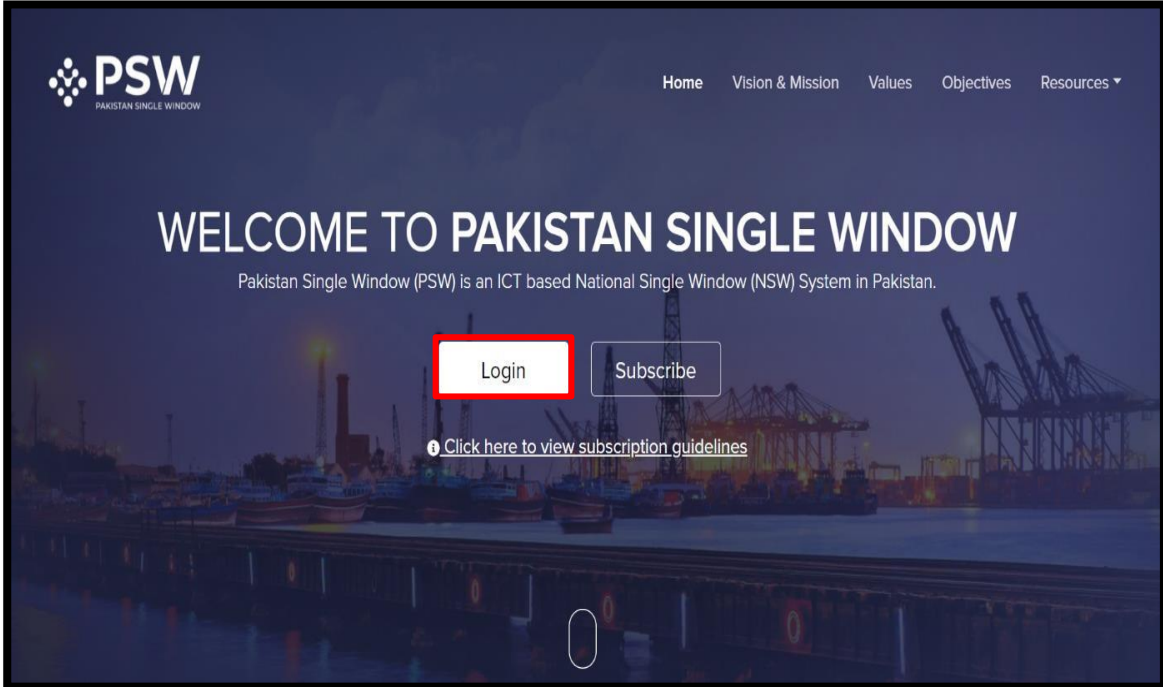
Figure 1

ii. After clicking on the login button, you will be redirected to the login interface. Here, you will be required to enter your login credentials.
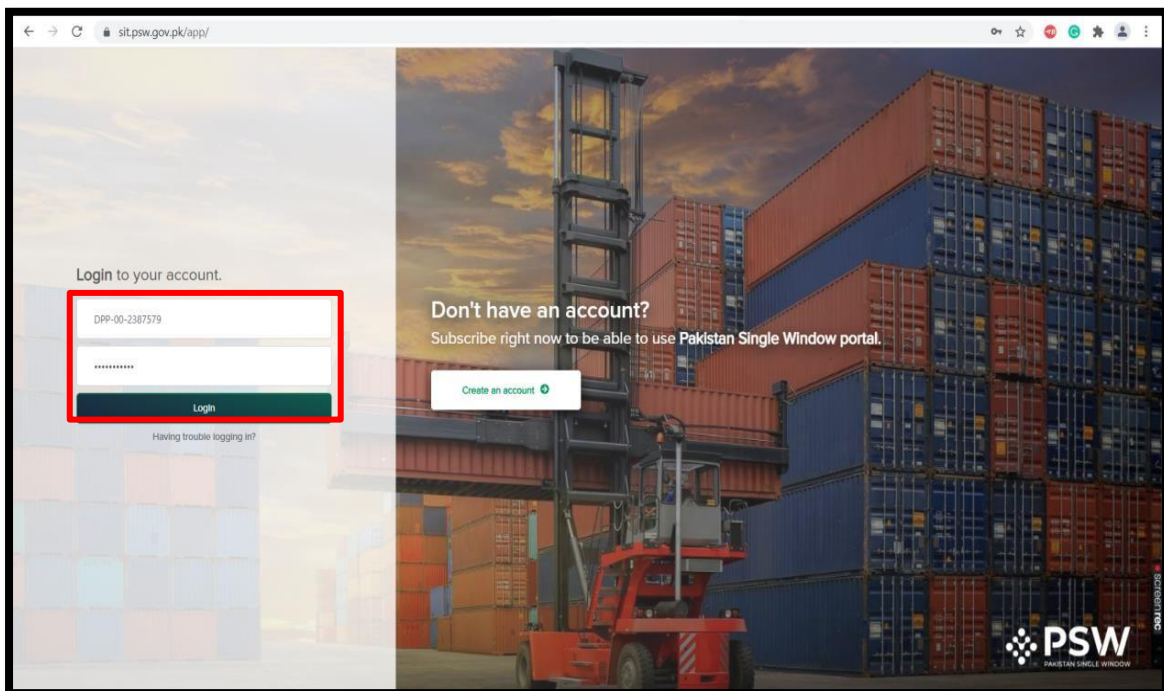
Figure 2

5.2. ENTITY REGISTRATION

i. Upon successful log-in, a dashboard will appear, click on the 'Registration' button.
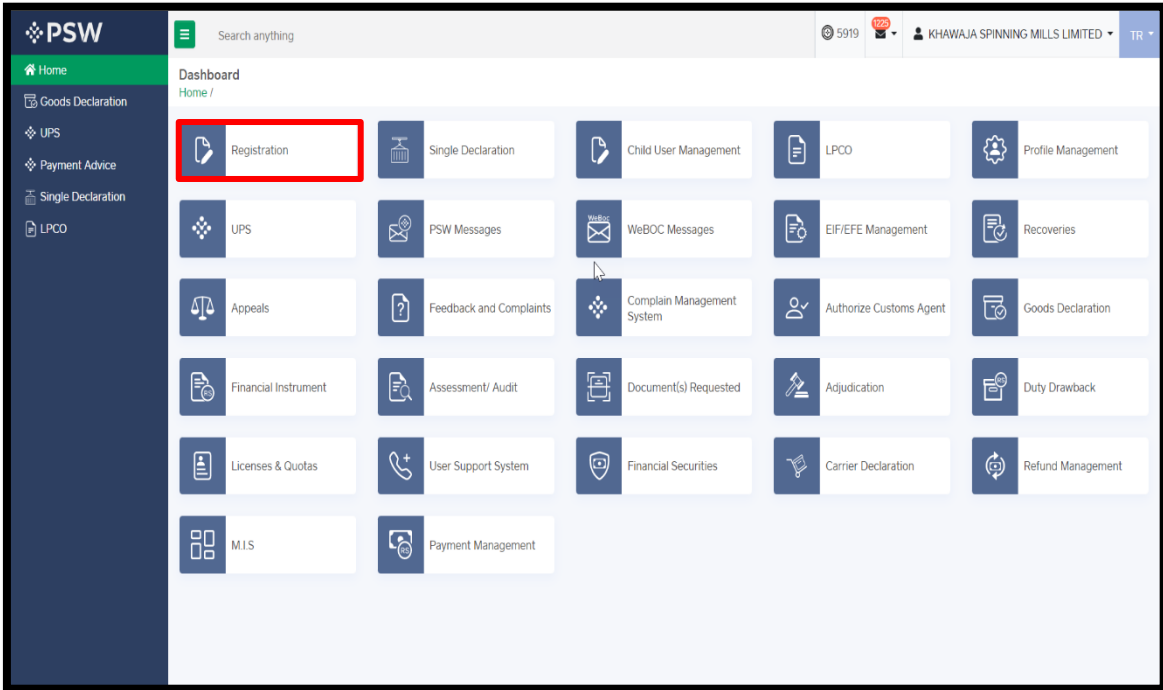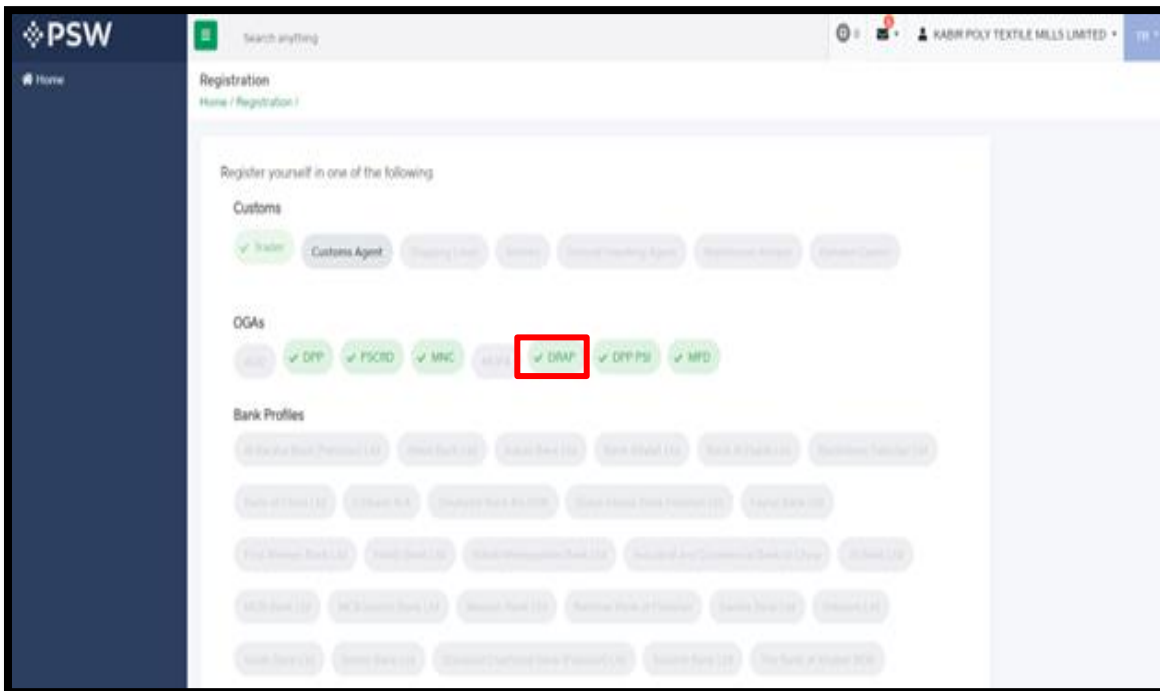

Figure 3

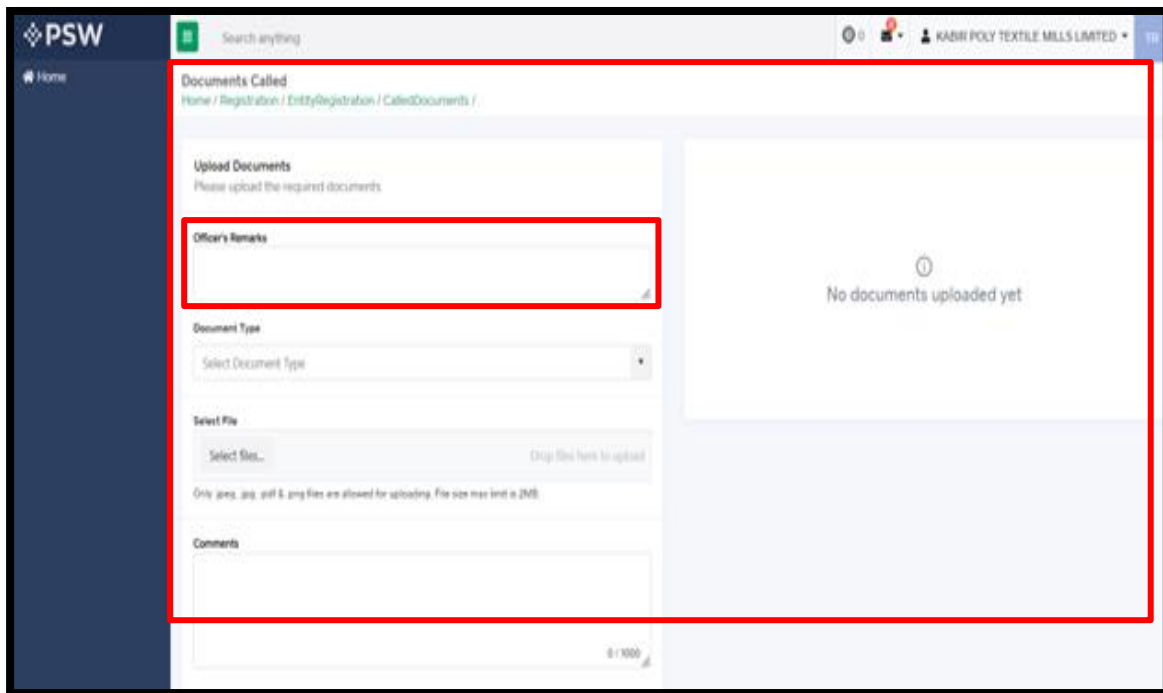ii. Under the OGAs grid, select 'DRAP'.
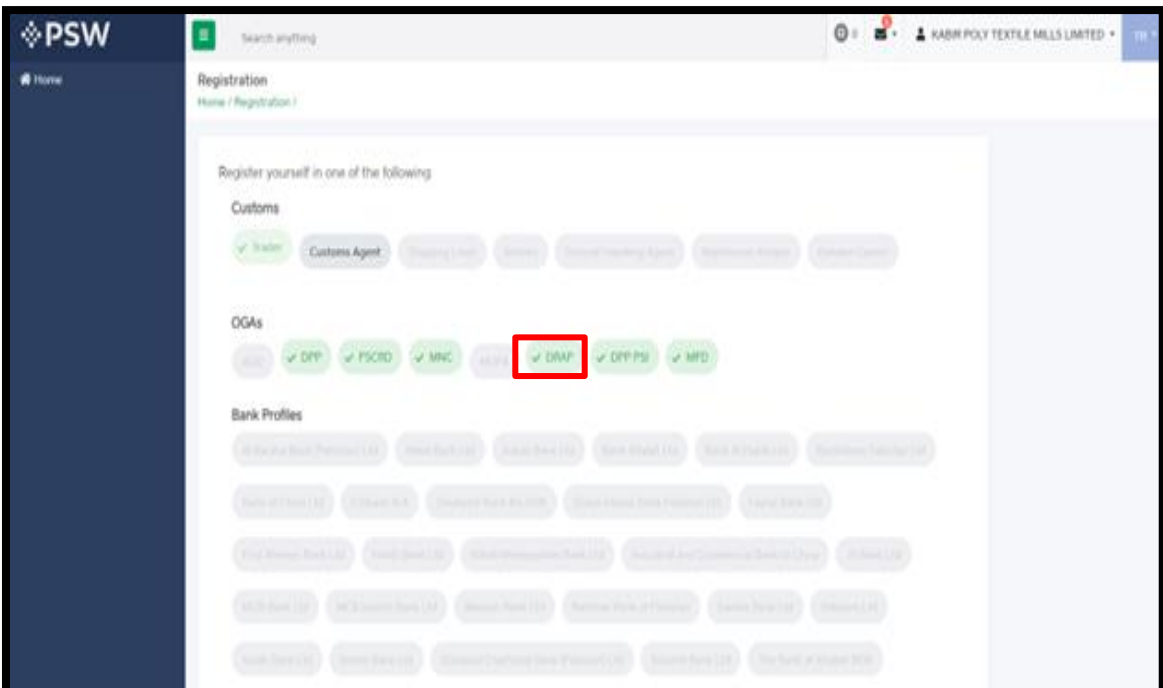
Figure 4

