User Manual

for

SUGAM- An e-Governance solution

Periodic Safety Update Report (PSUR) Module

by

Central Drugs Standard Control Organization (CDSCO)

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Periodic Safety Update Report (PSUR) Module for Sugam Portal

A new module i.e. Periodic Safety Update Report has been incorporated in the SUGAM portal.

In order to submit a PSUR report, the applicant needs to follow the below-mentioned steps:

1. Login with applicant credentials and click on "Submit Application". The following dashboard will appear as shown below in the figure.

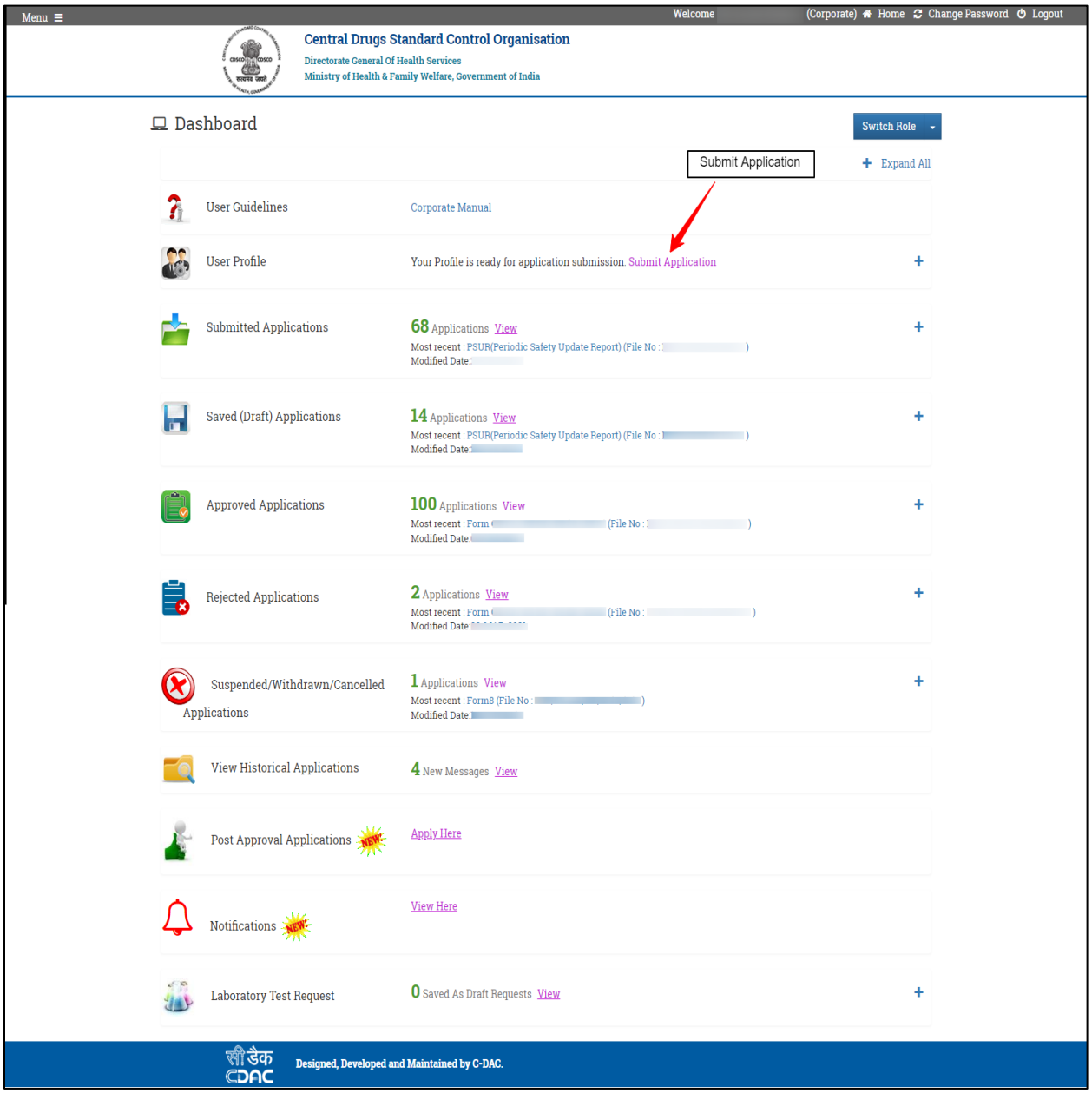

Figure 1: Applicant Dashboard

2. Once the user clicks on "Submit Application" link, the following screen will appear as shown below. The applicant needs to select the respective department of approved file/license for which he/she wants to submit PSUR application for.

