USER GUIDE FOR ONLINE IMPORT / EXPORT APPLICATIONS SOFTWARE

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Drug Regulatory Authority of Pakistan
Islamabad – Pakistan.

HISTORY

This is the first edition of this user guide.

APPLICATION- Guidance for industry

This user guide is applicable to the manufacturers, importers and exporters that intends to import or exports of therapeutic goods in the country including raw materials and finished drugs, biologicals, medical devices and alternative medicines. This document will aid following: -

i. Manufactures and Importers of therapeutic goods;
ii. Researchers, investigators or institutions intends to import investigational drugs products for clinical trials.

PURPOSE

This use guide is aimed at provision of assistance for submission of application, through electronic platform, for imports and exports of products to the Drug Regulatory Authority of Pakistan in compliance with the legal and regulatory requirements for all therapeutic goods including finished pharmaceutical and biological drug products, active pharmaceutical ingredients (APIs) and drug substances (DS), Medical Devices, and Health & OTC Product (e.g. nutraceuticals, herbals, ayurvedic and homeopathic products, biochemic and Chinese products) and their raw materials.

INTRODUCTION

In line with the vision of Prime Minister of Pakistan, and to facilitate the therapeutic goods' industry for ease of business and provision of conducive environment for compliance to regulatory requirement, Drug Regulatory Authority of Pakistan (DRAP) has introduced an electronic application management system which will enable applicants and regulators to communicate electronically for enhance provision of quality assured, safe and efficacious therapeutic goods.

This document is intended to provide step wise guidance to the users for submission of applications using this software and will assist in provision of applicable documentation. In case, applicants need any further technical assistance or have any query(s) with regard to use of this software, they may contact Division of Management Information System, DRAP @ addl-directormis@dra.gov.pk or call at 051-9107414 / 051 9107412.

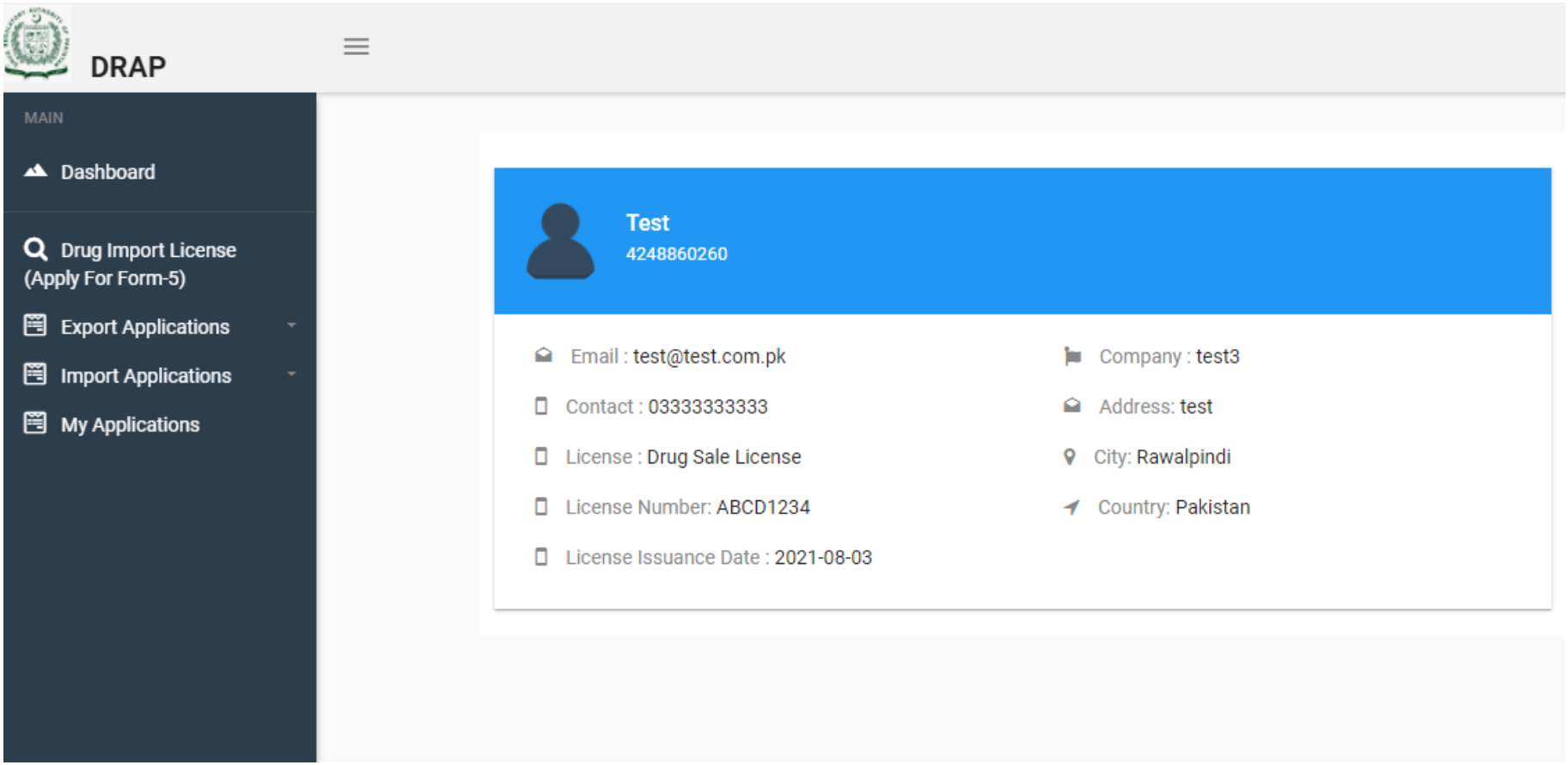
Step-1: Login Screen

(i) Access the software application using: ie.dra.gov.pk

(ii) Please use same user and password provided for online fee challan system.

