

## User Manual

for

**Medical Device- 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**

**Centre for Development of Advanced Computing**  
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## Periodic Safety Update Report (PSUR) Module for Medical Device Portal

A new module i.e. Periodic Safety Update Report has been incorporated in the Medical Device portal. Only Importer/Manufacturers can apply for the PSUR.

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

1. Login with applicant credentials and click on the tile “Apply for Periodic safety Updated Report”. The following dashboard will appear as shown below in the figure.

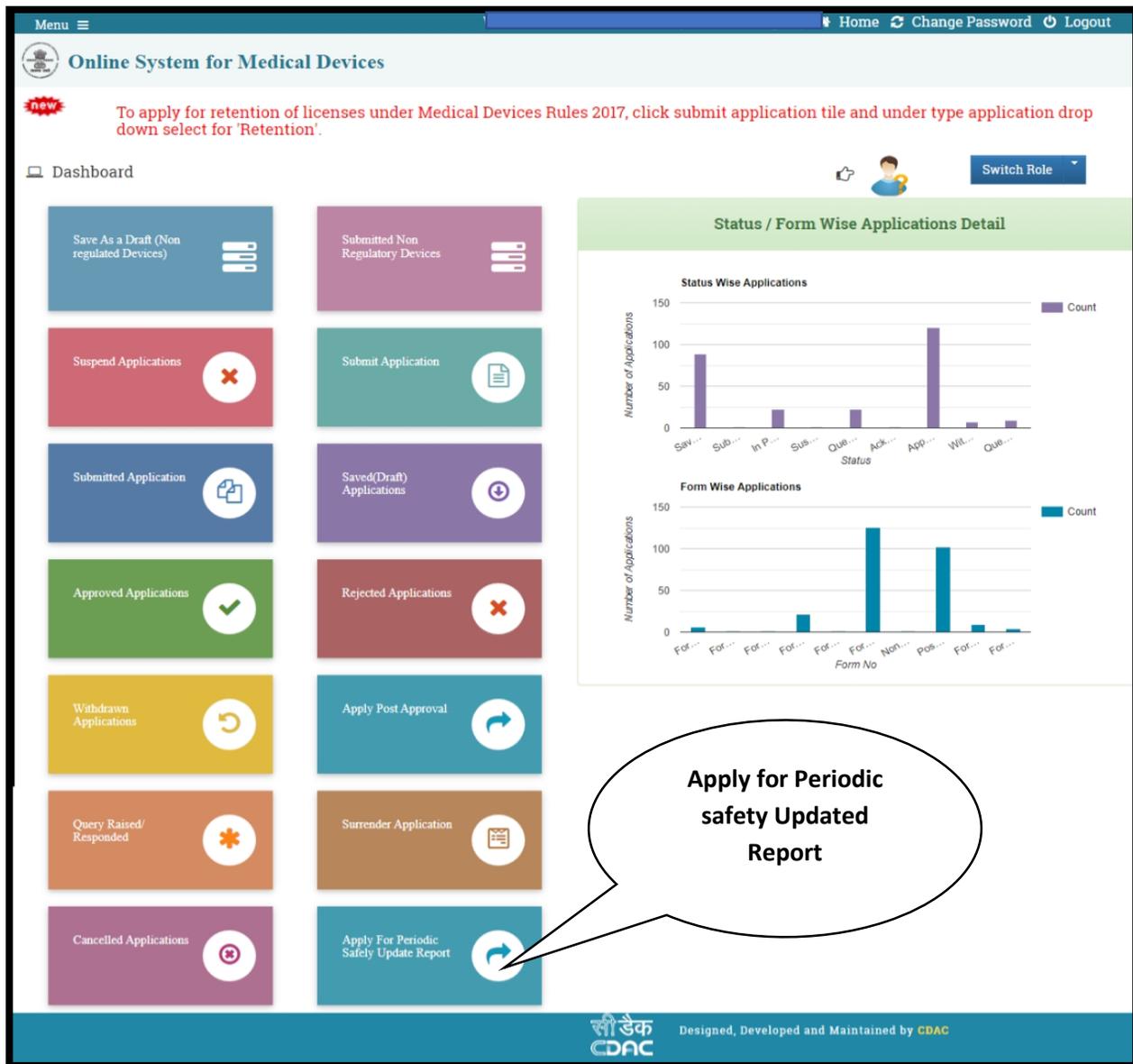
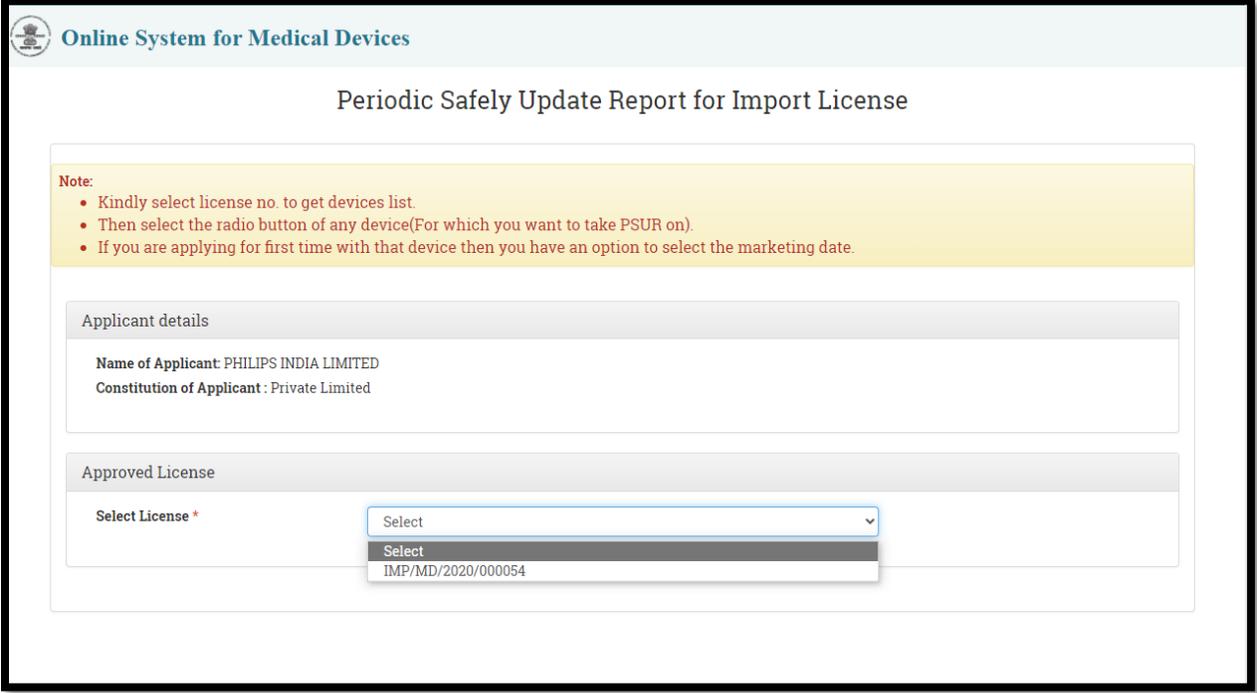


