Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

Notice

File No.: IT-13011(11)/1/2023-eoffice **Date:** 16 JAN 2024

Subject – Launching of additional Forms on National Single Window System (NSWS) Portal- reg.

This is in continuation to this office notice dated 01.01.2024 whereby 3 Forms i.e. MD-01, MD-12 and MD-16 were made 'Live' on NSWS portal w.e.f. 01.01.2024.

Now following additional Forms have also been developed and will be made 'Live' on NSWS w.e.f. **16.01.2024**:-

1. Application for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis- CT-10.
2. Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study-CT-12.
3. Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study-CT-13.
4. Application for grant of licence to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis -CT-16.

Further Form 12 i.e. 'Application for licence to import drugs for purpose of examination, test or analysis' will also be made 'Live' on **24.01.2024**.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said five activities through NSWS portal only and the existing SUGAM online portal for the said activities will be disabled w.e.f. **10.02.2024.**

The NSWS portal can be browsed through *https://www.nsws.gov.in* and a user guide is also attached herewith for guidance for ready reference.

This is for information of all concerned stakeholders.

Encl.: As above

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To:

1. All the concerned stakeholders
2. CDSCO Website

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DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY
GOVERNMENT OF INDIA

National Single Window System

User Guide:

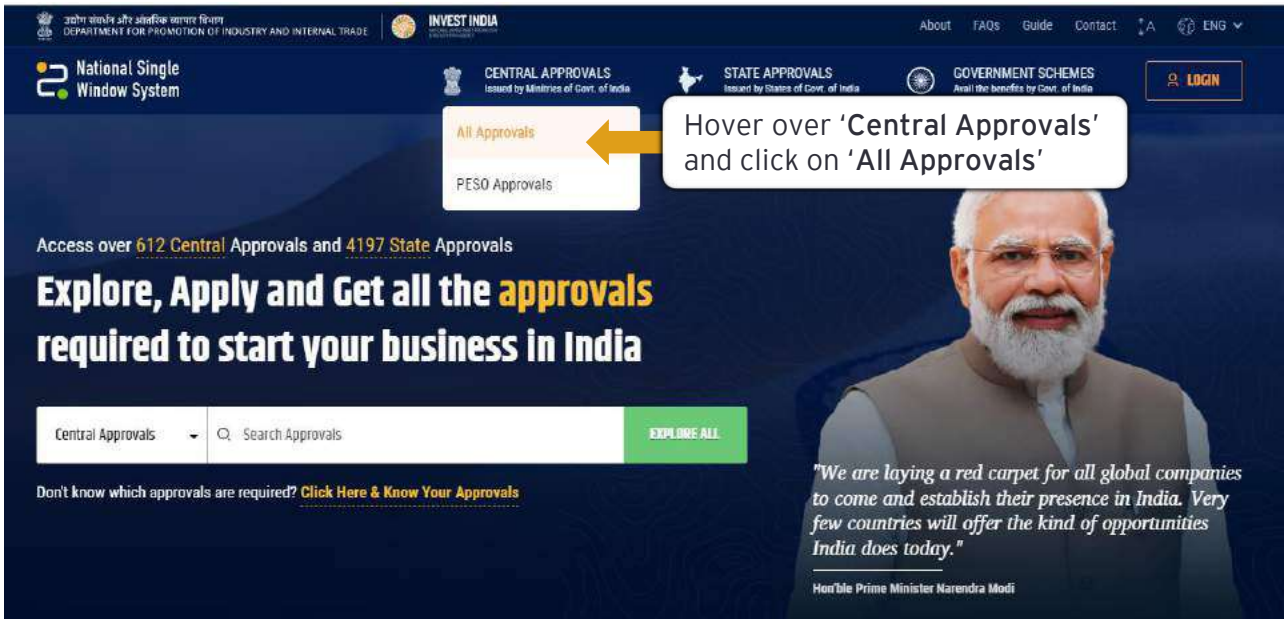
How to apply for CDSCO Approval

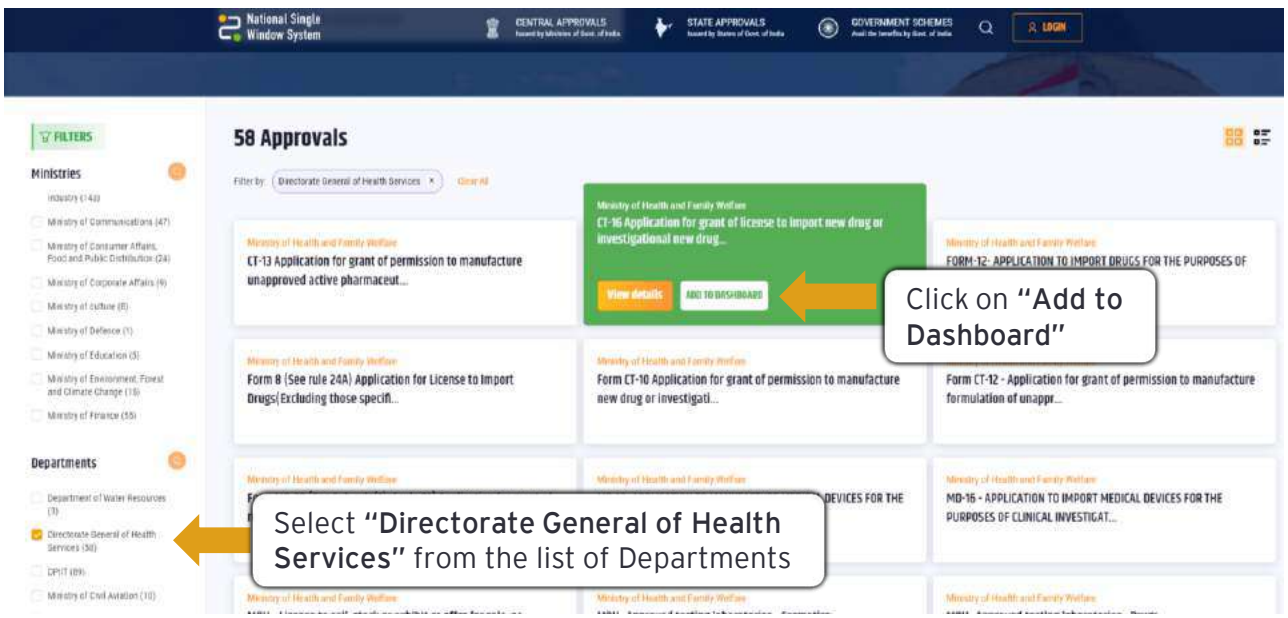
National Single Window System (https://www.nsws.gov.in/)

National Single Window System

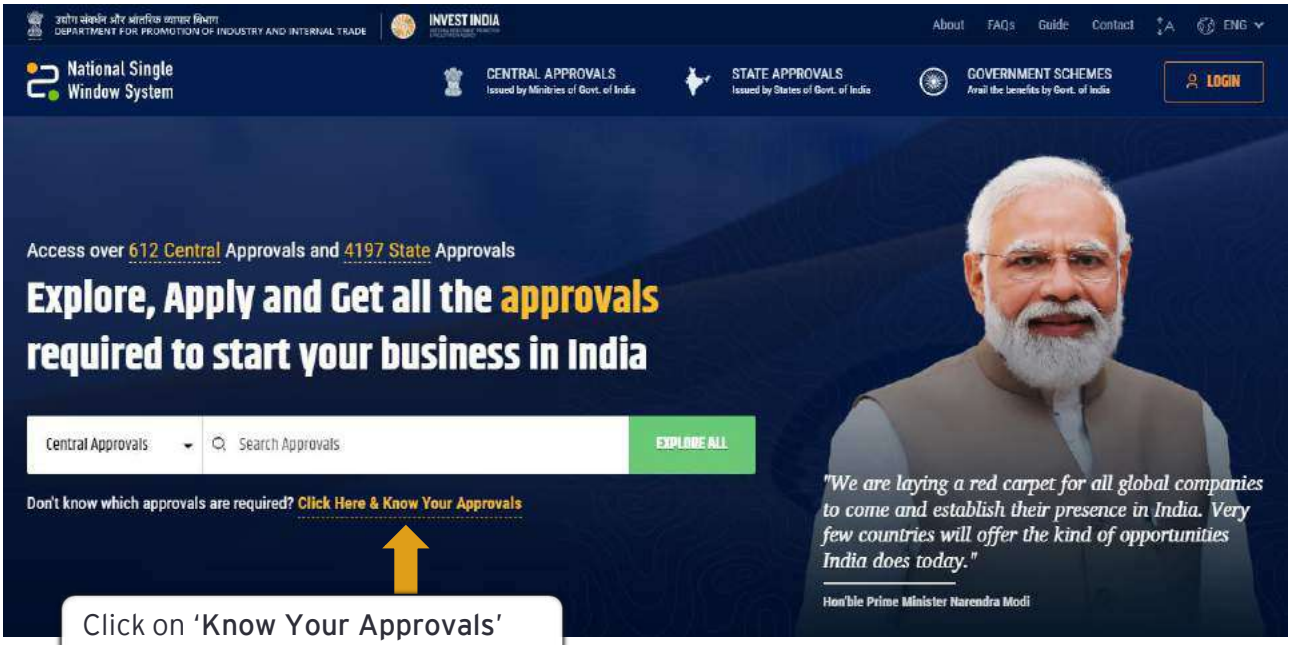
Table of Contents

How to view, add approval from 'All Approvals'

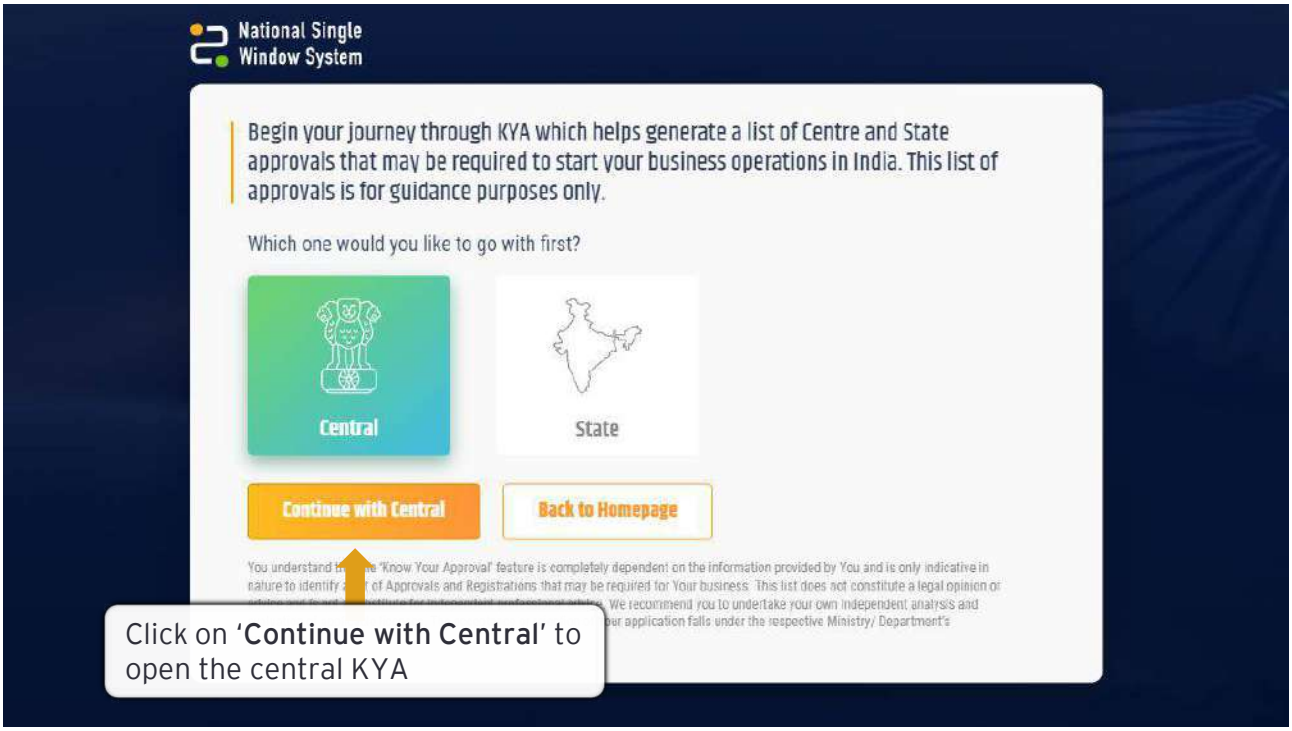




How to view, add approval through Central KYA

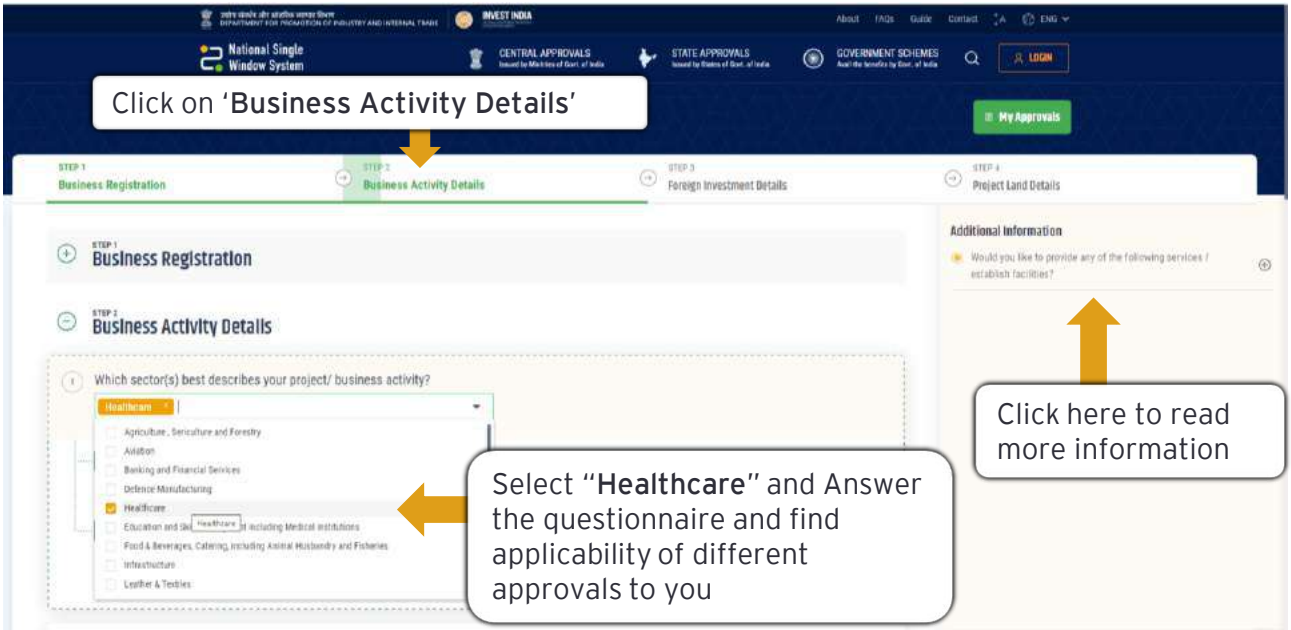


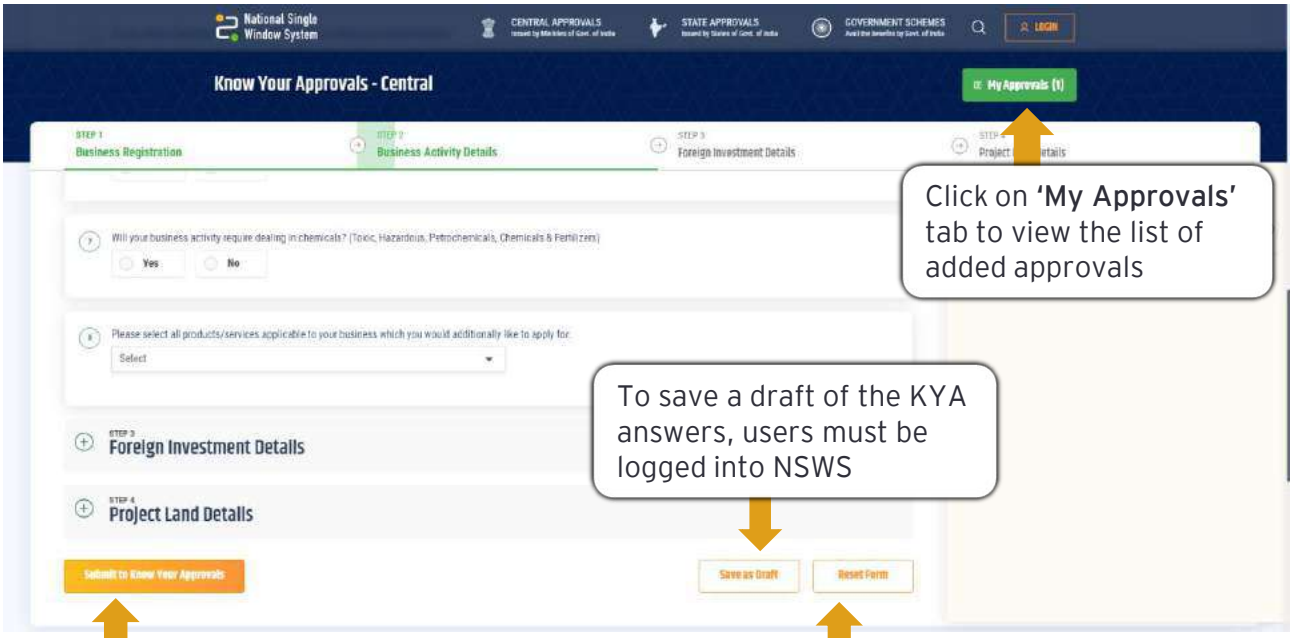
Click on '**Know Your Approvals**' on the NSWS homepage



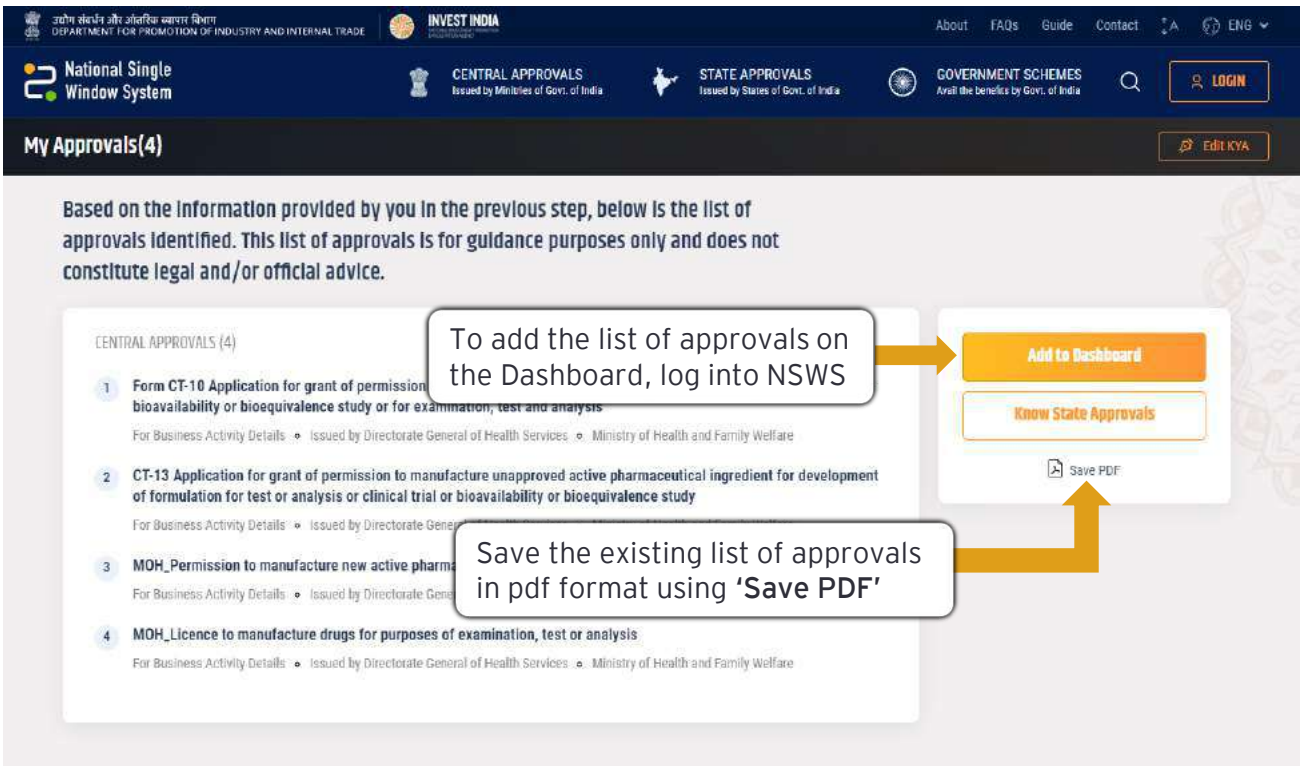
Click on '**Continue with Central**' to open the central KYA

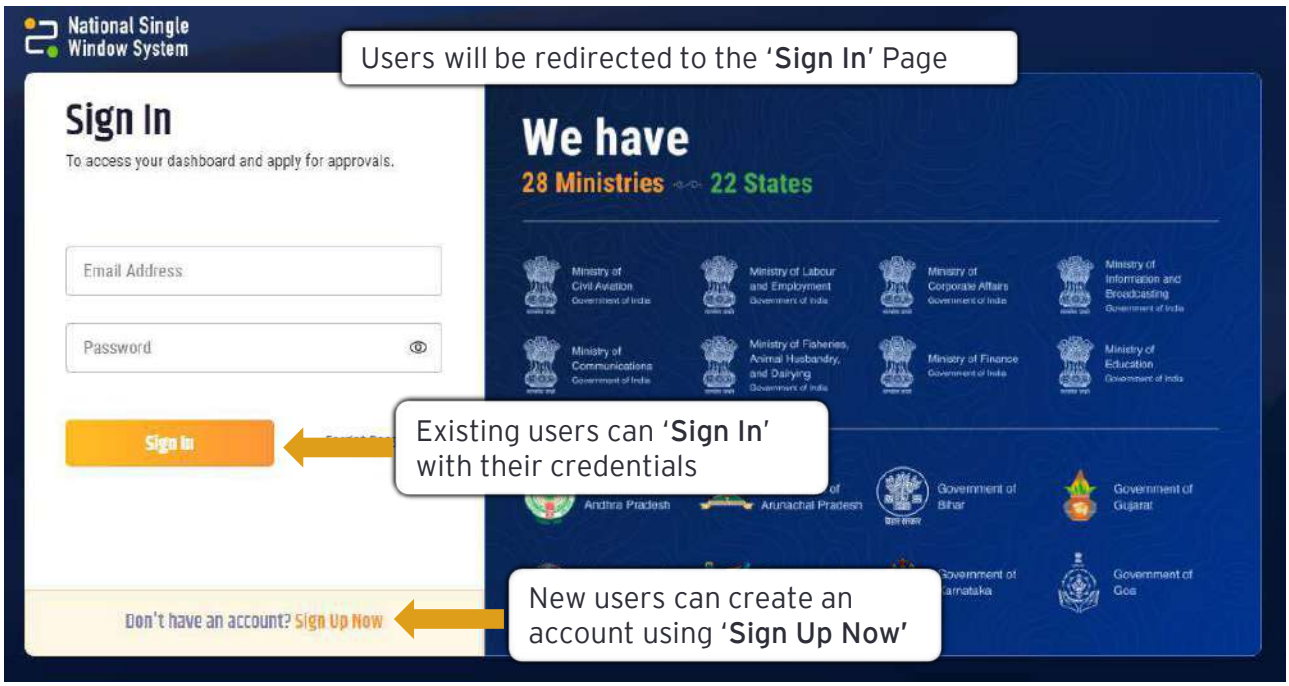
How to view, add approval through Central KYA