Step: II

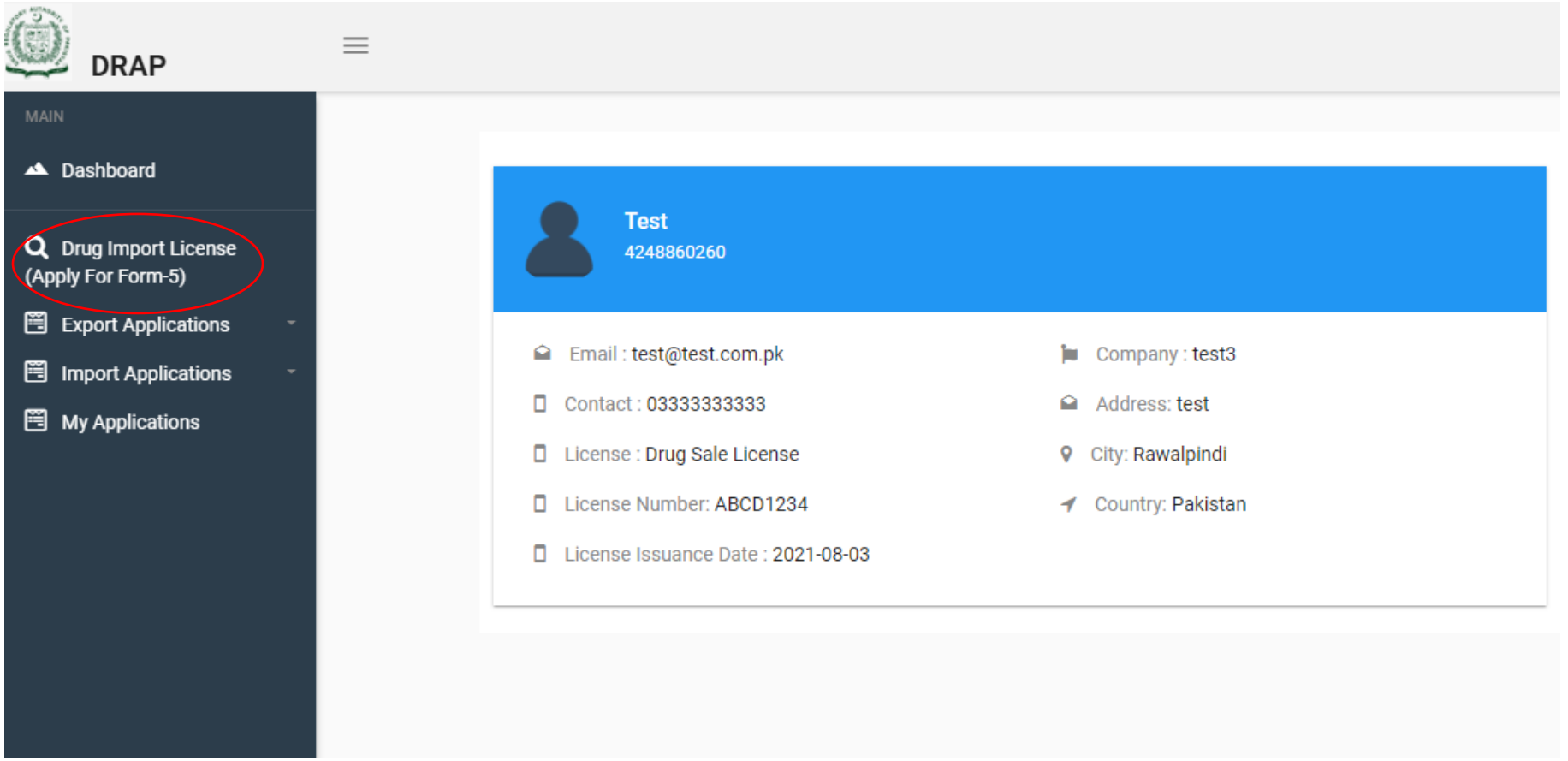
After Login following screen will appear.



