

# User Manual

for

**SUGAM- An e-Governance solution**

**Periodic Safety Update Report (PSUR) Module**

by

**Central Drugs Standard Control Organization (CDSCO)**



Directorate General of Health Services  
Ministry of Health & Family Welfare, Government of India

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(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

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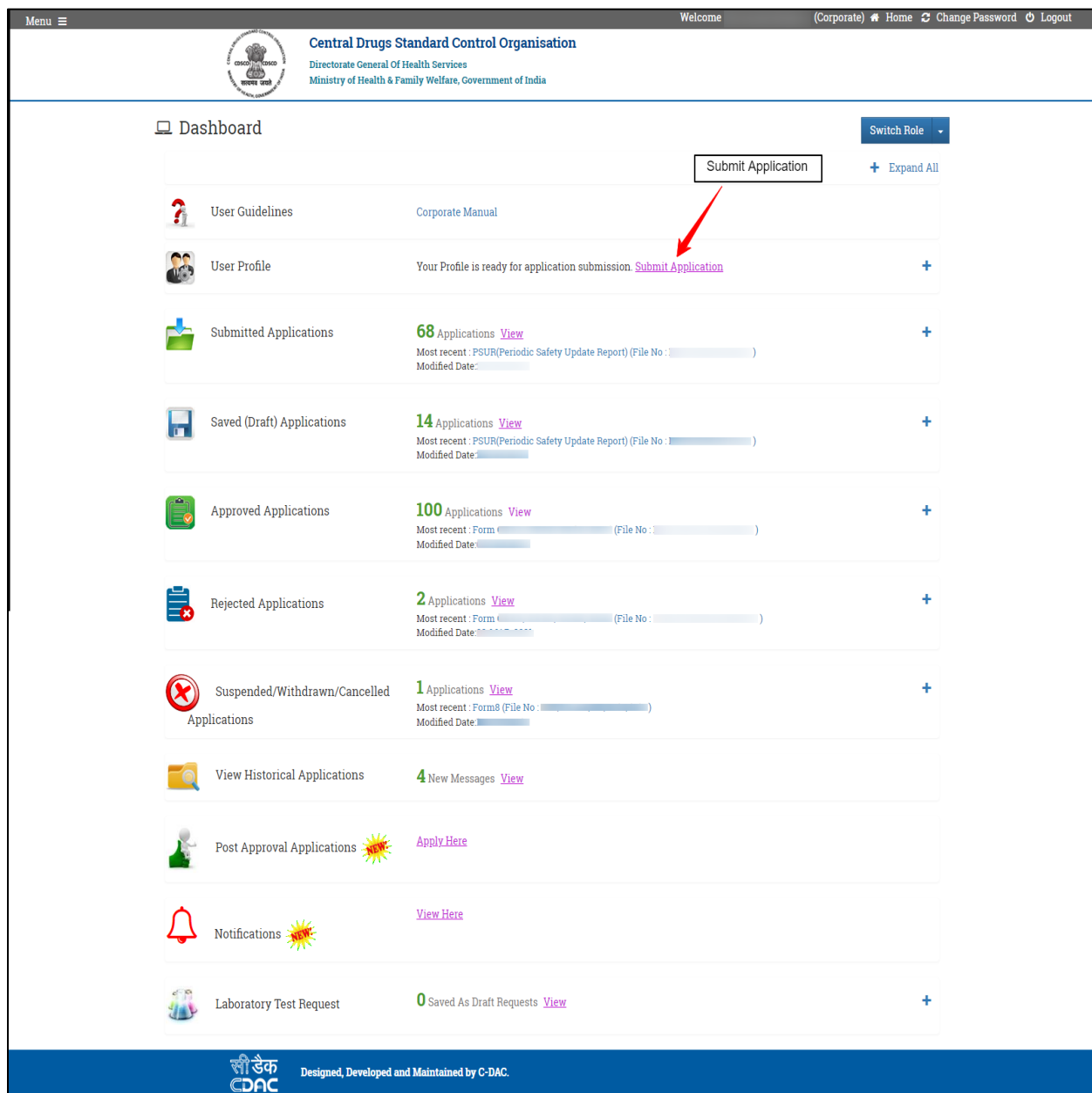
Phone: 91-120-2210800 Website: <http://www.cdac.in>