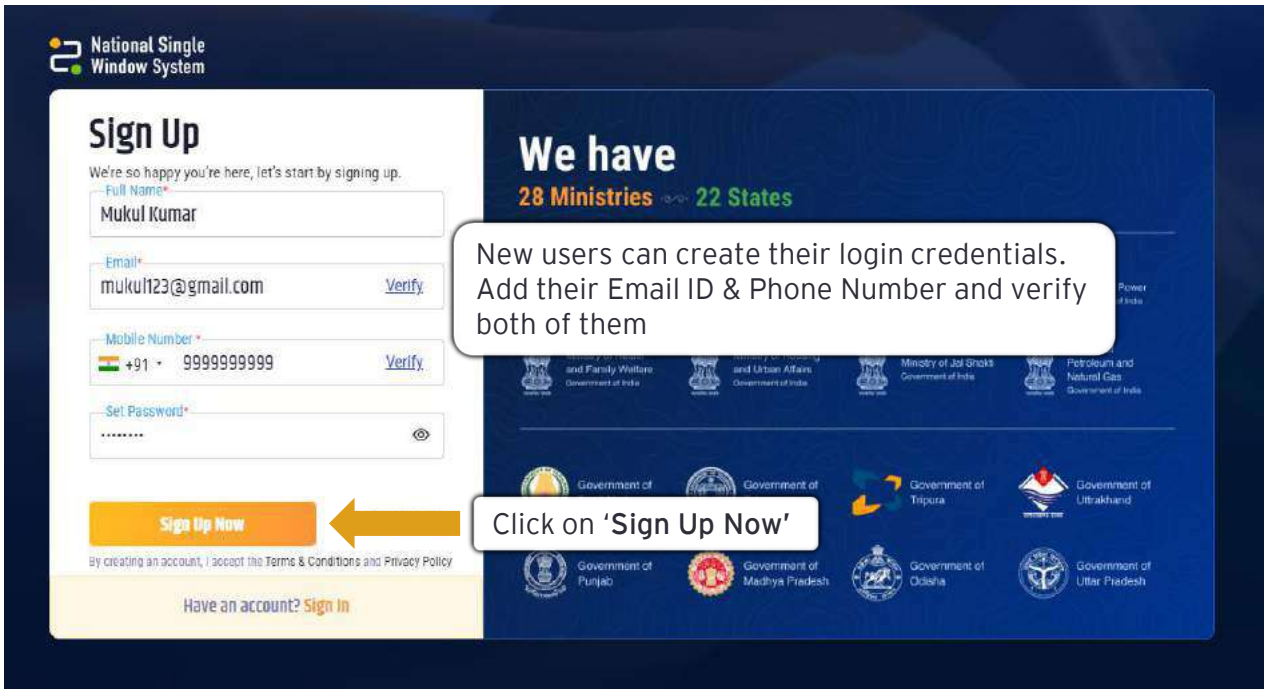


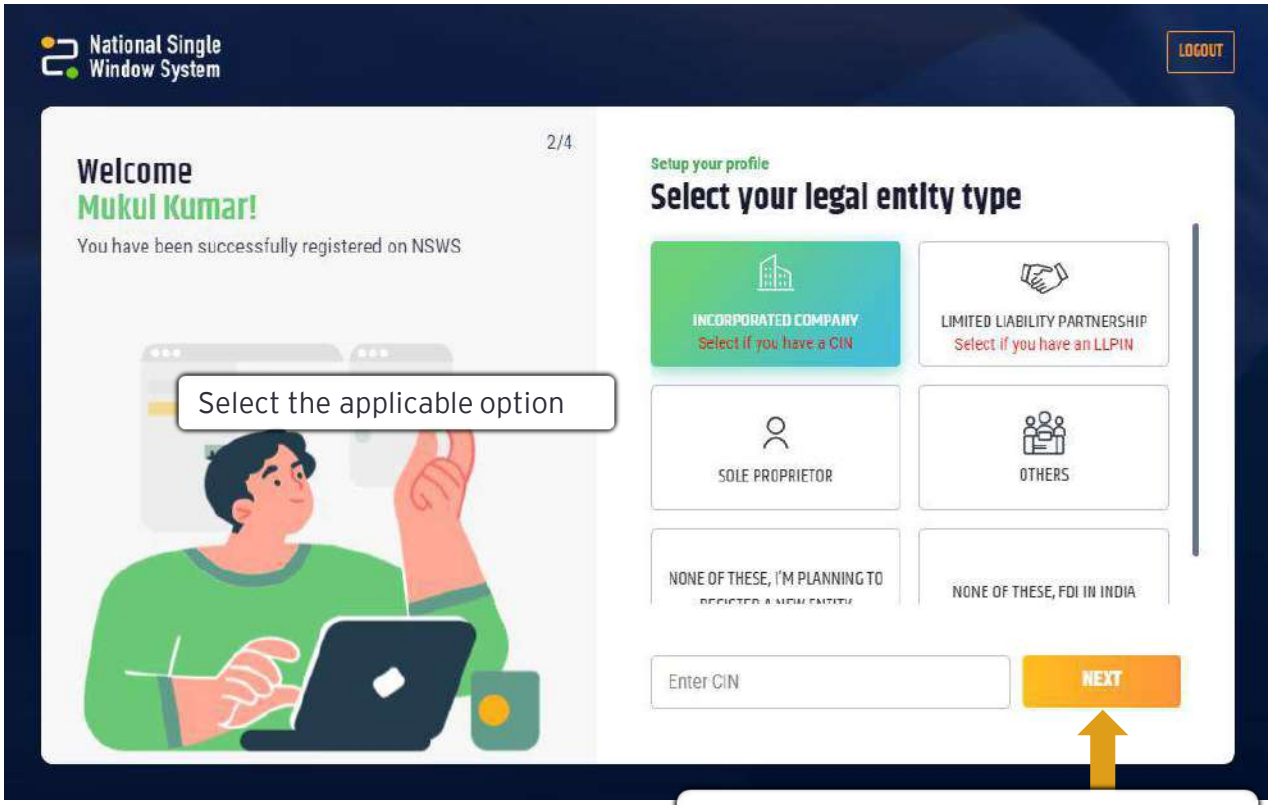
How to add identified approval to the Dashboard



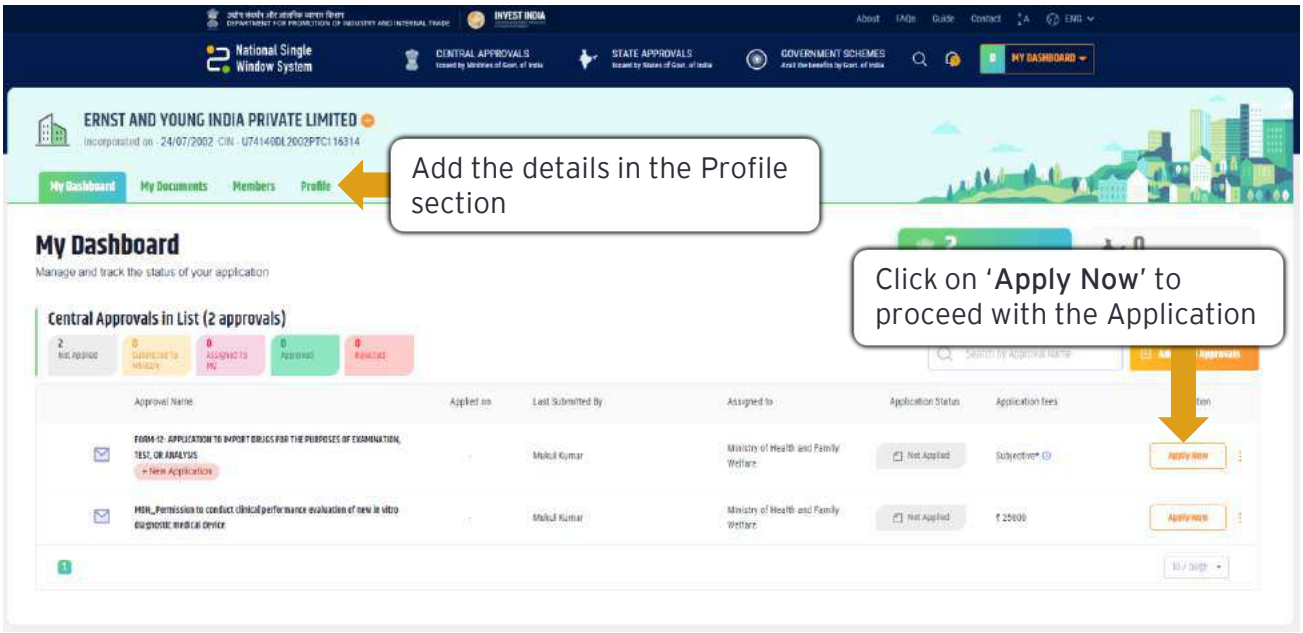


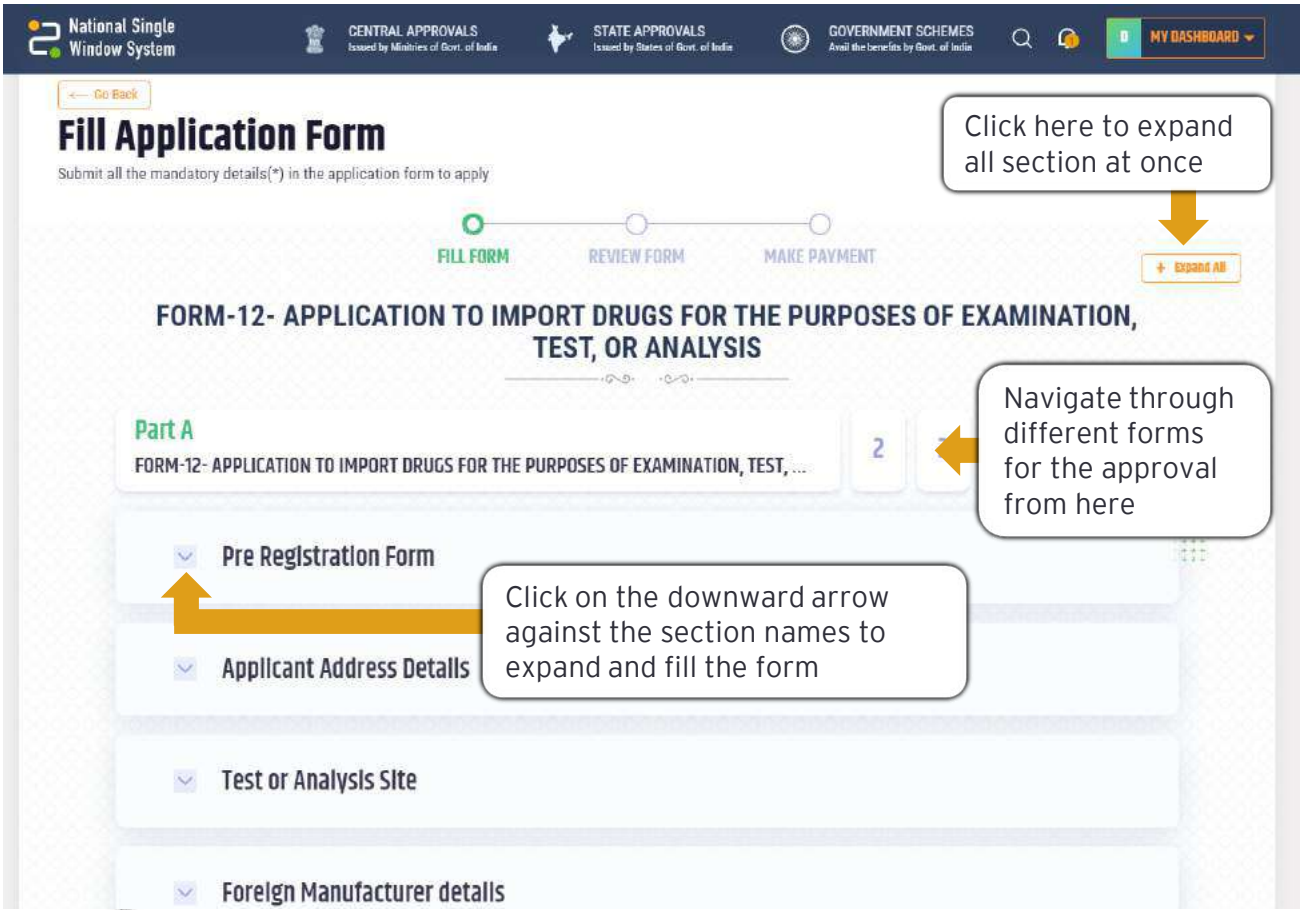
How to login and apply for approval (New User)





How to fill the application form





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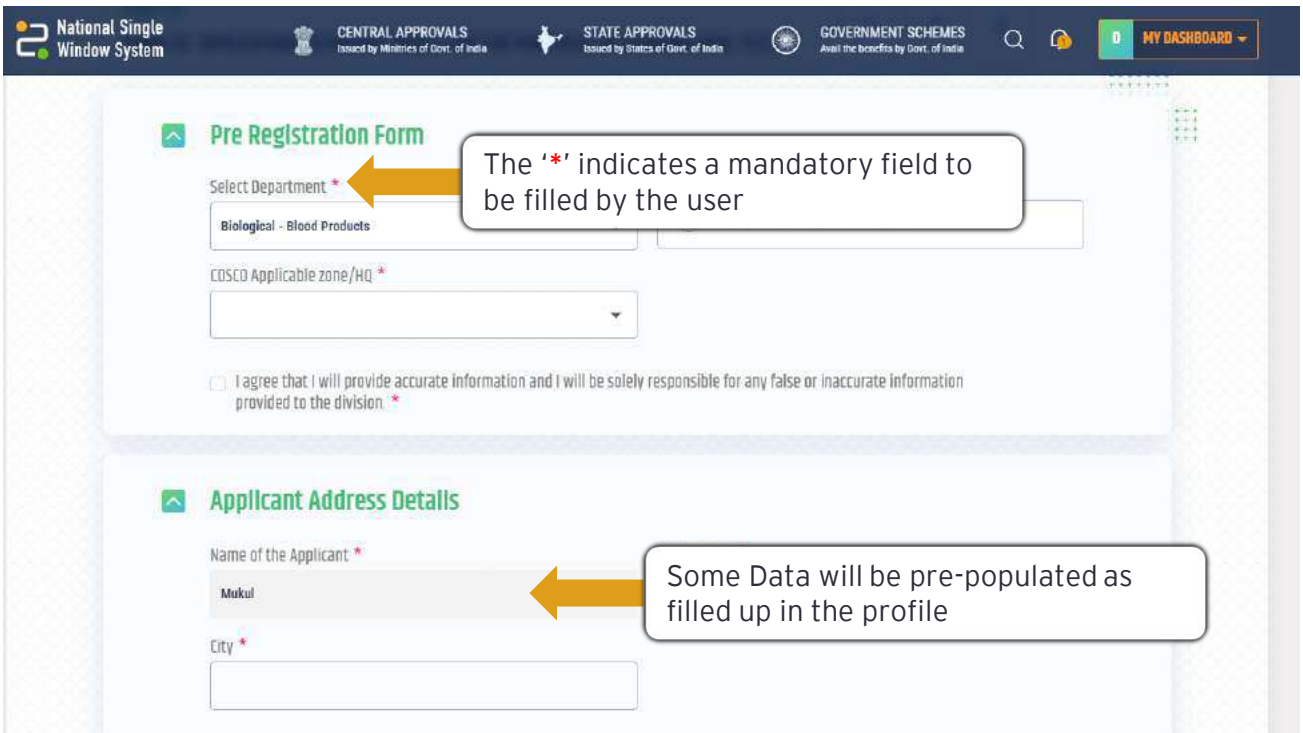
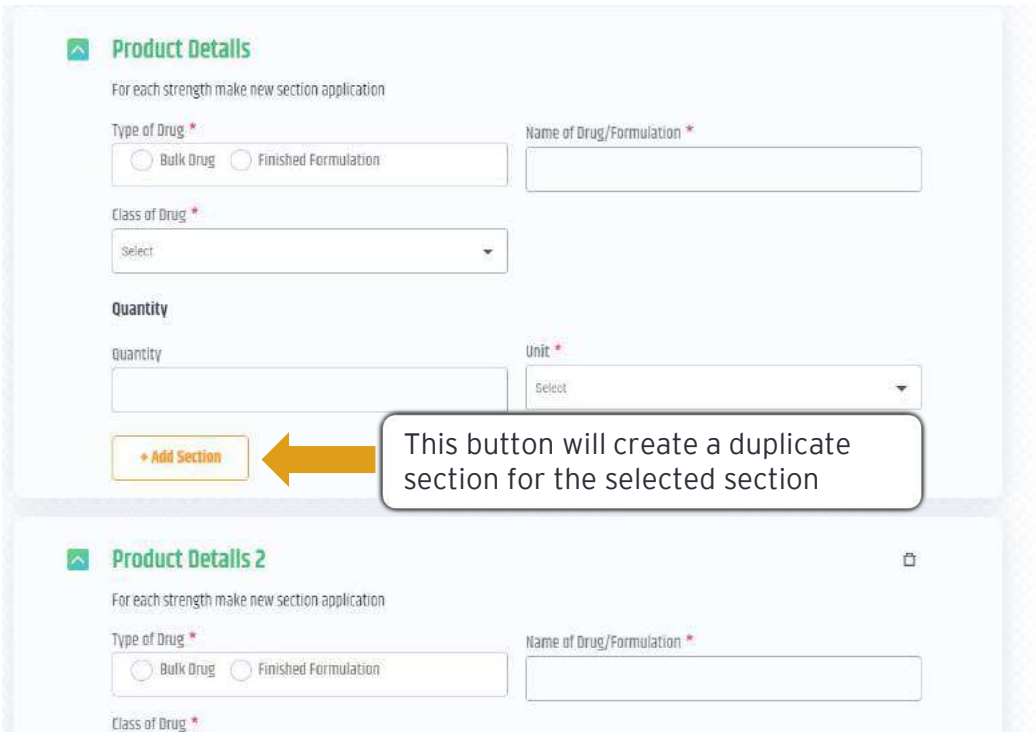
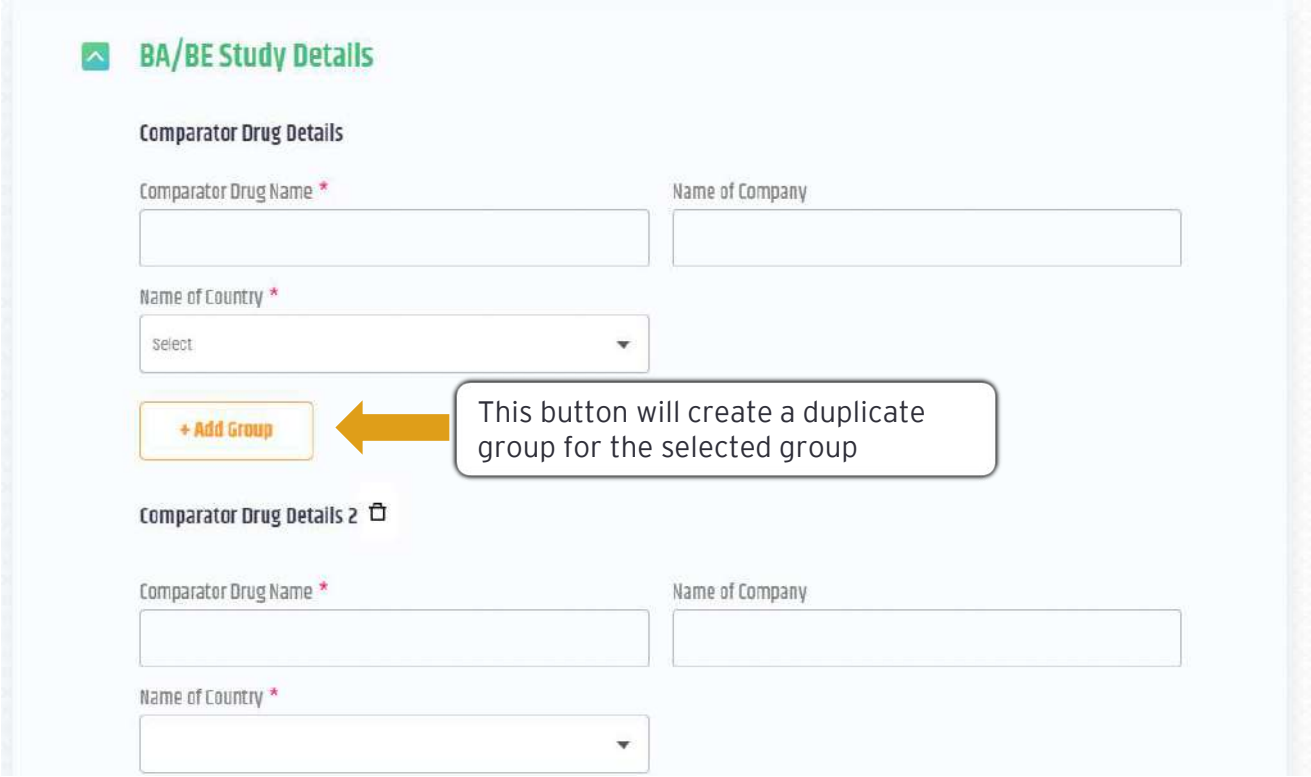
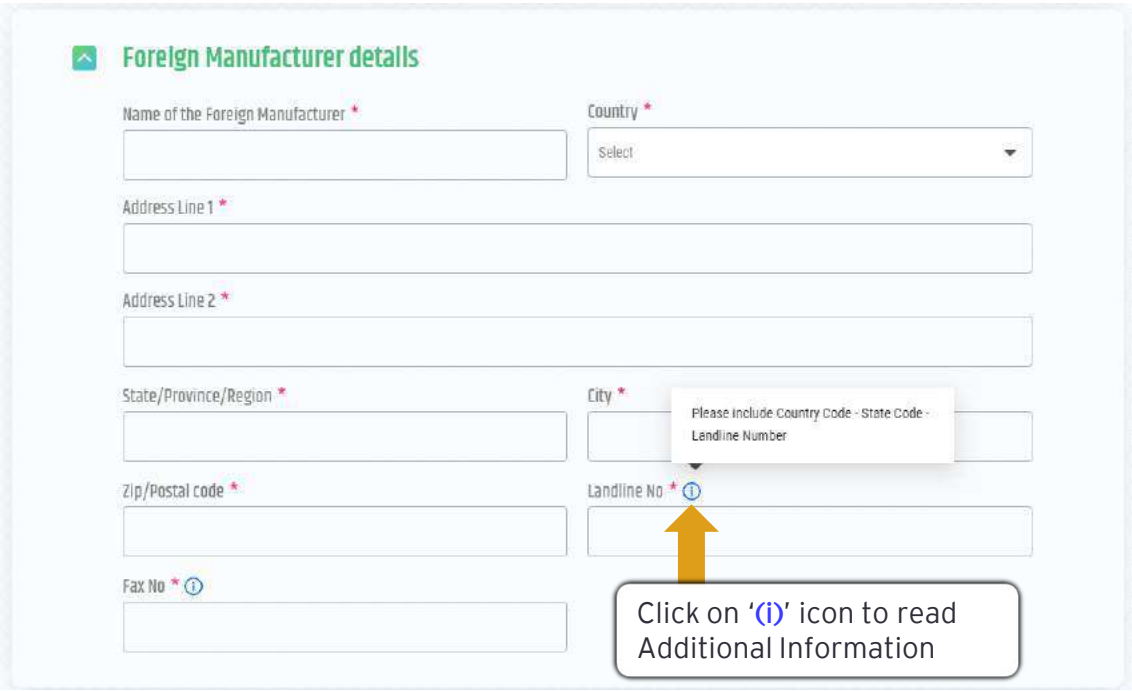