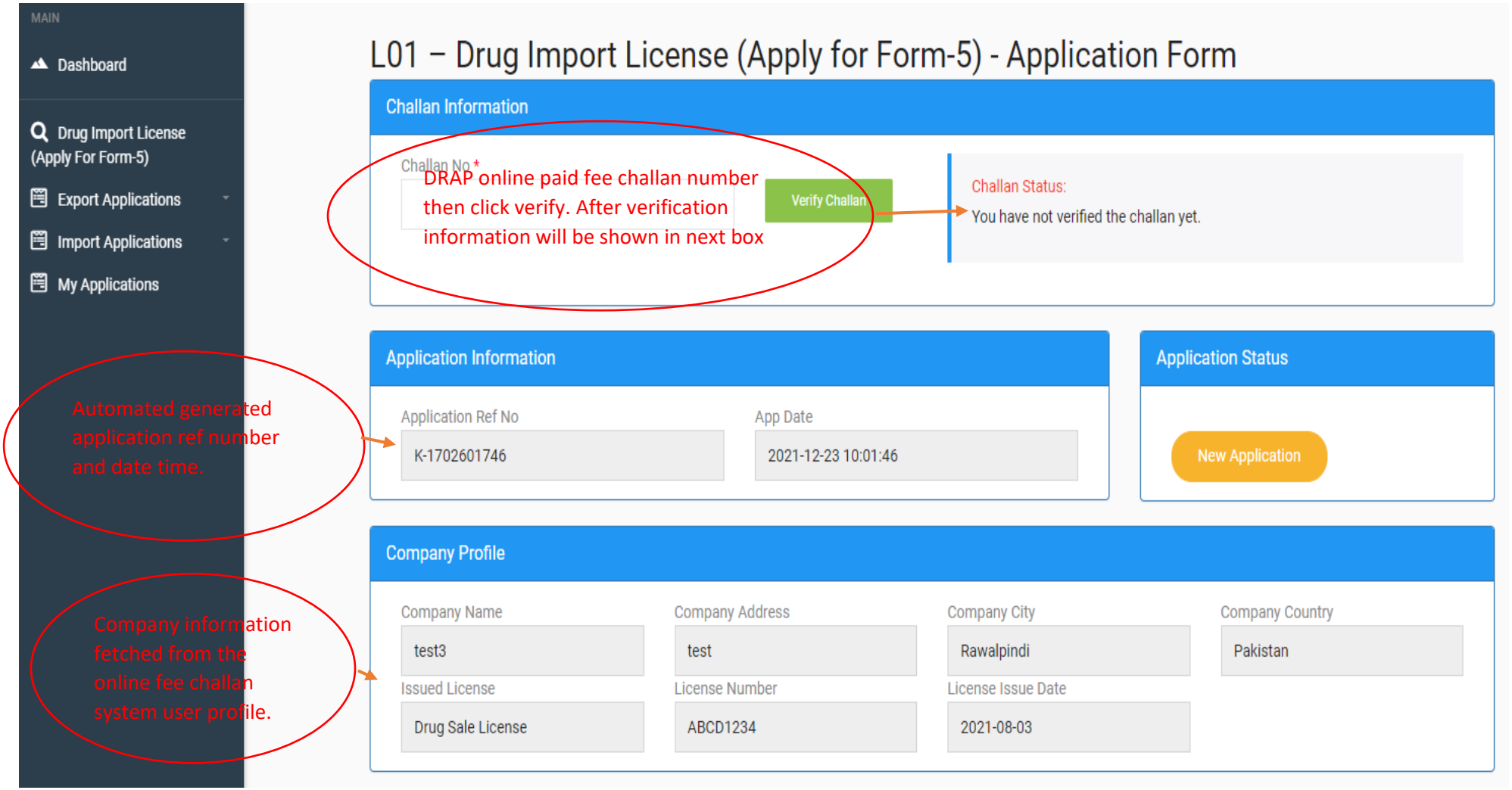
Left Panel showing different types of tabs such as application for Drug Import License, Export Applications, Import Applications, My Applications.

1. Application for Drug Import License

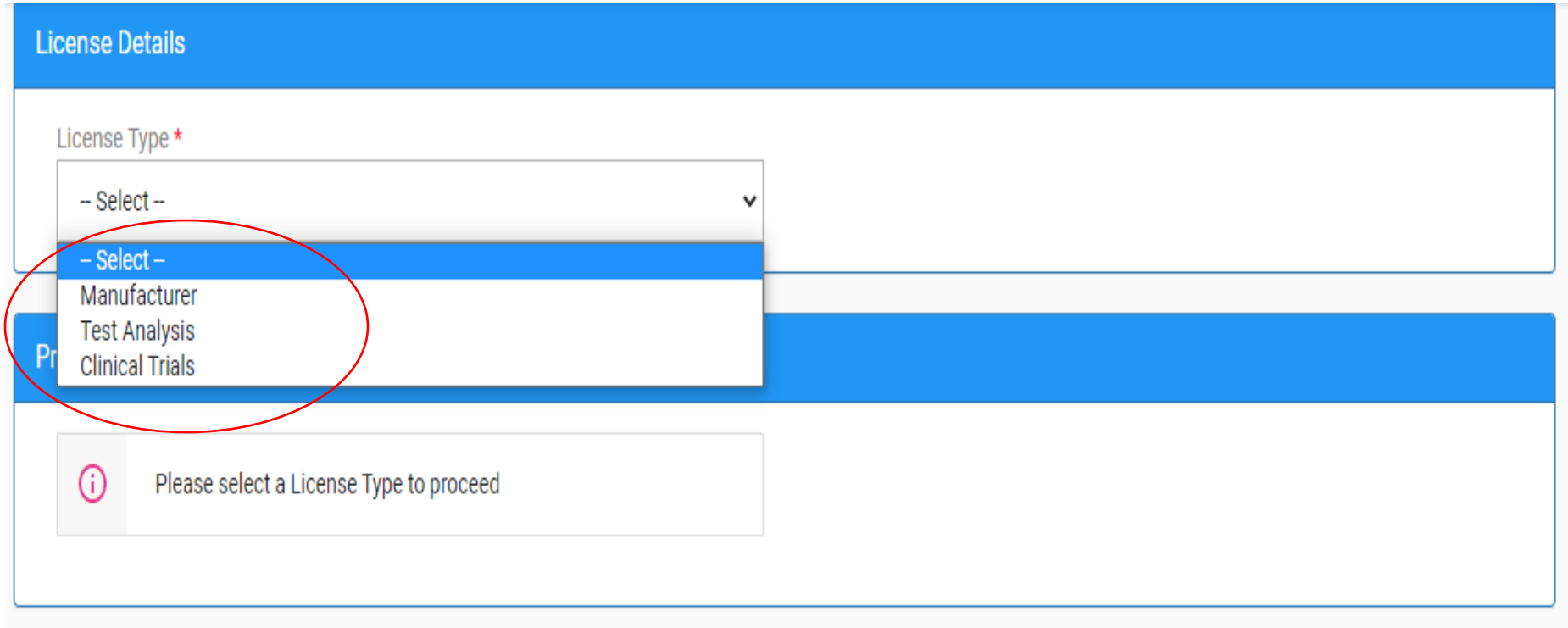
Click on Drug Import License (as indicated below)