iii.   Click on the "Entity Registration' button.
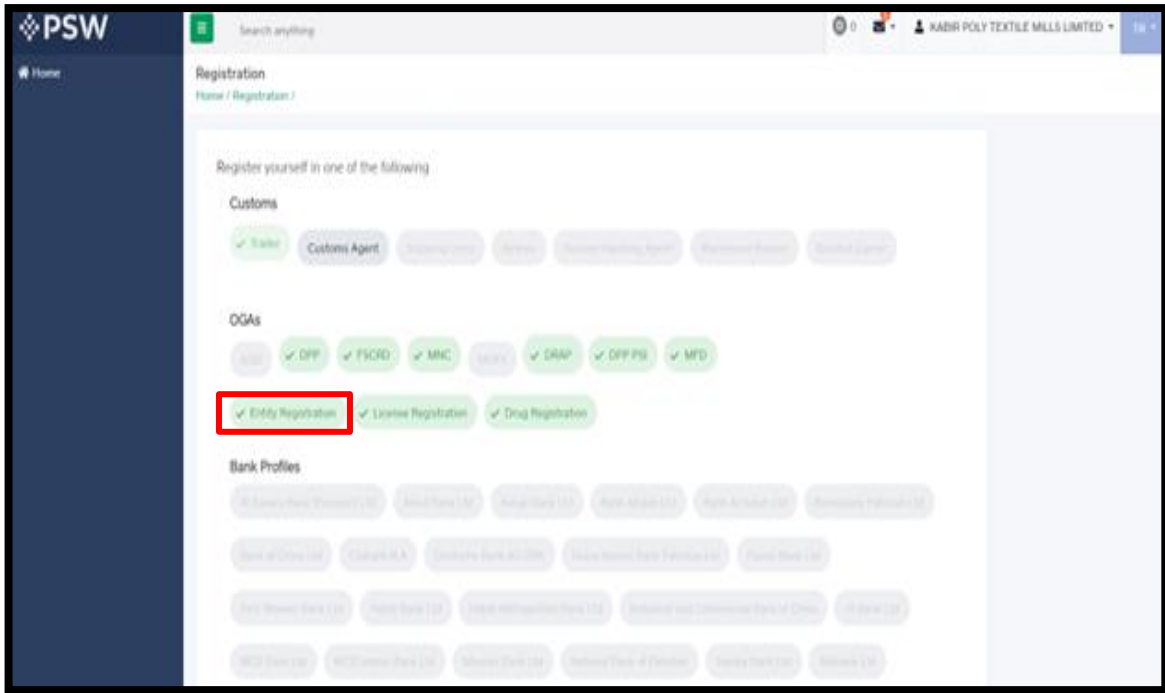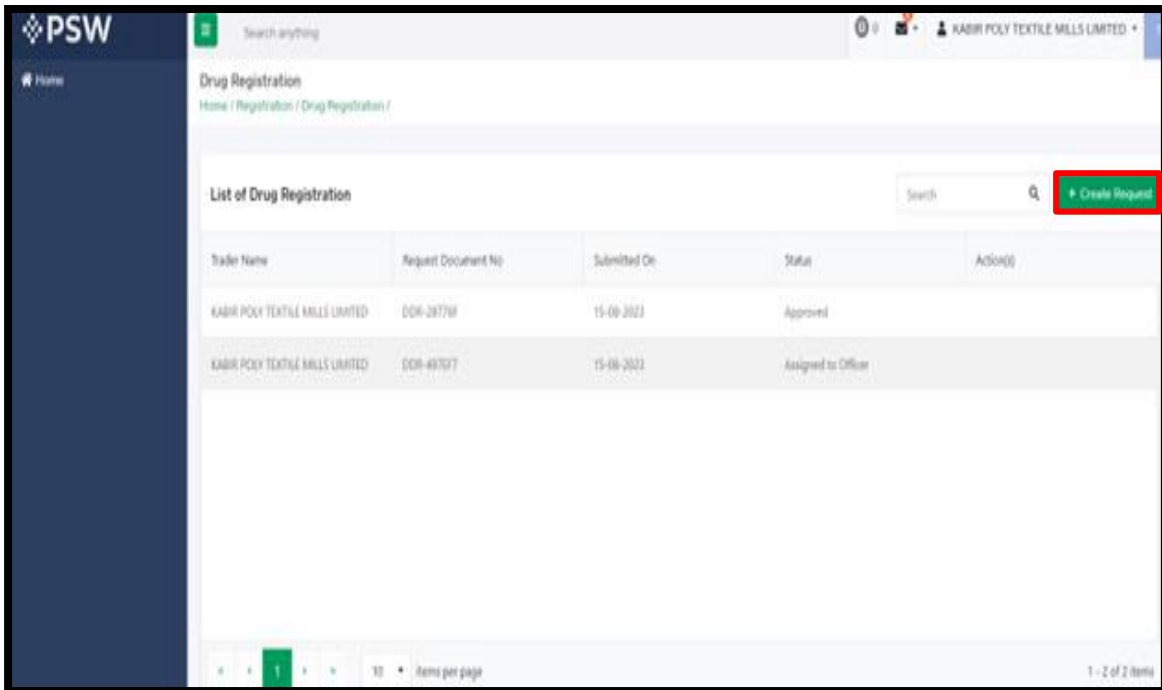

Figure 5

iv.   Click on the 'Create Request' button.
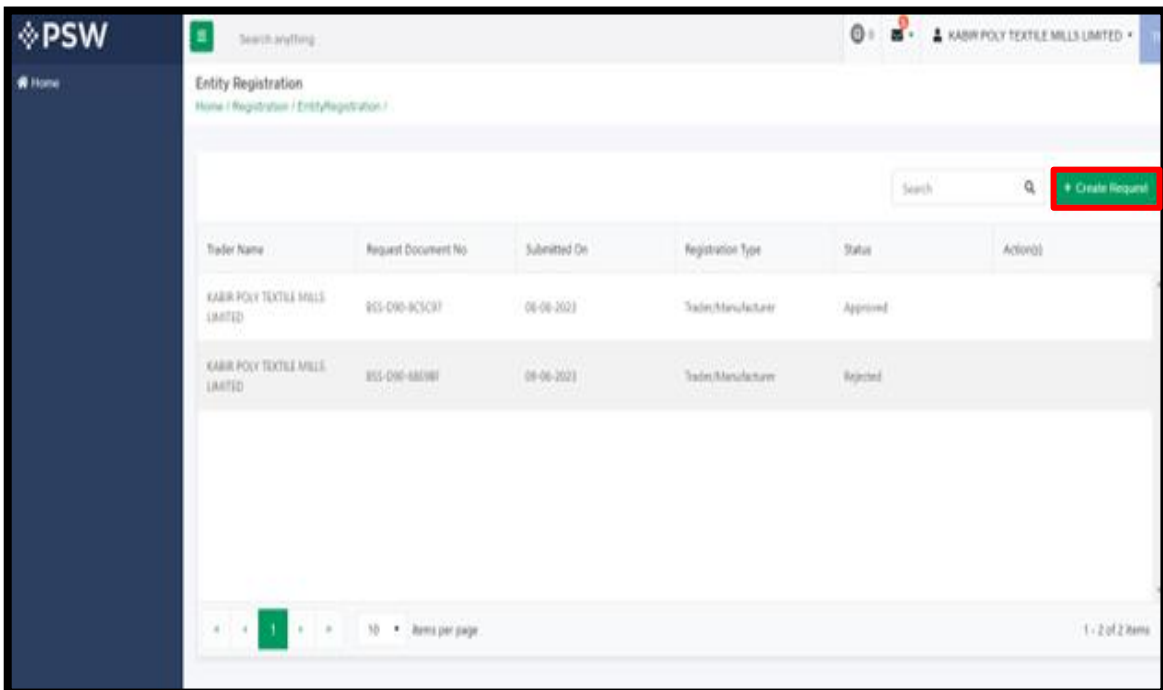
Figure 6

v. Select the 'Type of Registration' and press "Confirm" button.
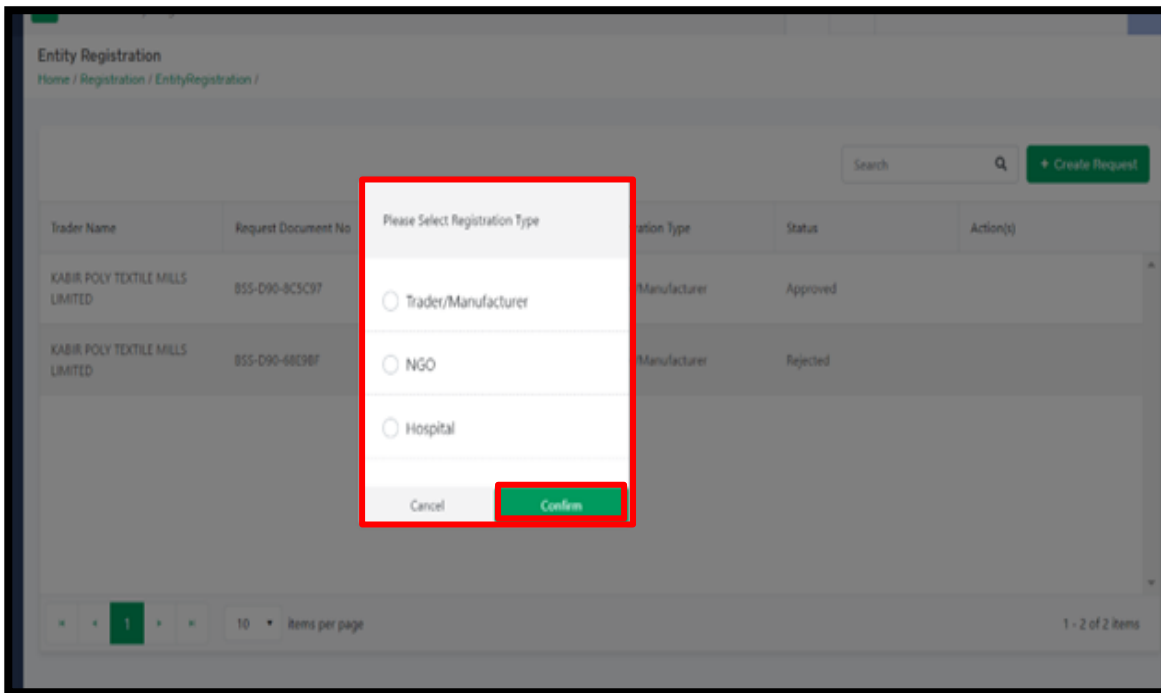
Figure 7

vi. Select the 'City' and 'Type of Partnership' from the dropdown list.
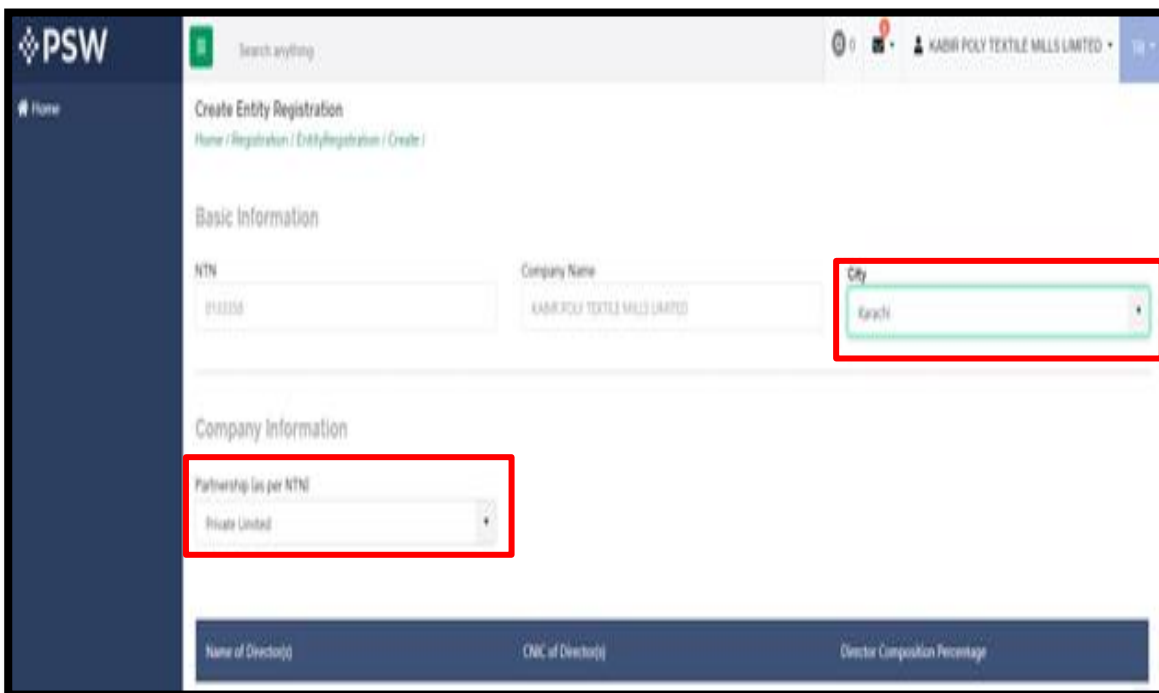
Figure 8

vii. Select the 'Document' type from the dropdown list and upload it by clicking on the 'Select Files' button. Now press 'Submit' button to complete the request.
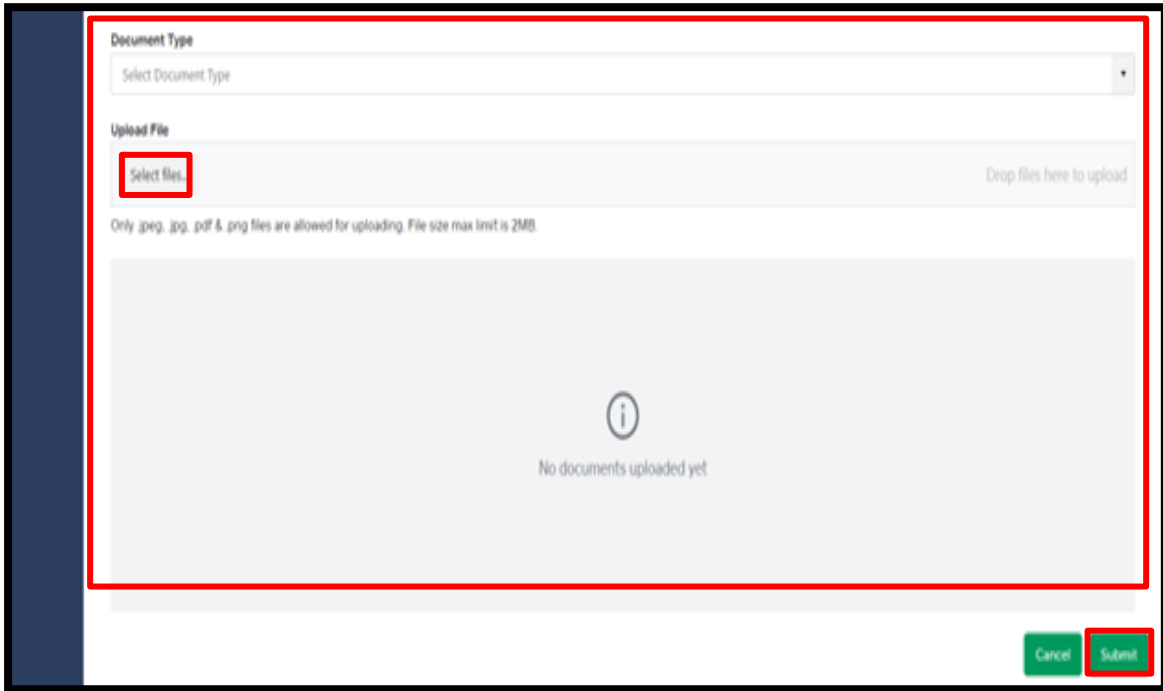
Figure 9

viii. After Submission, you can also view the status of your request(s) whether it is Submitted, Assigned to Officer, Approved, or Rejected.
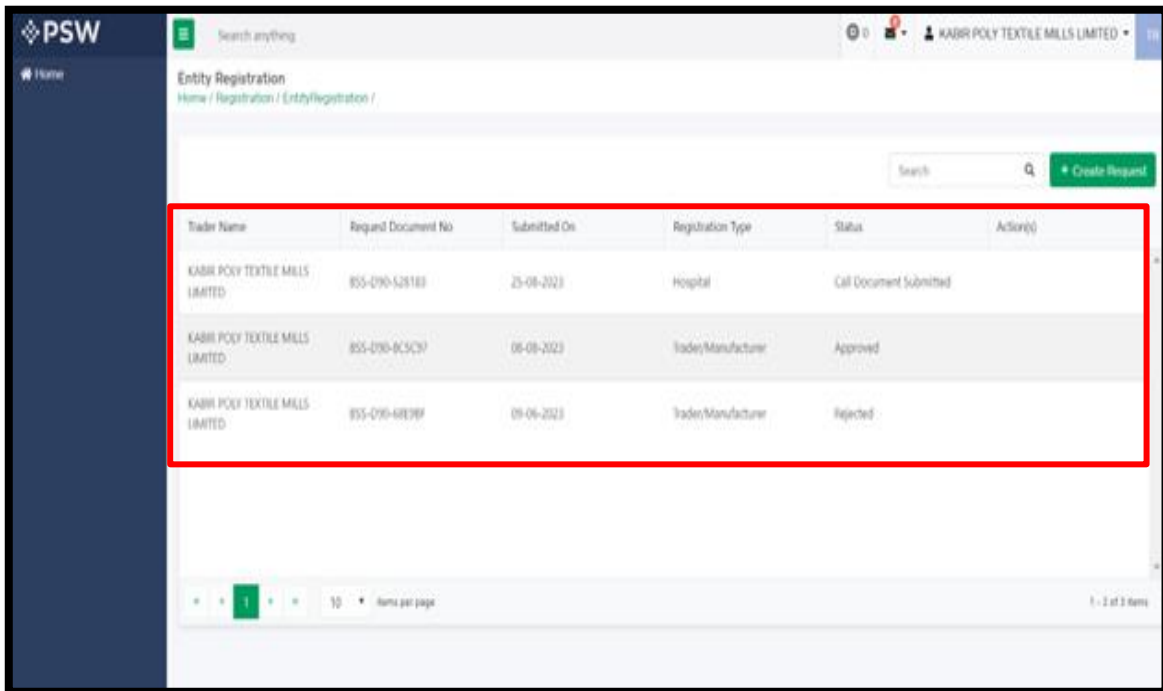
Figure 10