## 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.



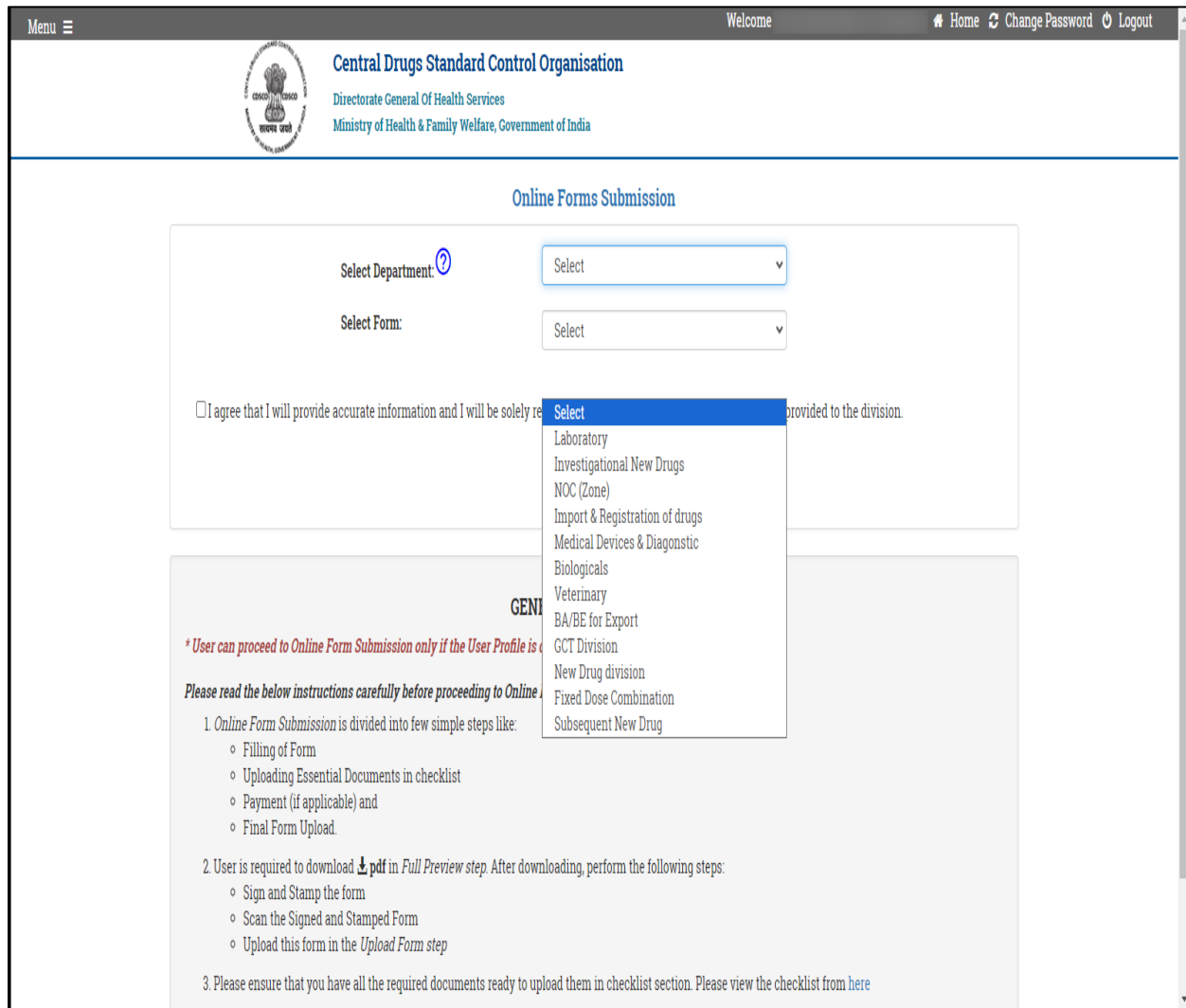
The screenshot shows the Applicant Dashboard for the PSUR module. At the top, there is a navigation bar with 'Menu', 'Welcome', '(Corporate)', 'Home', 'Change Password', and 'Logout'. The main header identifies the 'Central Drugs Standard Control Organisation' as the 'Directorate General Of Health Services' under the 'Ministry of Health & Family Welfare, Government of India'. The dashboard itself is titled 'Dashboard' and features a 'Switch Role' dropdown and a '+ Expand All' button. A prominent 'Submit Application' button is highlighted with a red arrow. Below this, the dashboard is organized into several sections, each with an icon, a title, and a count of items:

- User Guidelines:** Corporate Manual
- User Profile:** Your Profile is ready for application submission. [Submit Application](#)
- Submitted Applications:** 68 Applications [View](#). Most recent: PSUR(Periodic Safety Update Report) (File No.: [redacted]), Modified Date: [redacted]
- Saved (Draft) Applications:** 14 Applications [View](#). Most recent: PSUR(Periodic Safety Update Report) (File No.: [redacted]), Modified Date: [redacted]
- Approved Applications:** 100 Applications [View](#). Most recent: Form [redacted] (File No.: [redacted]), Modified Date: [redacted]
- Rejected Applications:** 2 Applications [View](#). Most recent: Form [redacted] (File No.: [redacted]), Modified Date: [redacted]
- Suspended/Withdrawn/Cancelled Applications:** 1 Applications [View](#). Most recent: Form [redacted] (File No.: [redacted]), Modified Date: [redacted]
- View Historical Applications:** 4 New Messages [View](#)
- Post Approval Applications:** [Apply Here](#)
- Notifications:** [View Here](#)
- Laboratory Test Request:** 0 Saved As Draft Requests [View](#)

At the bottom of the dashboard, there is a footer with the 'सी डैक CDAC' logo and the text 'Designed, Developed and Maintained by C-DAC'.

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.



Menu Welcome Home Change Password Logout

**Central Drugs Standard Control Organisation**  
 Directorate General Of Health Services  
 Ministry of Health & Family Welfare, Government of India

**Online Forms Submission**

Select Department:

Select Form:

I agree that I will provide accurate information and I will be solely responsible for the information provided to the division.

**GENI**

*\* User can proceed to Online Form Submission only if the User Profile is complete*

**Please read the below instructions carefully before proceeding to Online Form Submission**

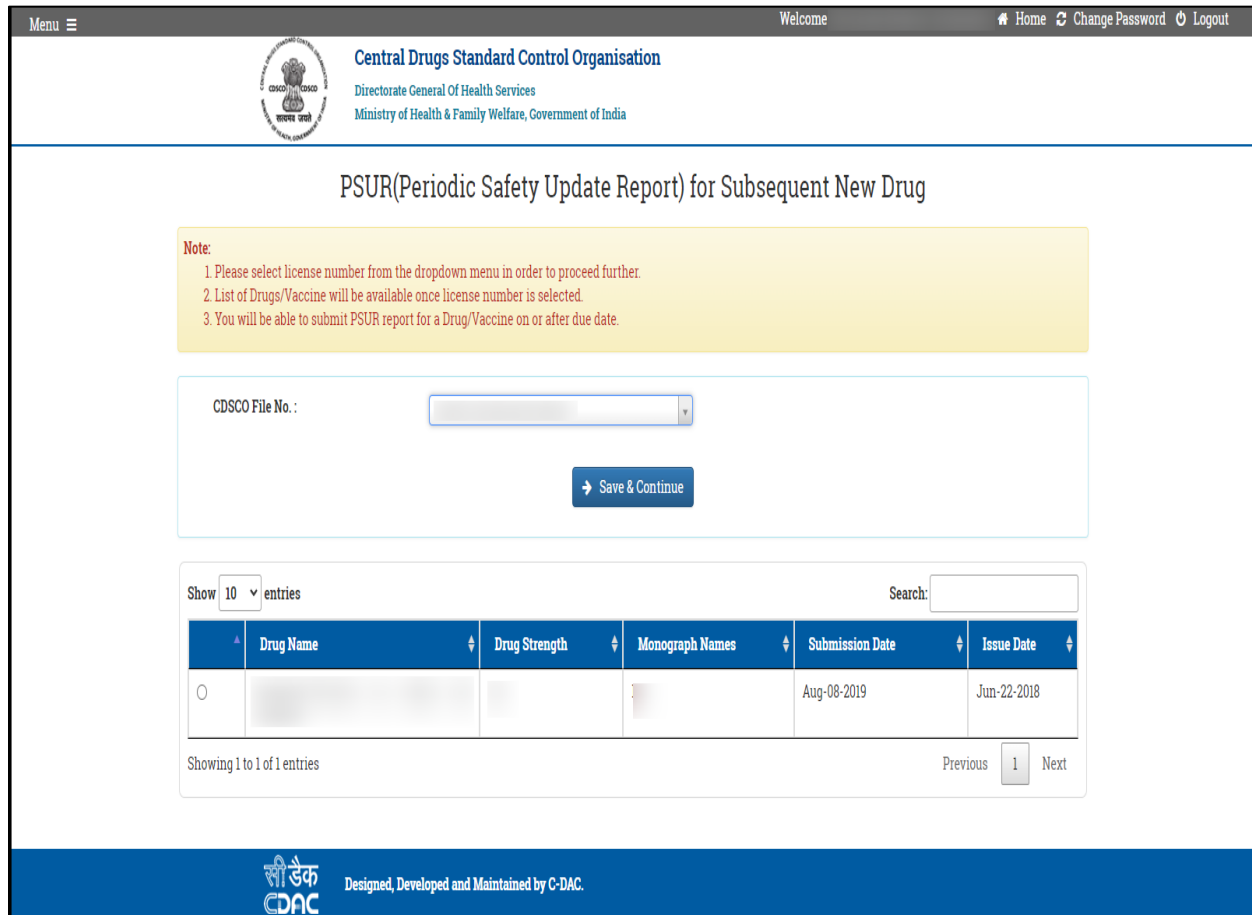
1. *Online Form Submission* is divided into few simple steps like:
  - Filling of Form
  - Uploading Essential Documents in checklist
  - Payment (if applicable) and
  - Final Form Upload.
2. User is required to download [pdf](#) in *Full Preview step*. After downloading, perform the following steps:
  - Sign and Stamp the form
  - Scan the Signed and Stamped Form
  - Upload this form in the *Upload Form step*
3. Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