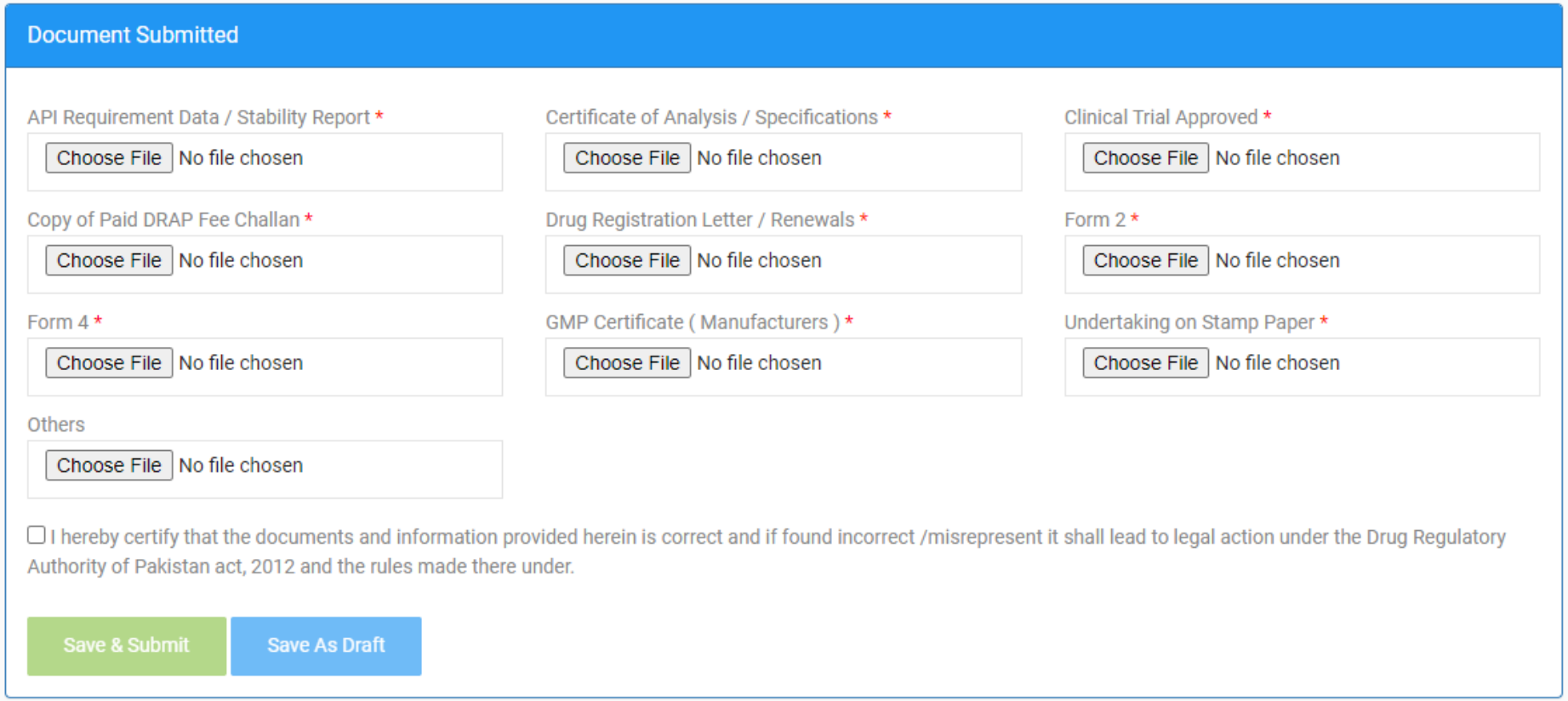
The following form will open and fill the information carefully prior to submit the application.