ix. If the documents are called by the officer, you can submit the required documents by clicking on the 'Called Documents' screen. Here you can also view the remarks added by the officer.
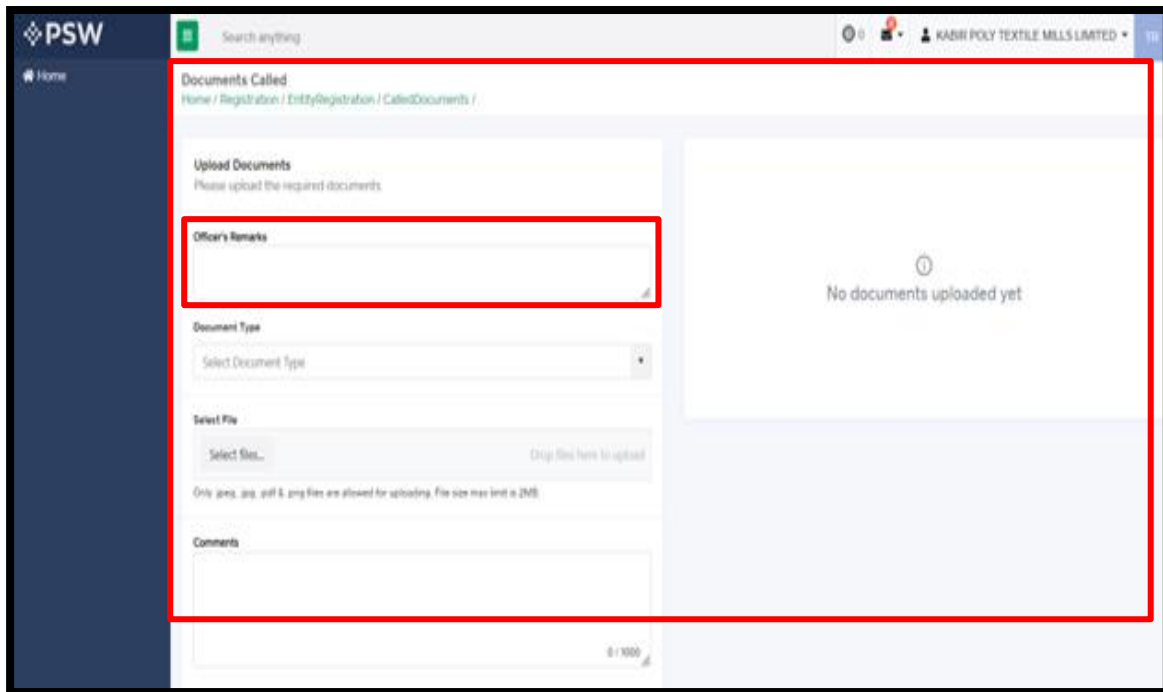
Figure 11

5.3. DRUG SALES LICENSE REGISTRATION

i.   Upon successful log-in, a dashboard will appear, click on the 'Registration' button.
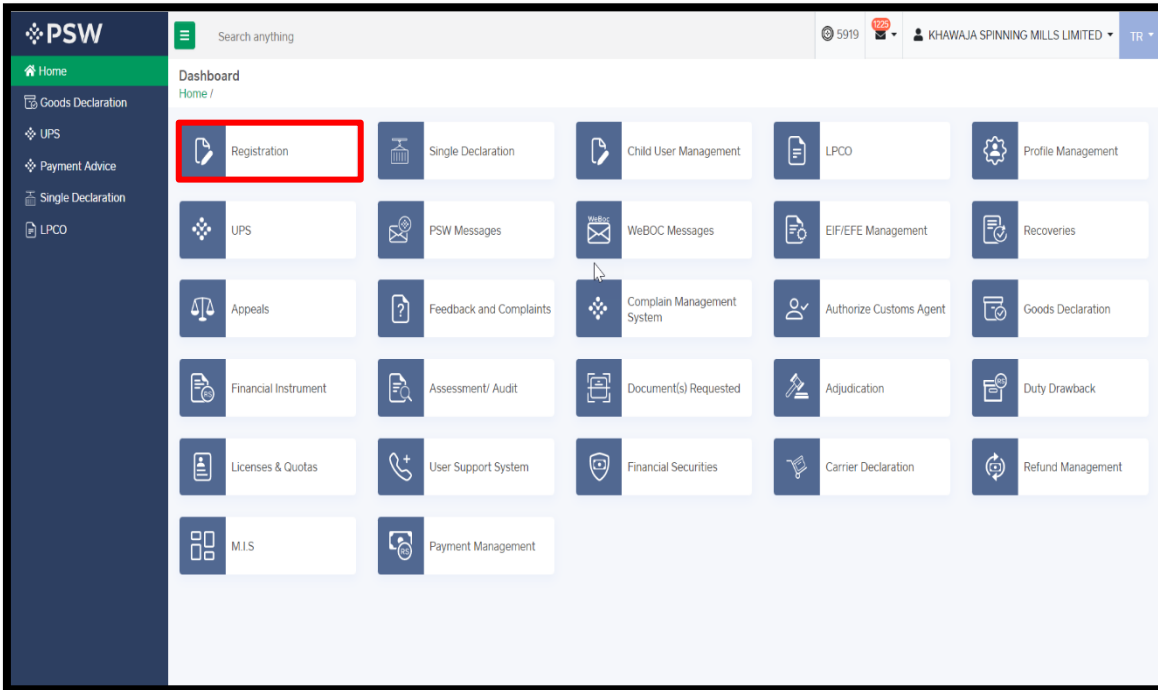
Figure 12

ii.   Under the OGAs grid, select 'DRAP'.
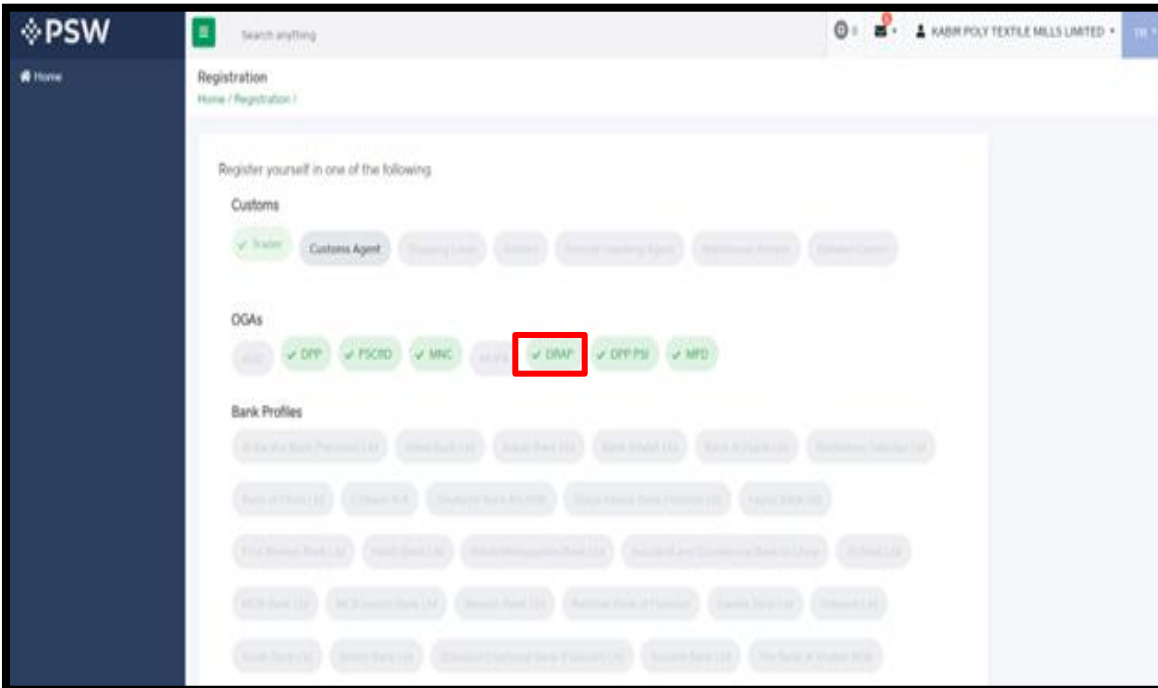
Figure 13

iii.   Click on the "License Registration' button.
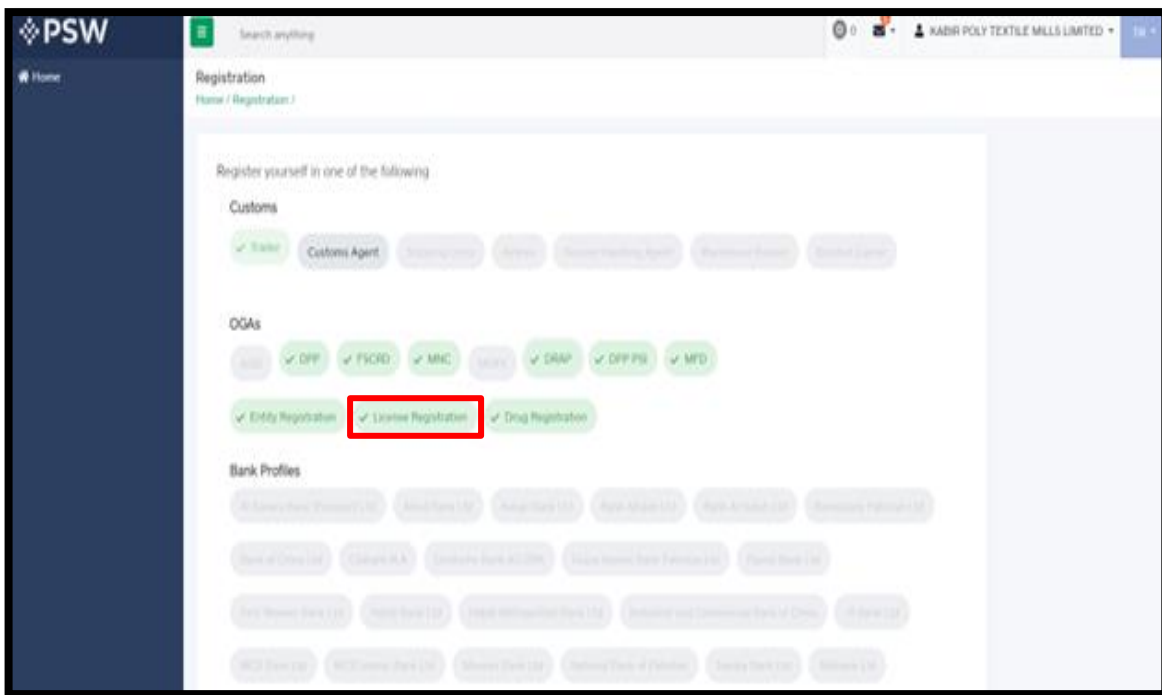
Figure 14

iv.   Click on the 'Drugs Sale License' button.
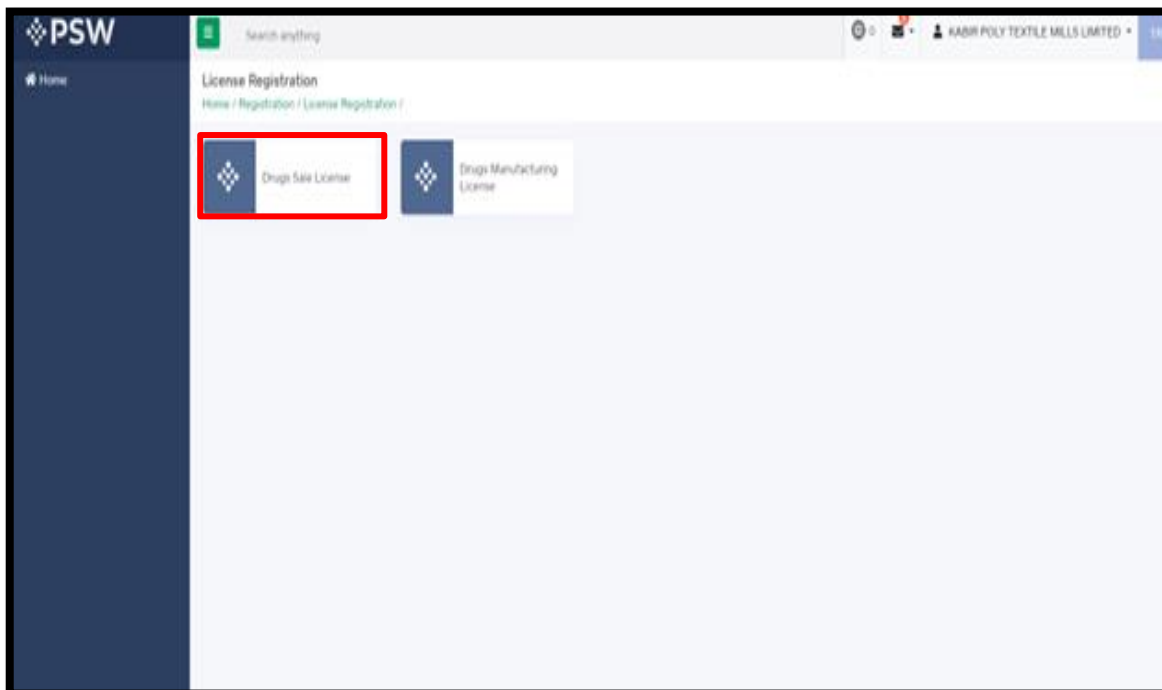
Figure 15

v.   Click on the 'Create Request' button.
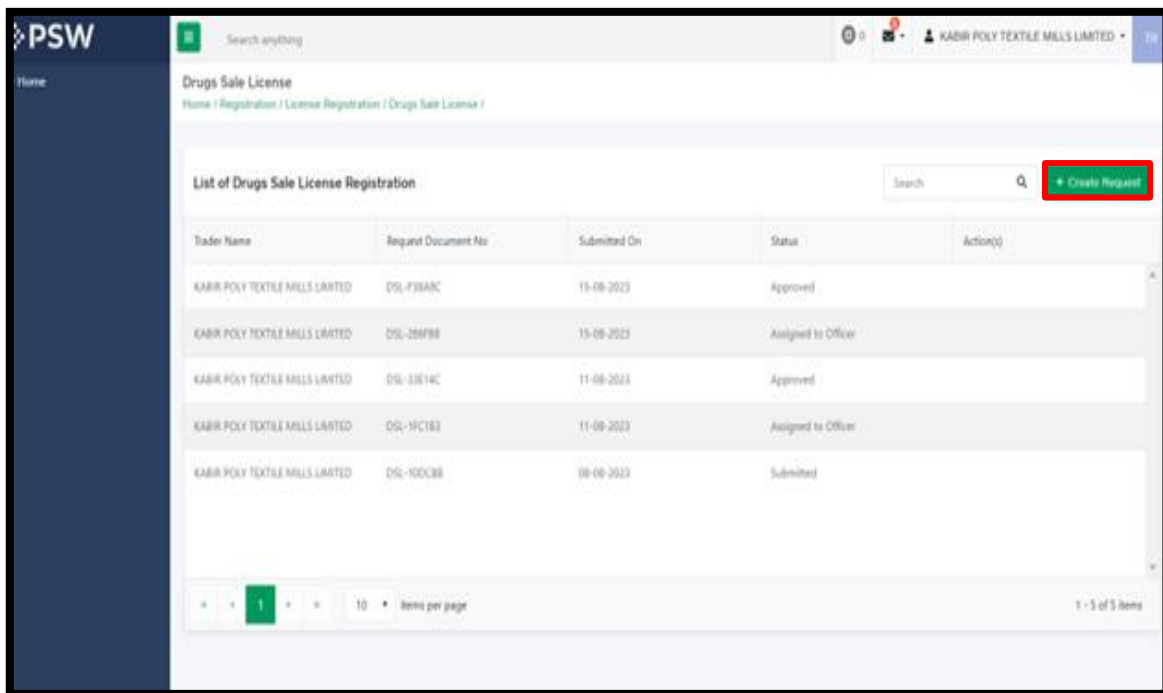
Figure 16

vi.   Provide the required information.
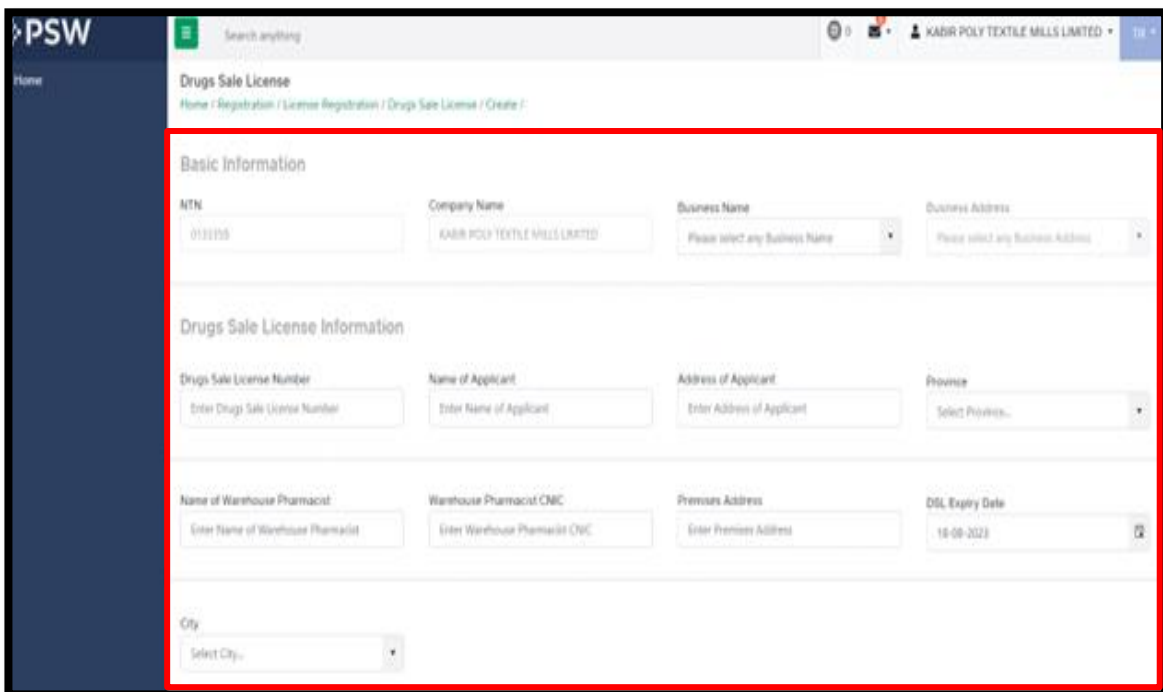
Figure 17

vii.   Select the 'Document' type from the dropdown list and upload it by clicking on the 'Select Files' button. Now press 'Submit' button to complete the request.