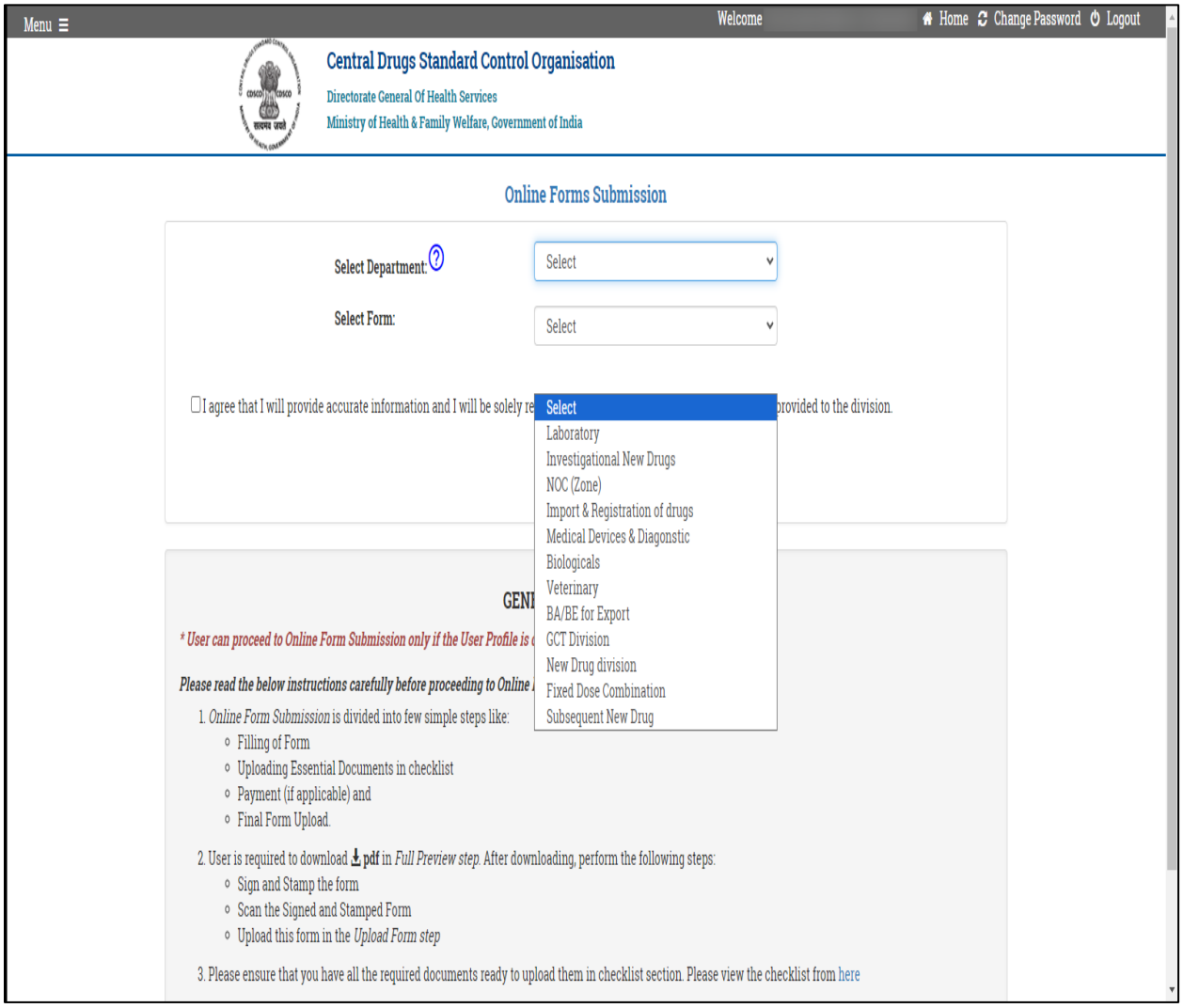

Figure 2: Online Forms Submission

There are various departments from which the user can choose, however, the PSUR Module is only available for the following departments:

- Biologicals
- Fixed Dose Combination
- Subsequent New Drug
- New Drug Division
- Veterinary
- Investigational New Drugs

- Import and Registration of drugs

3. Once the user clicks on the desired department, he needs to select "**PSUR**" under the **Select Form** section. Now, the Applicant can proceed by clicking on the Proceed button present on the same page.