Select the license type



Upload relevant documents (* is mandatory uploading and only pdf file not more than 2MB size)

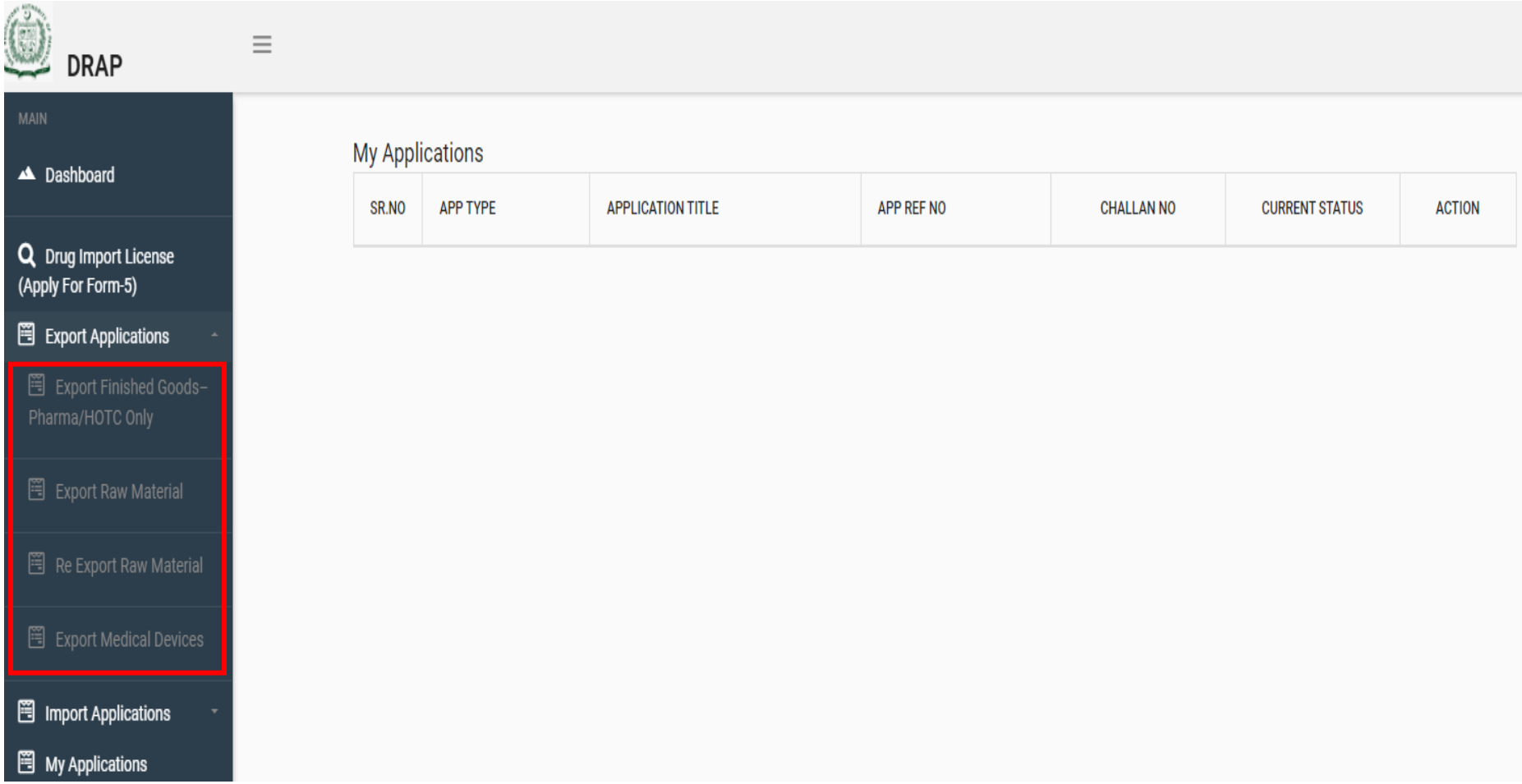


1. After uploading documents check the box to certify the information which you have provided is correct after that there are two options Save as Draft (means your application is saved at your own dashboard) and save & submit (means your application has been submitted to DRAP for further proceedings).