Figure 18

viii.   After Submission, you can also view the status of your request(s) whether it is Submitted, Assigned to Officer, Approved, or Rejected.

Figure 19

x.   If the documents are called by the officer, you can submit the required documents by clicking on the 'Called Documents' screen. Here you can also view the remarks added by the officer.
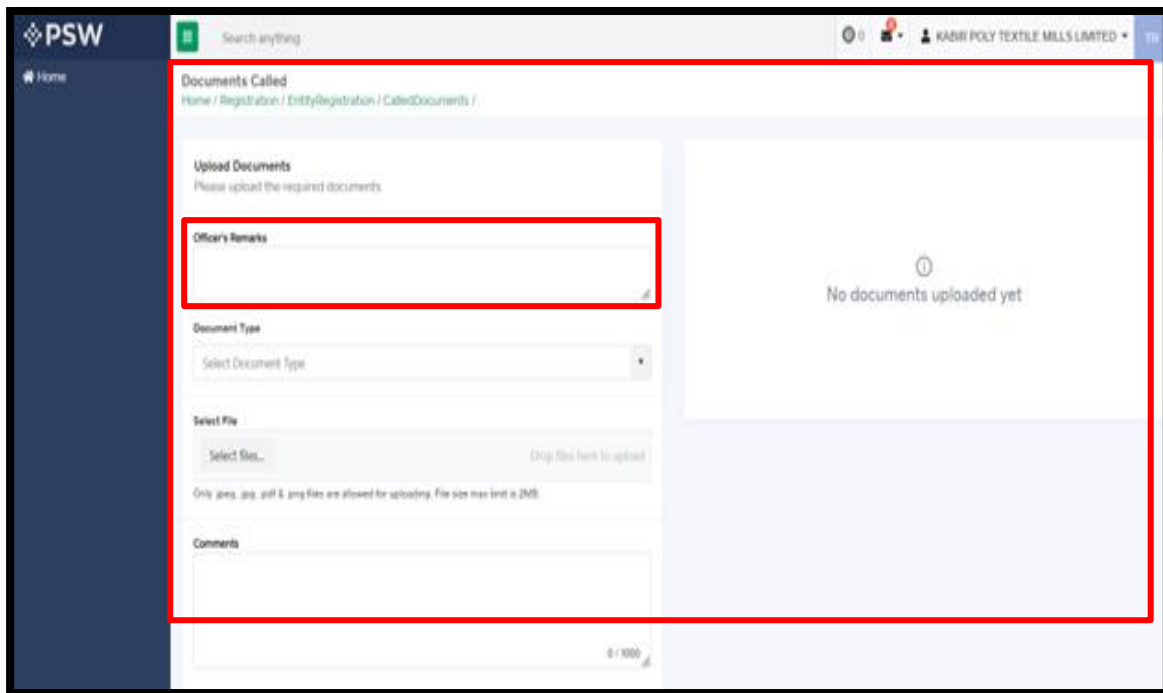
Figure 20

5.4. DRUG MANUFACTURING LICENSE REGISTRATION

i.   Upon successful log-in, a dashboard will appear, click on the 'Registration' button.
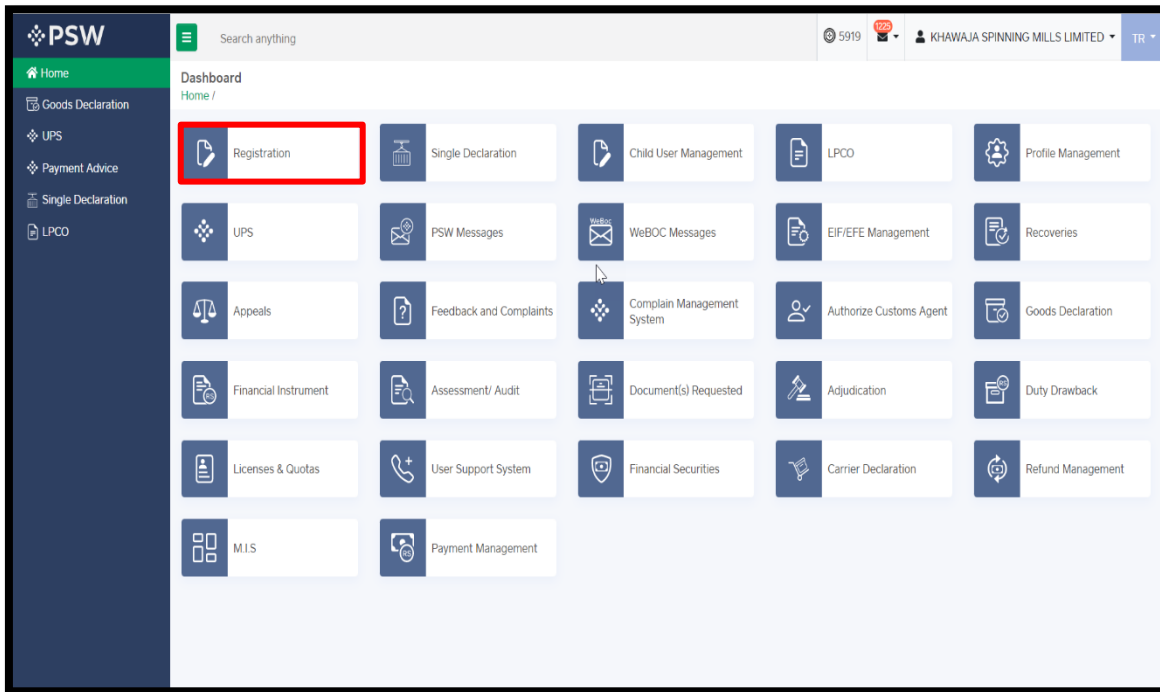
Figure 21

ii.   Under the OGAs grid, select 'DRAP'.

Figure 22

Copyright © Pakistan Single Window

iii.   Click on the "License Registration' button.
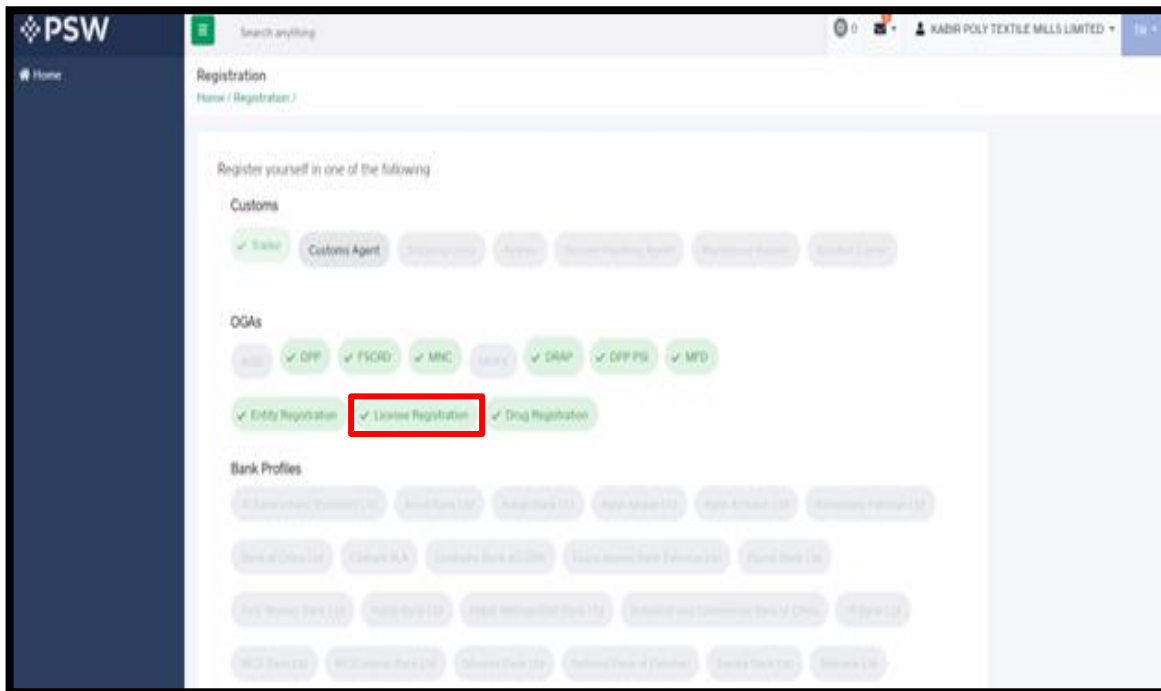
Figure 23

iv.   Click on the 'Drugs Manufacturing License' button.
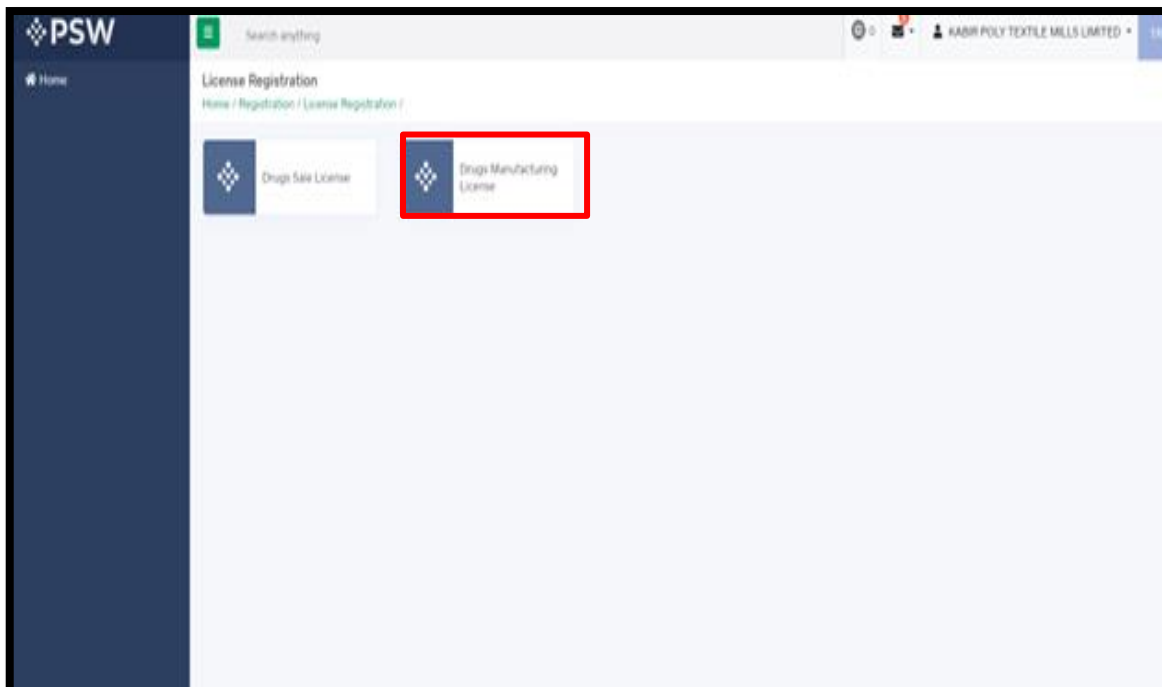
Figure 24

v. Click on the 'Create Request' button.
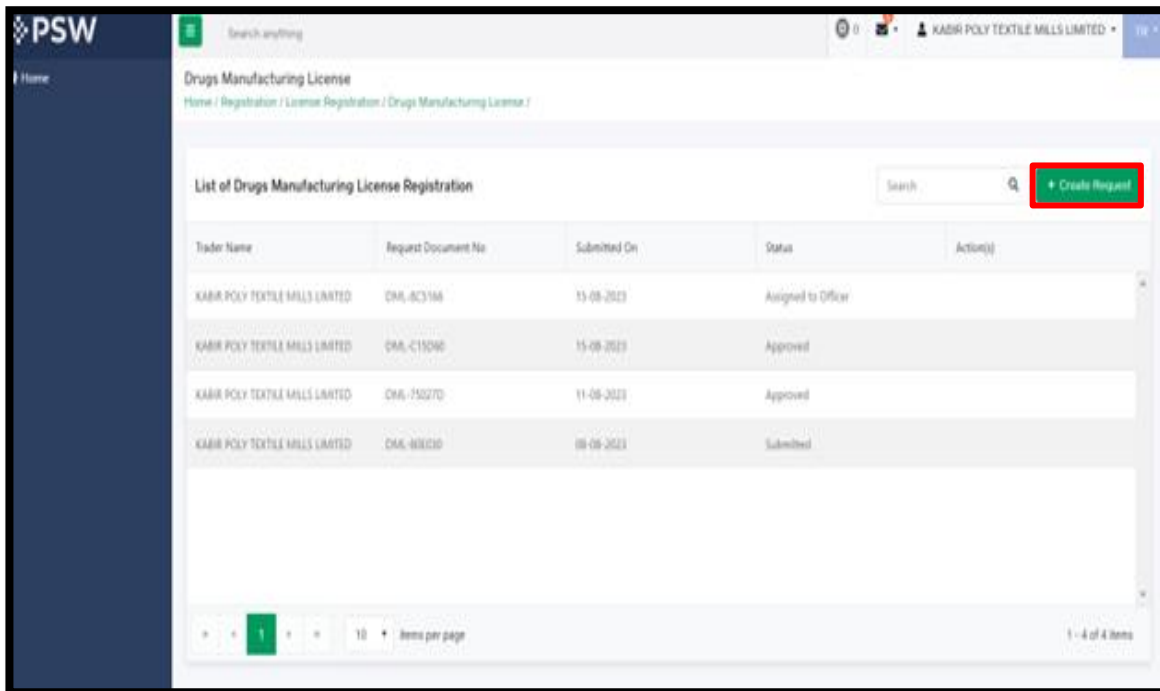
Figure 25

vi. Provide the required information.
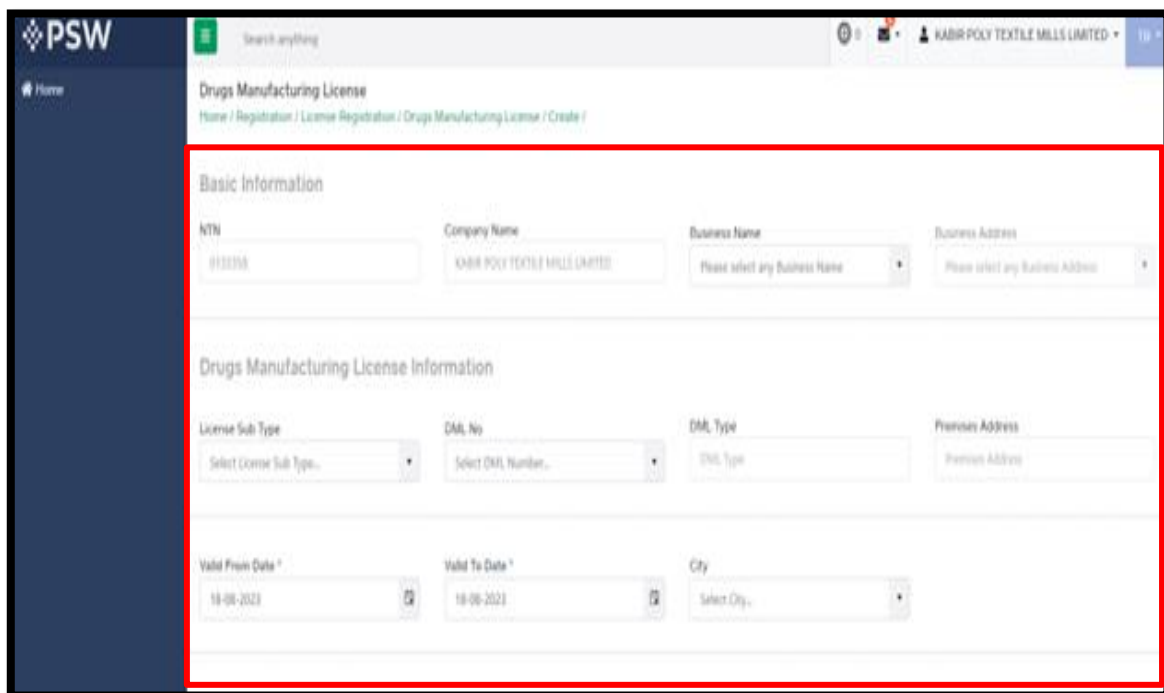
Figure 26

vii. Provide the details of Qualified Technical Person against License.