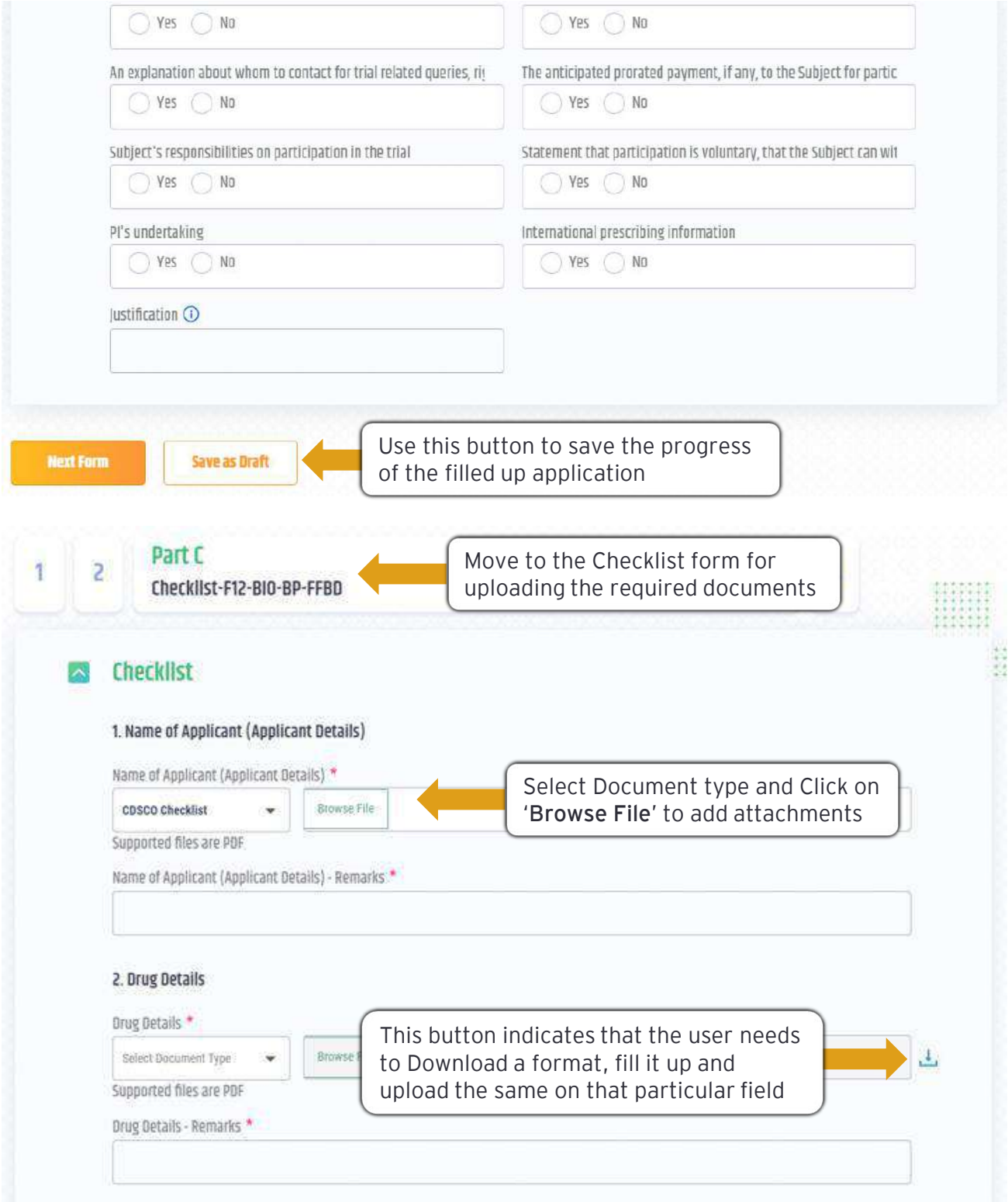


How to fill the application form

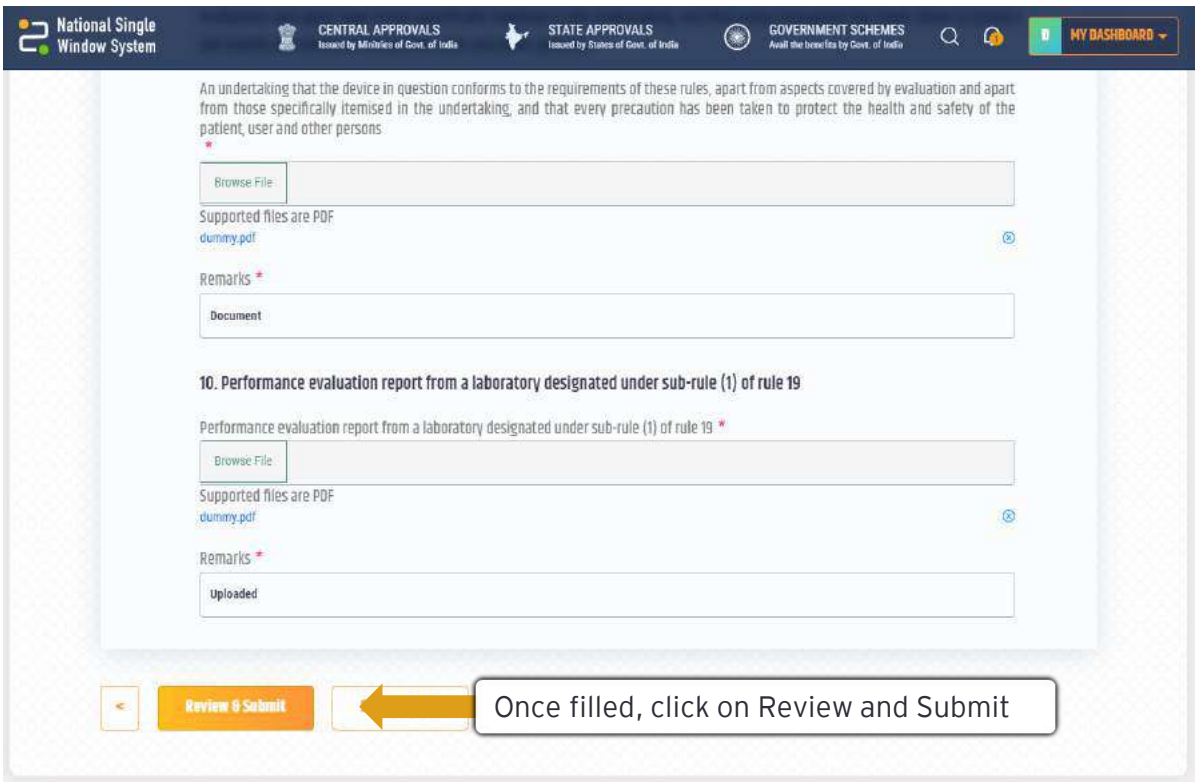


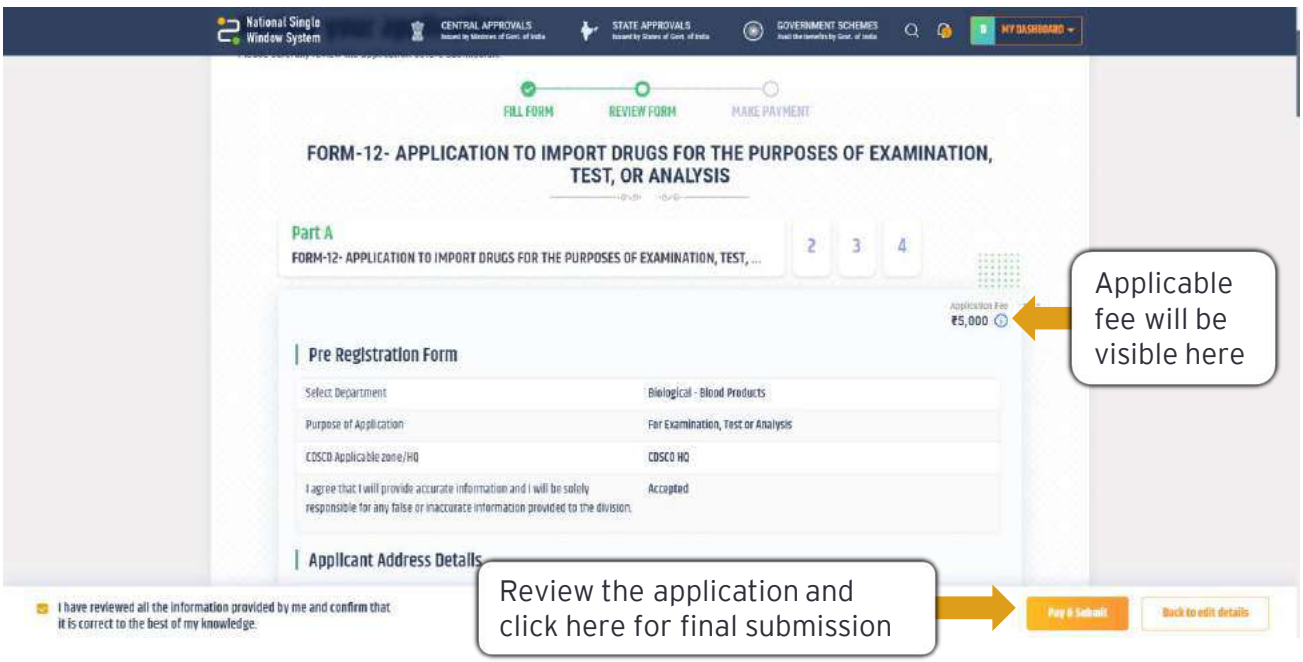


How to fill the application form

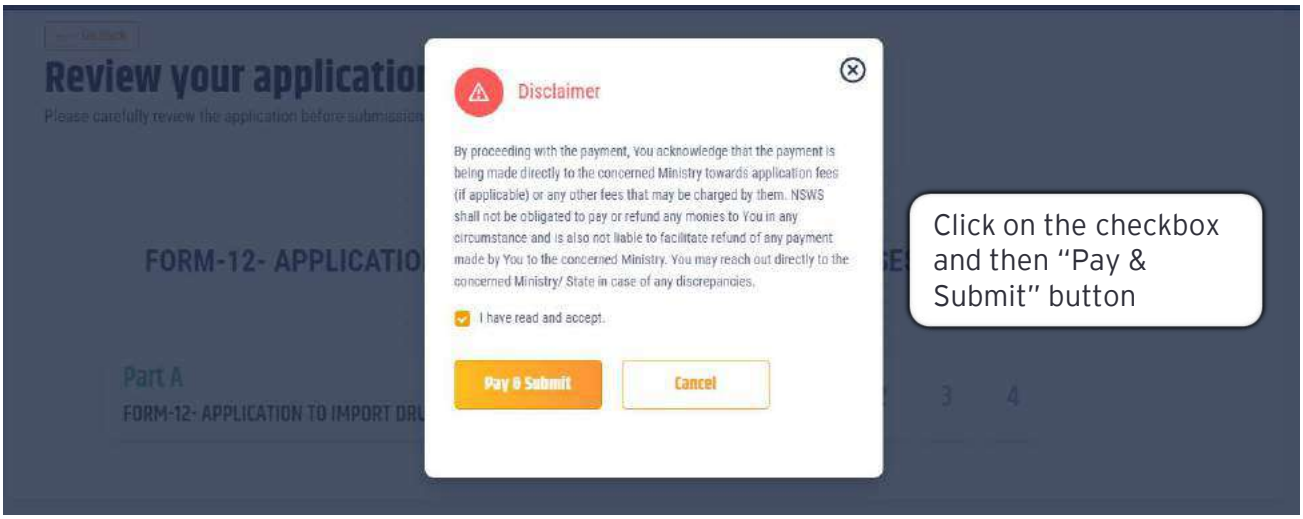


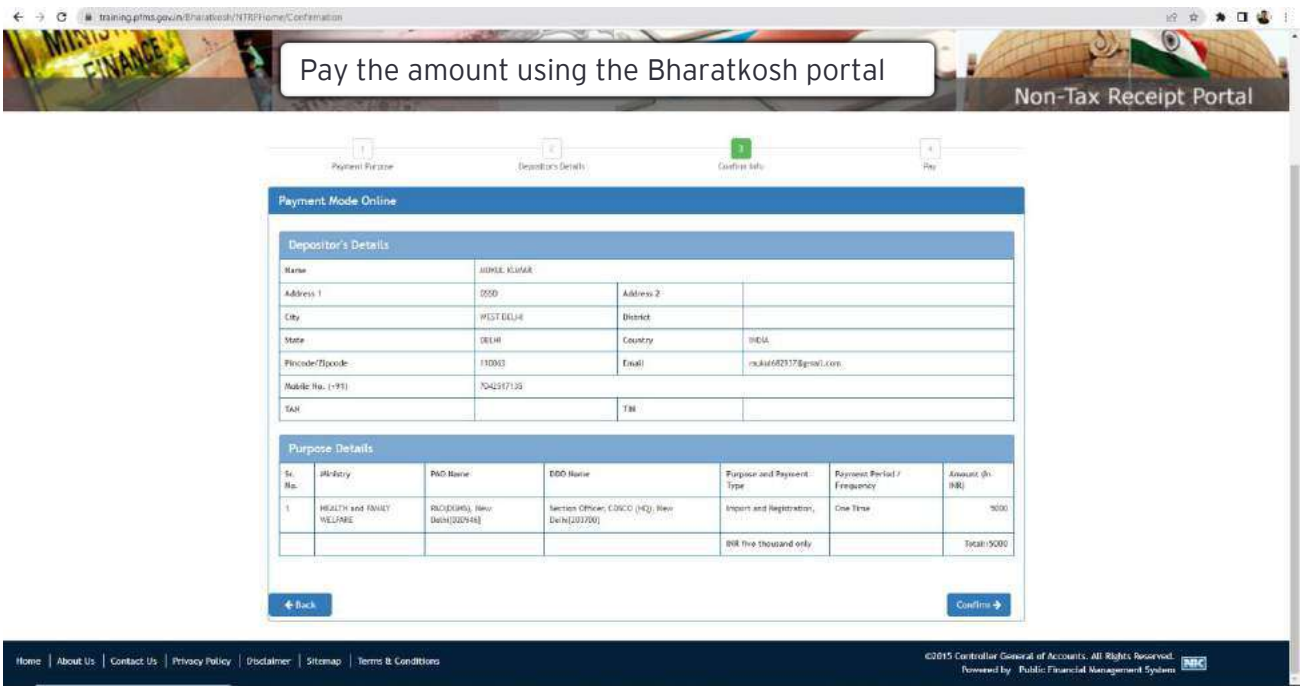
How to fill the application form



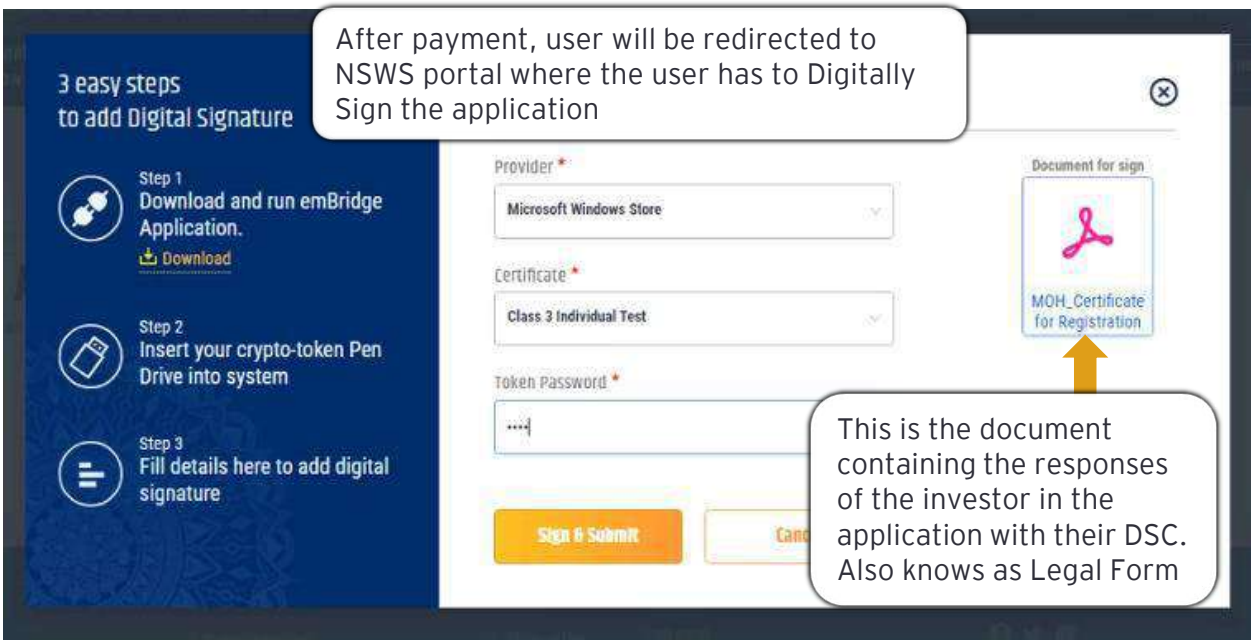


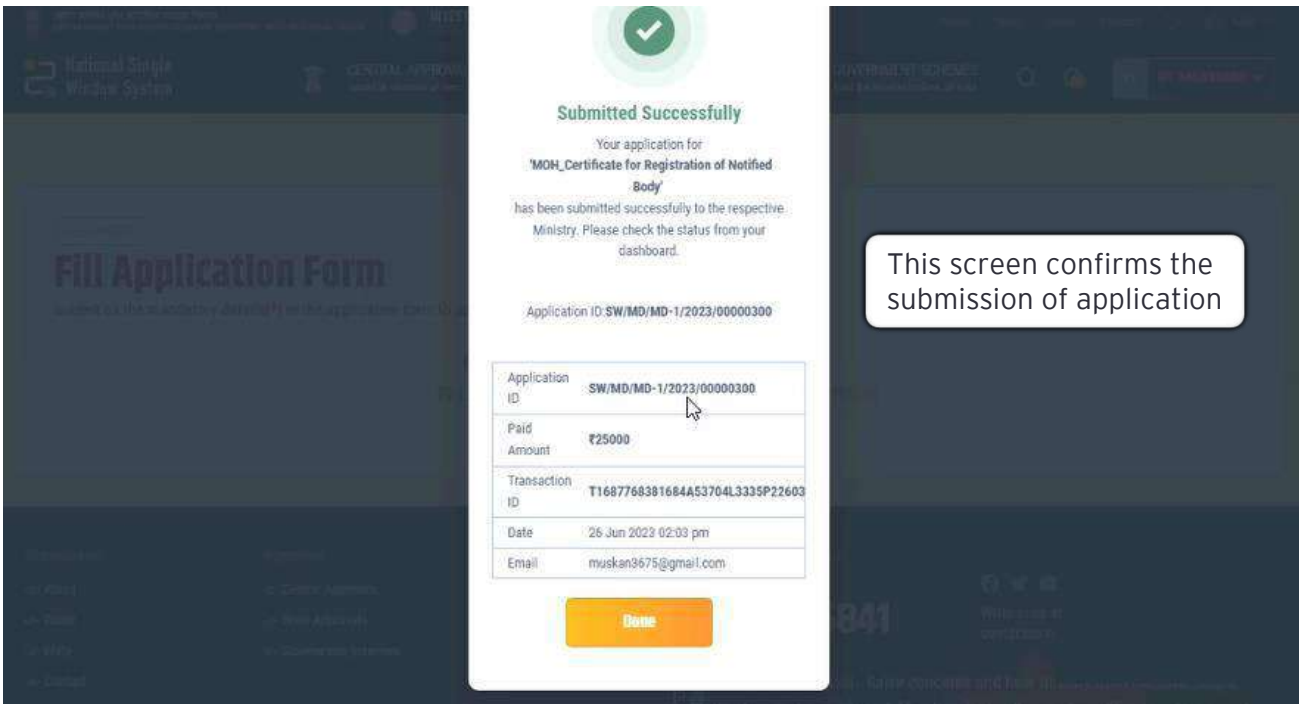
How to fill the application form



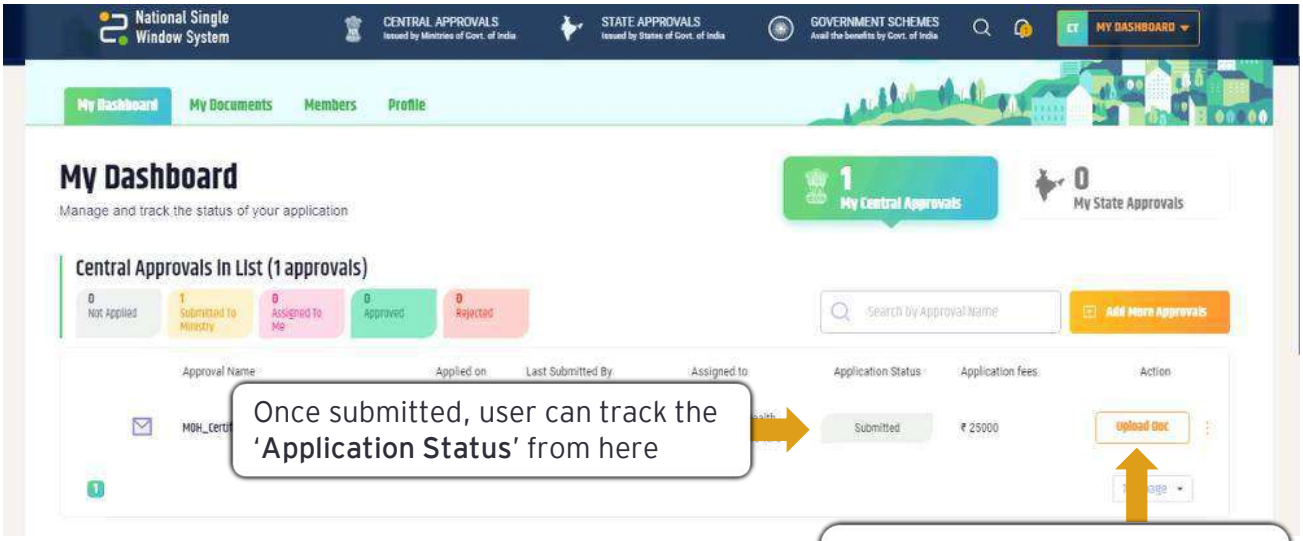


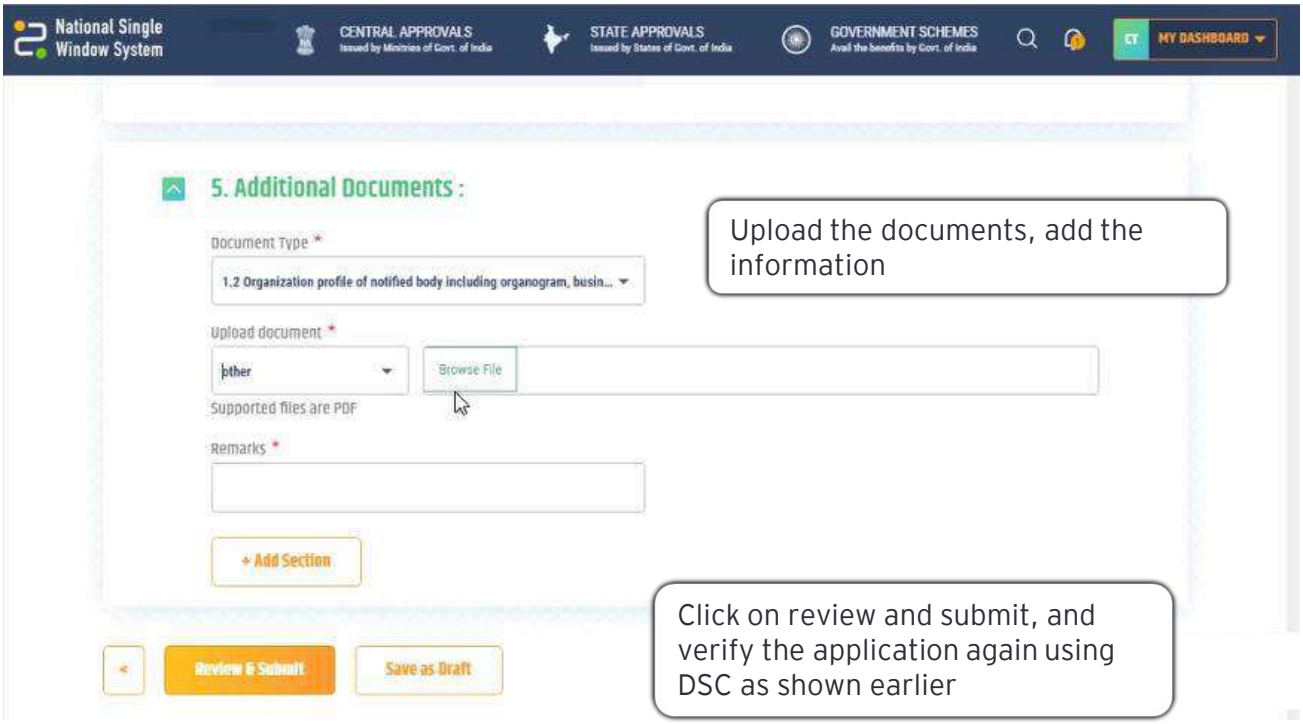
How to fill the application form



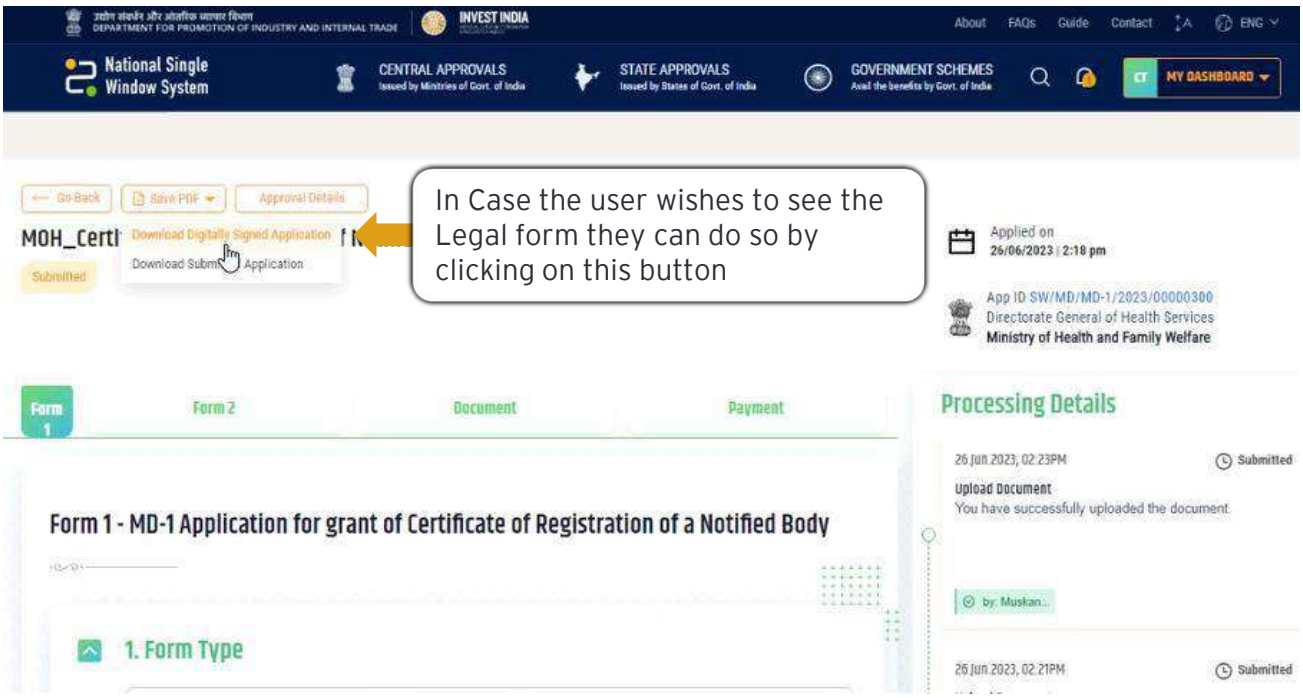


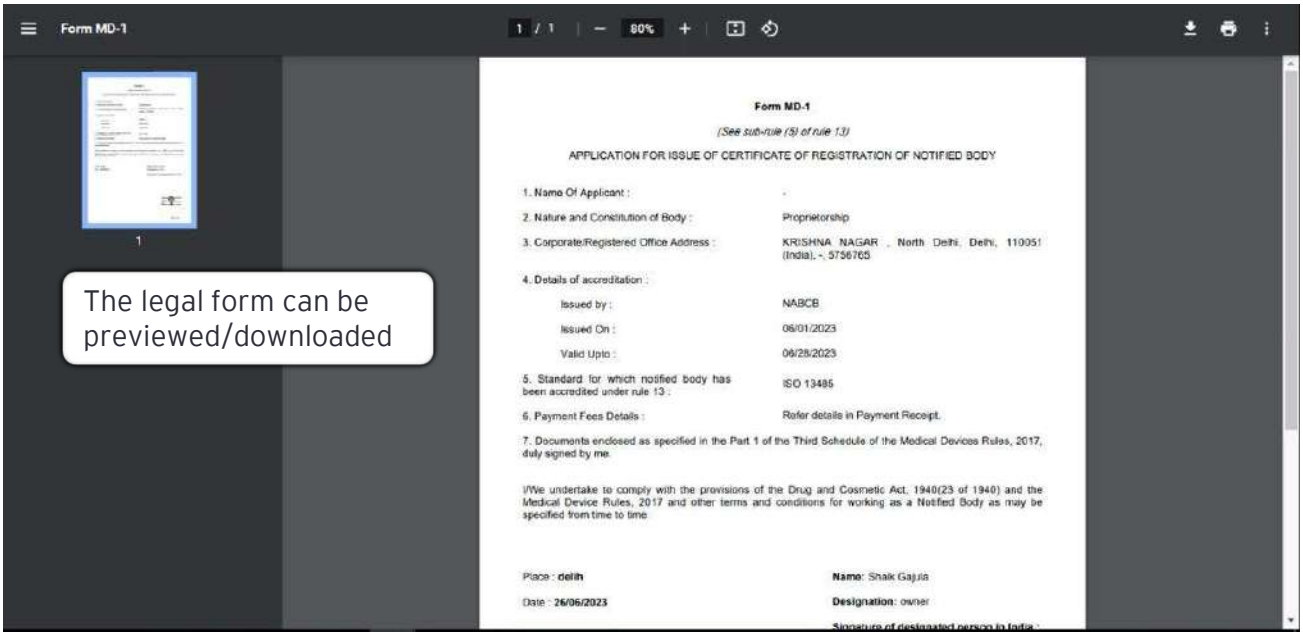
How to fill the application form



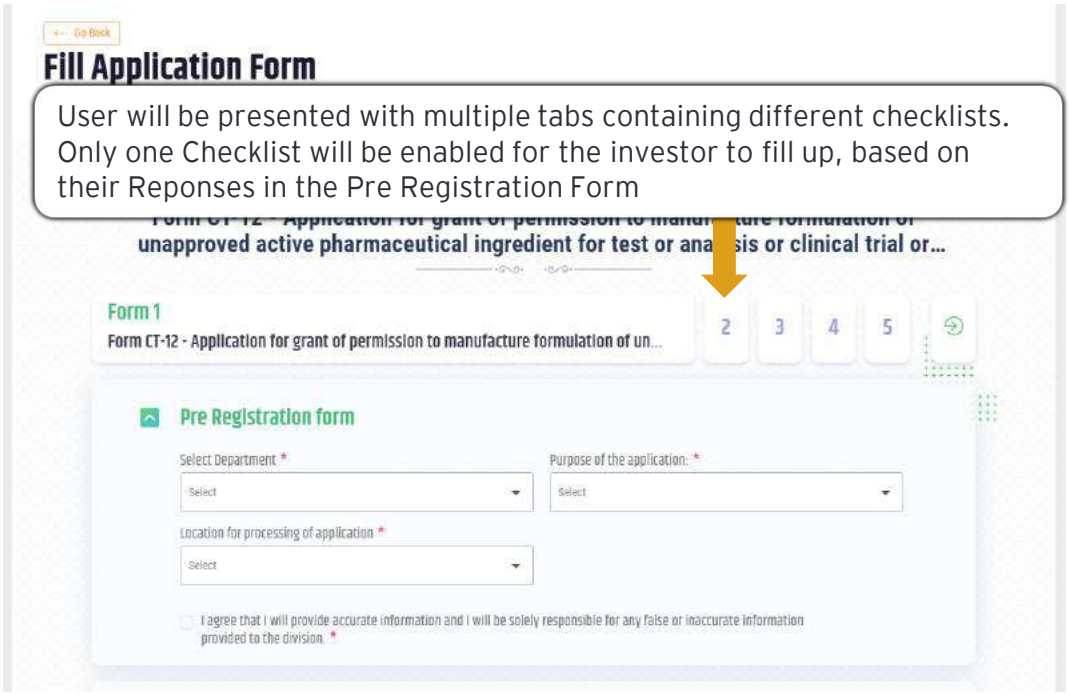


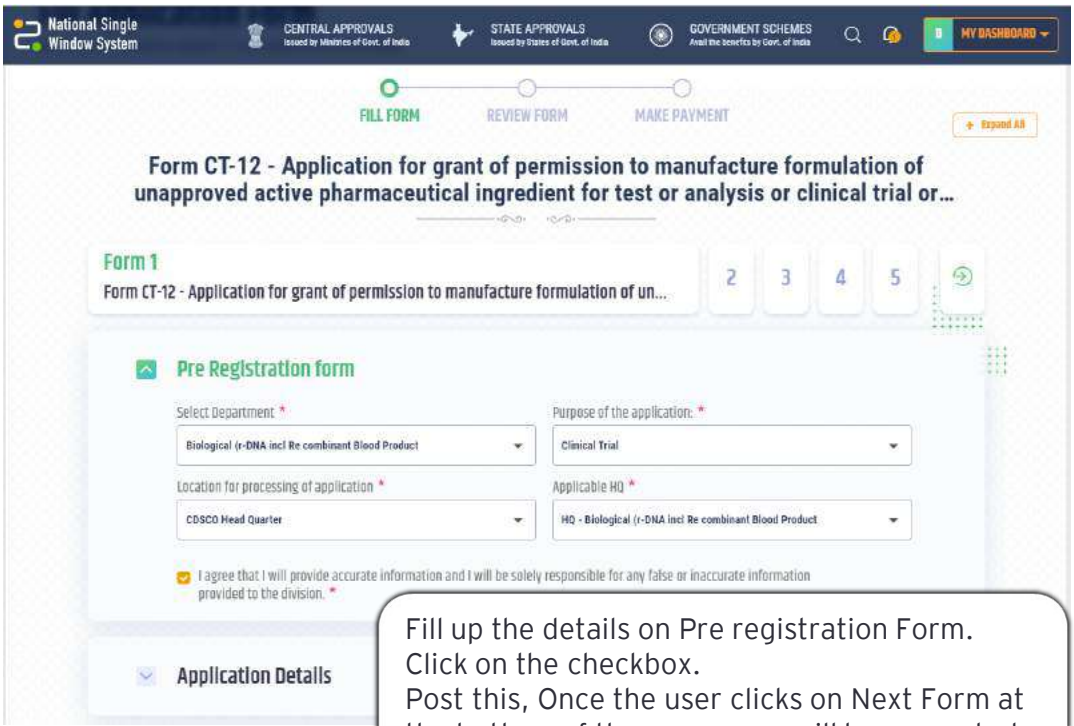
How to view the application form (Legal Form)