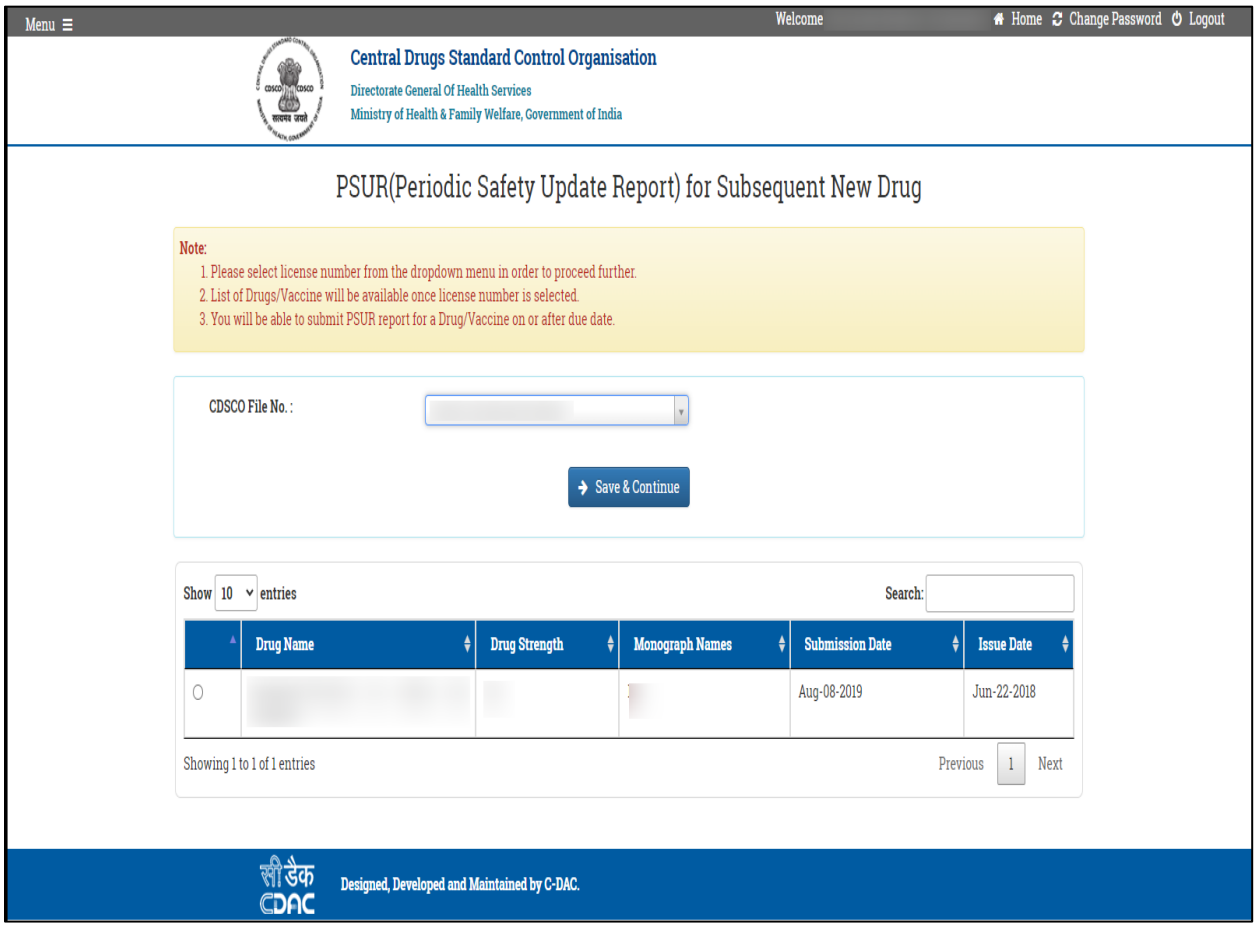

Figure 3: PSUR for Subsequent New Drug

4. On PSUR application, user can select desired application and then list of associated drugs/vaccine will be available as shown below.

NOTE: You will be able to submit PSUR report for a Drug/Vaccine on or after due date.