Figure 27

viii. Select the 'Document' type from the dropdown list and upload it by clicking on the 'Select Files' button; then press the 'Add Technical Person' button.

Figure 28

ix.   After submitting the details of the Technical Person(s), now click on the 'Submit' button.
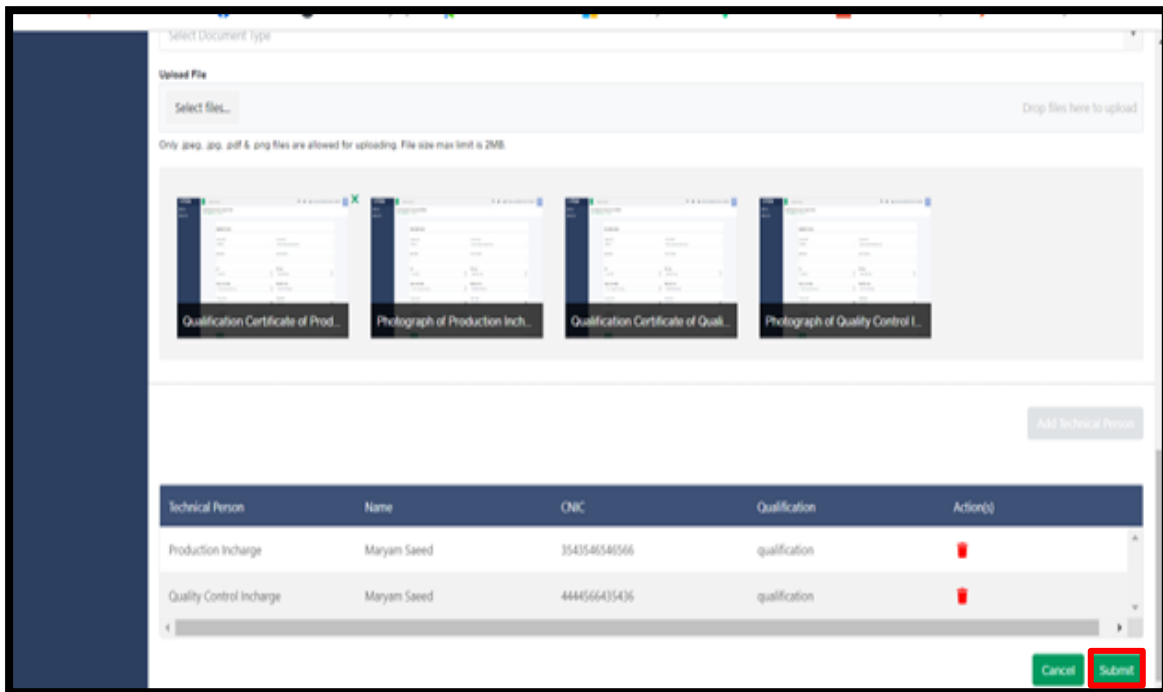
Figure 29

x.   After Submission, you can also view the status of your request(s) whether it is Submitted, Assigned to Officer, Approved, or Rejected.
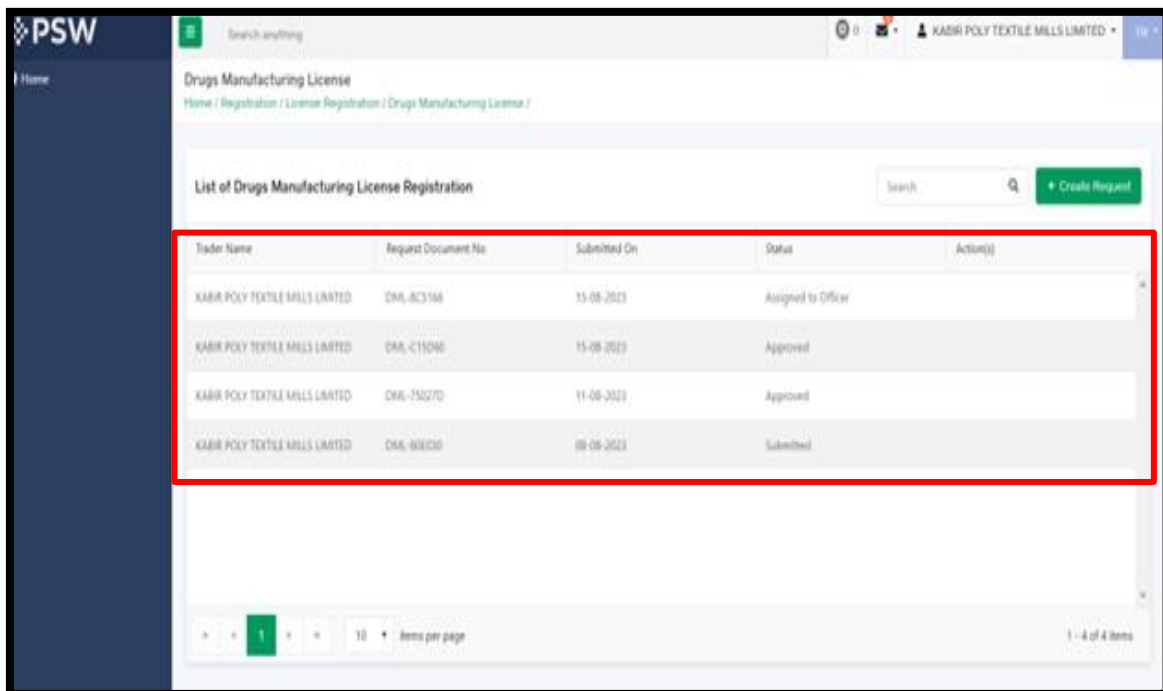
Figure 30

xi.   If the documents are called by the officer, you can submit the required documents by clicking on the 'Called Documents' screen. Here you can also view the remarks added by the officer.

Figure 31

5.5. DRUG REGISTRATION

i. Upon successful log-in, a dashboard will appear, click on the 'Registration' button.
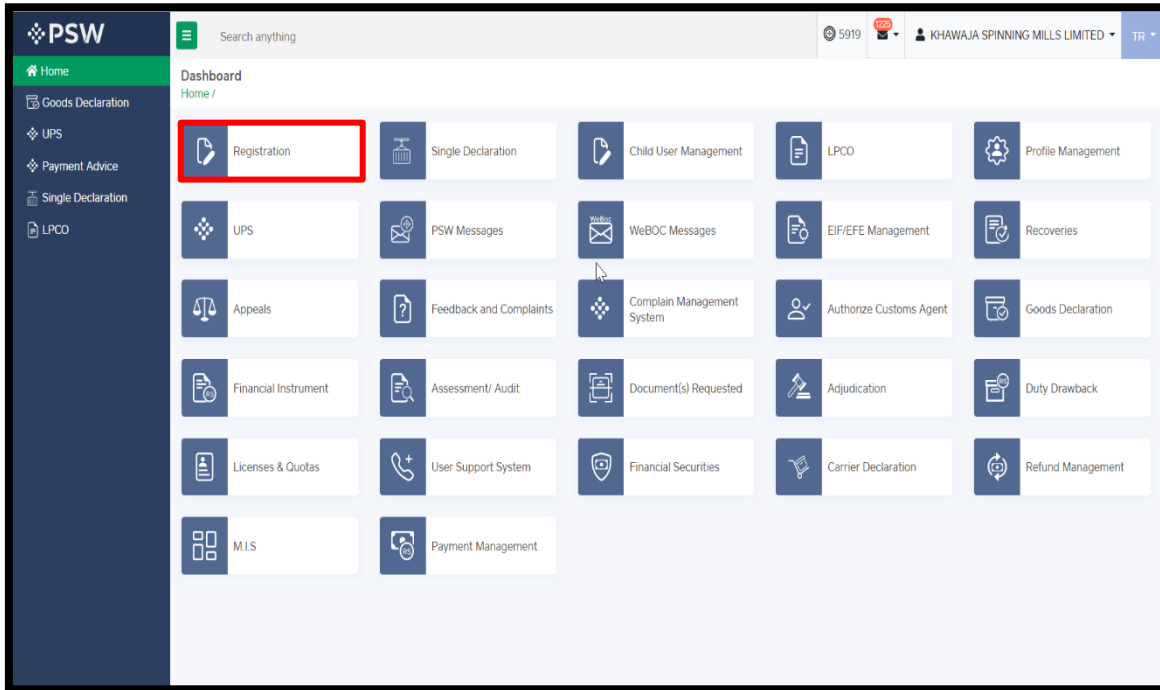
Figure 32

ii. Under the OGAs grid, select 'DRAP'.
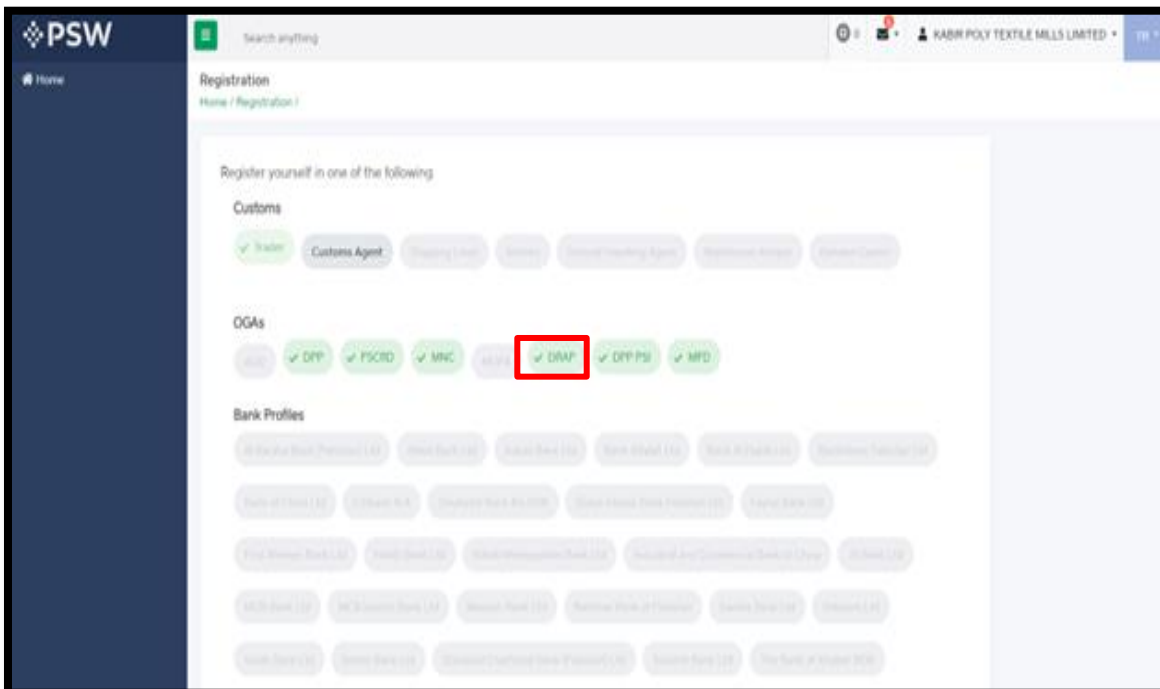
Figure 33

iii. Click on the "Drug Registration' button.
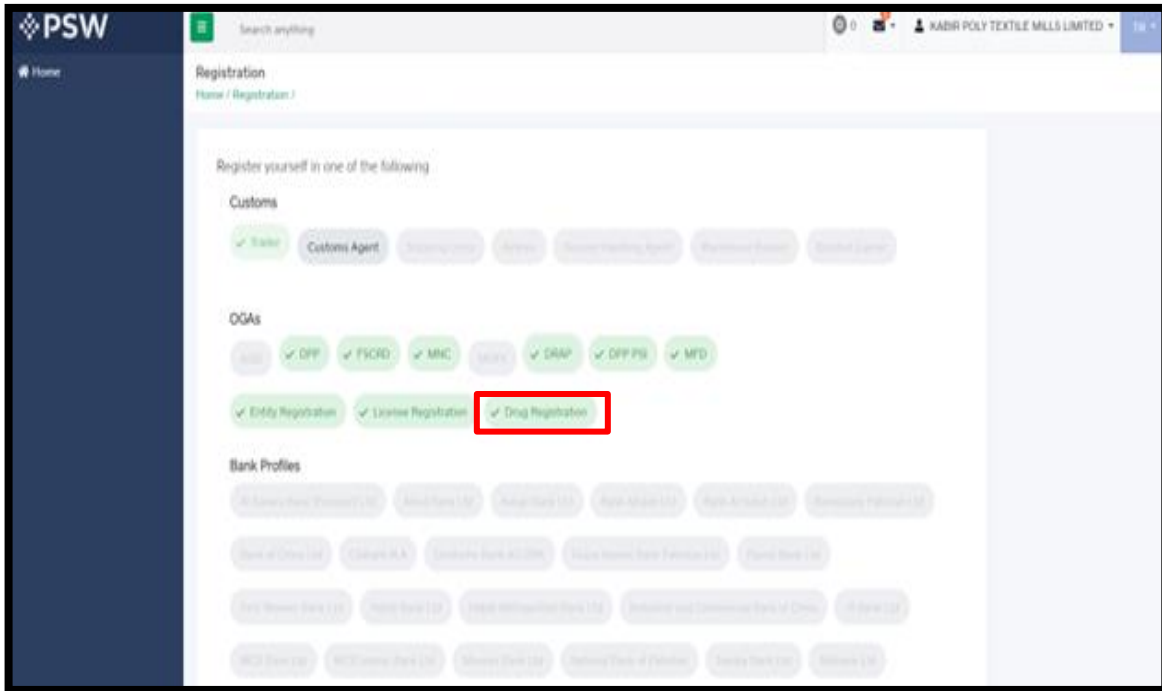
Figure 34

iv. Click on the 'Create Request' button.

Figure 35

v.   Provide the required information.

Figure 36

vi.   Under the Pack Size Details section, provide the required information related to 'Pack Size' and then click on the 'Add Pack Size' button.

Figure 37

vii.   Now click on the 'Submit' button to complete the request.

Figure 38

viii. After Submission, you can also view the status of your request(s) whether it is Submitted, Assigned to Officer, Approved, or Rejected.

Figure 39

ix.   If the documents are called by the officer, you can submit the required documents by clicking on the 'Called Documents' screen. Here you can also view the remarks added by the officer.
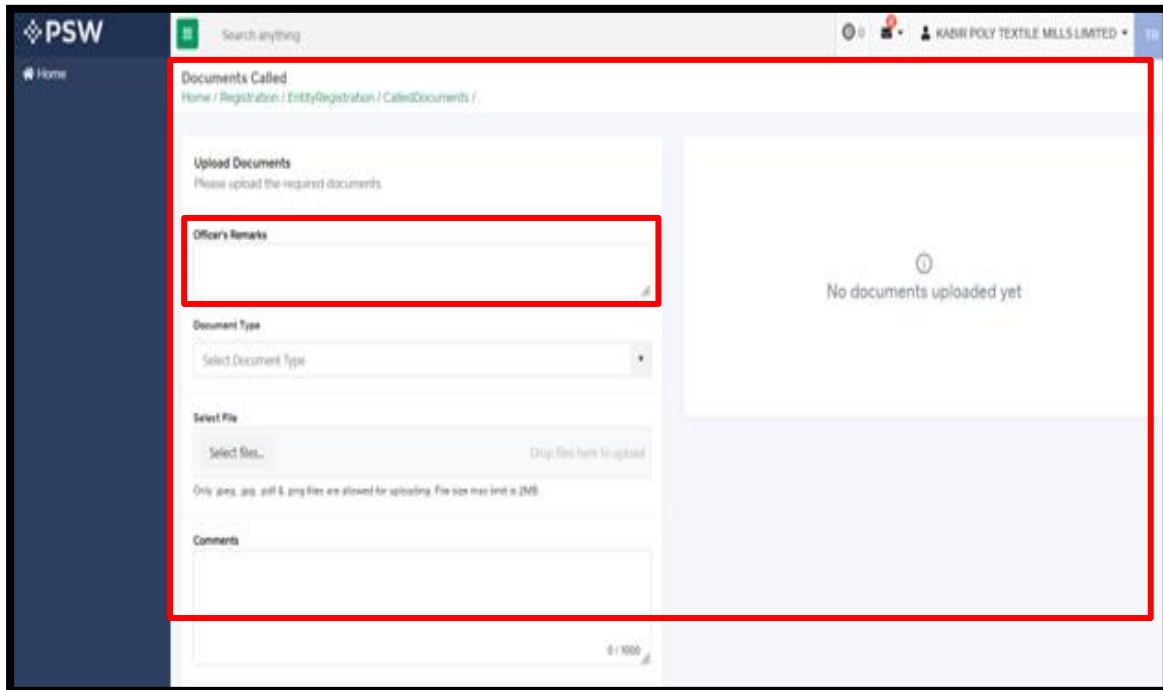
Figure 40