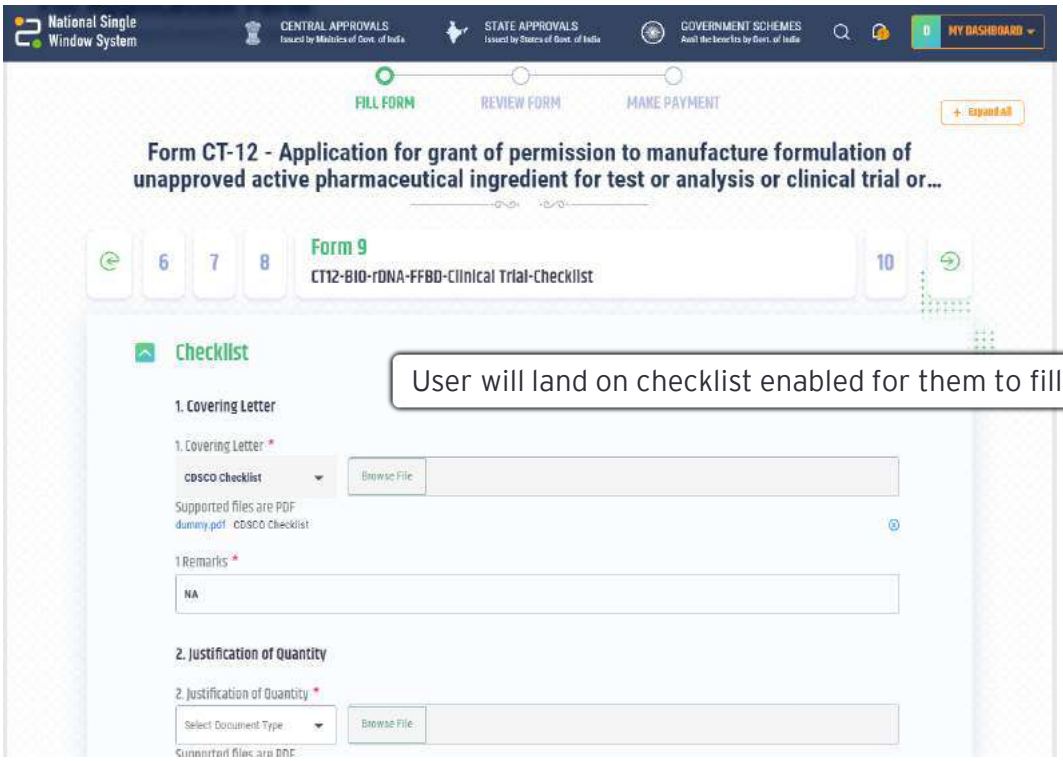


Checklist Activation

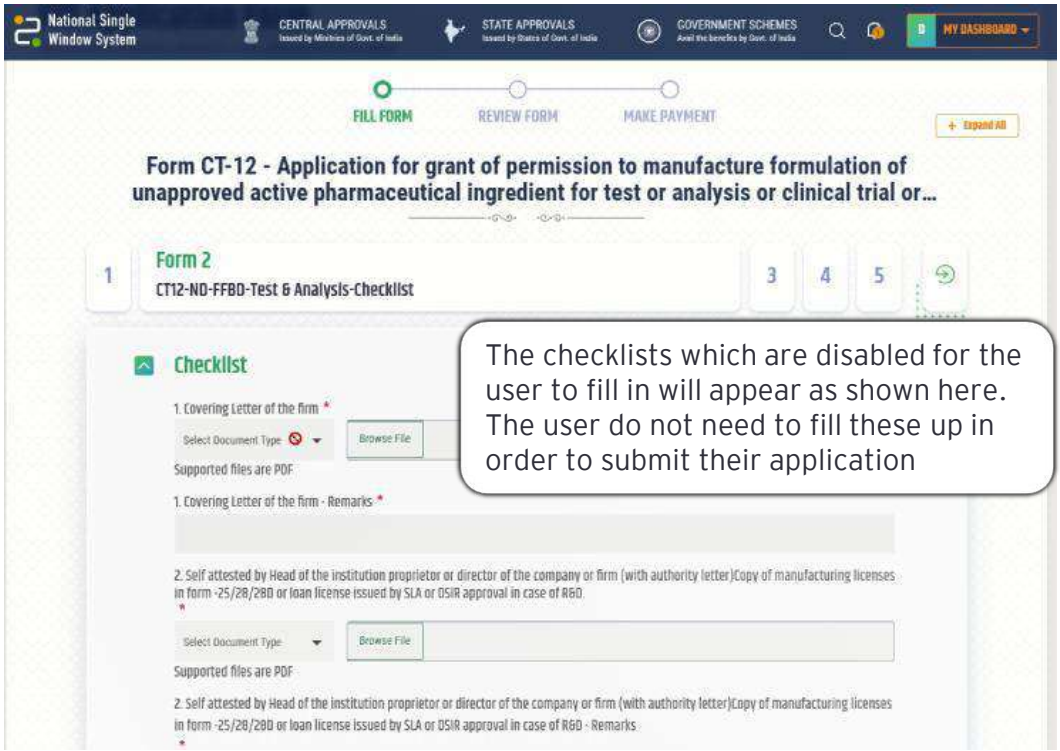




Checklist Activation



User will land on checklist enabled for them to fill up



The checklists which are disabled for the user to fill in will appear as shown here. The user do not need to fill these up in order to submit their application

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DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY
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What are the technical Requirements for NSWS

System Requirements for National Single Window Portal

- Windows OS (XP or higher)
- MAC OS (X 10.9 or higher with latest updates)
- **View/ Download Pdf**: Download the pdf reader to view and download the pdf files from the link: https://get.adobe.com/reader/)
- Platform requires a minimum screen size of 976px wide , but using 1024px or higher is recommended
- **Digital Signature Certificate (DSC)**: Latest version of emBridge software need to be installed in the system which acts a connecting link/driver between the NSWS and DSC

Web browsers best suited for National Single Window System

- Google Chrome
- Mozilla Firefox
- Apple Safari

Have any further questions?

Please submit your queries and feedback on:

https://www.nsws.gov.in/contact-us

Email: contactus-nsws@investindia.org.in

Ph: 1800 102 5841

(Monday - Saturday, 9am - 6pm)

Last Updated on 14 March 2023

DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE

MINISTRY OF COMMERCE & INDUSTRY, GOVERNMENT OF INDIA

सत्यमेव जयते

National Single Window System (NSWS)

CDSCO

Ministry User Guide

INVEST INDIA

NATIONAL INVESTMENT PROMOTION AND FACILITATION AGENCY

National Single Window System

Table of Contents

1 About This Manual

1.1 Purpose of this Manual

The purpose of this manual is to provide guidance to the CDSCO Ministry/Department users concerning:

- ❖ Services and Functionalities provided by National Single Window System (NSWS) for approval application processing.
- ❖ Step-by-step guide on how to evaluate approvals applications received through NSWS.

1.2 Organization of This Manual

This manual has been organized into the following parts:

- ❖ Overview of NSWS
- ❖ NSWS Ministry/Department User Services

1.3 Acronyms, Abbreviations, Definitions

Term /Abbreviation	Definition / Full Form
Approval	Approvals, as used in this document, refer to any regulatory or legal clearance to be obtained from the government by any investors, entrepreneurs, businessperson, or business entity before commencing any business activity in India, including but not limited to Approvals, Registrations, Licenses, Permits, Clearances, Certifications etc.
ICC	Investment Clearance Cell
Investment Clearance Cell	Cell setup under Invest India, DPIIT, to facilitate investors. Responsible for developing and maintaining NSWS
KYA	Know Your Approval
National Single Window System (NSWS)	The digital portal serving as the national single window system under the Investment Clearance Cell

2 Introduction to NSWS

2.1 Objective of NSWS

The Hon'ble Minister of Finance, Government of India, during the budget speech on 1st February 2020, announced the setting up of an Investment Clearance Cell (ICC). The proposed ICC has been developed as an online portal, named NSWS, which will act as a National Single Window System (NSWS) for investors, entrepreneurs, and businesses.

NSWS enables investors to identify, apply, track and obtain approvals needed before starting any business operations in India. This eliminates the need for investors to visit multiple IT platforms and authorities to gather information and obtain approvals from different stakeholders.

NSWS aims to fulfill the following objective:

- Establish a single window mechanism to integrate the services provided by various central government ministries, departments, and select state governments related to starting and operating any business activity.
- Provide a single window interface for procuring approvals required to commence a business in India.
- Provide efficient, convenient, transparent, and integrated electronic services to investors.
- Provide a uniform and seamless experience to the investor through a unified interface.

2.2 Scope of NSWS

NSWS covers Central and State approvals required by any investor, both foreign or domestic, before starting any business operations or activities in India, including but not limited to registrations, licenses, permits, NOCs and approvals. It provides a platform for any investor to identify, apply track and obtain final decision on their applications. The final authority of approving or rejecting applications resides with the respective authorities.

2.3 Salient Features and Advantages of NSWS

NSWS has been designed keeping the investor at the centre, and boasts of the following features:

- Provides a single unified interface to investors to identify, apply, track and obtain approvals.
- Helps investors identify applicable approvals depending on the specific business activities being planned and other investor-specific context.
- Provides an 'Approval Repository' where the investor can select and apply for any approvals, as needed.
- Reduces the need to fill in same information at multiple places through intelligent auto-population.
- Provides ability to track status of an application and raise reminders to authorities, as per agreed process, if any.

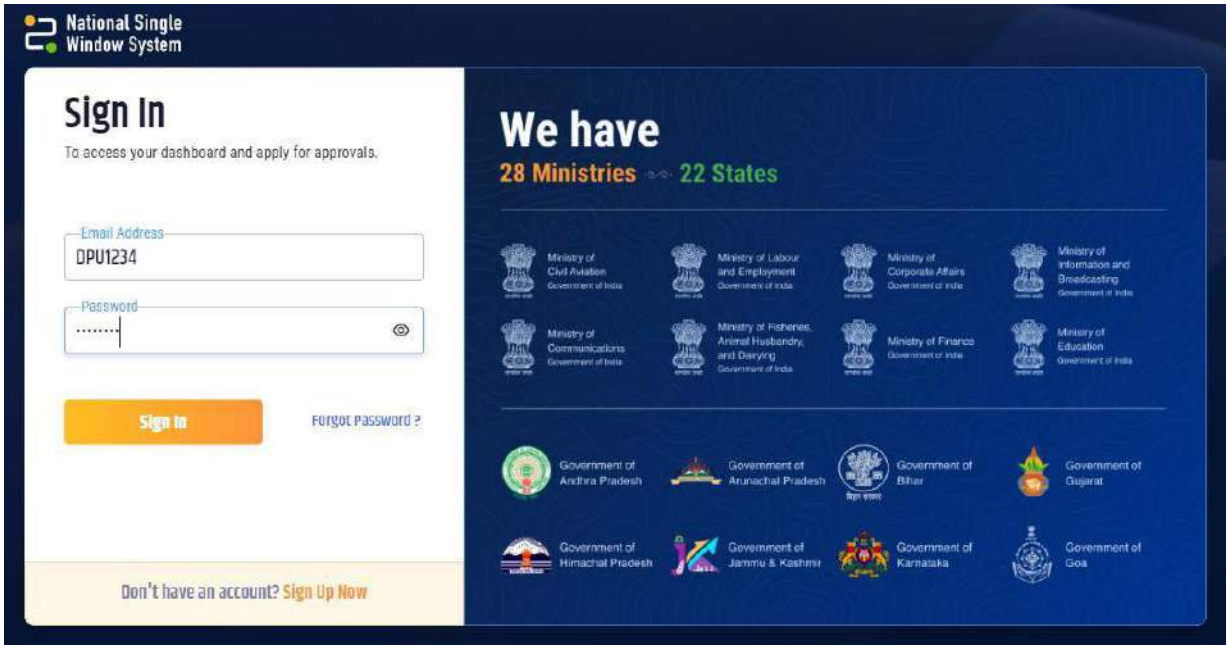
- Provides a unified document repository to where investors can upload and save their documents, and view and download documents issued to them by authorities.
- Provides an intuitive and easy to use communication module to respond to any clarifications or additional information requests raised by processing authority on submitted applications.
- Guides investor in situations where multiple forms or approvals need to be submitted in a specific sequence and timing.
- Provides a scheduler to arrange and conduct meetings online with concerned authorities, as per agreed process, if any.

3 Processing Applications on NSWS

3.1 Ministry Dashboard Overview

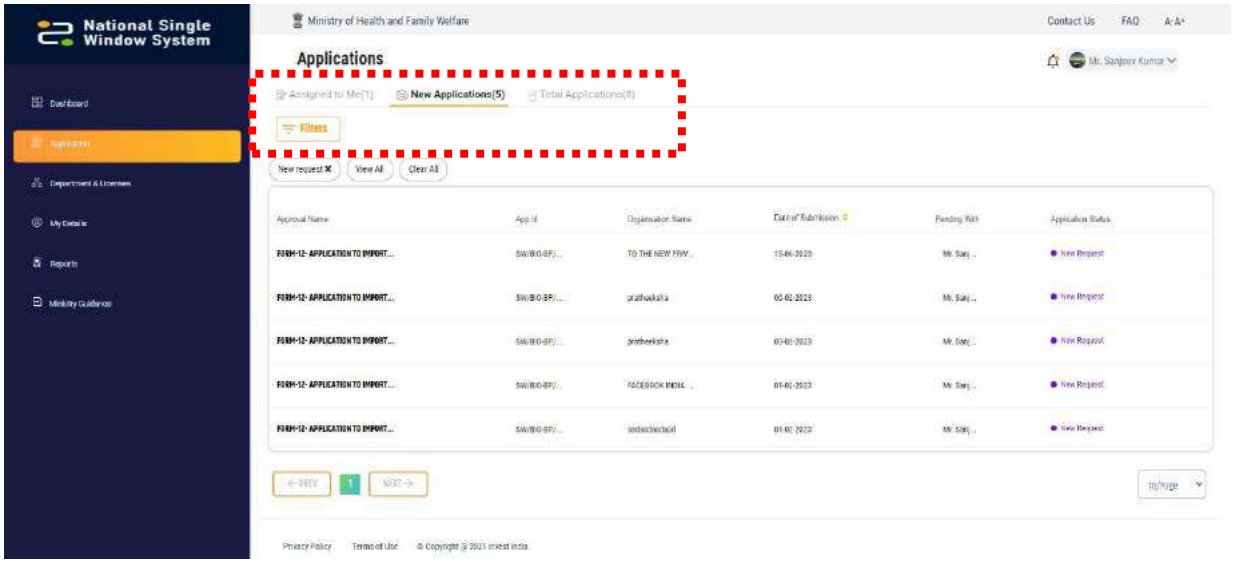
3.1.1 Ministry User Login

The authorised ministry officer can Login into the NSWS Ministry portal with the credentials available with them. The user can open the Ministry Login page from the Homepage of NSWS.



The Ministry Dashboard on Login: Upon logging-in the Ministry User will be redirected to the Dashboard. The Dashboard contains the count of Applications:

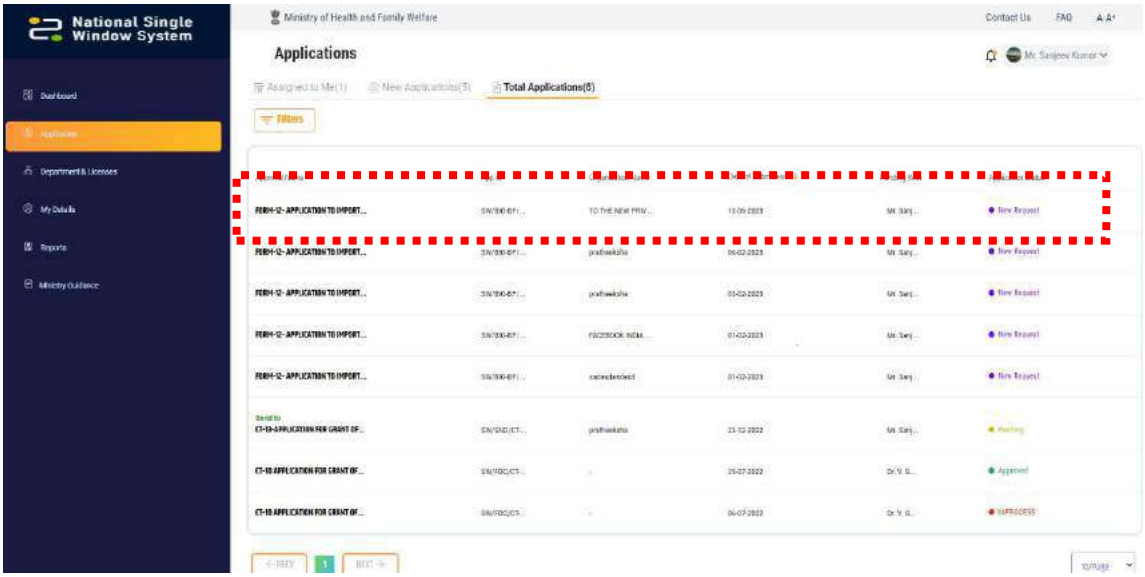
- *Assigned to me*: The applications that are pending for the specific logged in Ministry User to review.
- *New Application:* The fresh application that are applied by the investor and are yet to be reviewed.
- *Total Applications*: The total of the above stated Applications.



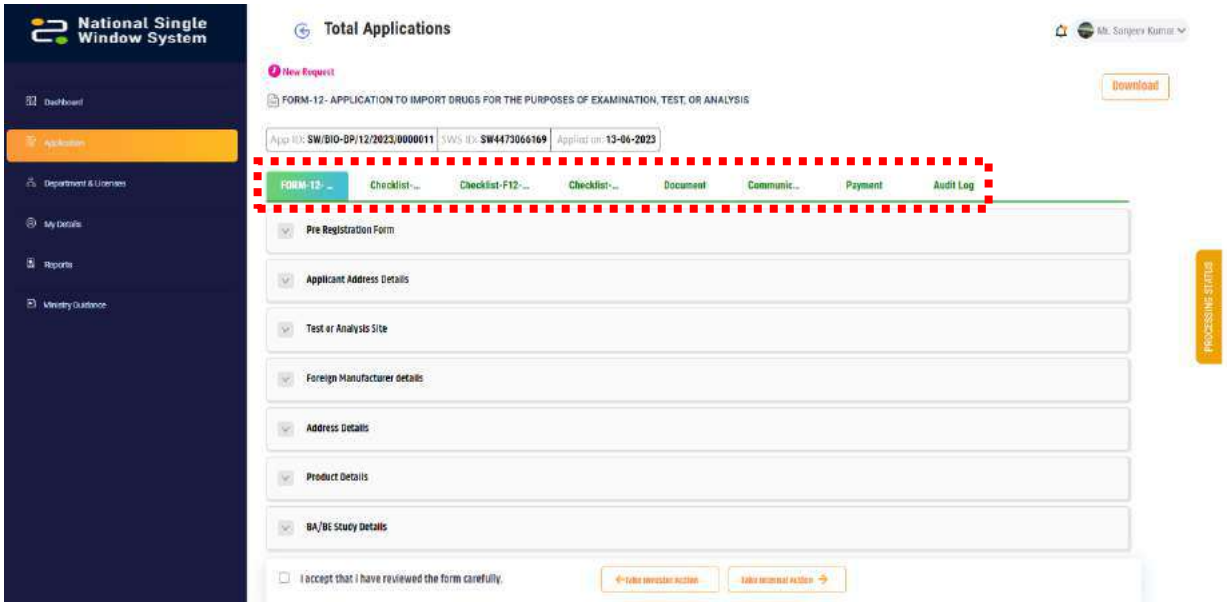
3.1.2 Viewing Applications

Upon opening Application tab, the system shall display status for the applied licenses. A fresh application will appear on top of the "Total Application" tab, or they can be opened by clicking on the "New Application" tab which will show all the new applications submitted by the users.

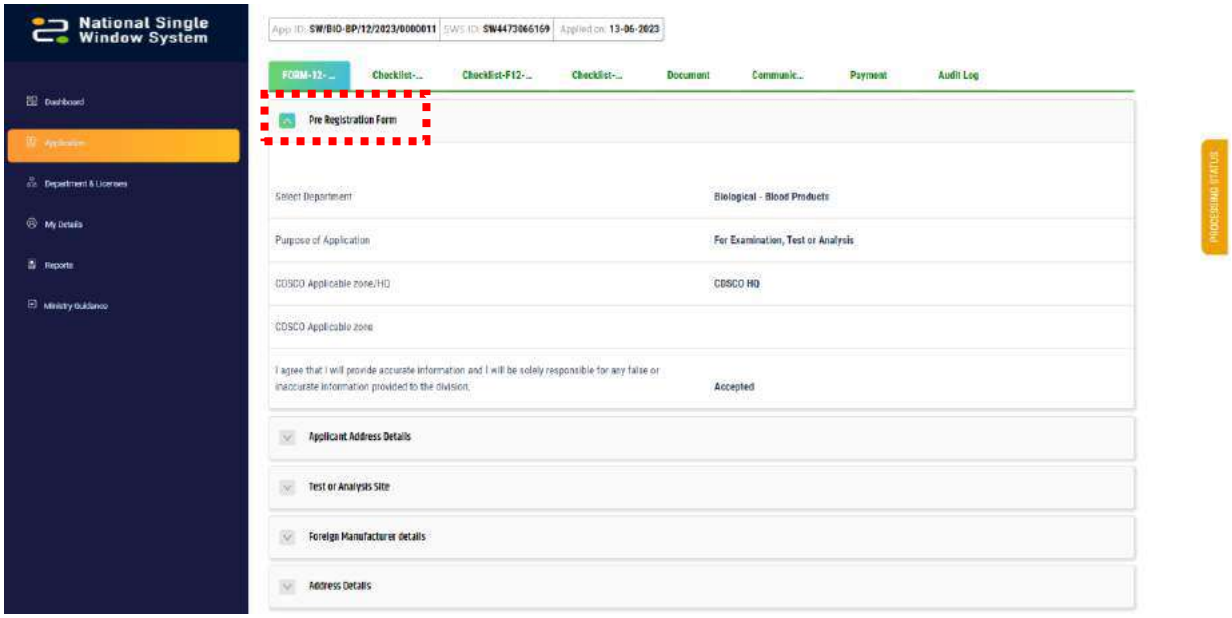
To open an application for scrutinization the user should click on the name of the approval



User can click on each section name to review the inputs filled by the investor



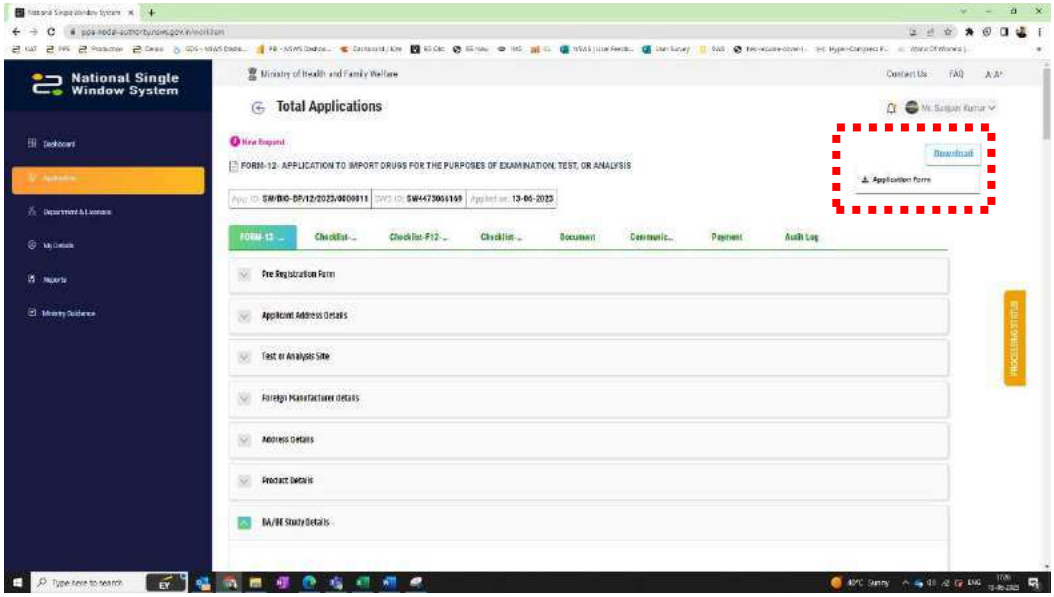
Ministry User can navigate the through a single form vertically.