5. Select a drug and proceed further with the checklist. The following window will open as shown in the figure below.

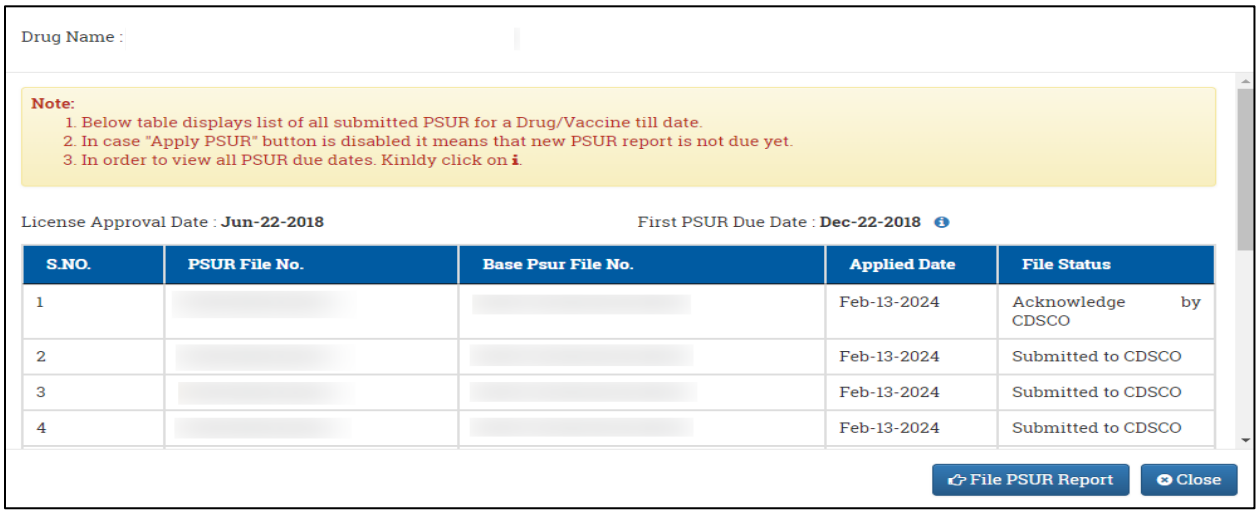

Figure 4: Drugs Checklist

The table shown in the image above displays list of all submitted PSUR for a Drug/Vaccine till date.

In case "Apply PSUR" button is disabled it means that new PSUR report is not due yet. Refer to the below figure for better understanding.

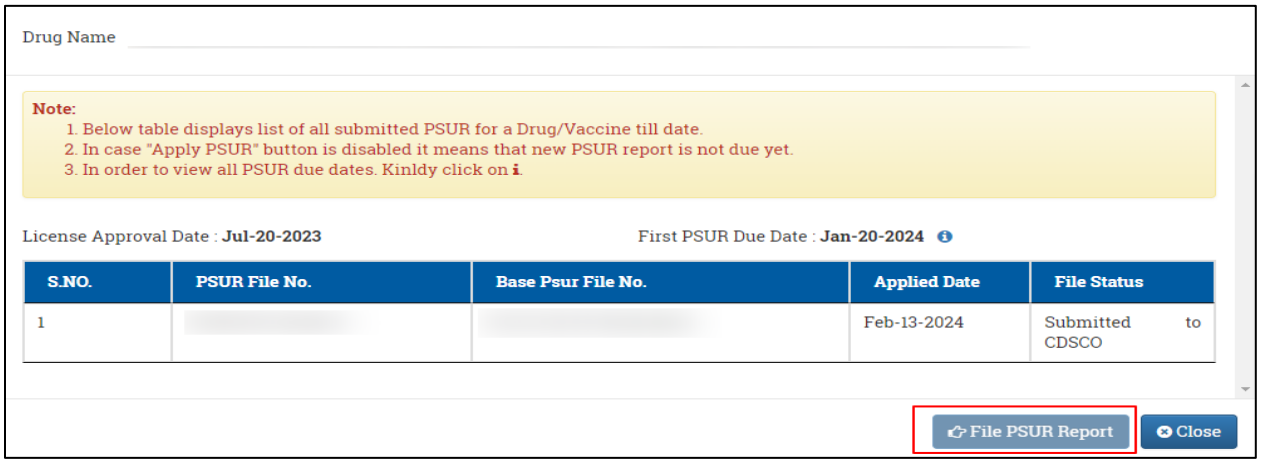

Figure 5: File PSUR button disabled

In order to view all PSUR due dates, applicant can click on the “i” icon present on the screen.

The “i” button will show all the dates which are due in the first, second, third, fourth, fifth and sixth PSUR.

For better understanding, please refer to the below image.