5.6. DRUG IMPORT LICENSE REQUEST

i.   Upon successful log-in, a dashboard will appear, click on the 'LPCO' button.
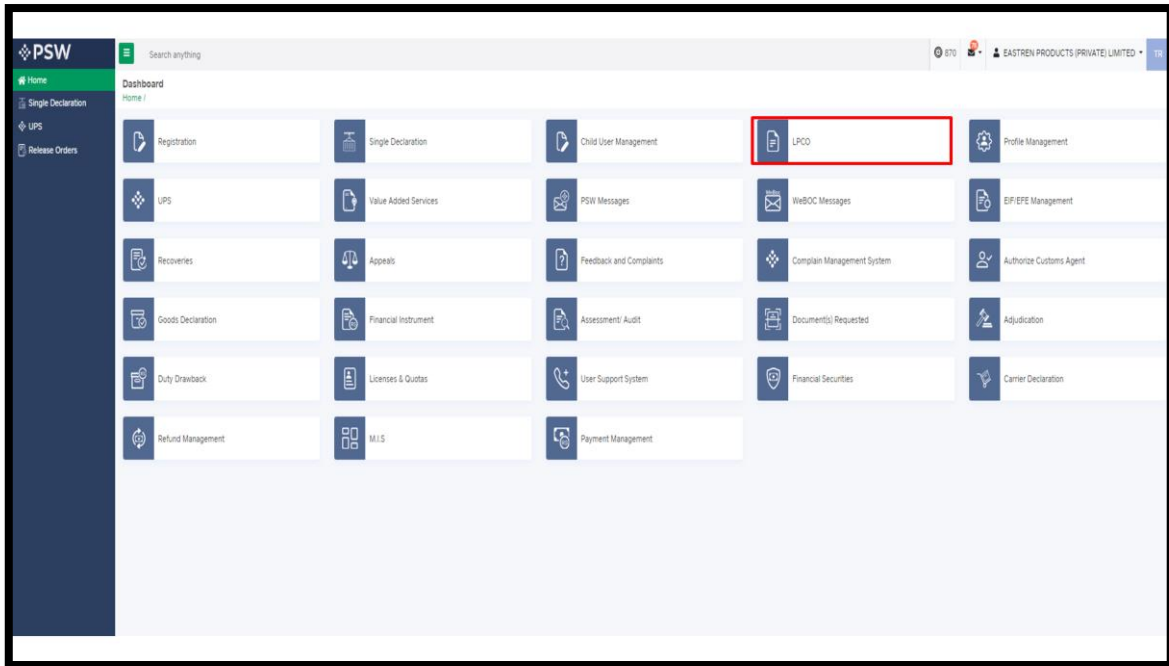
Figure 41

ii.   Click on the 'Import Licenses' button.
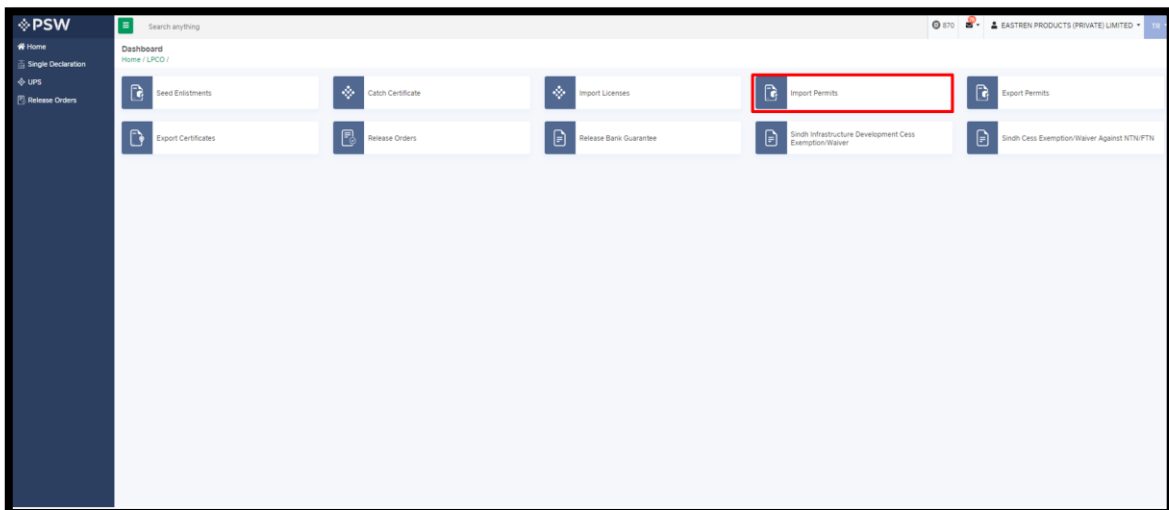
Figure 42

iii.   Click on the 'Create Import Licenses' button.
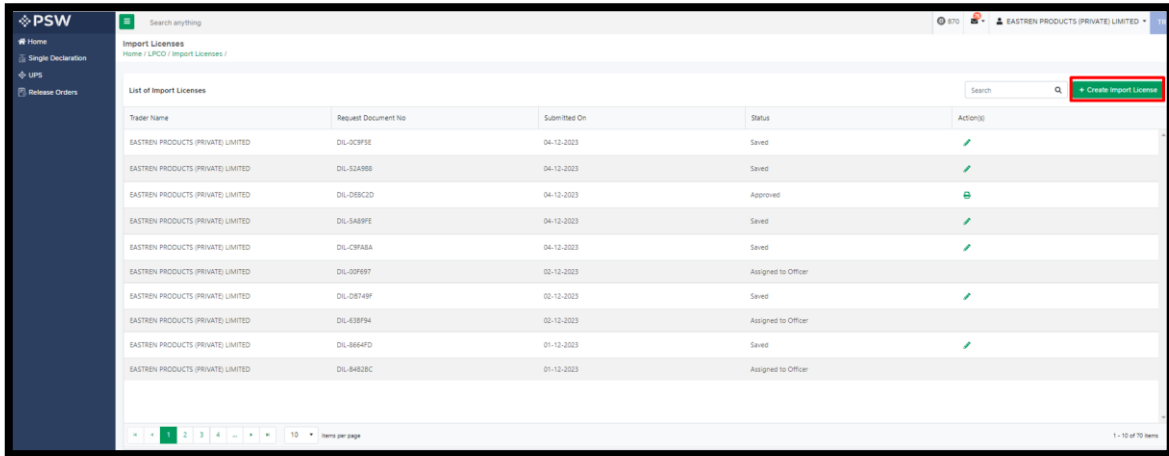
Figure 43

iv.   Select Agency to 'Create Import Licenses'
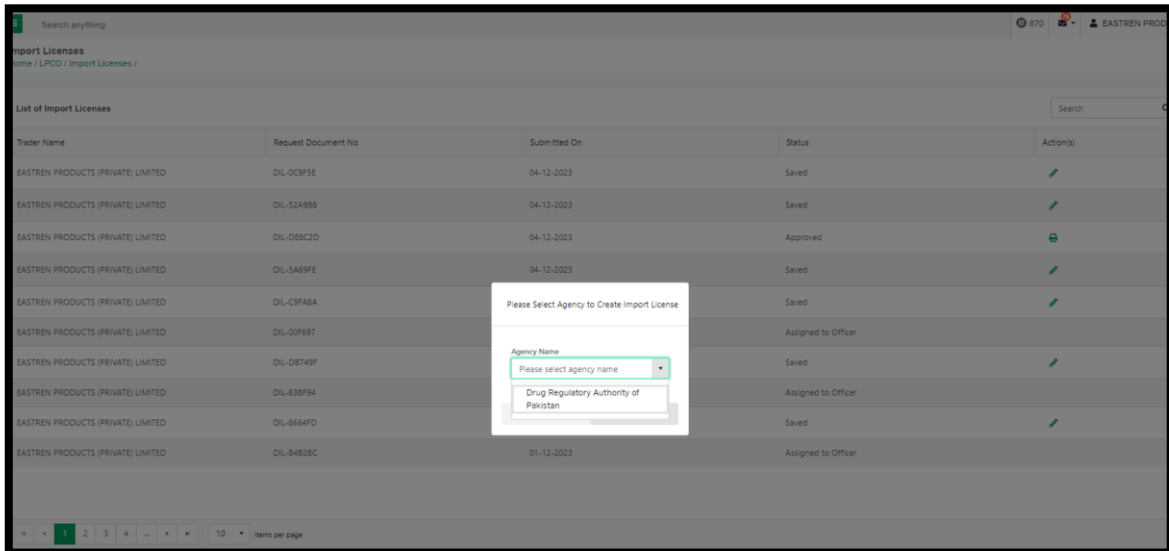
Figure 44

v. In the 'Basic Information' section, provide the required details.

Figure 45

vi. Select the 'Purpose of import' from the dropdown menu.

Figure 46

vii. Select the 'Business Name' and 'Business Address' from the dropdown menu.

Figure 47

viii. Select the 'Foreign Manufacturer Country' from the dropdown menu and click on the 'Save & Proceed' button.

Figure 48

ix. In the 'Drug Information' section, provide the required details.

Figure 49

x.   Select 'DML No' from the dropdown menu.

- Drug Registration No. is mandatory only if the selected license type is commercial.

Figure 50

xi.   Select 'DML No' from the dropdown menu.

Figure 51

xii.   Select the 'Raw Material Type' from the dropdown menu.

Figure 52

xiii.   Select the 'HS Code' from the dropdown menu.

Figure 53

xiv.   Select the 'Specific Code' from the dropdown menu.

Figure 54

xv.   Select the 'Specific Description' from the dropdown menu.

Figure 55

xvi. After you've completed the necessary information, click on 'Add Drug Information' button.
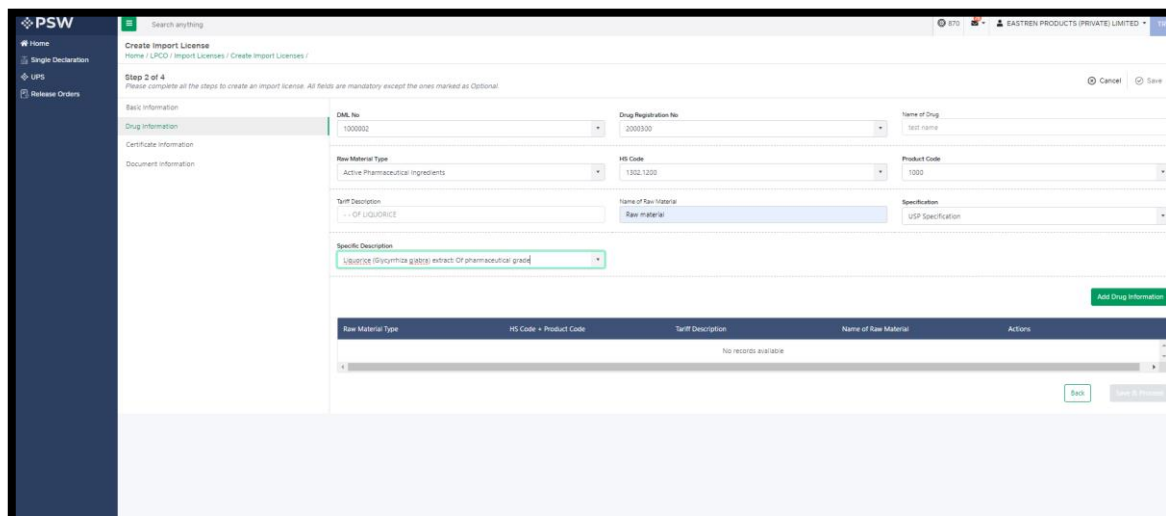
Figure 56

xvii. The 'Drug Information' that you have added will appear in the grid, allowing you to view and delete the records if needed.
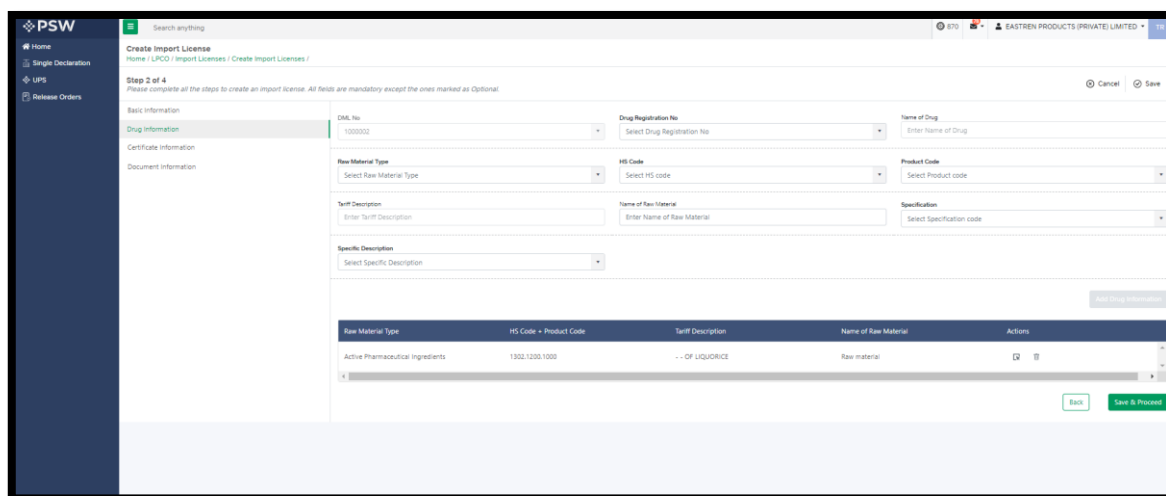
Figure 57

xviii.   Select the 'Certificate Category' from the dropdown menu.

Figure 58

xix.   Select the 'Name of Raw Material' from the dropdown menu.

Figure 59

xx.   Enter the 'Certificate No' & 'Scope of Drug'

Figure 60

xxi.   Select the Certificate 'Valid from Date' & 'Valid to Date'.

Figure 61

xxii.   Click on 'Select File' to upload the Certificate. After successful uploading of the Certificate, click on 'Add Certificate Information'.
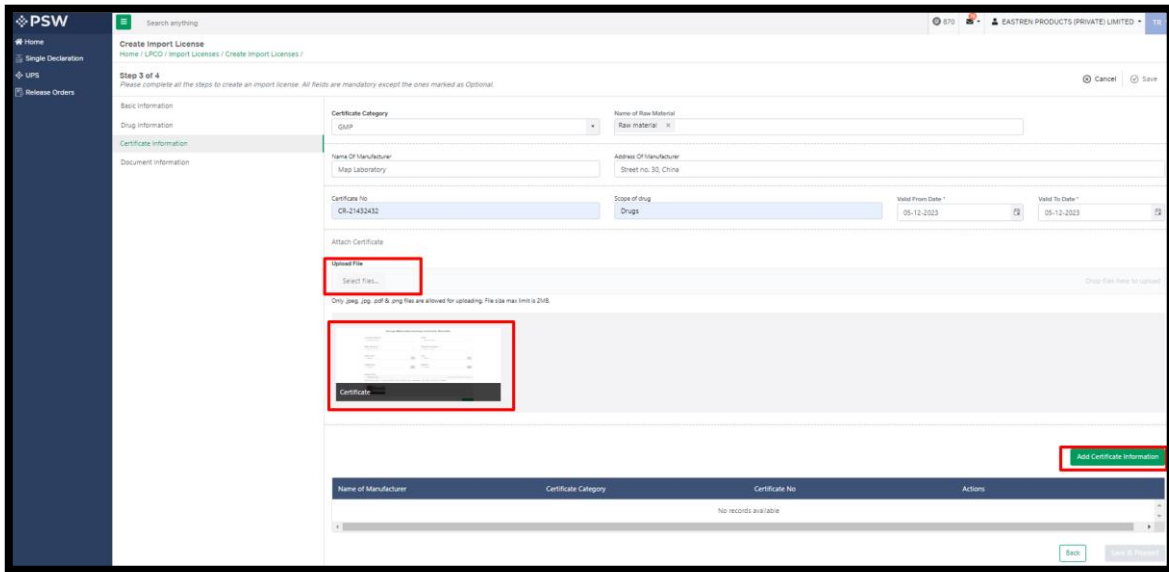
Figure 62