3.1.3 Unique Application ID

For each application there will be a Unique Application ID which will be displayed on Investor as well as the Ministry portal throughout the entire scrutinization journey.

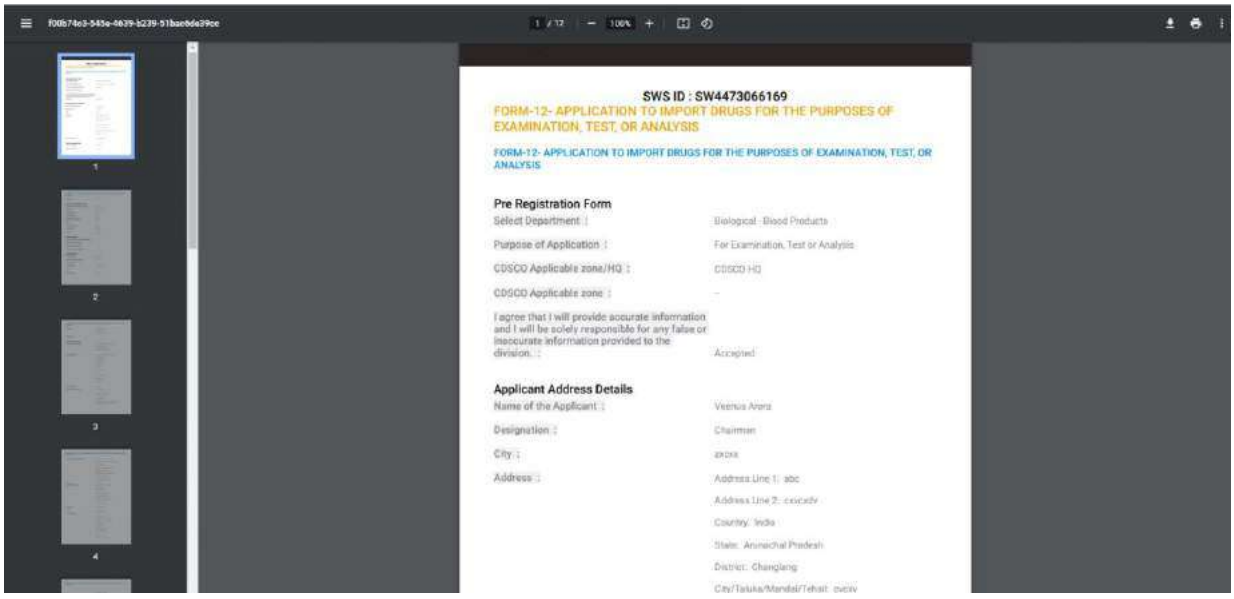
3.1.4 Download Application and Documents



An option to download the whole application submitted and the payment details is also provided to the Ministry User which will enable to easily visualize the Applicant's Input by the Ministry User. The button to preview the application is given on the top right corner as shown in the above image.

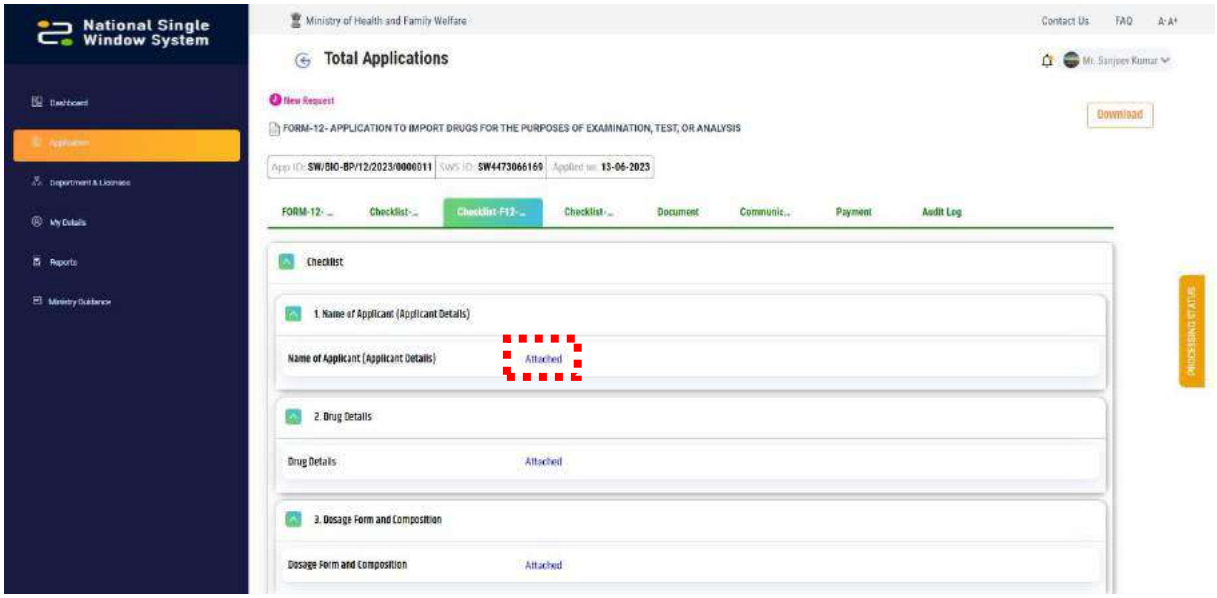
This Document will include application inputs by the investor and the Payment Receipt Details

On downloading it the application can be previewed as shown below, the same can be downloaded / printed.

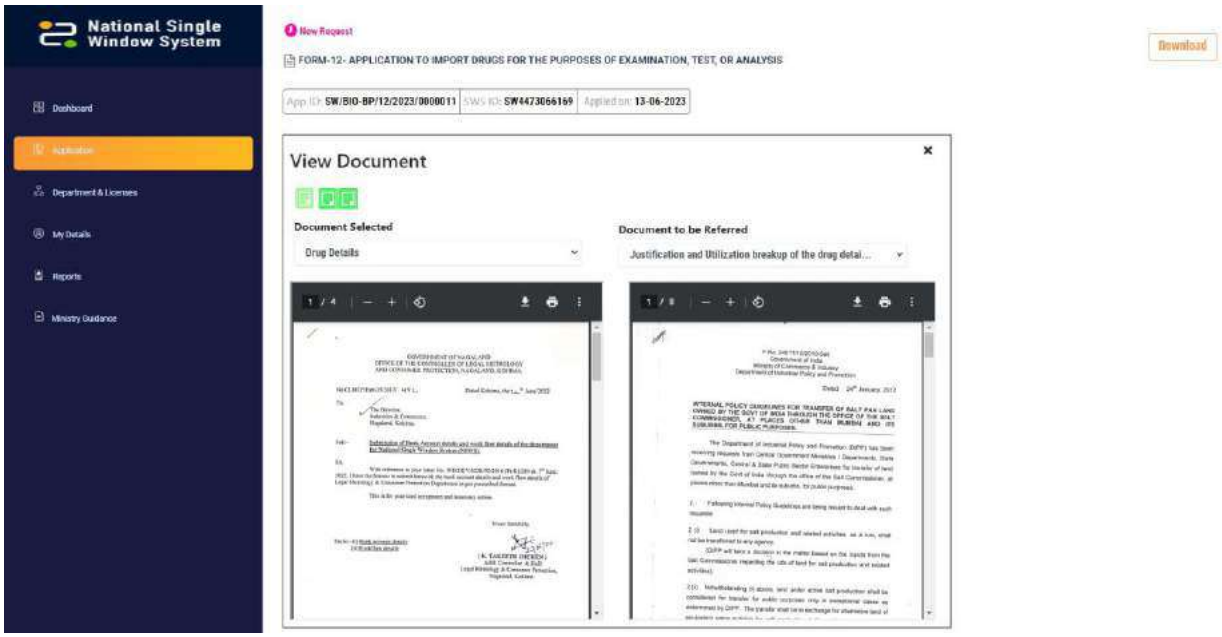


3.1.5 Viewing Documents

To view the documents submitted by the Investor, the Ministry User can click on the field and click on the Attached button beside such field. The Ministry User can click on the "Attached" button on the right side of each field to download the corresponding documents.

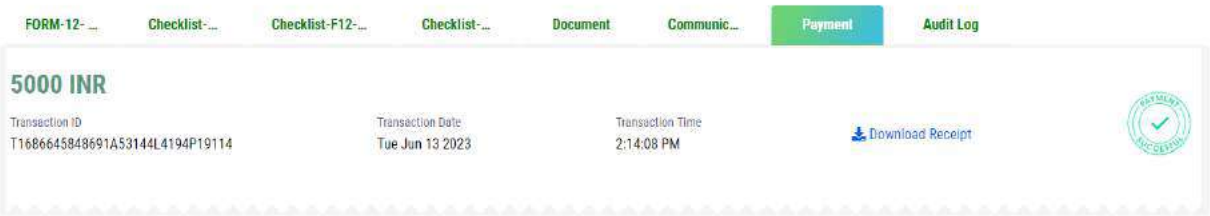


Upon clicking the attachment option, Ministry User will be presented with a split screen which will have two drop down lists having all the documents submitted by Investor in that particular Application in both of them. Thus, the Ministry user can view all the documents along with the option of comparing different documents.



3.1.6 Payment Status

User will be shown with the payment details of the submitted application by clicking on the Payment tab.



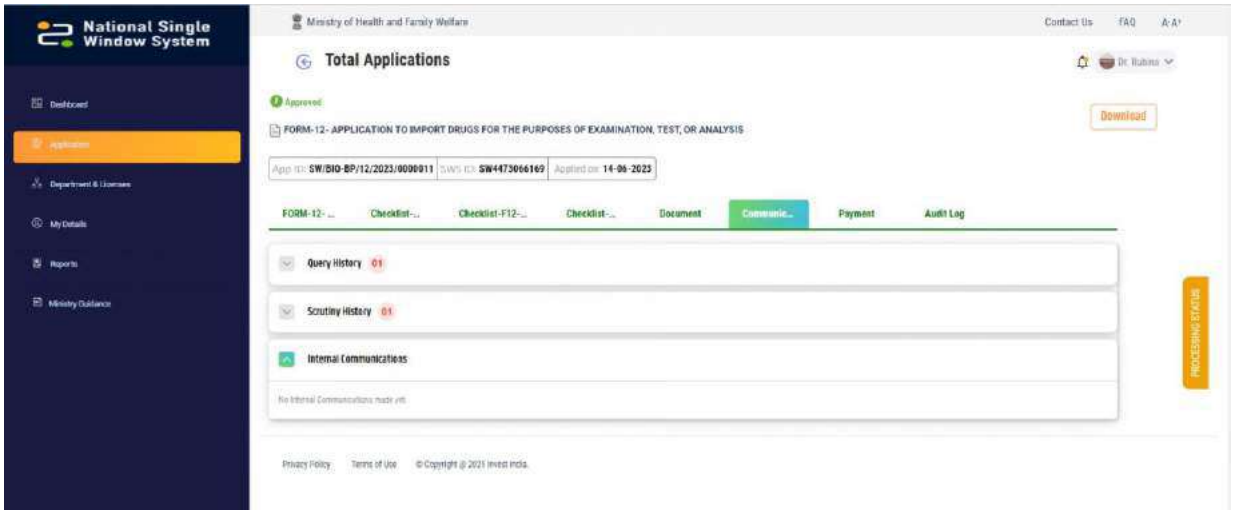
The download invoice button will download a PDF having the payment receipt as shown below

Payment Receipt

License	FORM-12- APPLICATION TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST, OR ANALYSIS
SWS ID	SW4473066169
Transaction ID	T1686645848691A53144L4194P19114
Payment Reference Number	T1686645848691A53144L4194P19114
Bank Reference Number	358800
CIN Number	20370013062300050333
Payment Amount	5000
Currency Code	INR
Payment Type	CREDIT CARD
Payment Status	SUCCESS
Payment Date and Time	13/06/2023 14:14:09

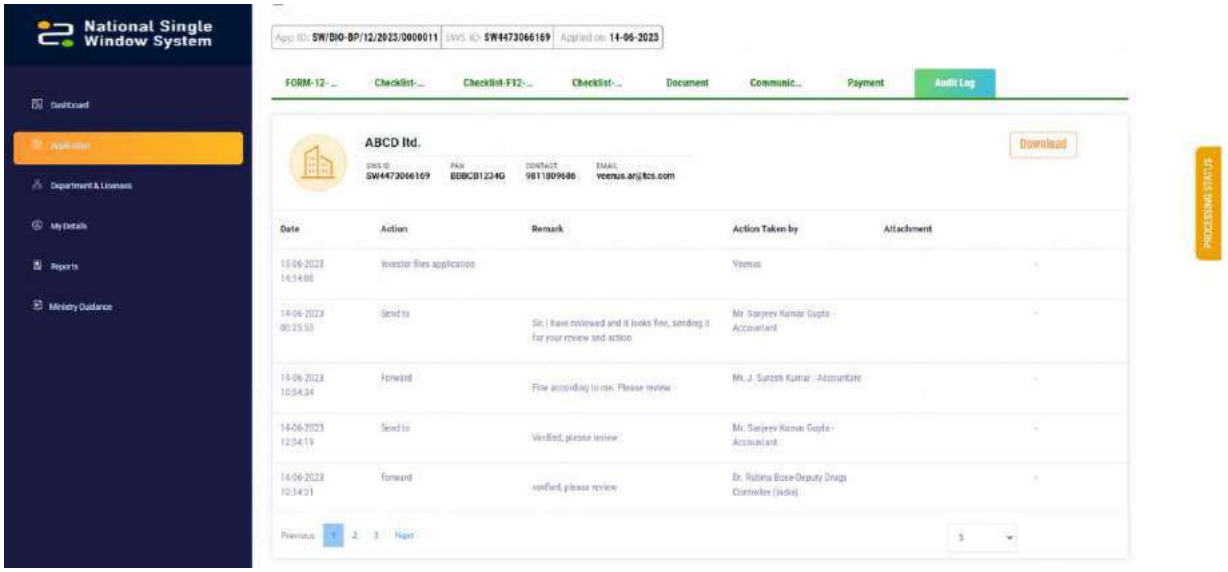
3.1.7 Communication

This tab will show all the Scrutiny and Query raised between the Ministry and Investor. The terms will be explained in the guide.



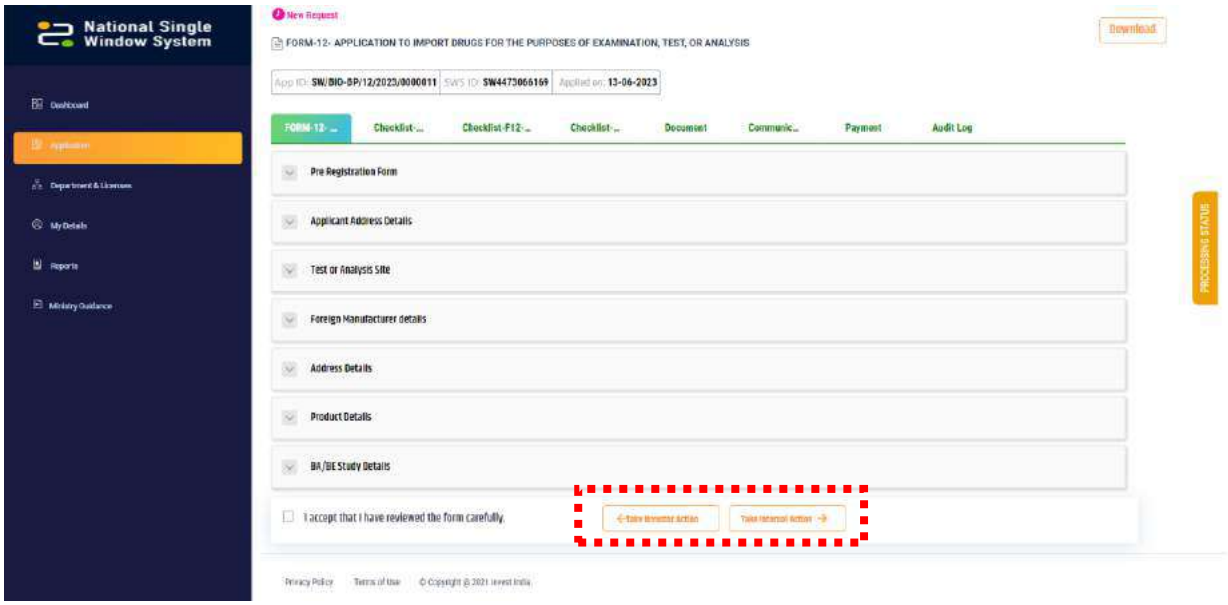
3.1.8 Audit Log

Audit log shows all the actions taken on the particular application taken the Ministry users and Investor



3.2 Process for Application Review

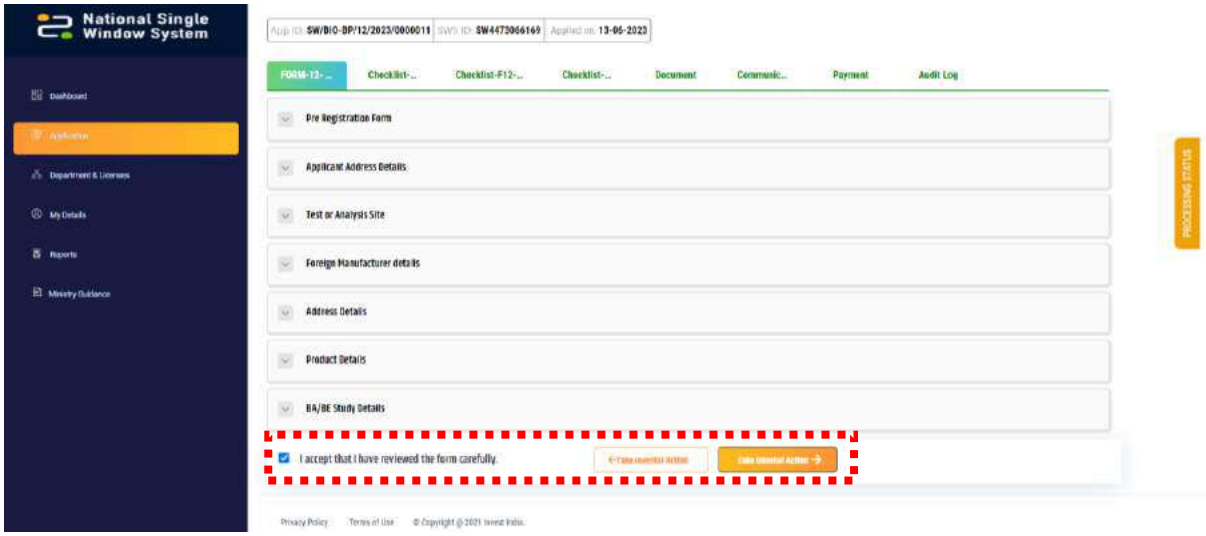
Ministry User will be provided with two tabs as shown below



3.2.1 Take Internal Action

A ministry user can use this option when they have to communication regarding the application within the ministry.

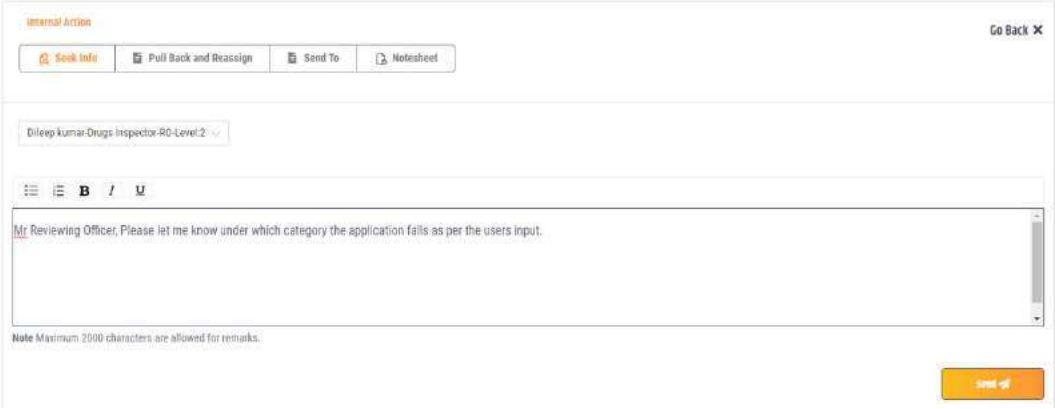
Click on checkbox for “I accept that I have reviewed the form carefully” and then click on “Take Internal Action”



A ministry user can perform the following Internal Actions:

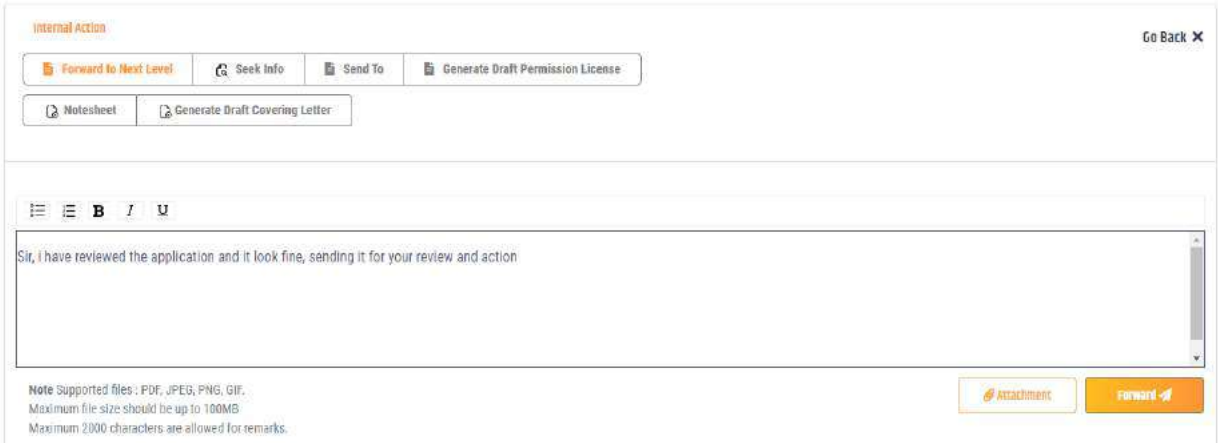
3.2.1.1 Seek Info

In case the ministry user wants to ask some specific information from any other user from the workflow, the application still remains with the same officer.



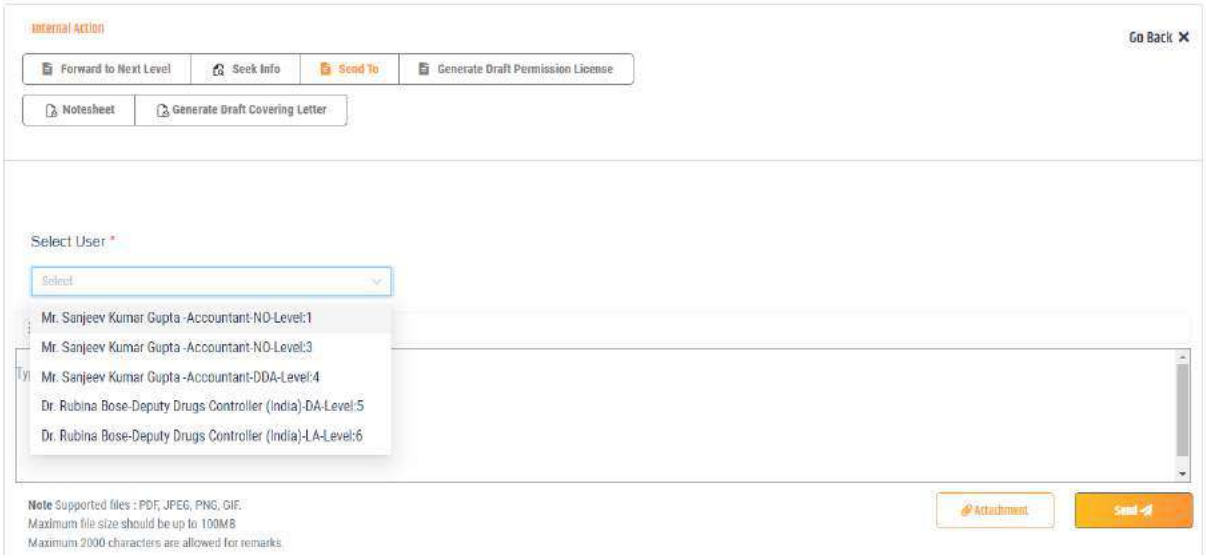
3.2.1.2 Forward to next level

In case the user wants to forward application for review to his immediate superior officer.



3.2.1.3 Send to

In case a ministry user wants to assign or reassign this application to any level user in the workflow. This will transfer the application to the assignee on which they can act upon.