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.



Menu ☰ Welcome Home Change Password Logout

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 Directorate General Of Health Services  
 Ministry of Health & Family Welfare, Government of India

### PSUR(Periodic Safety Update Report) for Subsequent New Drug

**Note:**

1. Please select license number from the dropdown menu in order to proceed further.
2. List of Drugs/Vaccine will be available once license number is selected.
3. You will be able to submit PSUR report for a Drug/Vaccine on or after due date.

CDSCO File No. :

[Save & Continue](#)

Show 10 entries Search:

Drug Name	Drug Strength	Monograph Names	Submission Date	Issue Date
			Aug-08-2019	Jun-22-2018

Showing 1 to 1 of 1 entries Previous 1 Next

सी डैक CDAC Designed, Developed and Maintained by C-DAC.

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.

Drug Name : \_\_\_\_\_

**Note:**

1. Below table displays list of all submitted PSUR for a Drug/Vaccine till date.
2. In case "Apply PSUR" button is disabled it means that new PSUR report is not due yet.
3. In order to view all PSUR due dates. Kindly click on **i**.

License Approval Date : Jun-22-2018 First PSUR Due Date : Dec-22-2018 ⓘ

S.NO.	PSUR File No.	Base Psur File No.	Applied Date	File Status
1	_____	_____	Feb-13-2024	Acknowledge by CDSKO
2	_____	_____	Feb-13-2024	Submitted to CDSKO
3	_____	_____	Feb-13-2024	Submitted to CDSKO
4	_____	_____	Feb-13-2024	Submitted to CDSKO

🔗 File PSUR Report
✖ Close

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.

Drug Name : \_\_\_\_\_

**Note:**

1. Below table displays list of all submitted PSUR for a Drug/Vaccine till date.
2. In case "Apply PSUR" button is disabled it means that new PSUR report is not due yet.
3. In order to view all PSUR due dates. Kindly click on **i**.

License Approval Date : Jul-20-2023 First PSUR Due Date : Jan-20-2024 ⓘ

S.NO.	PSUR File No.	Base Psur File No.	Applied Date	File Status
1	_____	_____	Feb-13-2024	Submitted to CDSKO

🔗 File PSUR Report
✖ Close

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.