xxiii.   The 'Drug Information' that you have added will appear in the grid, allowing you to view and delete the records if needed.
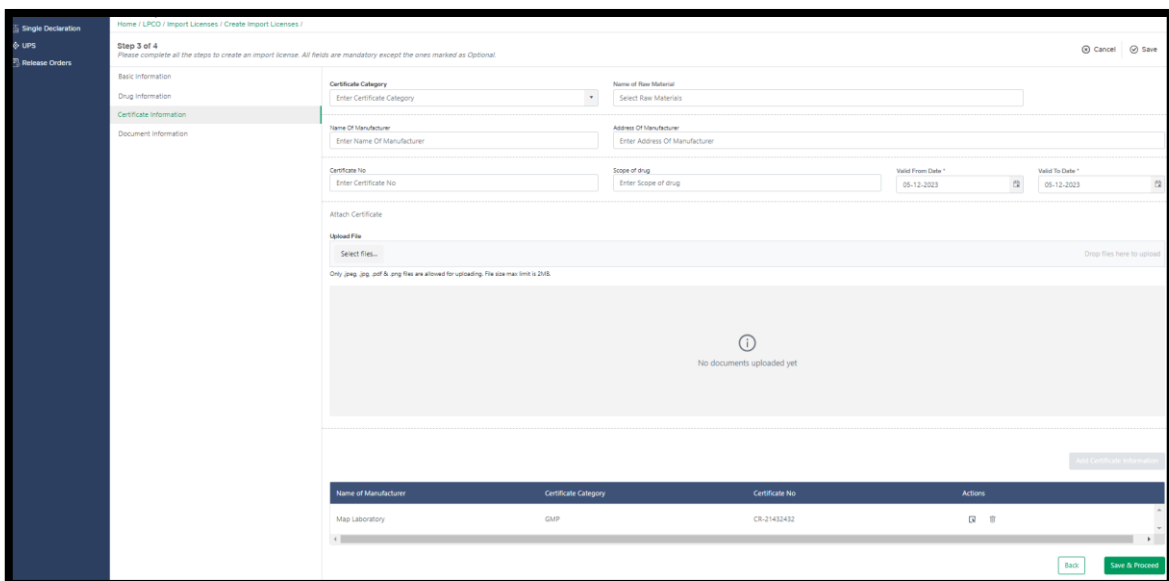
Figure 63

xxiv.   Select the 'Document Type' from the dropdown menu.
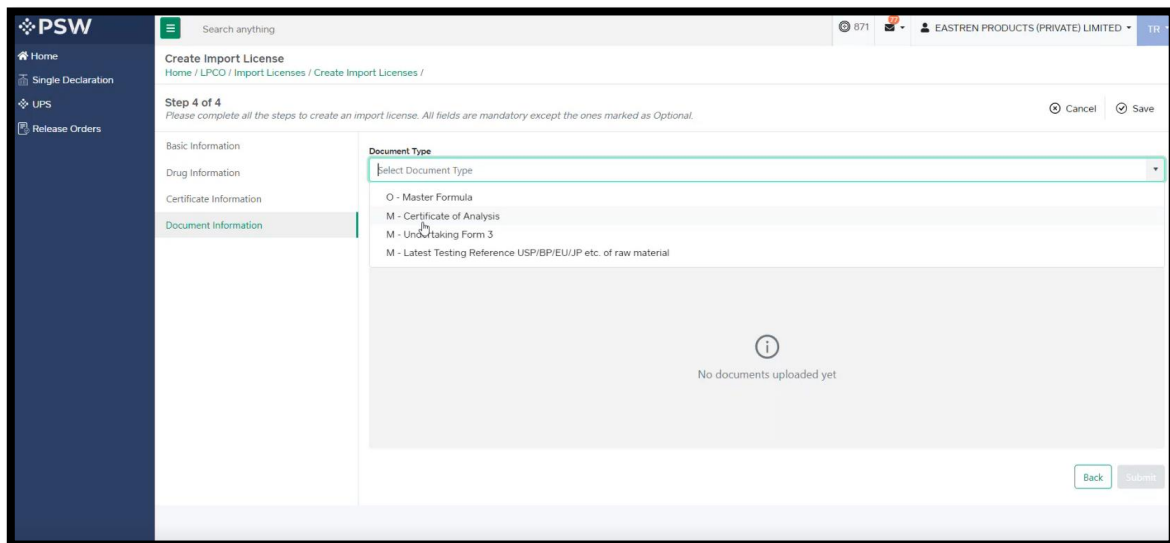
Figure 64

xxv.   Click on select filed to upload the 'Relevant Documents'.
- After you've completed the necessary information, the Submit' button will become active.
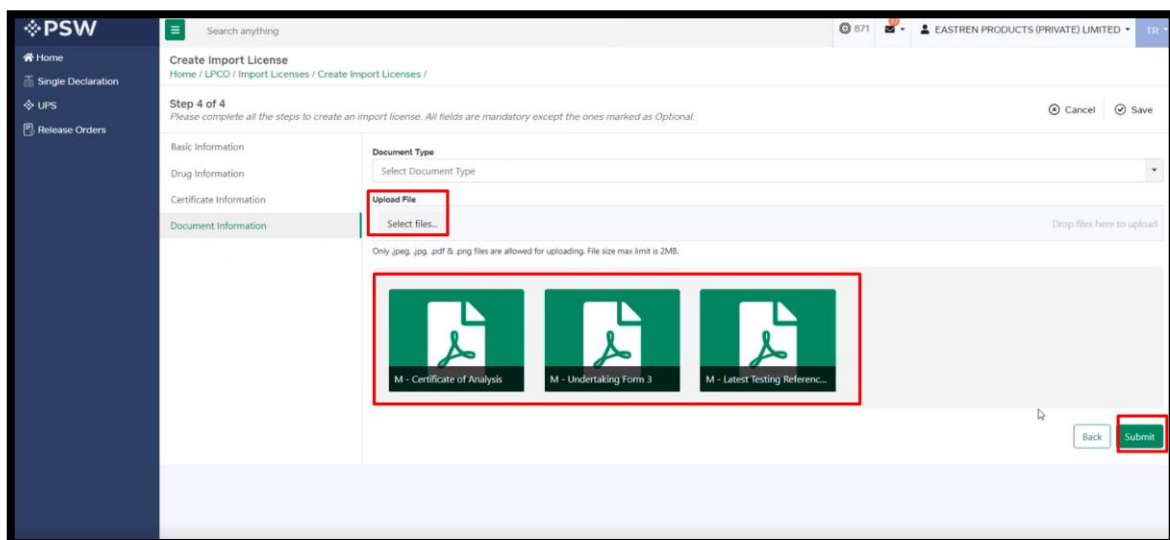
Figure 65

xxvi.   On the submit button a confirmation popup will appear.
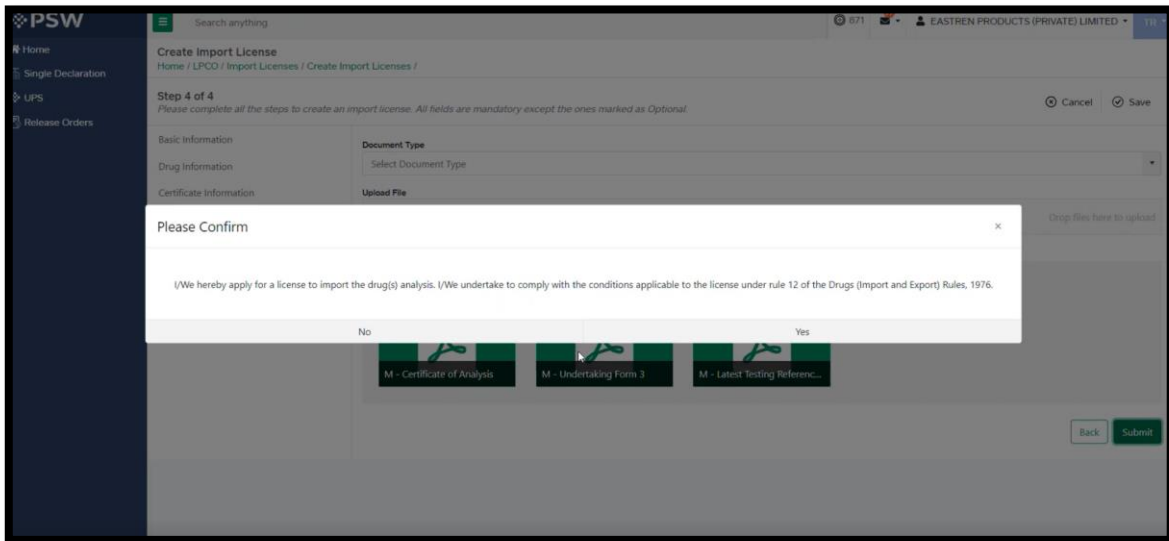
Figure 66

xxvii.   After submitting, a pop-up will appear displaying the PSID and charges.
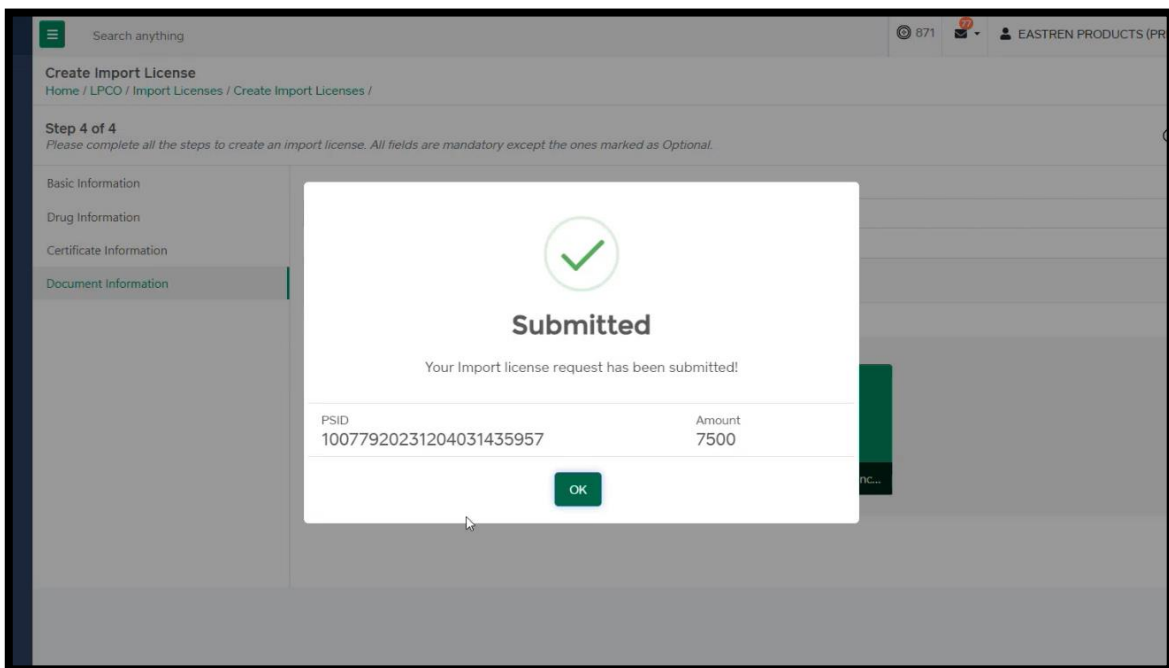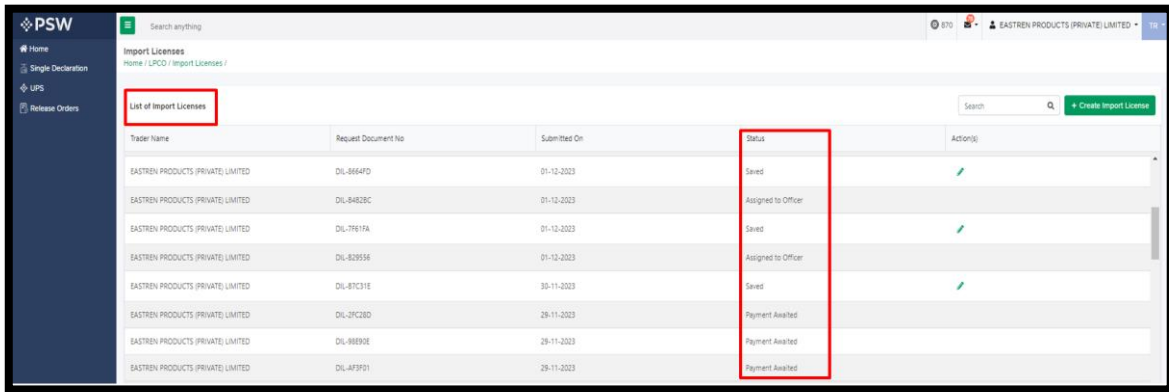
Figure 67

xxviii. The list of added import licenses will be displayed on the grid along with their respective statuses.

Figure 68

5.6.1. PAYMENT

i. Upon successful log-in, a dashboard will appear, click on the 'UPS' button.
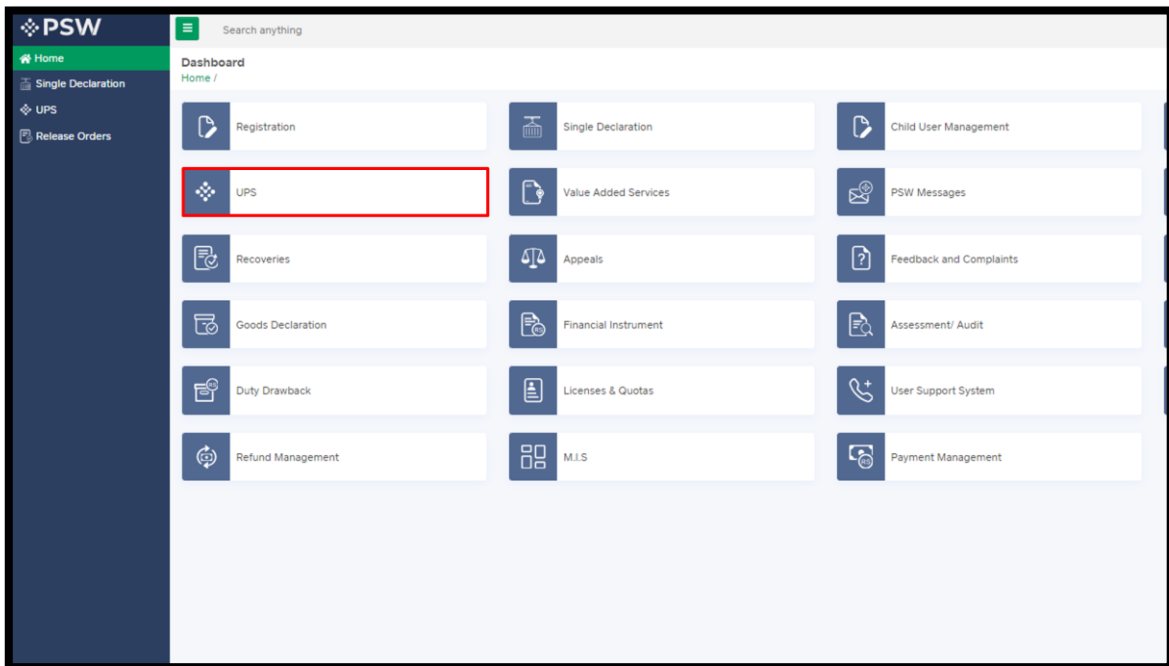
Figure 69

ii. In the action menu, clicking on the icon will display the list of payment advice. Additionally, you can search for the PSID using the search bar, and the button will become active.

Figure 70

iii. You can use the PSID to pay the fee through PD account or any of the following ADC (Alternate Delivery Channel) modes:
- Bank Counter
- ATM
- Internet Banking
- Mobile Banking

Figure 71

iv.   Upon successful payment, the request will be assigned to an officer.

Figure 72

v.   After an officer approves the request, the status will be updated to 'Approved'. You can download the issued Drugs Import License by clicking on the print icon.