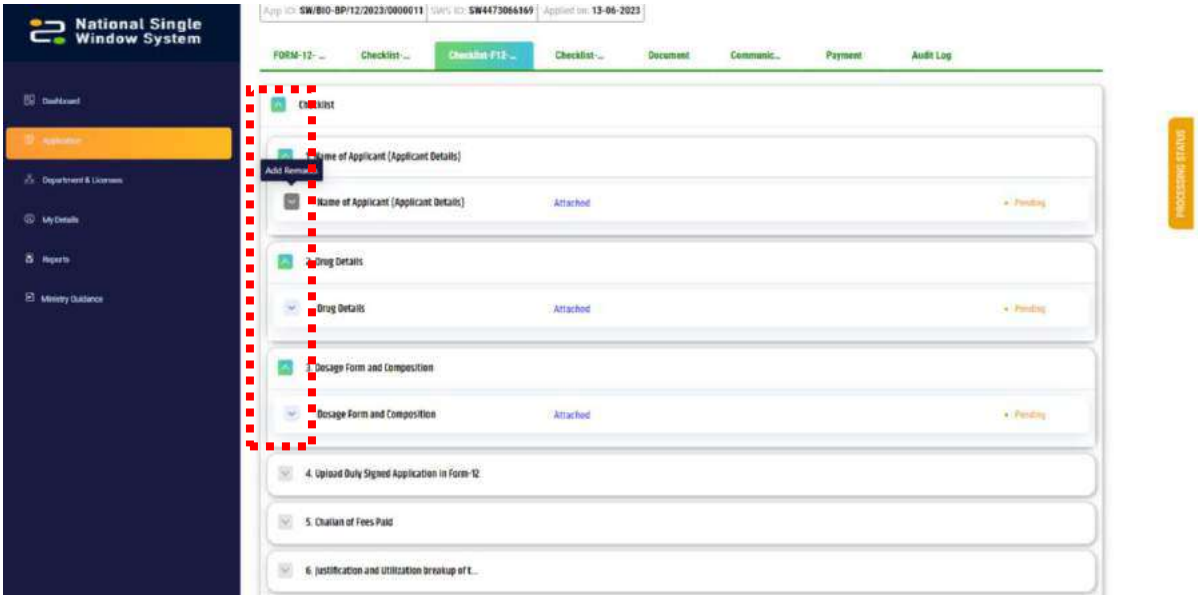
3.2.1.4 Pull Back and Reassign

If the application is with a particular officer and they may not be able to process it (for example a leave or any official engagement), then the higher-level user to such officer can use this function to pull back the license from such user and reassign it to another officer.

3.2.1.5 Review Checklist items

A ministry user has to review the checklist documents one by one in order to move the application to his higher-level officer. This process has to be done from Level 2 onwards till final level officer. There onwards, Each level officer has to complete this process.

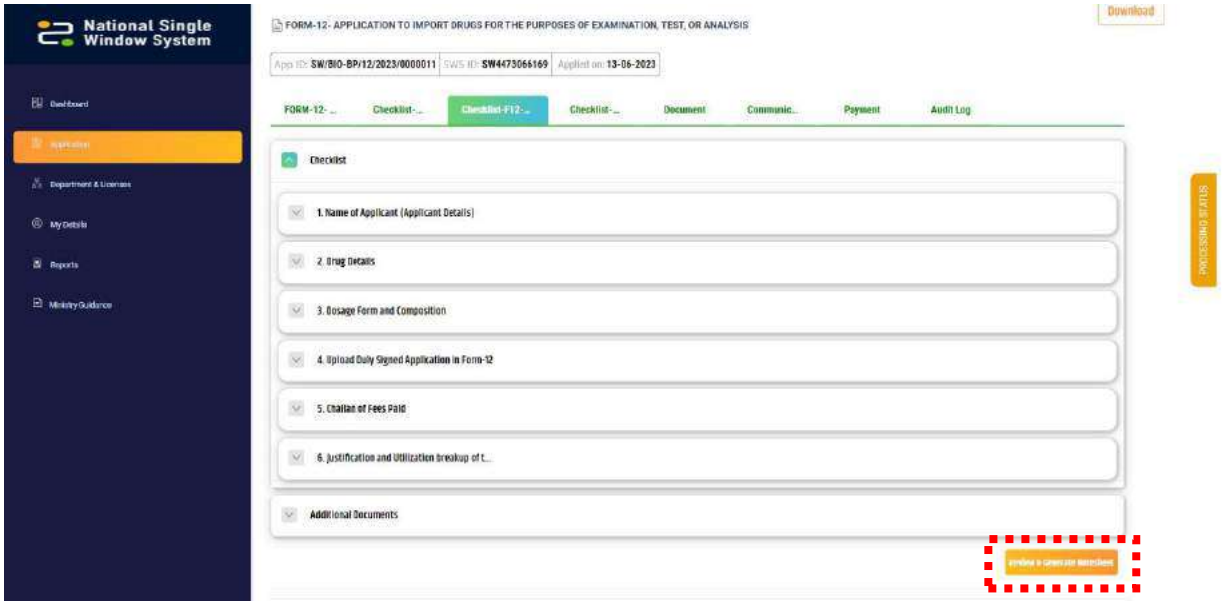
User has to click on Checklist from the top vertical tab and open each item. Then click on the downward arrow beside each line item.



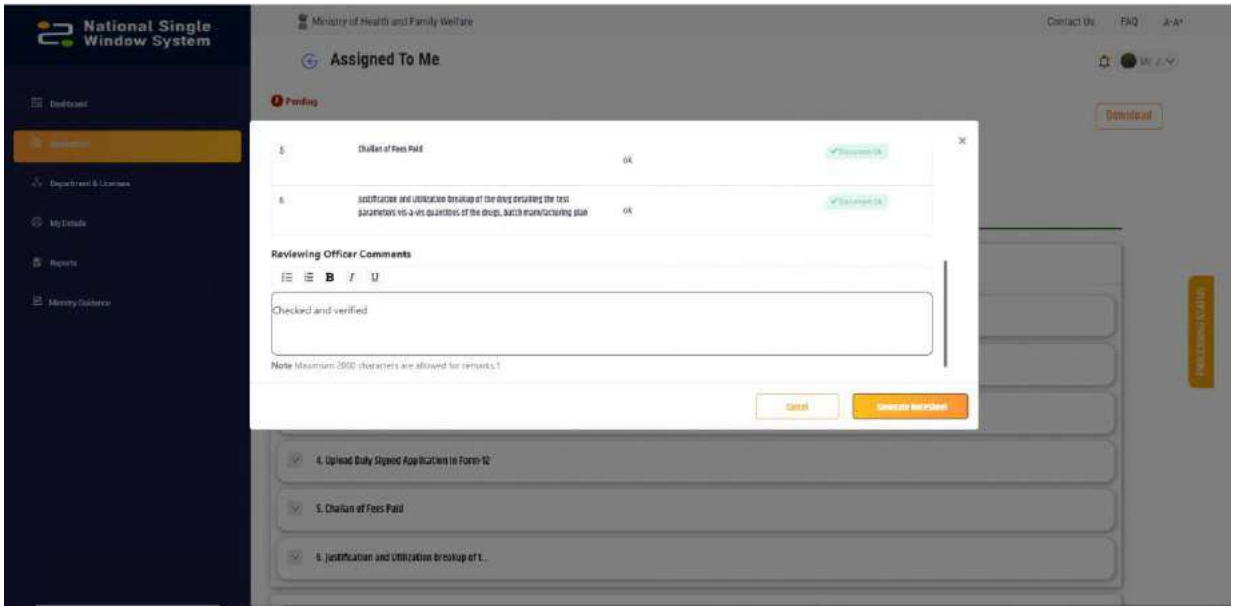
User can either raise query on the document which will be communicated to the investor, or they can provide their confirmation.

3.2.1.6 Generate Notesheet

Once completed with the review of all items in the checklist, user has to generate Notesheet from the showed option in order to move forward with the application

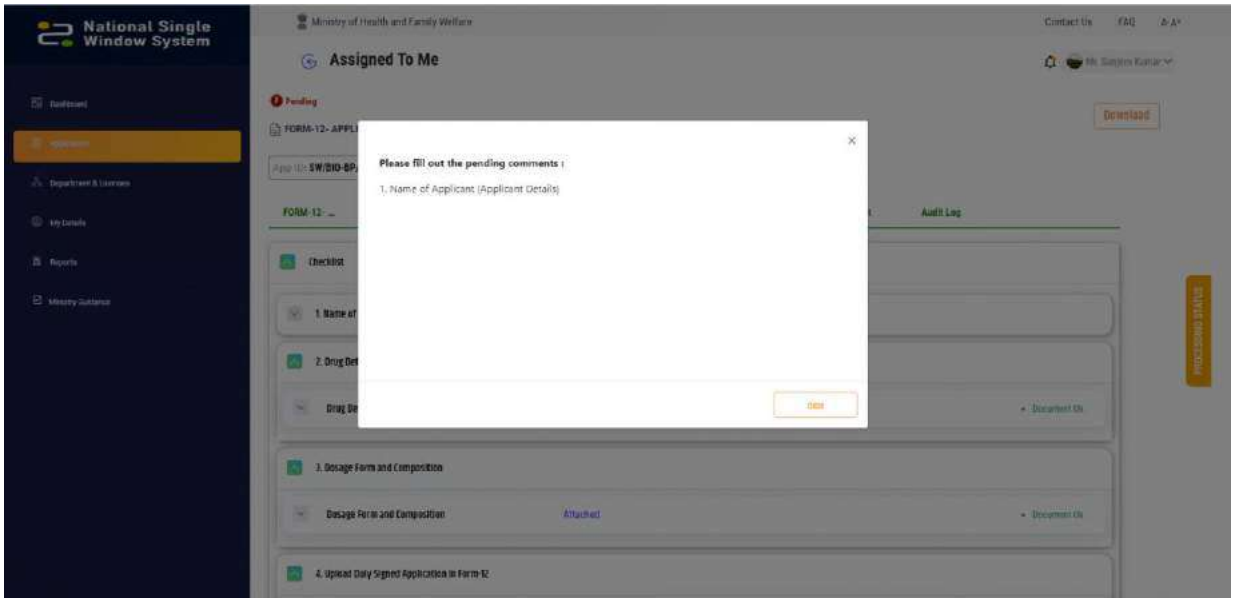


Provide confirmation through the comments and Generate Notesheet



A Ministry user has to complete “Review Checklist Items” and “Generate Notesheet” action as shown in 3.2.1.5 and 3.2.1.6, respectively, to forward the application

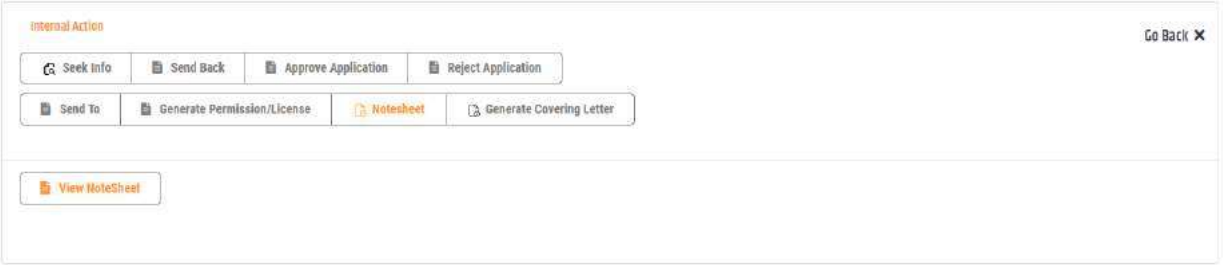
In case the user has missed a checklist item to verify, the system will communicate the same by showing this screen



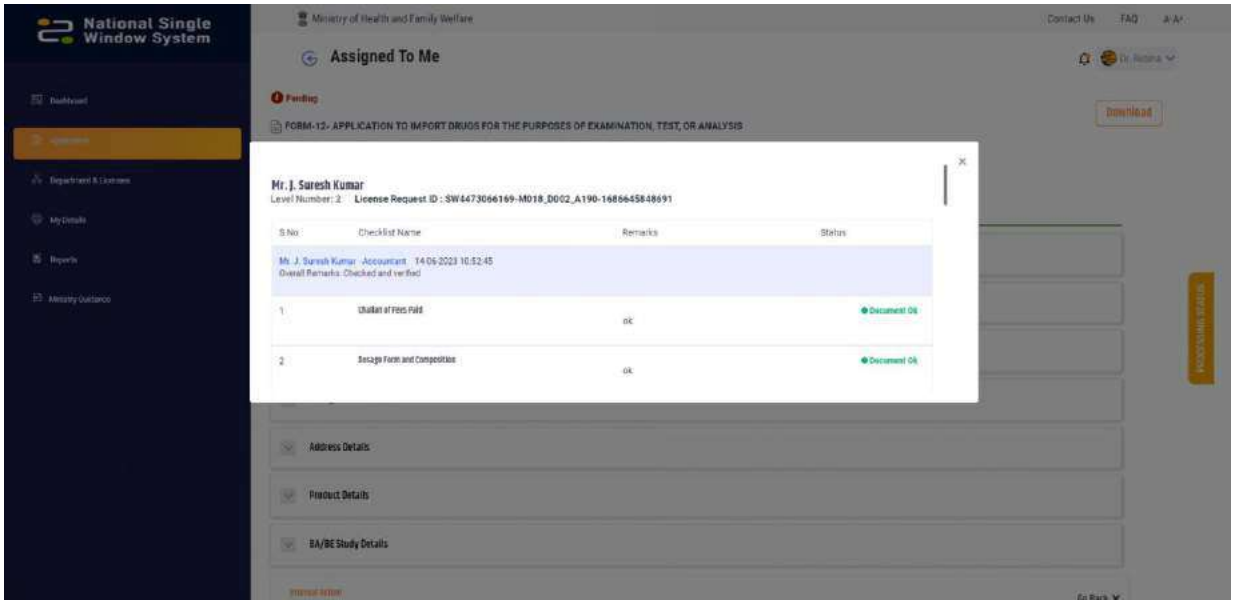
3.2.1.7 Send Back

In case the ministry user wants to send it back to the last user for reviewing it again

3.2.1.8 View Notesheet

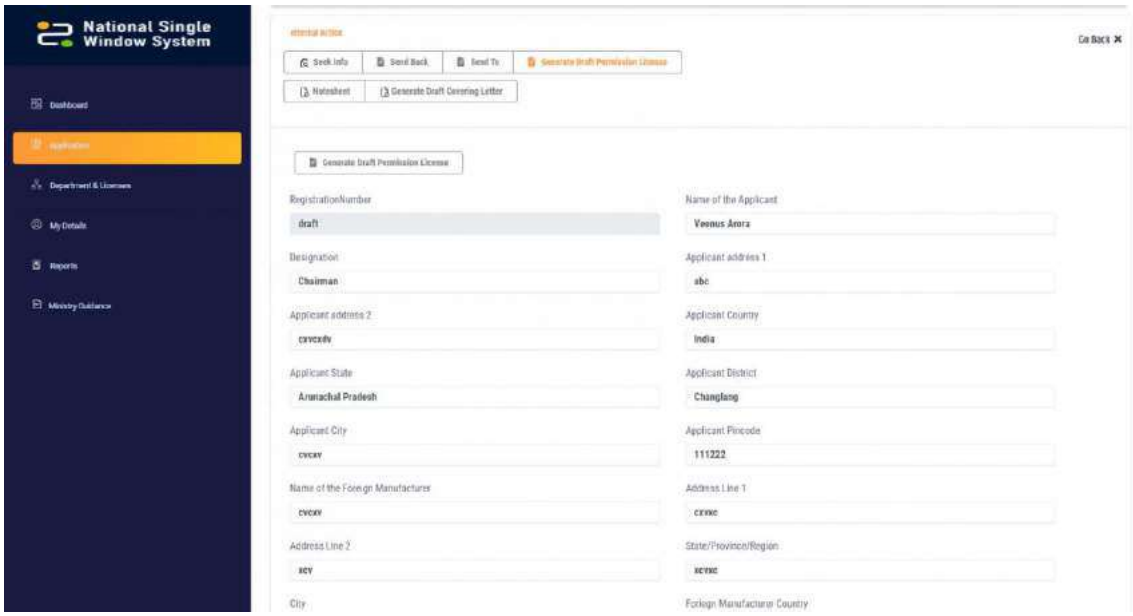


Notesheet captures actions taken by ministry users on checklist documents

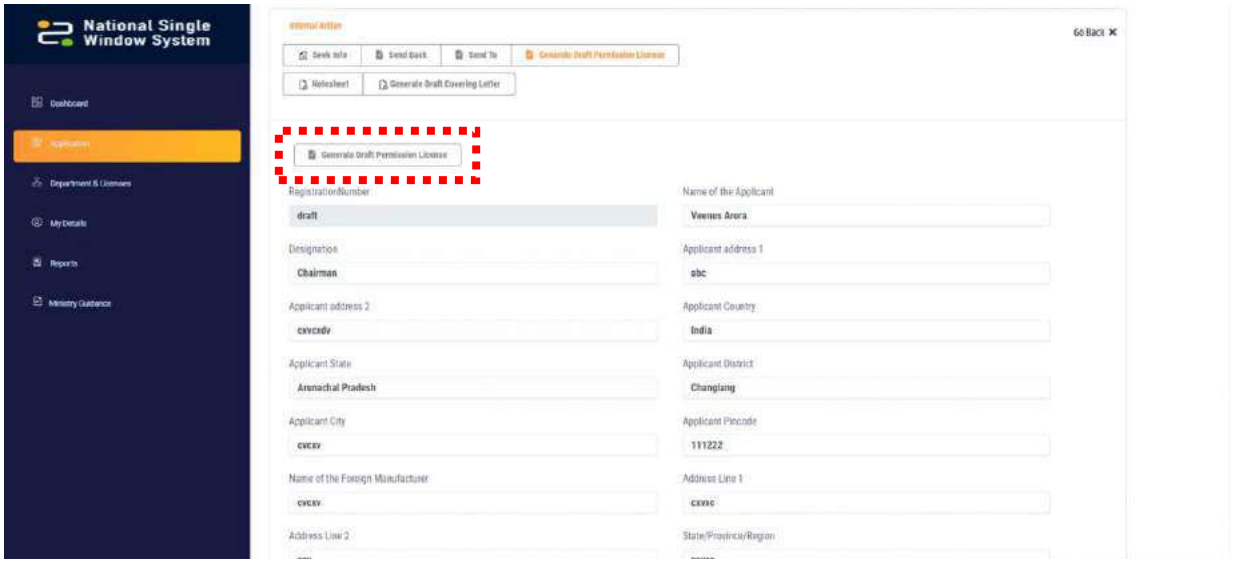


3.2.1.9 Draft Permission License

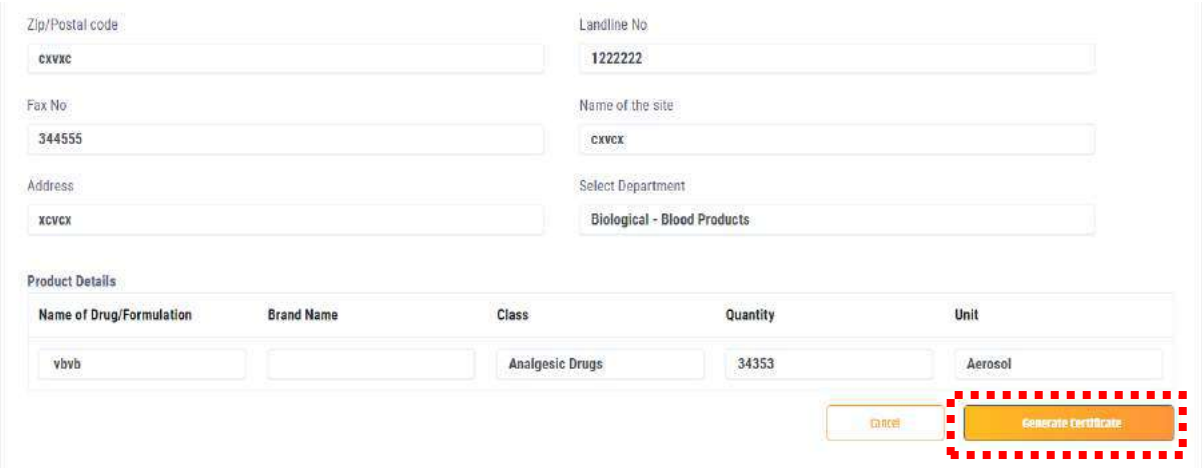
- Ministry user can generate draft license using this option. User can click on the button and update or edit the required details.



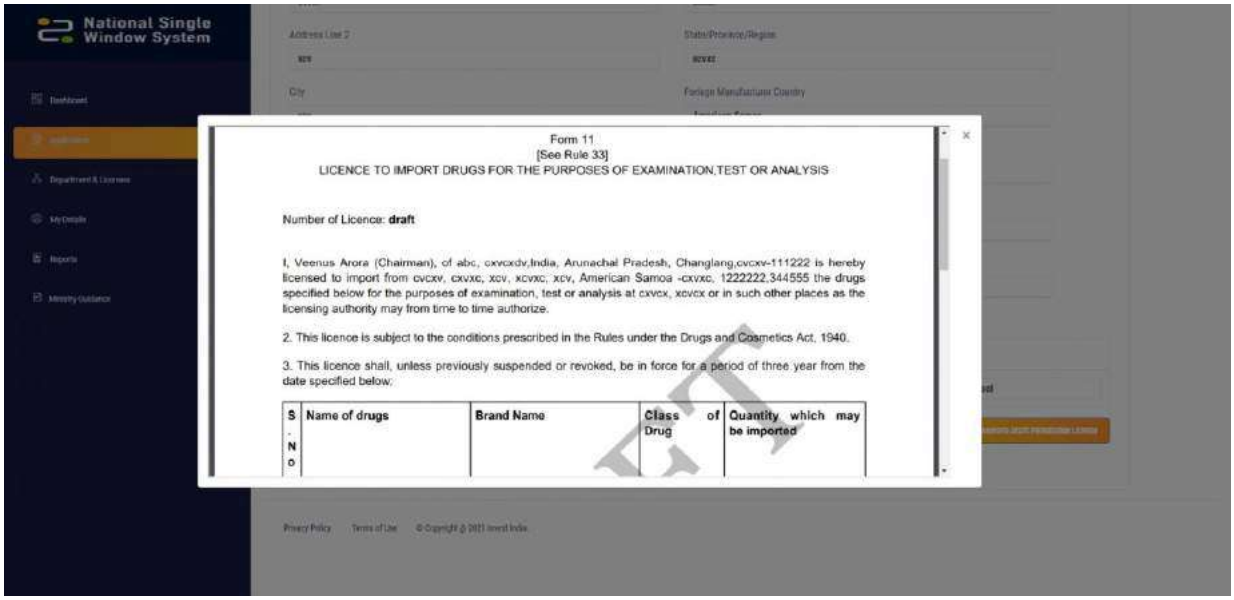
- Click on Generate “Draft Permission License” as shown



❖ Click on “Generate Certificate” on bottom of the page

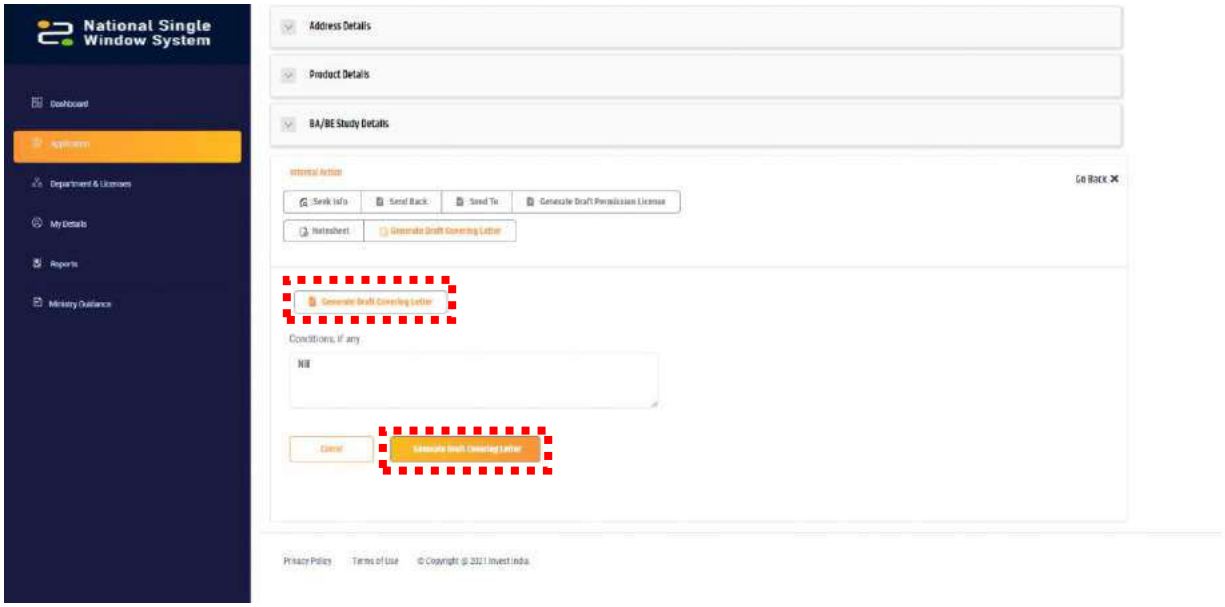


❖ The Draft License will be generated

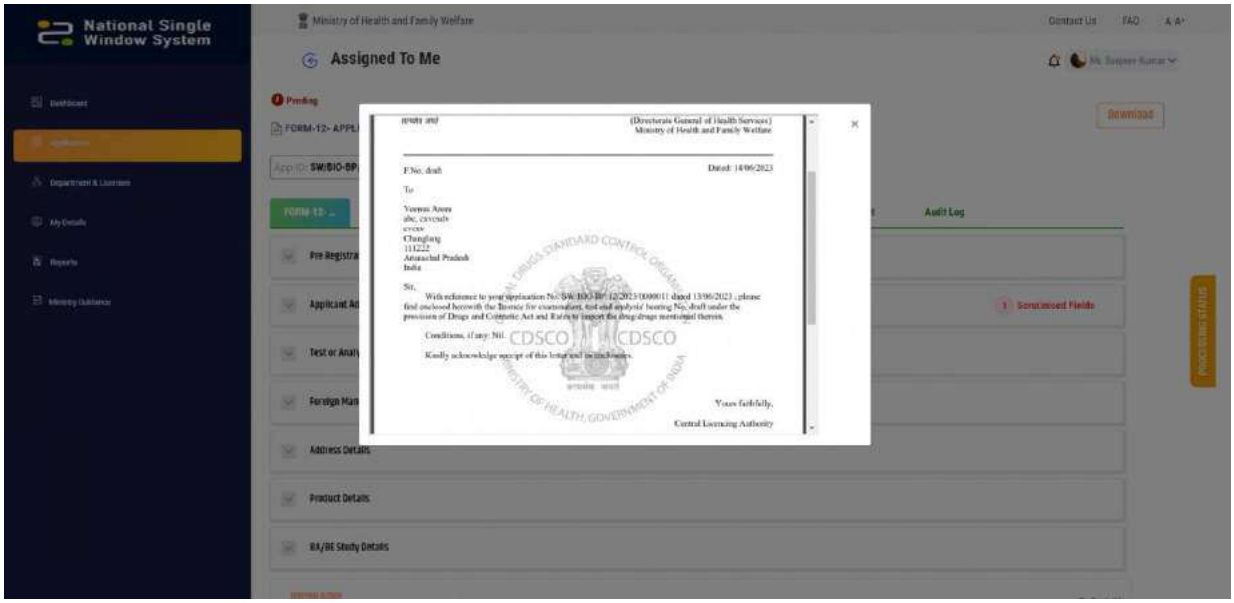


3.2.1.10 Generate Draft Covering Letter

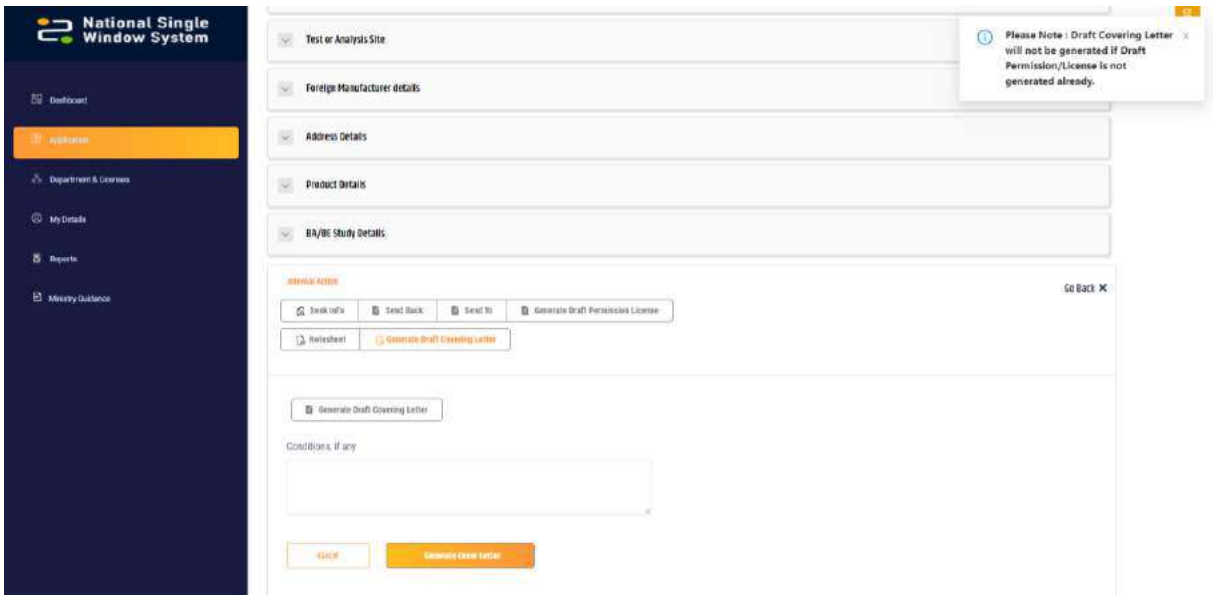
Ministry User can generate Draft Covering Letter using this option. Click on the buttons shown and add remarks.