Figure 1: Applicant Dashboard

- Once the user clicks on “Submit Application” link, the following screen will appear as shown below. The applicant needs to select the License from the drop down respective for which he/she wants to submit PSUR application for.



**Online System for Medical Devices**

### Periodic Safety Update Report for Import License

**Note:**

- Kindly select license no. to get devices list.
- Then select the radio button of any device(For which you want to take PSUR on).
- If you are applying for first time with that device then you have an option to select the marketing date.

**Applicant details**

Name of Applicant: PHILIPS INDIA LIMITED  
Constitution of Applicant : Private Limited

**Approved License**

Select License \*  
Select  
Select  
IMP/MD/2020/000054

Figure 2: Select License from the drop-down

- After selecting the Licensing type (Manufacturing/Import) from the drop down the user needs to select the respective device from the drop for which he/she want to submit the PSUR, Shown below.

**Note:**

- Kindly select license no. to get devices list.
- Then select the radio button of any device(For which you want to take PSUR on).
- If you are applying for first time with that device then you have an option to select the marketing date.

**Applicant details**

Name of Applicant: PHILIPS INDIA LIMITED  
 Constitution of Applicant : Private Limited

**Approved License**

Select License \*

**Device Details**

Show  entries Search:

| Select Device:        | Device Name                   | Brand Name                                  | Intended Use  | Marketing Date |
|-----------------------|-------------------------------|---|---|----------------|
| <input type="radio"/> | Catheter, Class Type: Class D | ELCA - Coronary Laser Atherectomy Catheter. | The Laser Catheters are used in conjunction with the Spectranetics CVX-3000 Exci... <a href="#">Show More</a> | 27-Feb-2024    |

Previous **1** Next

**Radio button to select product**

Figure 3: Select License from the drop-down

4. After selecting the license type from the drop-down menu, the user will see all the device information. The user needs to select the radio button of the device for which they want to take PSUR.