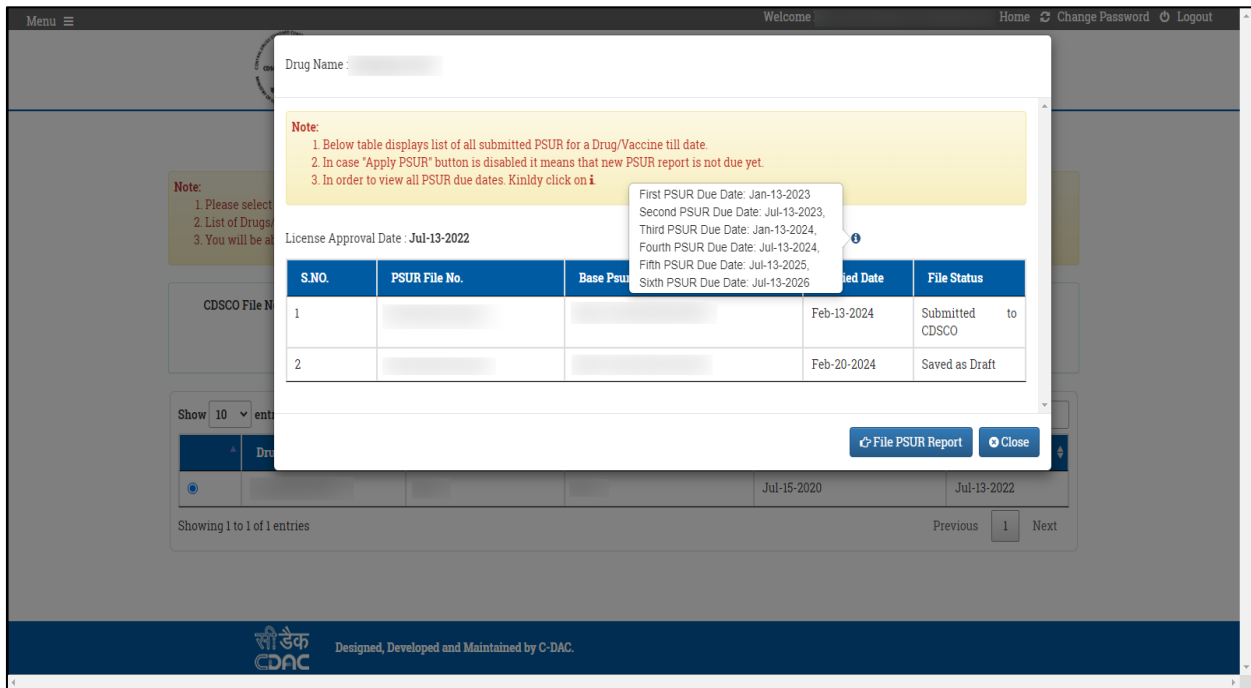


Figure 6: PSUR Due Dates

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

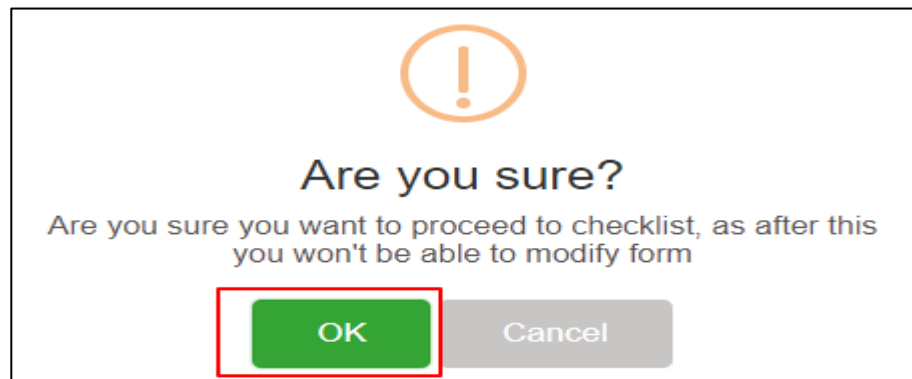



Figure 7: Confirmation window

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.**

Menu ☰



**Central Drugs Standard Control Organisation**  
Directorate General Of Health Services  
Ministry of Health & Family Welfare, Government of India

Home Change Password Logout


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### Upload Essential Documents