The document will be generated



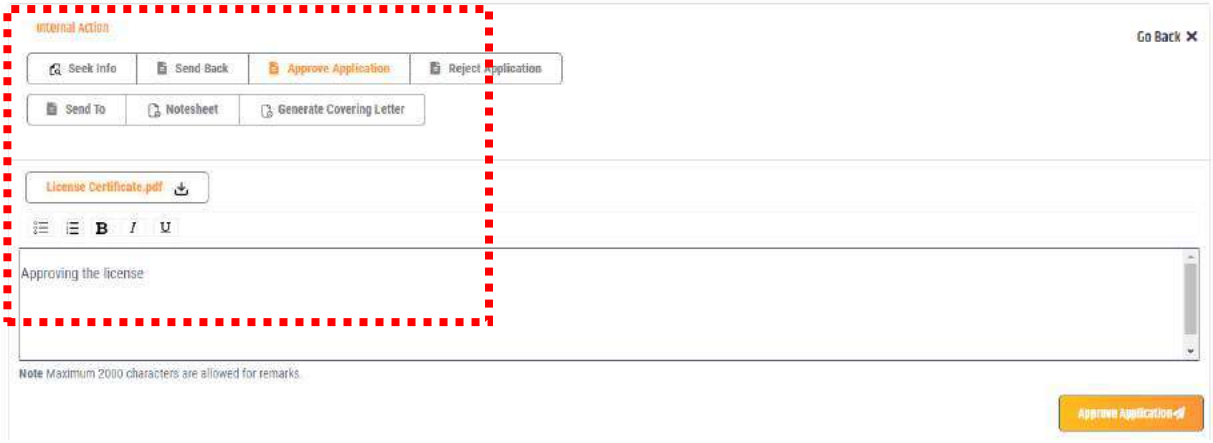
Condition: In case the user wants to “Generate Draft Covering Letter” , the ministry user has to first generate the “Draft Permission License” first. Otherwise, user will be provided with such a message



3.2.1.11 Approve Application

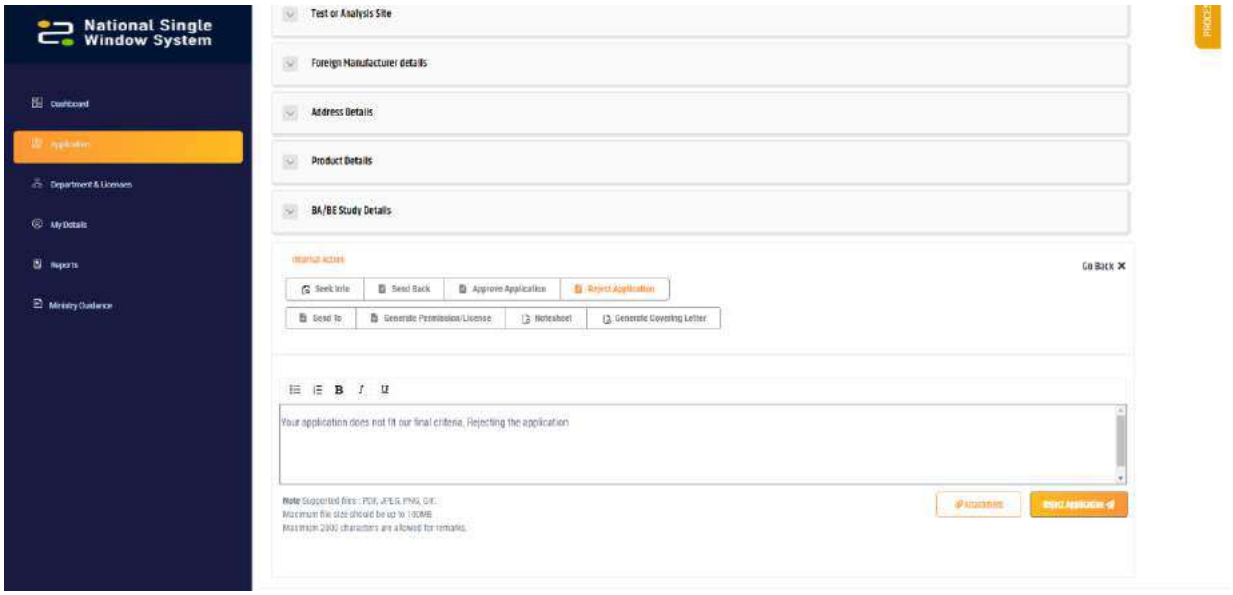
In case final level Ministry User finds the Application correct they would provide Final Approval using this option attaching the License Certificate.

User has to first generate the “Generate Permission/License” for such Approval



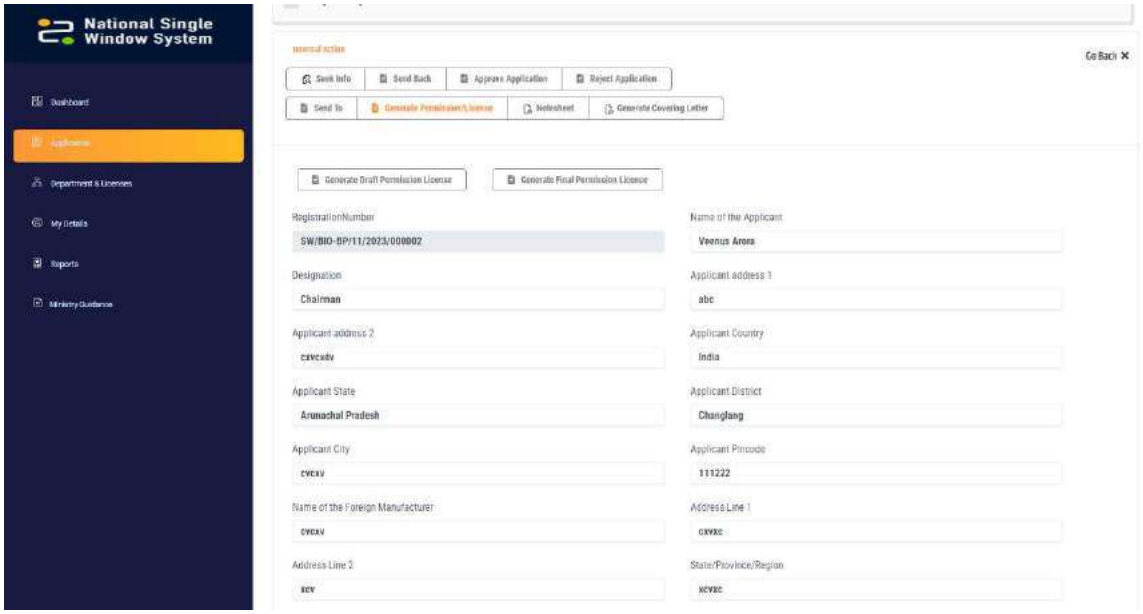
3.2.1.12 Reject Application

In case the ministry user is the final approver they would provide Final Rejection using the “Reject Application” option.

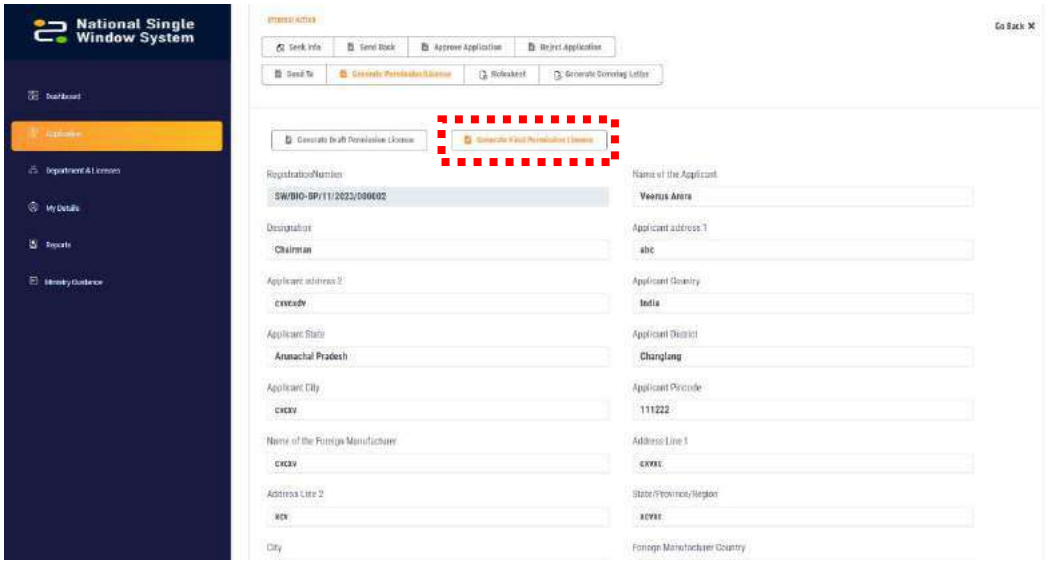


3.2.1.13 Generate Permission/License

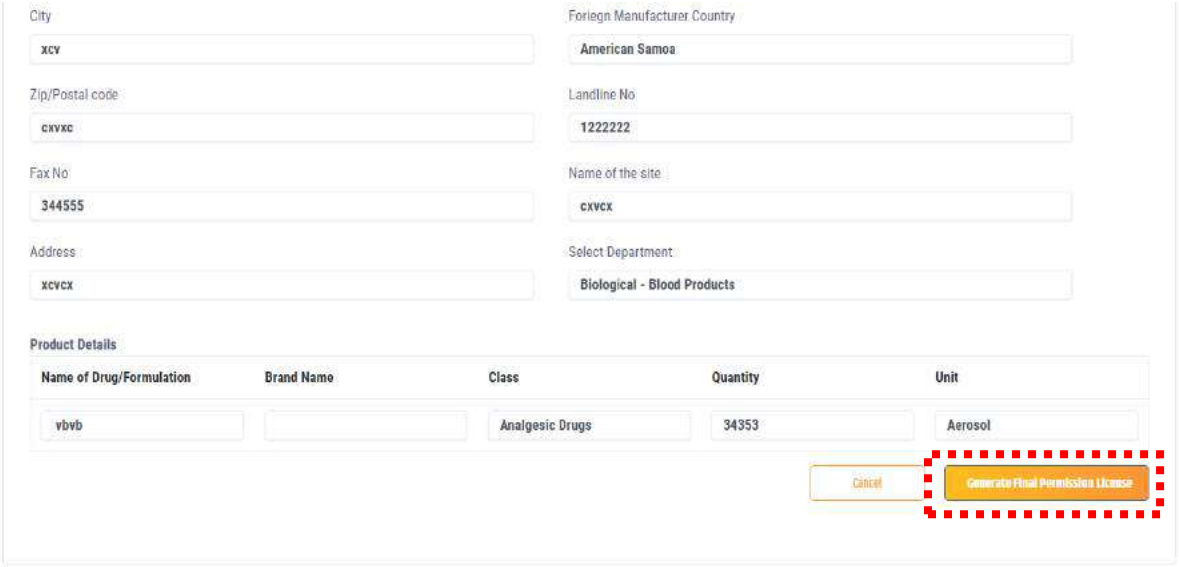
- ❖ Ministry user can generate final license using this option. User can click on the button and update or edit the required details.



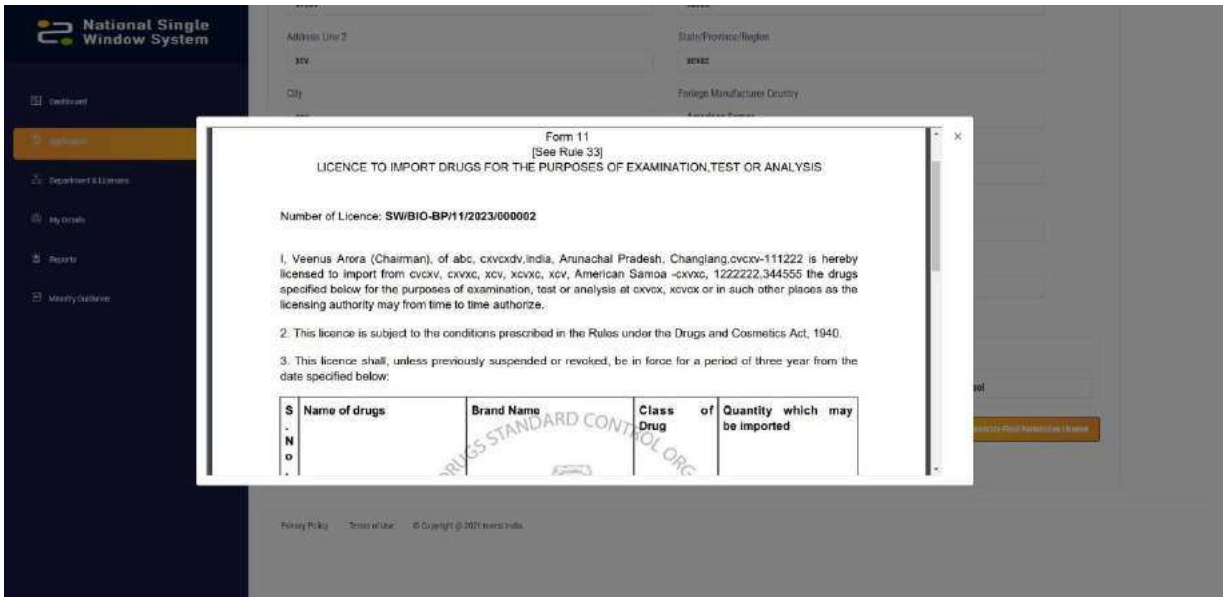
❖ Click on “Generate Final Permission License” as shown



❖ Click on “Generate Certificate” on bottom of the page

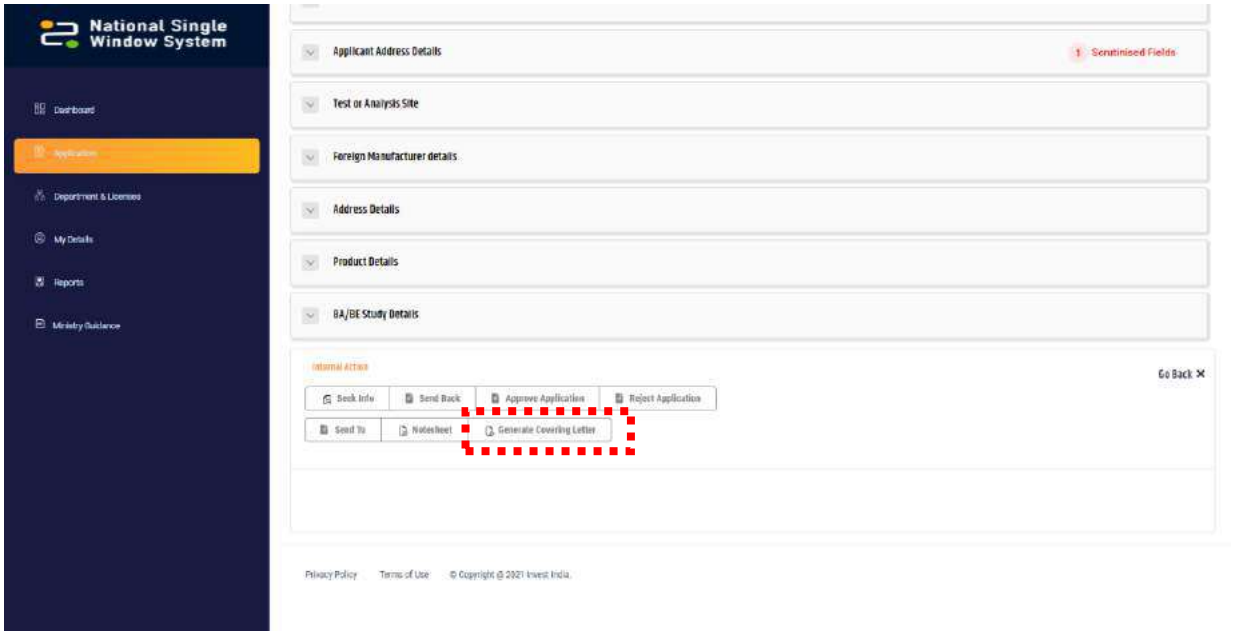


❖ The Final License will be generated

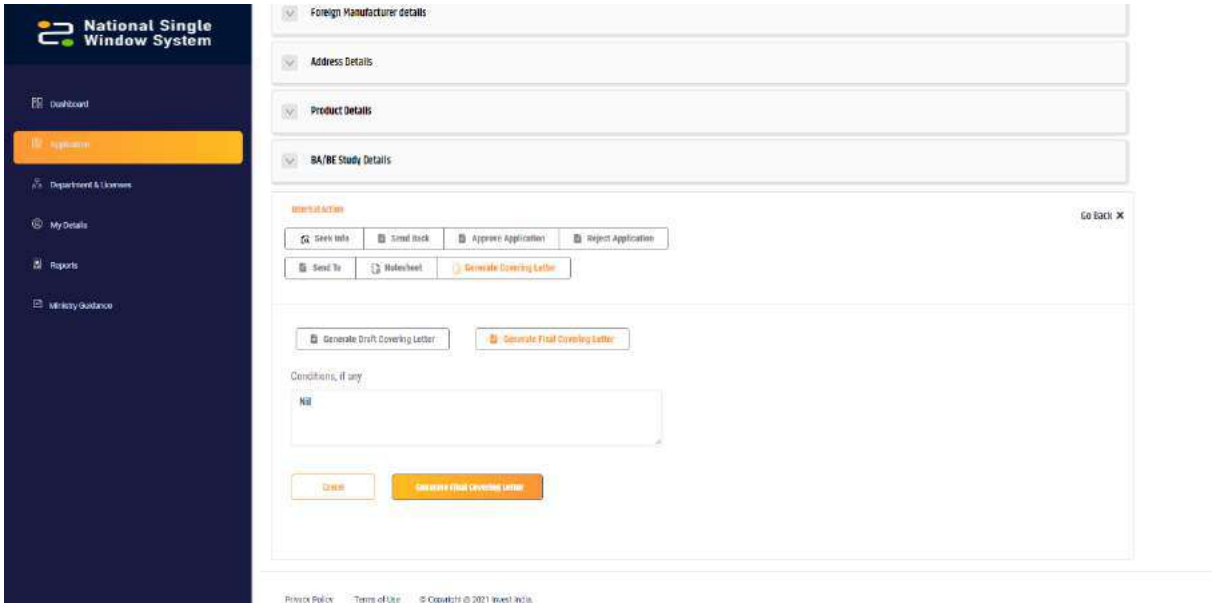


3.2.1.14 Generate Covering Letter

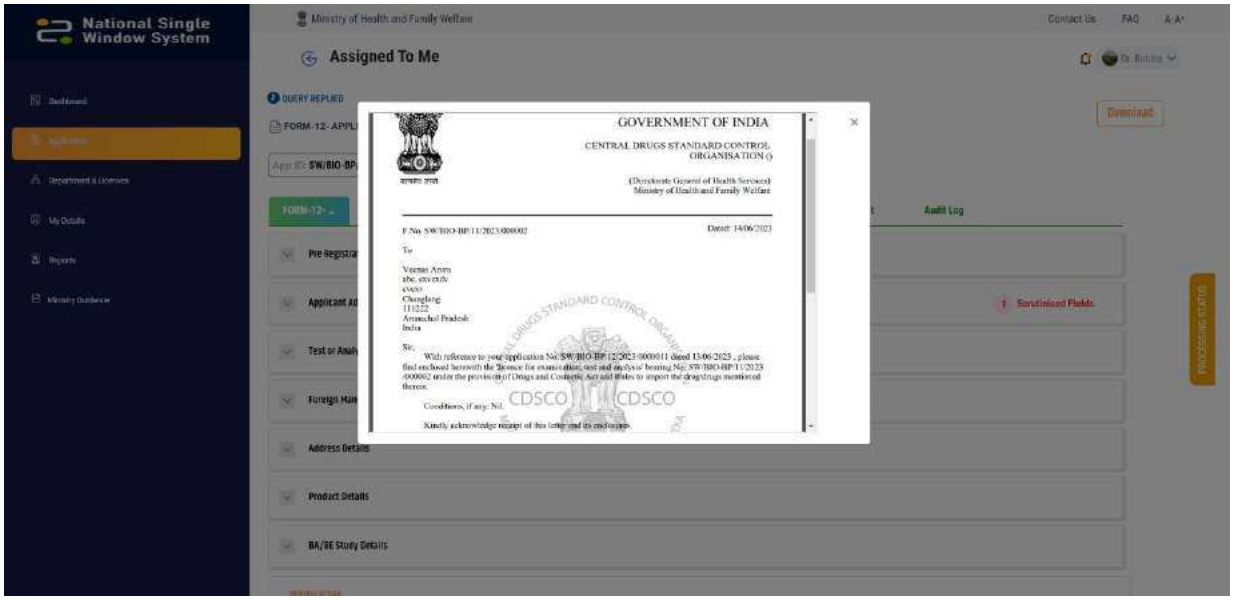
Ministry User can generate Final Covering Letter using this option.



Click on the buttons shown and add remarks.



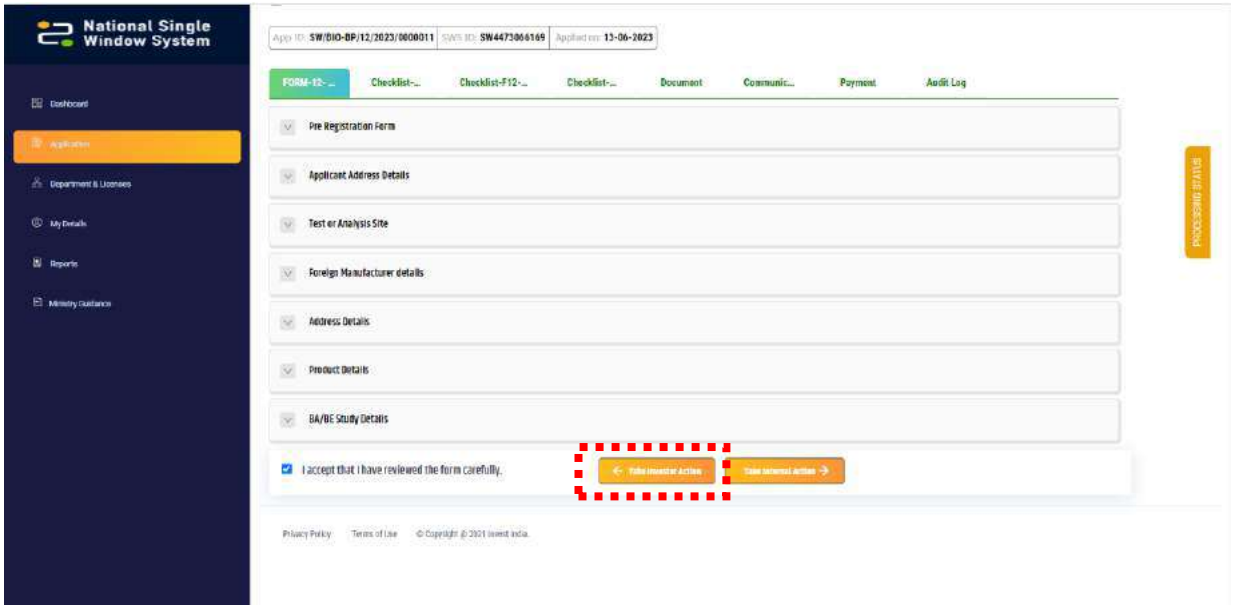
The document will be generated



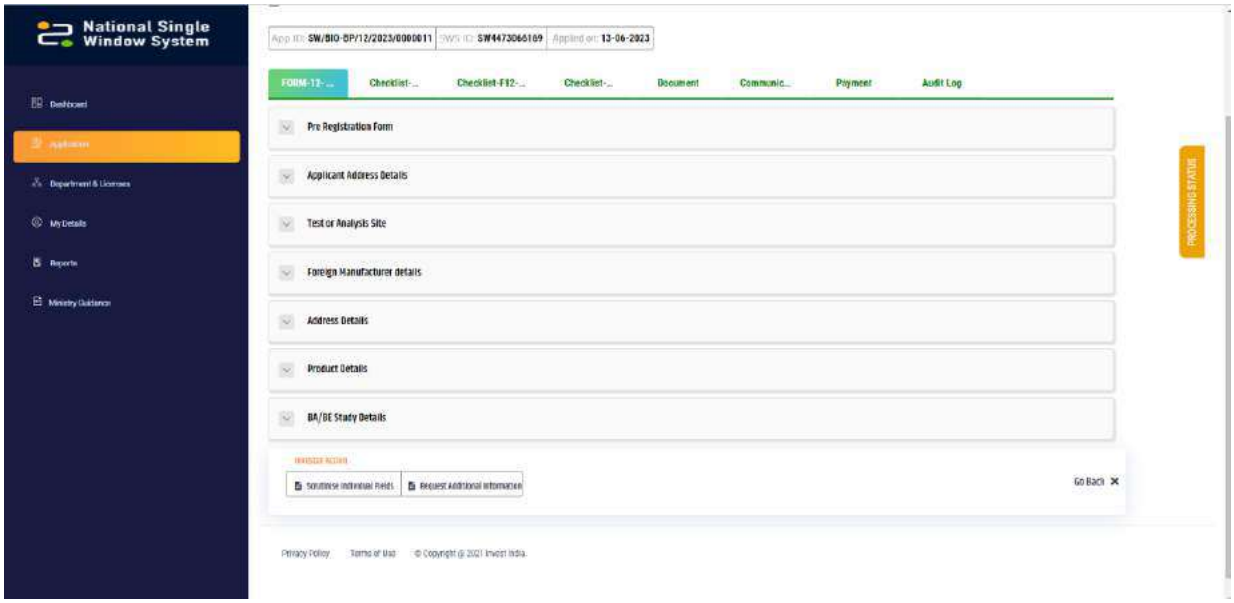
Condition: In case the user wants to “Generate Covering Letter” , the ministry user has to first generate the “Permission License” first.