2. Once application submitted to DRAP, applicant cannot change any information

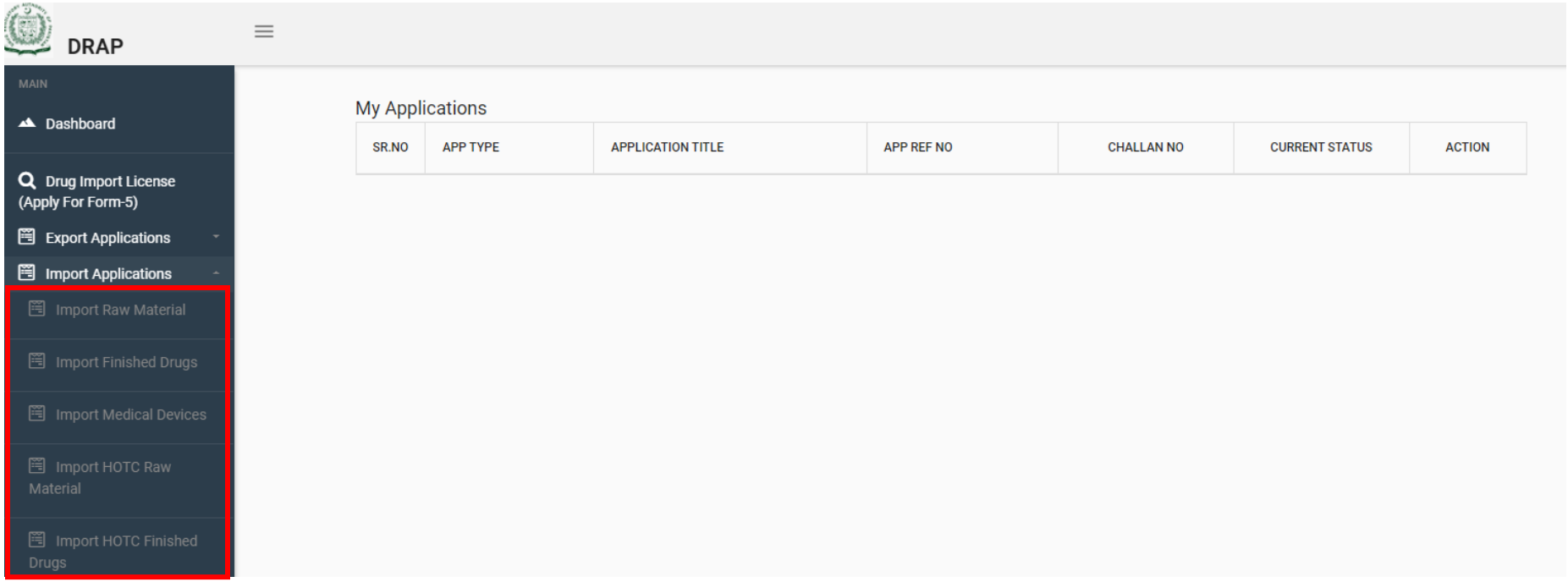
2. Export Applications

There are 4 options for export purpose as indicated below, applicant can apply to click on the desired tab.



3. Import Applications

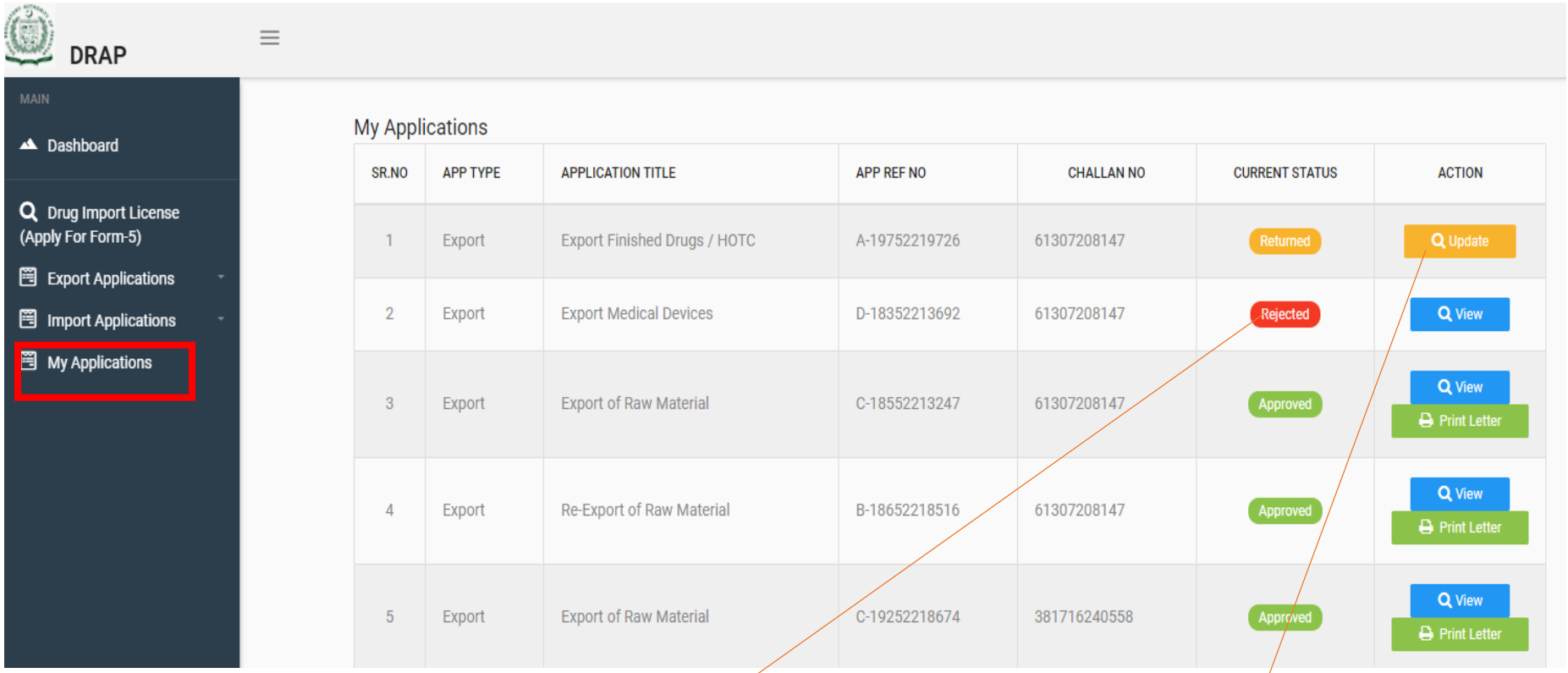
There are 05 types of options available as indicated below, applicant can apply to click on the desired tab.



After completion of desired forms save and submit the application then you will get electronic reference number for future record.

4. Status of all applications

Applicants can check the status of all applications to click on the option “My Applications” as indicated below in left panel.