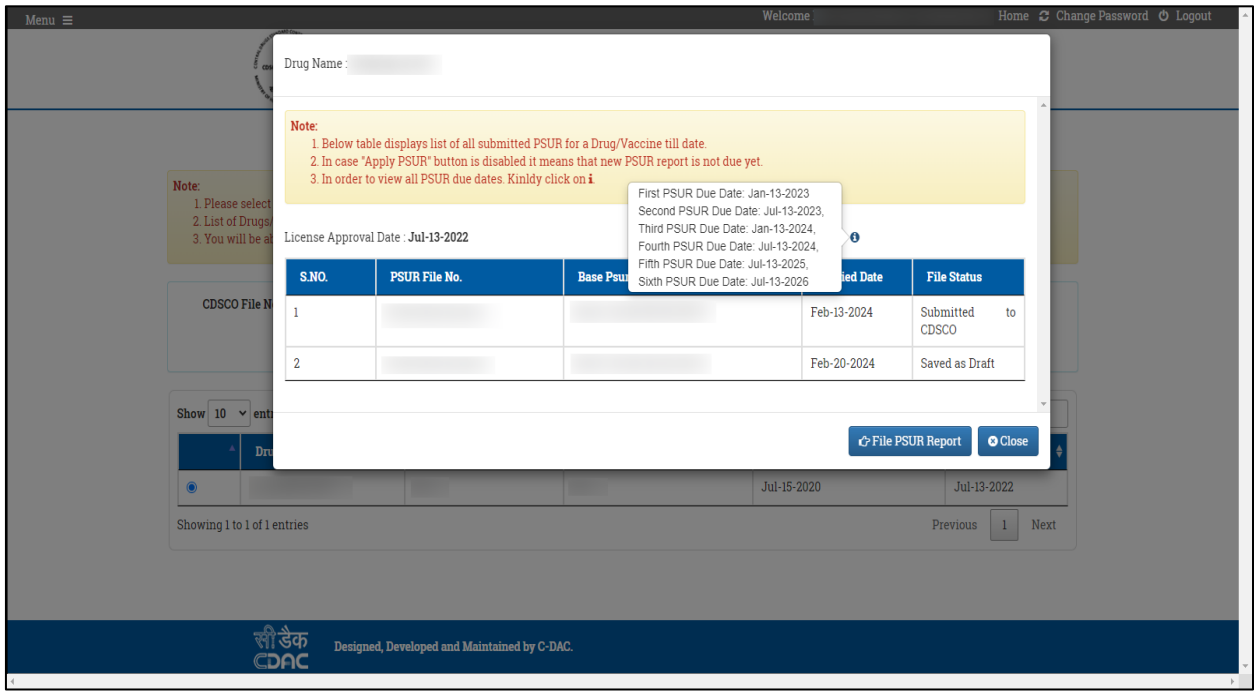

Figure 6: PSUR Due Dates

Once the user clicks on **File PSUR Report**, a confirmation window will open as shown below.

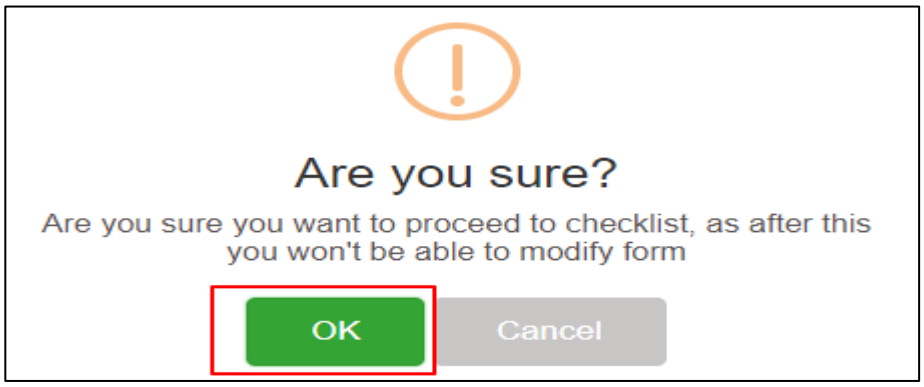

Figure 7: Confirmation window

After clicking on OK, the checklist window will open, wherein the Applicant needs to upload all the essential documents.

NOTE: All checklist items are mandatory. In case of unavailability of document the Applicant needs to give proper justification regarding the unavailability of document and also upload supporting document.