**Applicant details**

**Name of Applicant:** PHILIPS INDIA LIMITED  
**Constitution of Applicant:** Private Limited

**Approved License**

**Select License \***

**Device Details**

Show  entries Search:

| Select Device:                   | Device Name                   | Brand Name                                  | Intended Use  | Marketing Date |
|----------------------------------|-------------------------------|---|---|----------------|
| <input checked="" type="radio"/> | Catheter, Class Type: Class D | ELCA - Coronary Laser Atherectomy Catheter. | The Laser Catheters are used in conjunction with the Spectranetics CVX-300® Exci... <a href="#">Show More</a> | 27-Feb-2024    |

Showing 1 to 1 of 1 entries Previous **1** Next

**Device Markeing Date**

**Select Date**

**Enter Marketing Date**

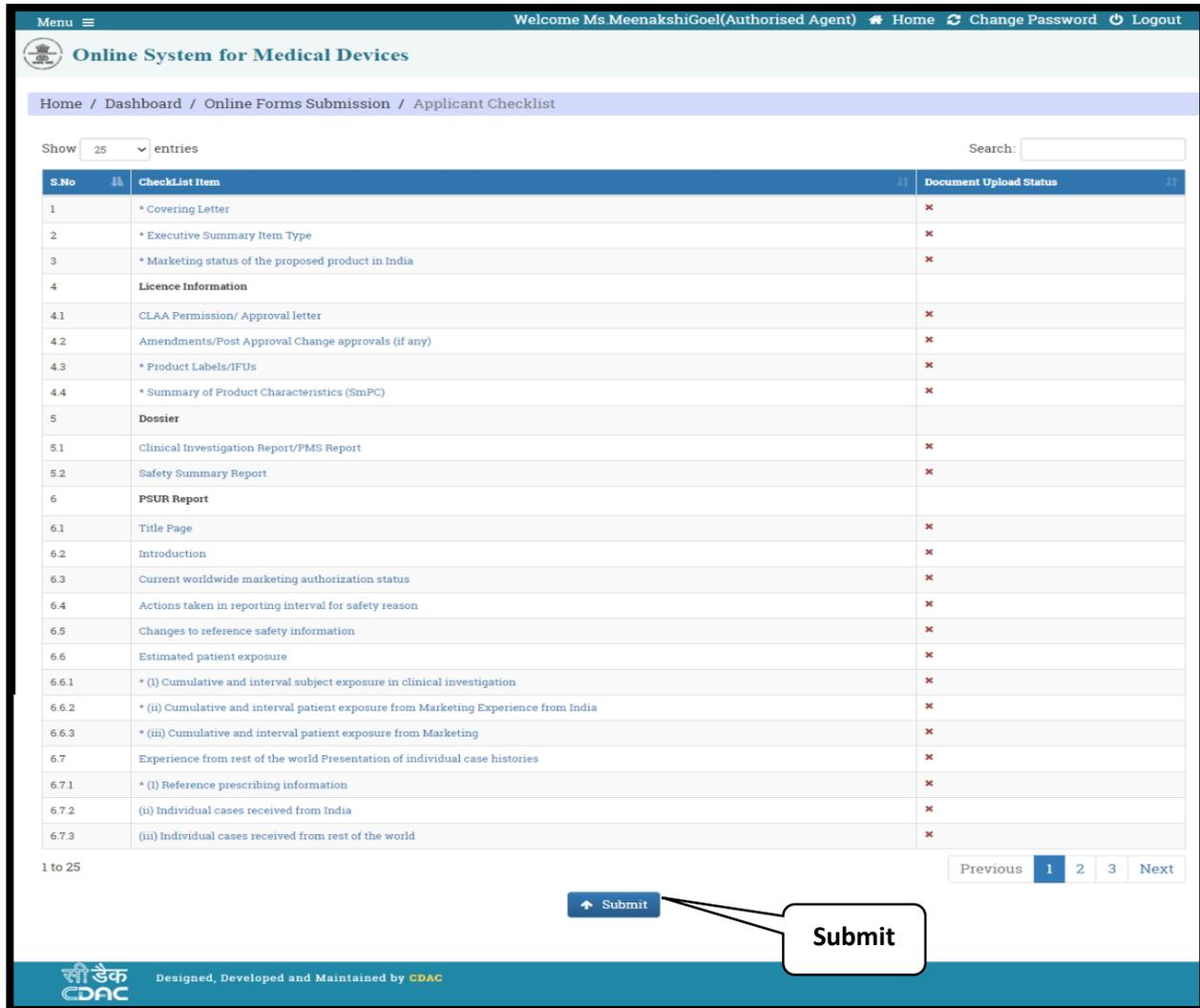
Figure 4: Entering Device Marketing Date

5. After selecting a device by clicking the radio button, they need to enter the device marketing date as shown. Then please click on save and Continue.