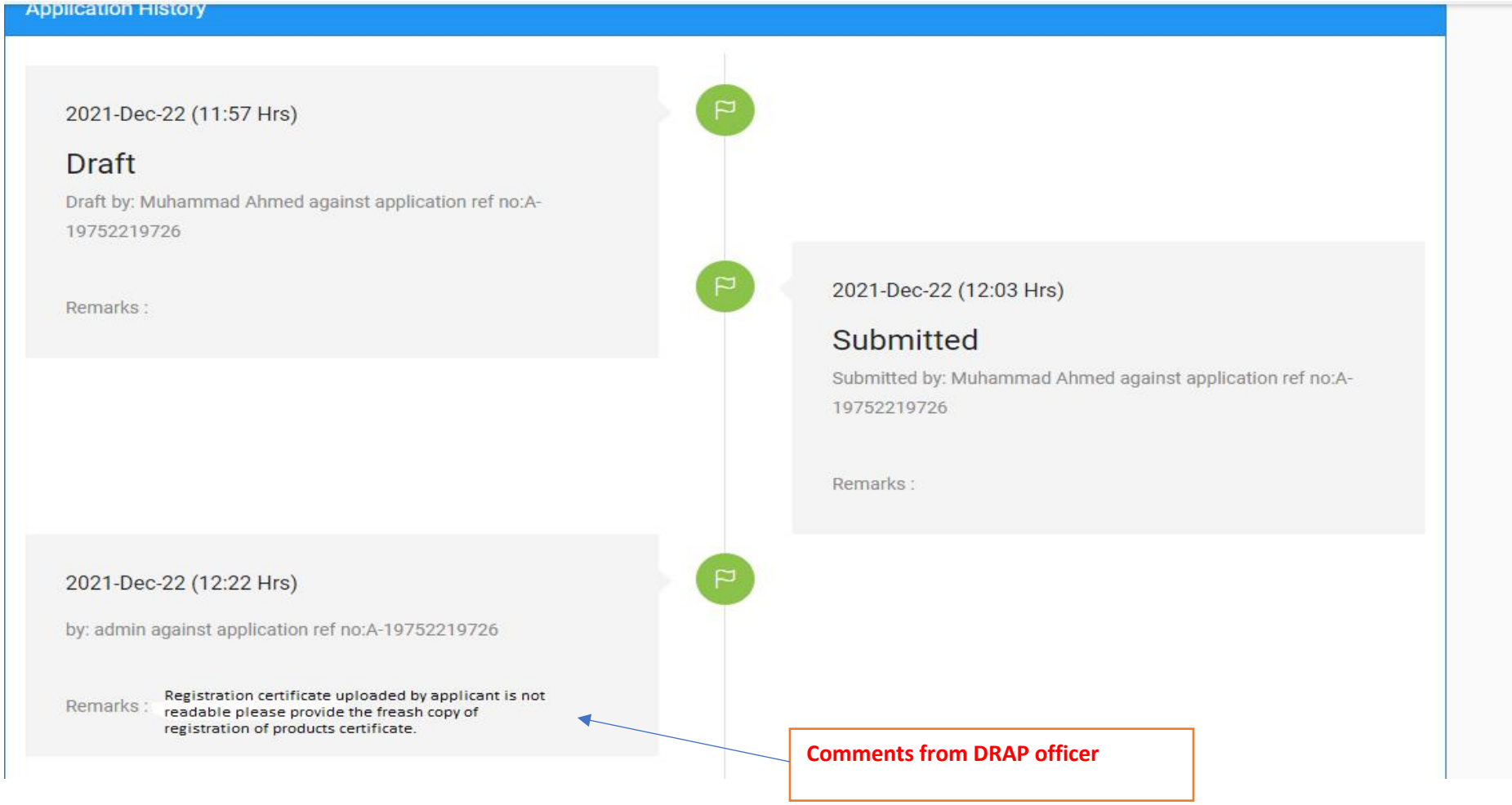


-Rejected application means DRAP office has rejected your application because of some misleading/falsified information.
-Applicant will require fresh application to reconsider the case.

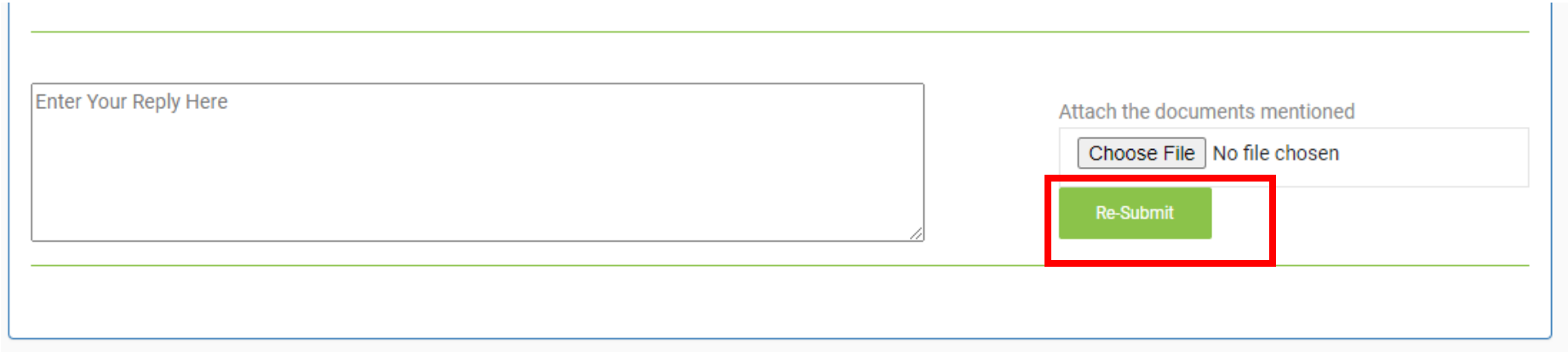
Returned application status means that DRAP desired some clarifications from applicant. Click on update button to view the comments from DRAP, after provision of desired information resubmit the application.