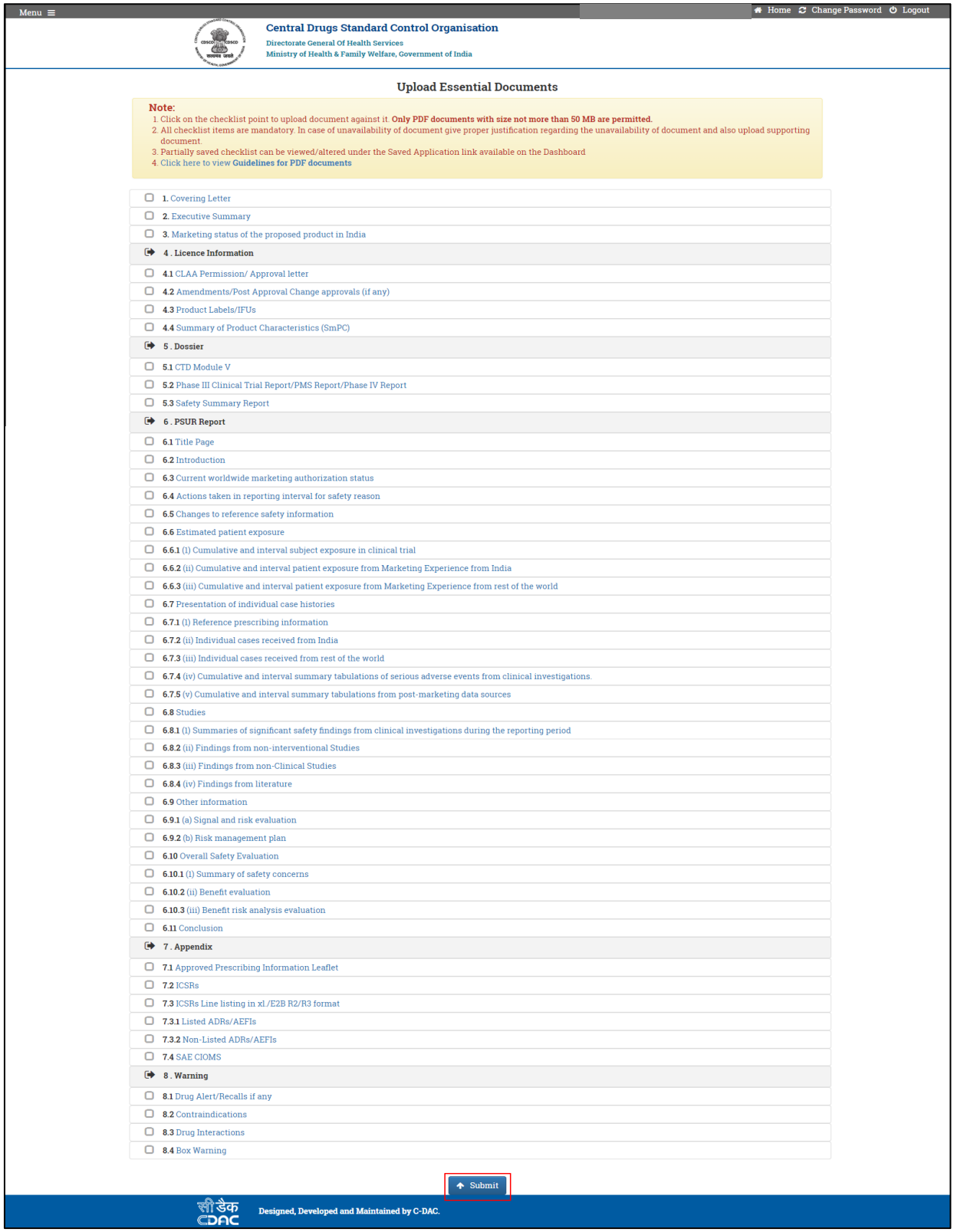

Figure 8: Checklist window

6. After uploading all the essential documents, the Applicant needs to submit the application by clicking on the Submit button present at the bottom of the page.

   A file number will be created after the submission of the application for future correspondence.

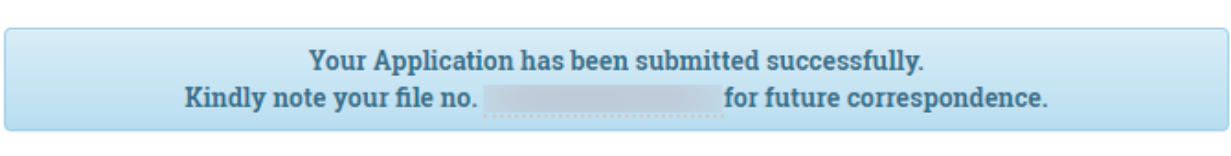

Figure 9: Submission confirmation