PSUR Module for Medical Device 2.0

- 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.



The screenshot displays the 'Applicant Checklist' page in the 'Online System for Medical Devices'. The page header includes 'Welcome Ms.MeenakshiGoel(Authorised Agent)' and navigation links for 'Home', 'Change Password', and 'Logout'. The breadcrumb trail is 'Home / Dashboard / Online Forms Submission / Applicant Checklist'. A search bar and a 'Show 25 entries' dropdown are present above the table.

| S.No  | CheckList Item   | Document Upload Status |
|-------|--|------------------------|
| 1     | * Covering Letter  | x                      |
| 2     | * Executive Summary Item Type  | x                      |
| 3     | * Marketing status of the proposed product in India                                  | x                      |
| 4     | <b>Licence Information</b>   |                        |
| 4.1   | CLAA Permission/ Approval letter   | x                      |
| 4.2   | Amendments/Post Approval Change approvals (if any)                                   | x                      |
| 4.3   | * Product Labels/IFUs  | x                      |
| 4.4   | * Summary of Product Characteristics (SmPC)  | x                      |
| 5     | <b>Dossier</b>   |                        |
| 5.1   | Clinical Investigation Report/PMS Report   | x                      |
| 5.2   | Safety Summary Report  | x                      |
| 6     | <b>PSUR Report</b>   |                        |
| 6.1   | Title Page   | x                      |
| 6.2   | Introduction   | x                      |
| 6.3   | Current worldwide marketing authorization status                                     | x                      |
| 6.4   | Actions taken in reporting interval for safety reason                                | x                      |
| 6.5   | Changes to reference safety information  | x                      |
| 6.6   | Estimated patient exposure   | x                      |
| 6.6.1 | * (i) Cumulative and interval subject exposure in clinical investigation             | x                      |
| 6.6.2 | * (ii) Cumulative and interval patient exposure from Marketing Experience from India | x                      |
| 6.6.3 | * (iii) Cumulative and interval patient exposure from Marketing                      | x                      |
| 6.7   | Experience from rest of the world Presentation of individual case histories          | x                      |
| 6.7.1 | * (i) Reference prescribing information  | x                      |
| 6.7.2 | (ii) Individual cases received from India  | x                      |
| 6.7.3 | (iii) Individual cases received from rest of the world                               | x                      |

At the bottom of the page, there is a 'Submit' button with an upward arrow. A callout box points to this button with the text 'Submit'. The footer of the page includes the CDAC logo and the text 'Designed, Developed and Maintained by CDAC'.

Figure 5: Submission of checklist

- 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.

## PSUR Module for Medical Device 2.0

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

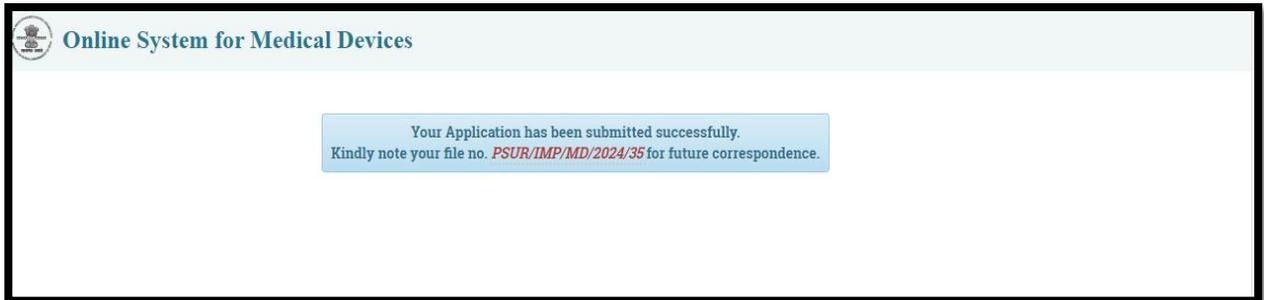


Figure 8: File has been submitted successfully