5. Process of returned Applications

After click on update the following section will appear in the bottom of application under "**Application History"** tab.

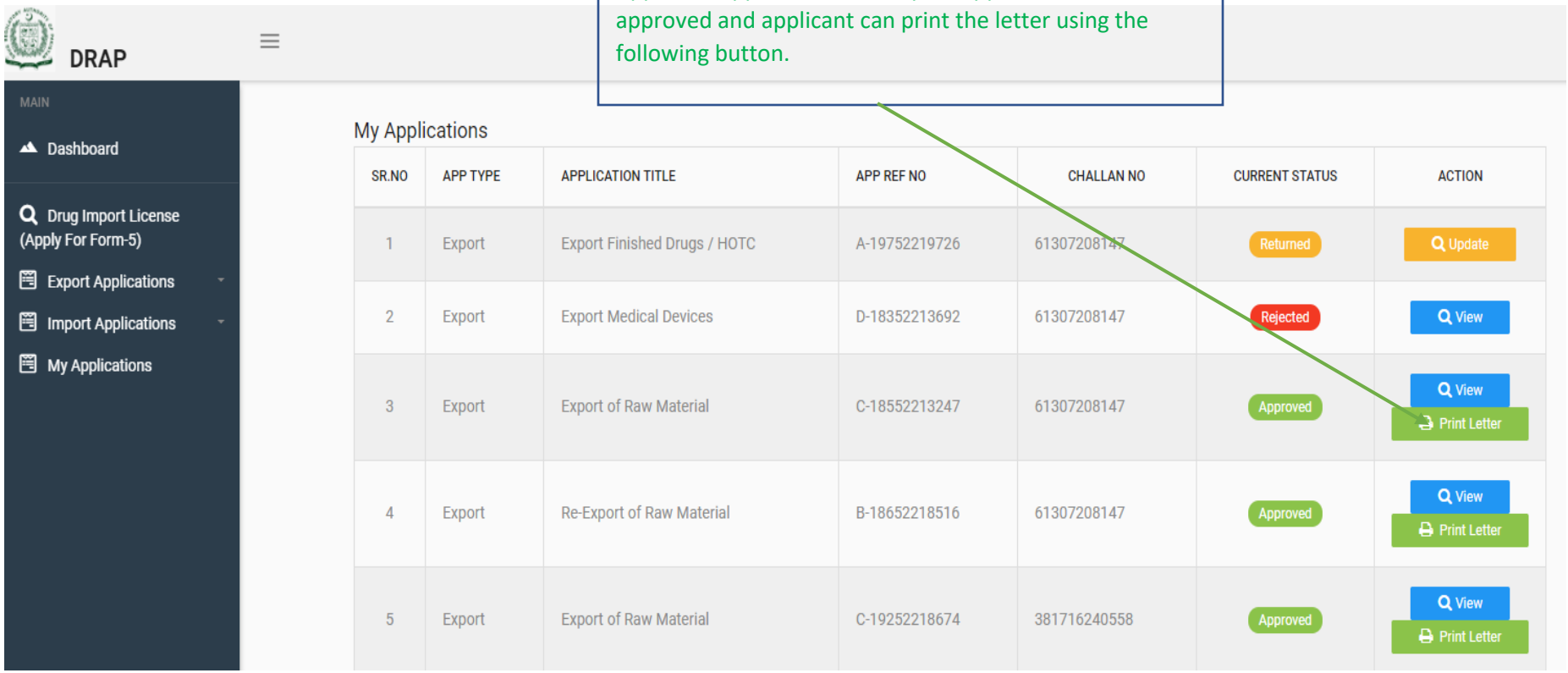


Applicant can type reply in the following box and upload the desired documents as needed. After upload click on the re-submit button as indicated below. Your application will be resubmitted to DRAP.



6. Printing of Letter (Approved Application)

Approved application means your application had approved and applicant can print the letter using the following button.



Note: Copy of Sample Letter shown on next slide.

Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
TF Complex, Sector G-9/4, Islamabad
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SAY NO TO CORRUPTION

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Computerized No C-18552213247 Date of issue 2021-Dec-20

Firm Name,Chemonics

Address, 2nd Floor NSTP H12 Islamabad

City. Islamabad

Subject: **NO OBJECTION CERTIFICATE**

Please refer to your application No. C-18552213247 dated 2021-12-20 12:28:15 on the subject cited above. The Drug Regulatory Authority of Pakistan has No Objection in exporting the below mentioned Raw Materal to **M**/s Chemonics 2nd Floor NSTP H12 Islamabad Islamabad Pakistan vide invoice no. 61307208147 dated 2021-Dec-31

Material Name	Batch No.	Mfg Date	Exp Date	Packs	Pack Size	Manufacturer	Quantity	Amount Unit Price (USD)
	TI-3212	2021-Dec-30	2025-Dec-31	10	20	**Chemonics**	**200**	2000

2. However, all other codal formalities may please be compiled at the time of Export.

3. Custom authorities are requested to check the consignment thoroughly at the time of export.

Muhammad Ishtiaq

Assistant Director (I&E)

This is computer generated document, hence signature is not required. This document can be verified using link XXXXXXXXXXXXX

DRUG REGULATORY AUTHORITY OF PAKISTAN

Telecom Foundation Complex, G-9/4, Islamabad, Pakistan

Email: addl-directormis@dra.gov.pk Phone:92-51-9107412

www.dra.gov.pk