3.2.2 Take Investor Action

In order to have communication with the investor, user needs to click on “Take Investor Action”



User will be provided with two options.

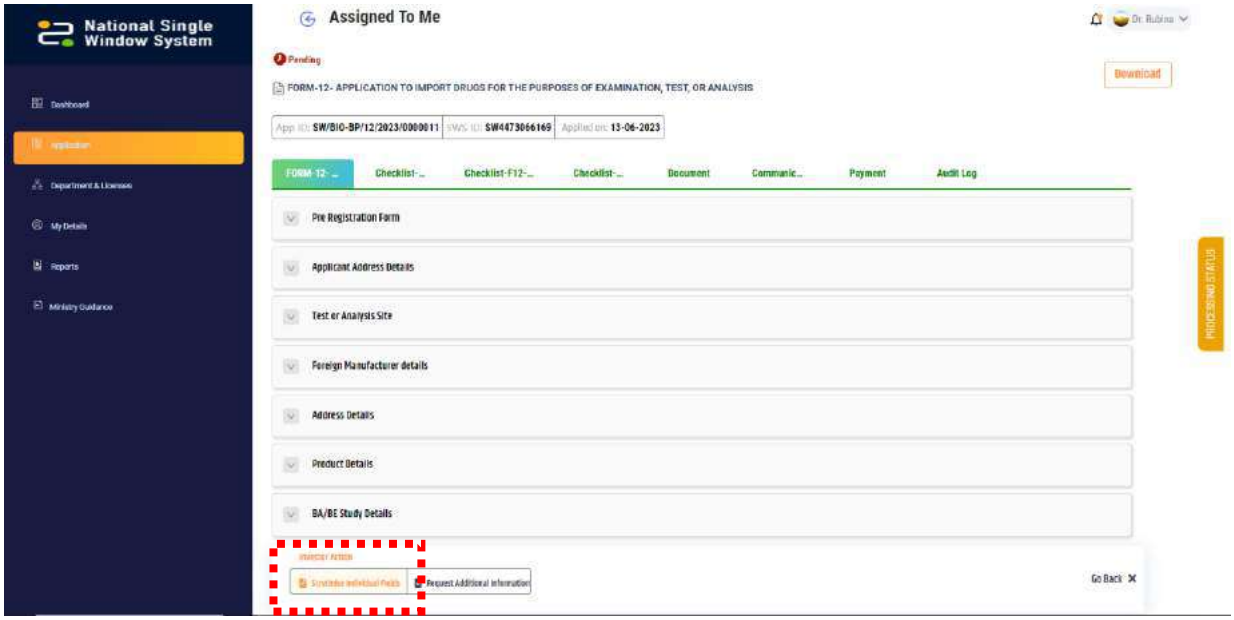


3.2.2.1 Scrutinize Individual Fields

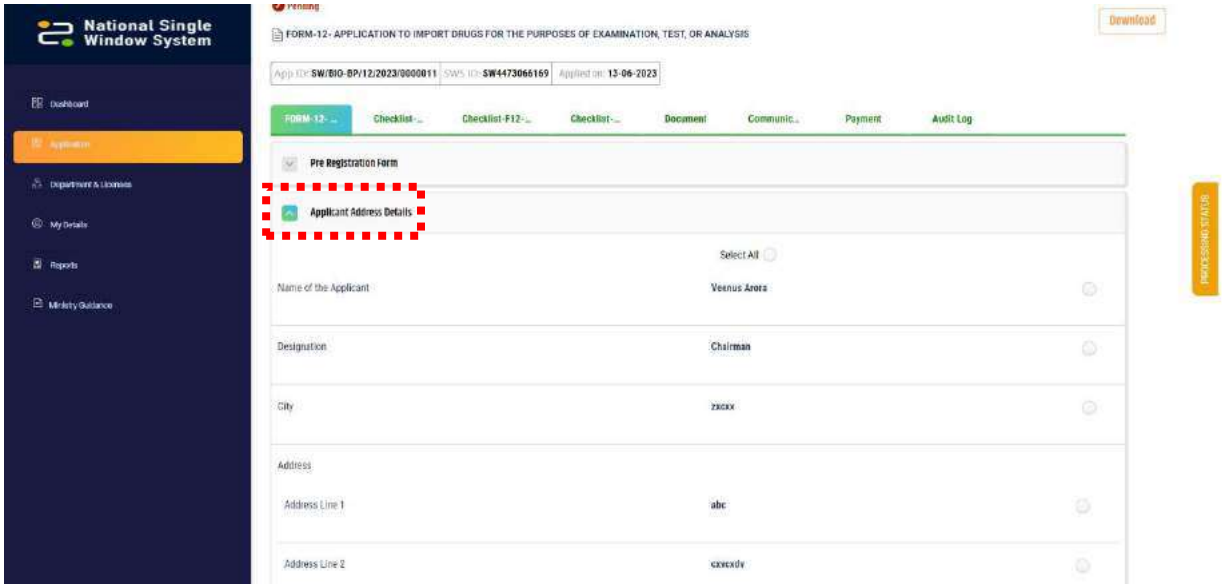
Scrutiny process is a functionality added by NSWS in the Mistry User's Dashboard which is used as an intimation sent by Ministry to the Investor in cases where the Ministry thinks that Investor has given incorrect information in any field(s). Consequently, the Investor will be given an option to re-fill those fields and Resubmit the Application. Note: User will have to generate Notesheet before performing such scrutiny.

Process for the same is captured below:

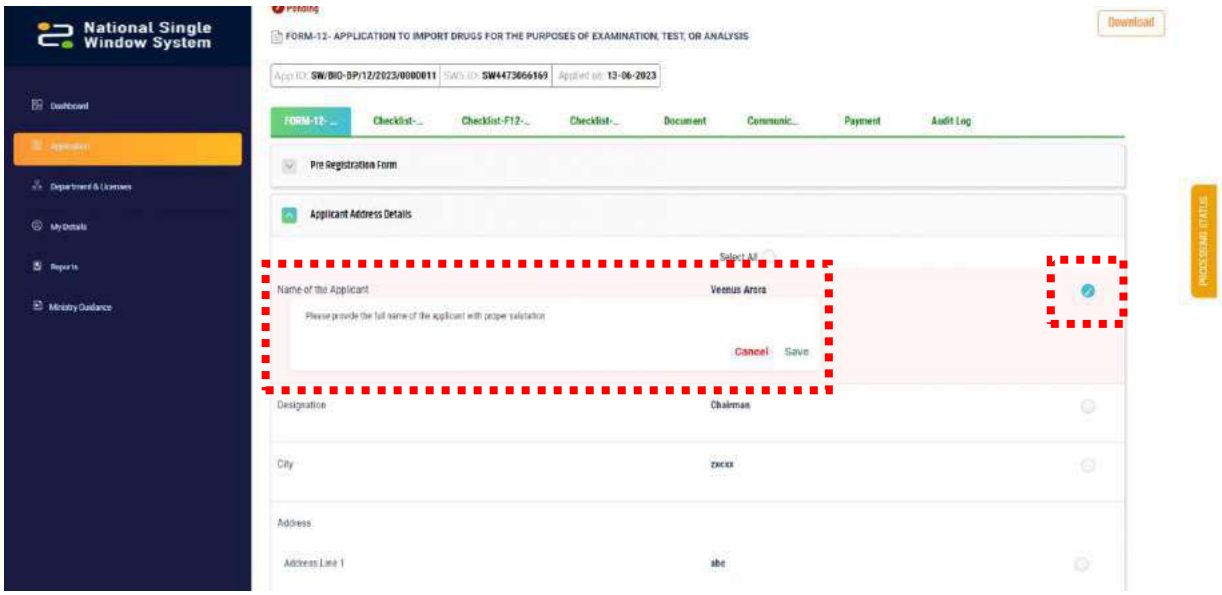
❖ Click on "Scrutinise individual fields".



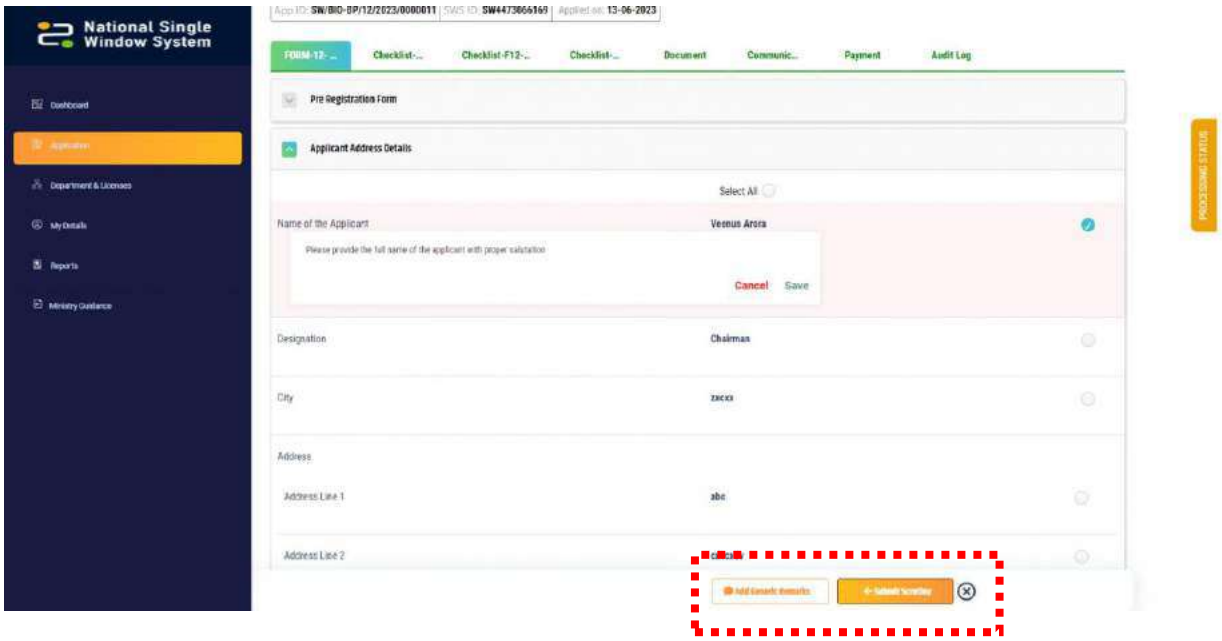
❖ Click on the arrow for the desired section



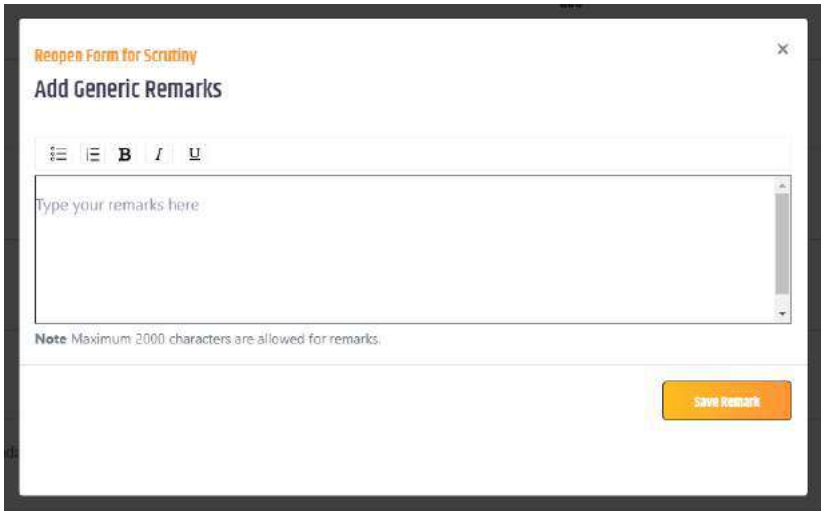
❖ Click on the Circle against the field(s) where action is required and add the required remarks and click on “Save”



❖ Finally click on “Submit Scrutiny” tab provided at the end of the page.



❖ Ministry User can also add some remarks in case they want to explain the issue more clearly.



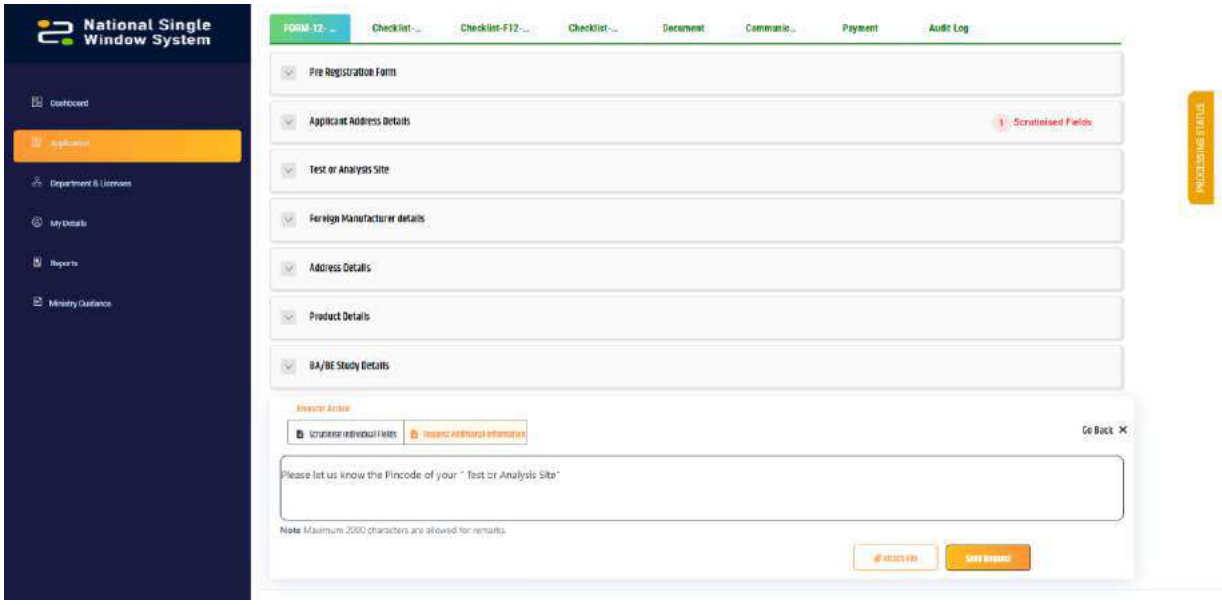
❖ The new input of the field will be visible on Ministry End once the investor will correct it and resubmit the Application.

Note: After the Investor resolves such query raised by Ministry user of any level, the application will automatically be assigned to the Reviewing Officer (Level 2).

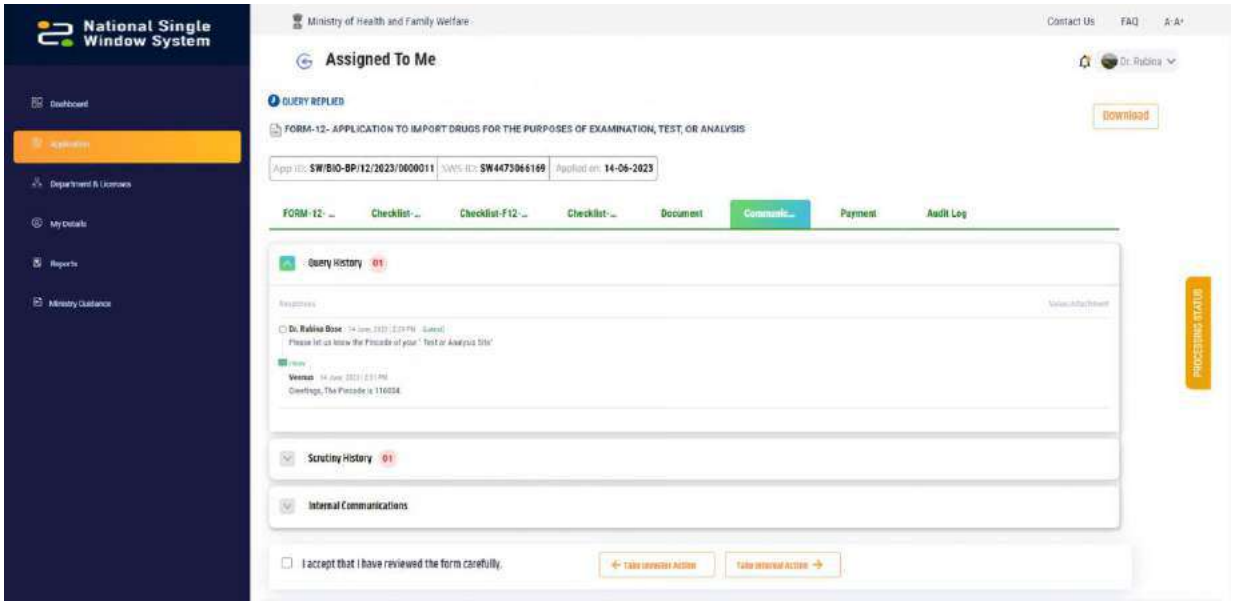
3.2.2.2 Request Additional Information

❖ In case the Ministry User want some general clarifications from the investor they can use this option.

❖ Ministry User has to click on “Request Additional Information” button. Add the required remarks and send the request.



❖ Once the investor replies on it, the same will appear on the commination tab as shown below

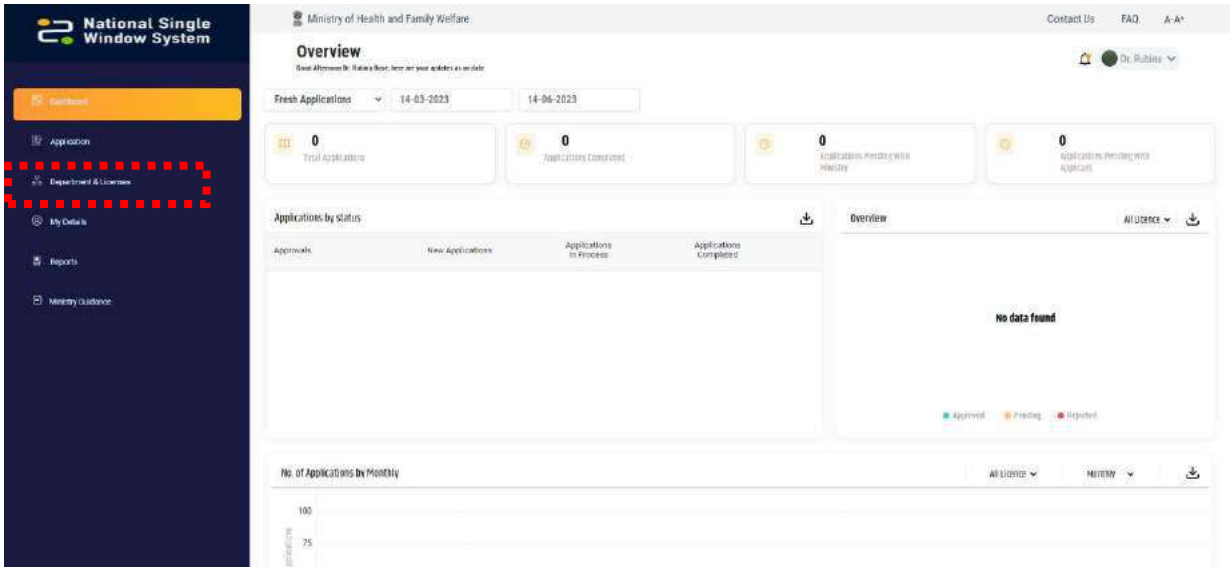


3.3 Ministry Users and Actions they can perform

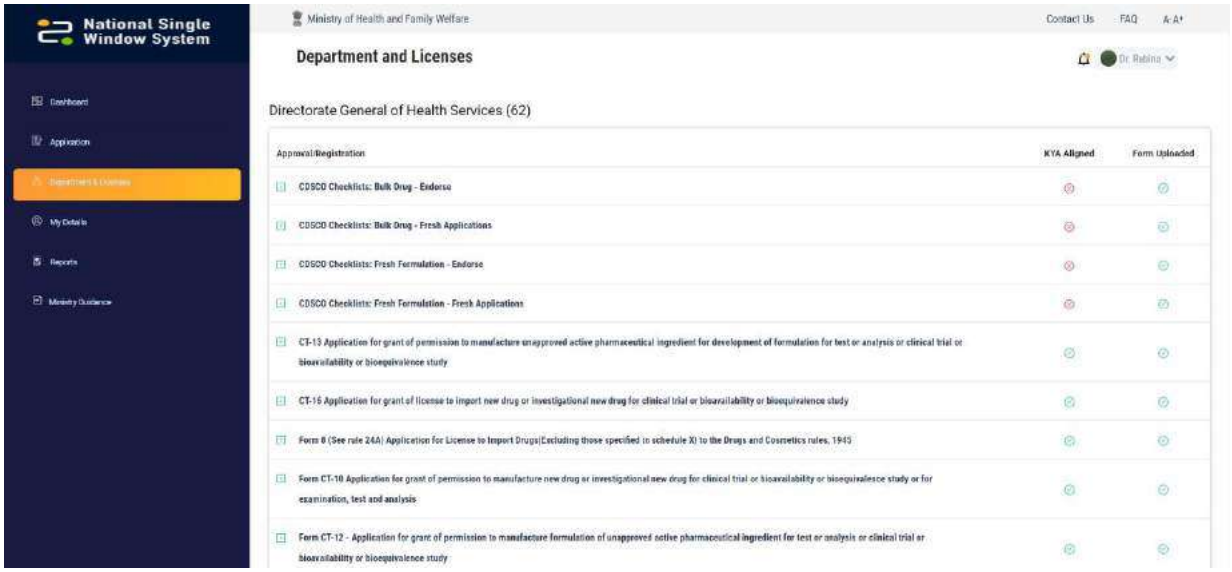
Level	Officer	Actions they can perform
1	N.O. (Nodal Officer)	• Seek Info • Pull Back and Reassign • Send To
2	R.O (Reviewing Officer)	• Notesheet Generation • Forward to next level • Send To, Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License
3	N.O. (Nodal Officer)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
4	D.D.A. (Deputy Deciding Authority)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
5	D.A. (Deciding Authority)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Generate Draft Permission/License • Notesheet
6	L.A. (Licensing Authority)	• Send To • Send Back • Seek Info • Generate Draft Covering Letter • Notesheet • Approve • Reject • Generate Final Permission Letter • Generate Final Covering Letter

4 Approval and Form Linking

Ministry User can also use the Ministry Dashboard for knowing the status of their Approvals for KYA and Form Linking. Ministry User upon login to the Ministry Dashboard should select the “Department and Licenses” tab.



The page will show the list of Approvals under CDSCO. The table will show status of each approval for their KYA and Form Alignment.



To know which forms are linked to an Approval the User should click on the Approval name (If the Form Uploaded Status is given as Yes). Clicking on the form name will open it in “Preview Mode”.


National Single Window System
Dashboard
Application
My Details
Reports
Ministry Guidance
Directorate General of Health Services (62)
Approval/Registration
KYA Aligned
Form Uploaded
COSCO Checklists: Bulk Drug - Endorse
COSCO Checklists: Bulk Drug - Fresh Applications
COSCO Checklists: Fresh Formulation - Endorse
COSCO Checklists: Fresh Formulation - Fresh Applications
CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study
Form CT-13 Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study
Checklist CT13-IND-FFBD-Test & Analysis
Checklist CT13-IND-FFBD-Clinical Trial
Checklist CT13-SND-FFBD-Test & Analysis
Checklist CT13-SND-FFBD-Clinical Trial/BABE
Checklist CT13-BIO-Vaccine-FFBD-Test & Analysis
Checklist CT13-BIO-rDNA-FFBD- Test & Analysis
Checklist CT13-BIO-rDNA-FFBD-Clinical Trial
Checklist CT13-ND-FFBD-Test & Analysis
Checklist CT13-ND-FFBD-Clinical Trial
Checklist CT13-BIO-Vaccine-FFBD-Clinical Trial
CT-16 Application for grant of license to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study

5 NSWS Support Center

NSWS has set-up a dedicated team for catering to the queries by Ministry personnel. NSWS also answers the queries of the users through the FAQs provided on the Help Page.

The SPOC (Single Point of Contact) from NSWS for CDSCO are

Mr. Agni Jasthi <ganesh.agni@investindia.org.in>

Mr. Vaibhav Yadav <vaibhavyadav@investindia.org.in>

Ministry users can directly coordinate with the SPOC for clarification of their queries.

If the Ministry wants to change anything on their Ministry Portals then they can contact the Invest India SPOC for the same.

--- END OF GUIDE ---