Figure 73

5.7. RELEASE ORDER REQUEST

    i.   Upon successful login, a dashboard will appear, click on the 'Single Declaration' button.
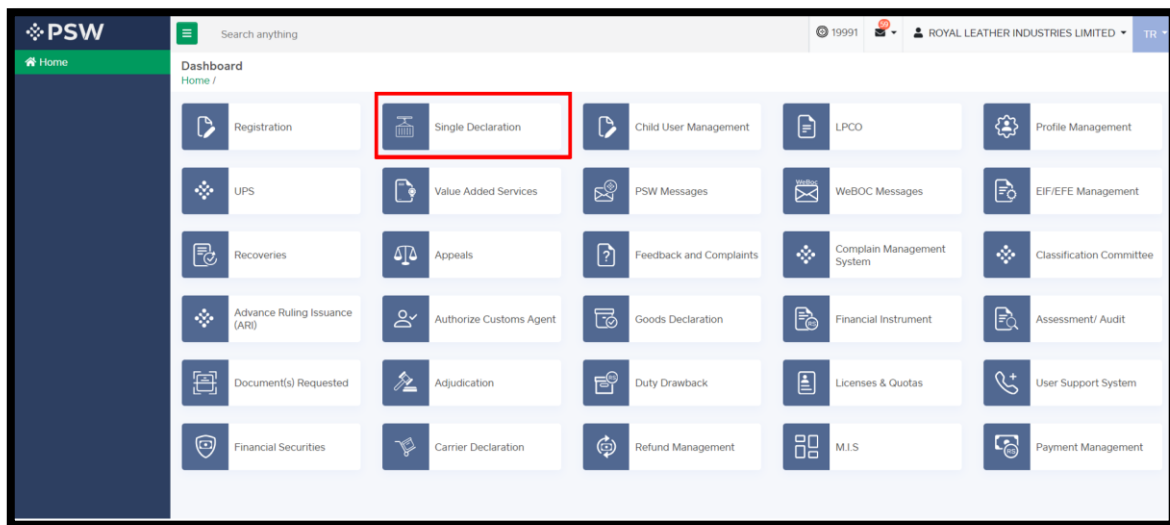
Figure 74

    ii.   Click on the ' Import Create Declaration' button.
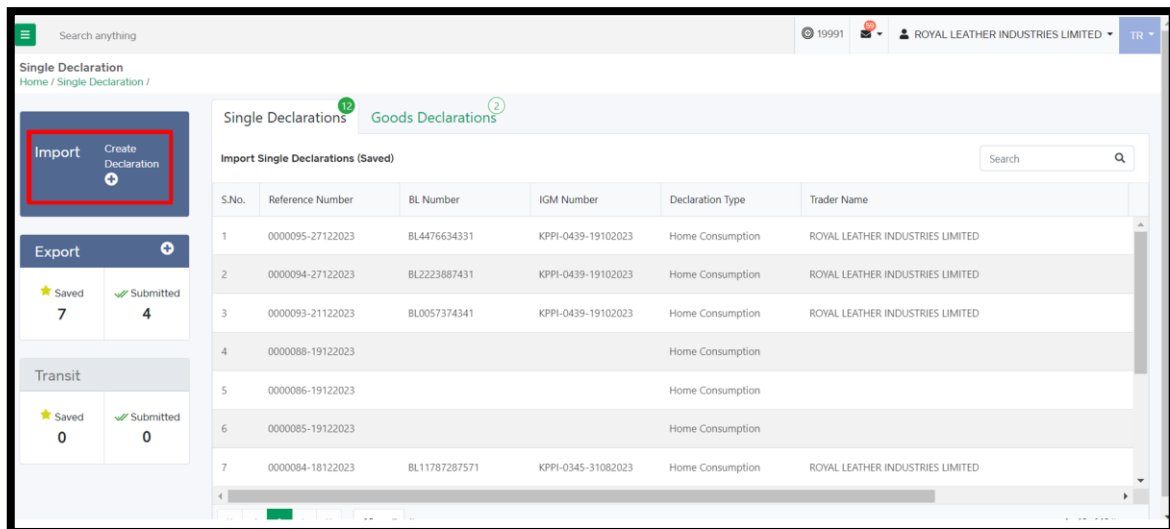
Figure 75

iii.   Select the Relevant Consignment Category & Declaration Type.
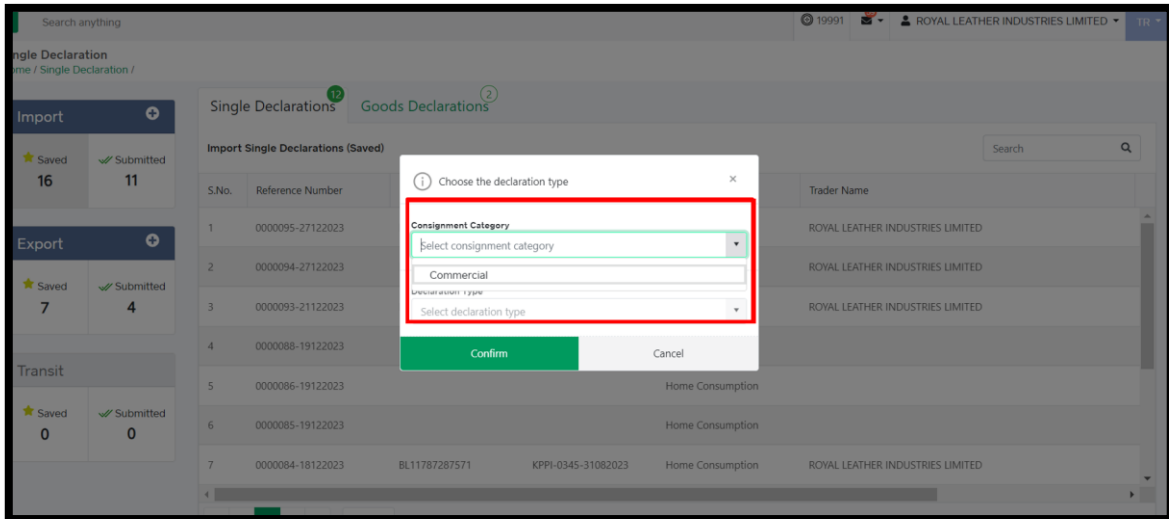
Figure 76

iv.   Fill in the necessary details on the 'Consignment Information' section and click on 'Save & Proceed' button to proceed to the next step.
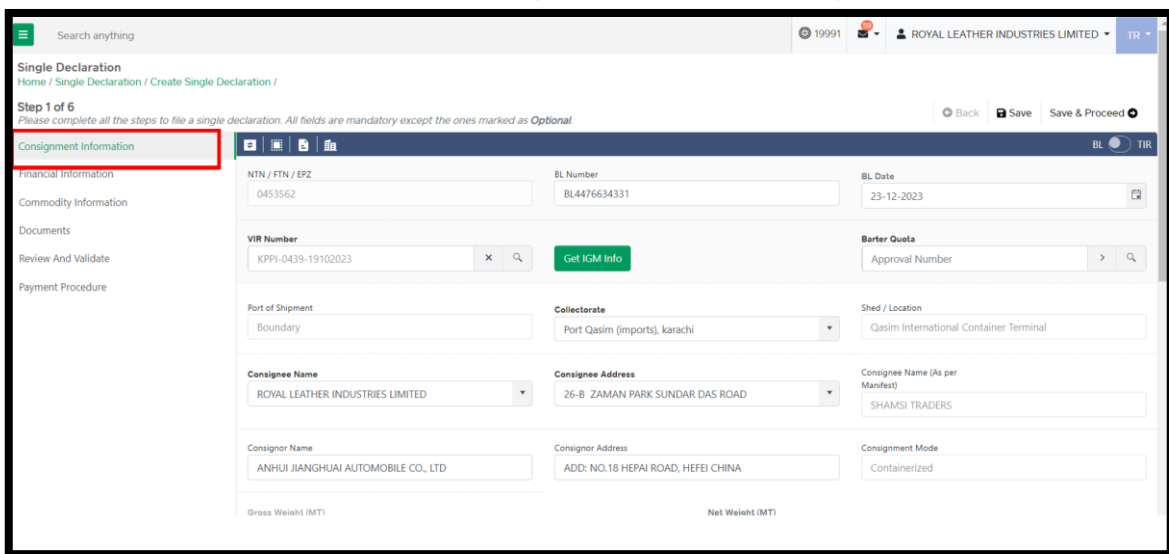
Figure 77

v.   Fill in the necessary details on the 'Financial Information' section by tagging relevant 'Financial Instrument'.

Figure 78

vi.   On the 'Commodity Information' section, click on the 'Add Commodity' button.

Figure 79

vii.   Select the 'HS Code' from the drop down menu.

Figure 80

viii.   Select the 'Product Code' from the drop down menu.

Figure 81

ix. Fill in the Supporting Information

Figure 82

x. In case of any SROs/Exemptions, click on the attachment option to tag the SRO/Exemption.

Figure 83

xi.　　Fill in the relevant OGA's Required information like purpose, specific description, name of drug, reason of import, packaging, batch details, and shelf life.

- After providing the required details, Click on the 'Get Documentary Requirement'.

Figure 84

xii.　　Please upload the required documents.

Figure 85

xiii. Added Commodity will be displayed on the 'List of Commodties table'. The same way, you can add multiple items/commodities.
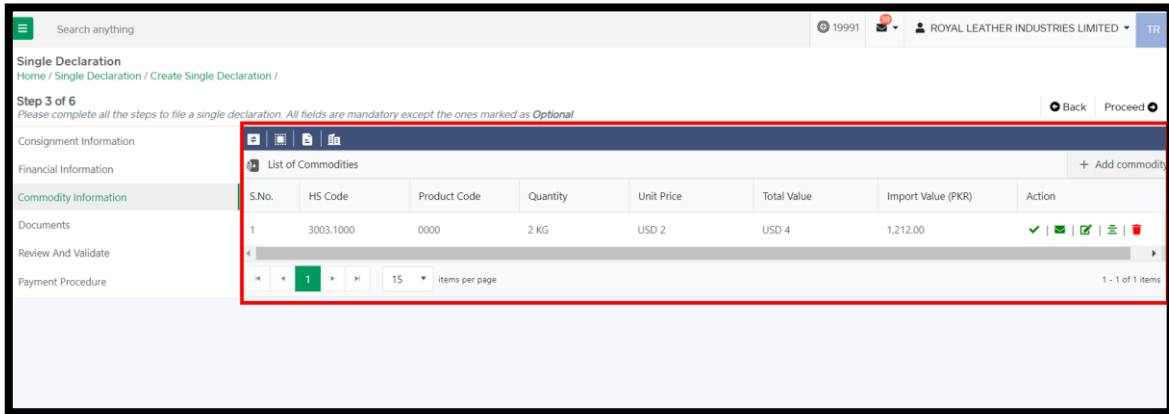

Figure 86

xiv. On the Documents section, select the the document type from the dropdown menu.
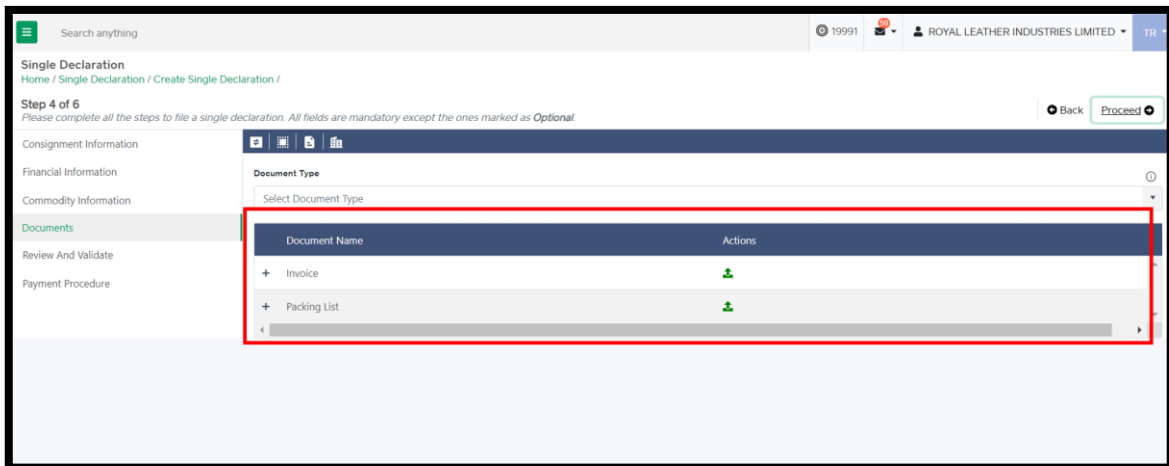
- Click on the Action icon to upload the document file

Figure 87

xv. On the 'Review and Validate form' review the information and Click on the Validate & Proceed for the validation.

Figure 88

xvi. Review the Payment fee.
- Click on 'Save and Submit' button.
- The Validation of SD will be Successful.

Figure 89

xvii.   You can use the PSID to pay the fee through PD account or any of the
          following ADC (Alternate Delivery Channel) modes:
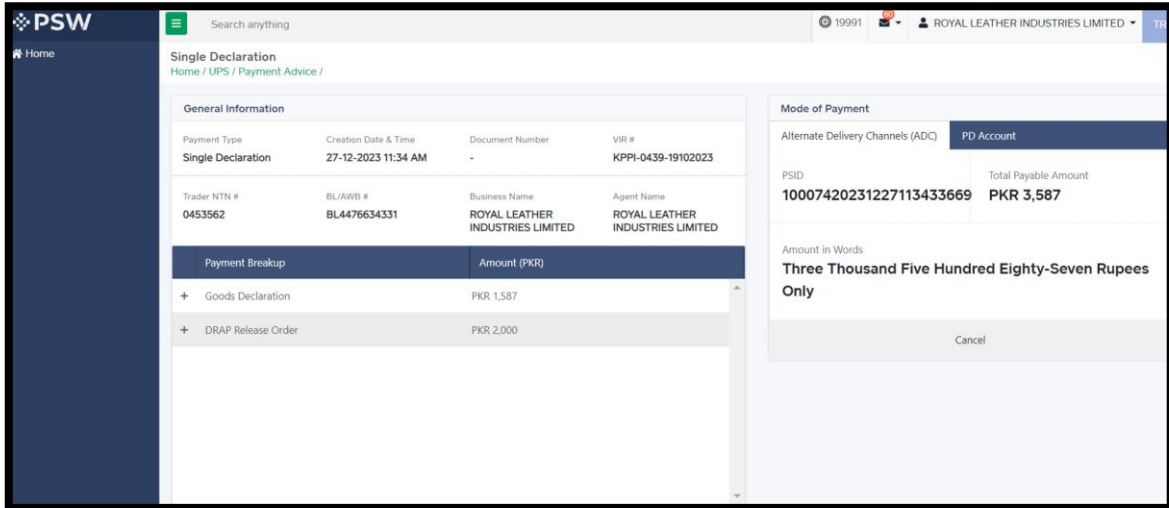- Bank Counter
- ATM
- Internet Banking
- Mobile Banking

Figure 90

xviii.   After Submission, you can also view the status of your request(s) whether it is
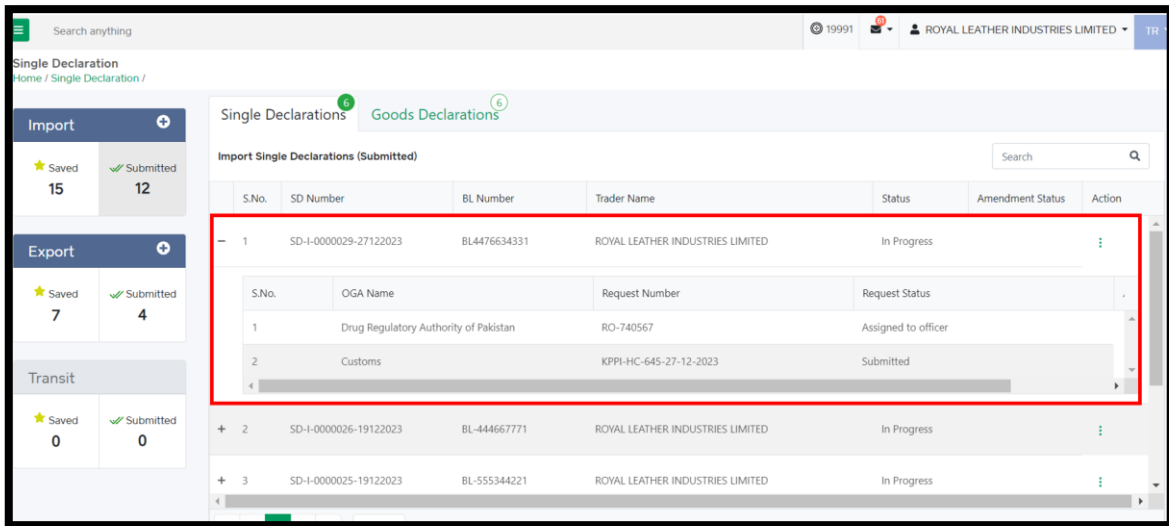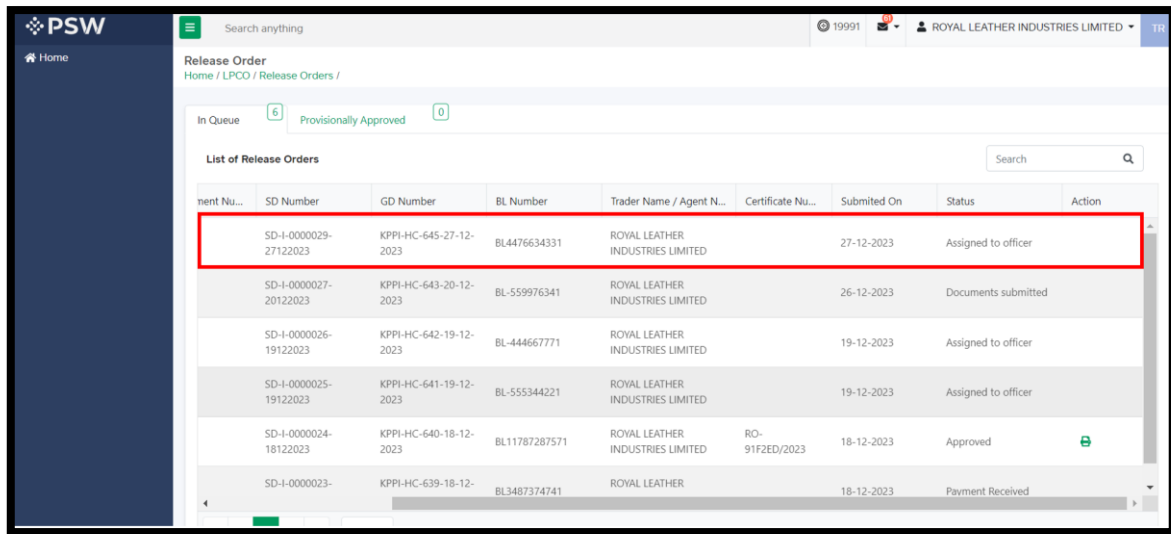   Submitted, Assigned to Officer, Approved, or Rejected.

Figure 91

xix.   You can also view the status of your request(s) whether it is Submitted, Assigned to Officer, Approved, or Rejected from LPCO/Release Orders.

Figure 92

6. CONTACT INFORMATION

If you require any assistance, please feel free to contact us as:

Email: support@psw.gov.pk
Phone: 021-111-111-779

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