**Note:**

1. Click on the checklist point to upload document against it. Only PDF documents with size not more than 50 MB are permitted.
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. Click here to view [Guidelines for PDF documents](#)

<input type="checkbox"/> 1. Covering Letter
<input type="checkbox"/> 2. Executive Summary
<input type="checkbox"/> 3. Marketing status of the proposed product in India
<b>4. Licence Information</b>
<input type="checkbox"/> 4.1 CLAA Permission/ Approval letter
<input type="checkbox"/> 4.2 Amendments/Post Approval Change approvals (if any)
<input type="checkbox"/> 4.3 Product Labels/IFUs
<input type="checkbox"/> 4.4 Summary of Product Characteristics (SmPC)
<b>5. Dossier</b>
<input type="checkbox"/> 5.1 CTD Module V
<input type="checkbox"/> 5.2 Phase III Clinical Trial Report/PMS Report/Phase IV Report
<input type="checkbox"/> 5.3 Safety Summary Report
<b>6. PSUR Report</b>
<input type="checkbox"/> 6.1 Title Page
<input type="checkbox"/> 6.2 Introduction
<input type="checkbox"/> 6.3 Current worldwide marketing authorization status
<input type="checkbox"/> 6.4 Actions taken in reporting interval for safety reason
<input type="checkbox"/> 6.5 Changes to reference safety information
<input type="checkbox"/> 6.6 Estimated patient exposure
<input type="checkbox"/> 6.6.1 (i) Cumulative and interval subject exposure in clinical trial
<input type="checkbox"/> 6.6.2 (ii) Cumulative and interval patient exposure from Marketing Experience from India
<input type="checkbox"/> 6.6.3 (iii) Cumulative and interval patient exposure from Marketing Experience from rest of the world
<input type="checkbox"/> 6.7 Presentation of individual case histories
<input type="checkbox"/> 6.7.1 (i) Reference prescribing information
<input type="checkbox"/> 6.7.2 (ii) Individual cases received from India
<input type="checkbox"/> 6.7.3 (iii) Individual cases received from rest of the world
<input type="checkbox"/> 6.7.4 (iv) Cumulative and interval summary tabulations of serious adverse events from clinical investigations.
<input type="checkbox"/> 6.7.5 (v) Cumulative and interval summary tabulations from post-marketing data sources
<input type="checkbox"/> 6.8 Studies
<input type="checkbox"/> 6.8.1 (i) Summaries of significant safety findings from clinical investigations during the reporting period
<input type="checkbox"/> 6.8.2 (ii) Findings from non-interventional Studies
<input type="checkbox"/> 6.8.3 (iii) Findings from non-Clinical Studies
<input type="checkbox"/> 6.8.4 (iv) Findings from literature
<input type="checkbox"/> 6.9 Other information
<input type="checkbox"/> 6.9.1 (a) Signal and risk evaluation
<input type="checkbox"/> 6.9.2 (b) Risk management plan
<input type="checkbox"/> 6.10 Overall Safety Evaluation
<input type="checkbox"/> 6.10.1 (i) Summary of safety concerns
<input type="checkbox"/> 6.10.2 (ii) Benefit evaluation
<input type="checkbox"/> 6.10.3 (iii) Benefit risk analysis evaluation
<input type="checkbox"/> 6.11 Conclusion
<b>7. Appendix</b>
<input type="checkbox"/> 7.1 Approved Prescribing Information Leaflet
<input type="checkbox"/> 7.2 ICSRs
<input type="checkbox"/> 7.3 ICSRs Line listing in xl /E2B R2/R3 format
<input type="checkbox"/> 7.3.1 Listed ADRs/AEFIs
<input type="checkbox"/> 7.3.2 Non-Listed ADRs/AEFIs
<input type="checkbox"/> 7.4 SAE CIOMS
<b>8. Warning</b>
<input type="checkbox"/> 8.1 Drug Alert/Recalls if any
<input type="checkbox"/> 8.2 Contraindications
<input type="checkbox"/> 8.3 Drug Interactions
<input type="checkbox"/> 8.4 Box Warning



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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.

**Your Application has been submitted successfully.**  
**Kindly note your file no. [REDACTED] for future correspondence.**

Figure 9: Submission confirmation