User Manual

for

Medical Device- 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 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.

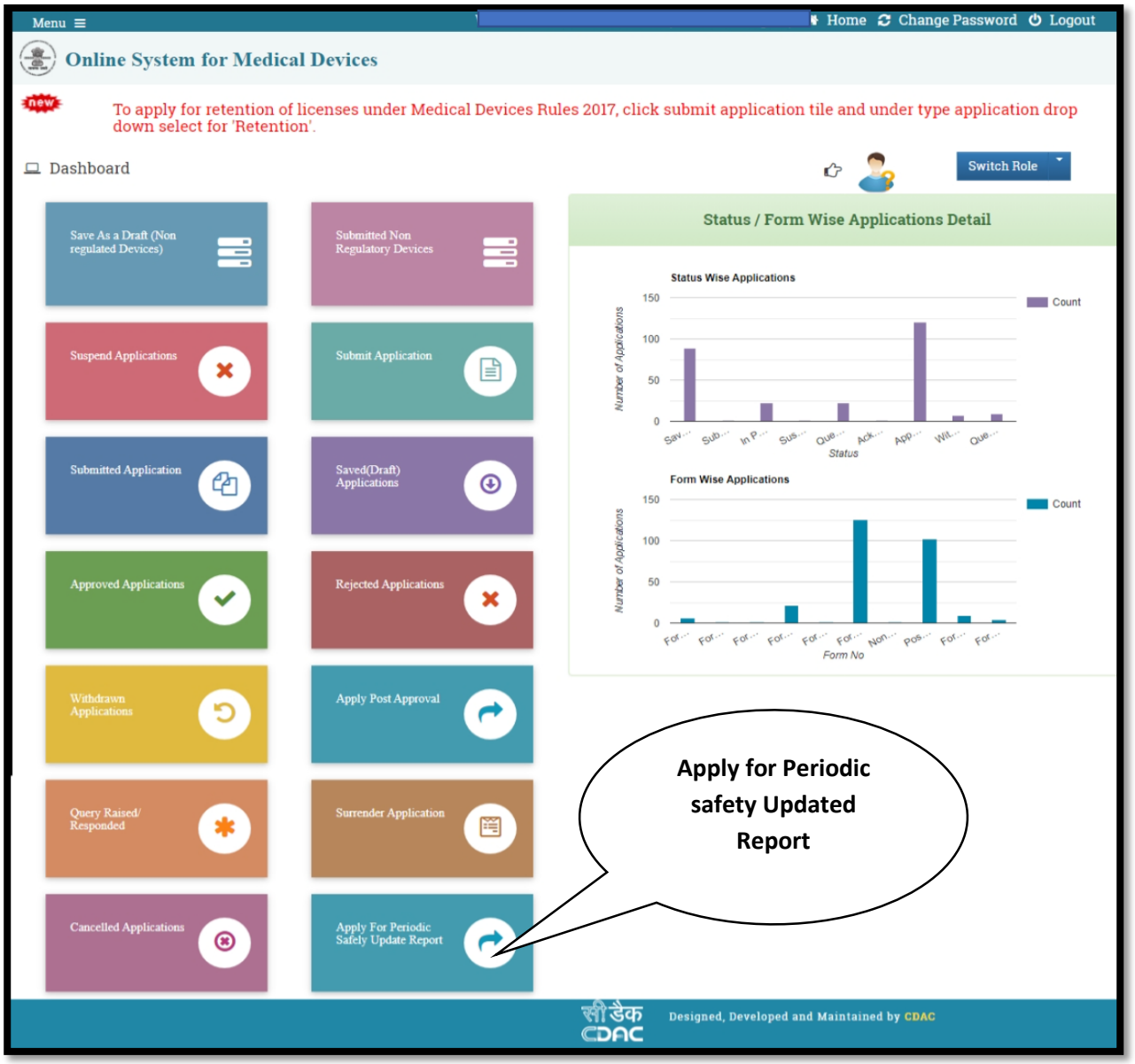

Figure 1: Applicant Dashboard

2. 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.

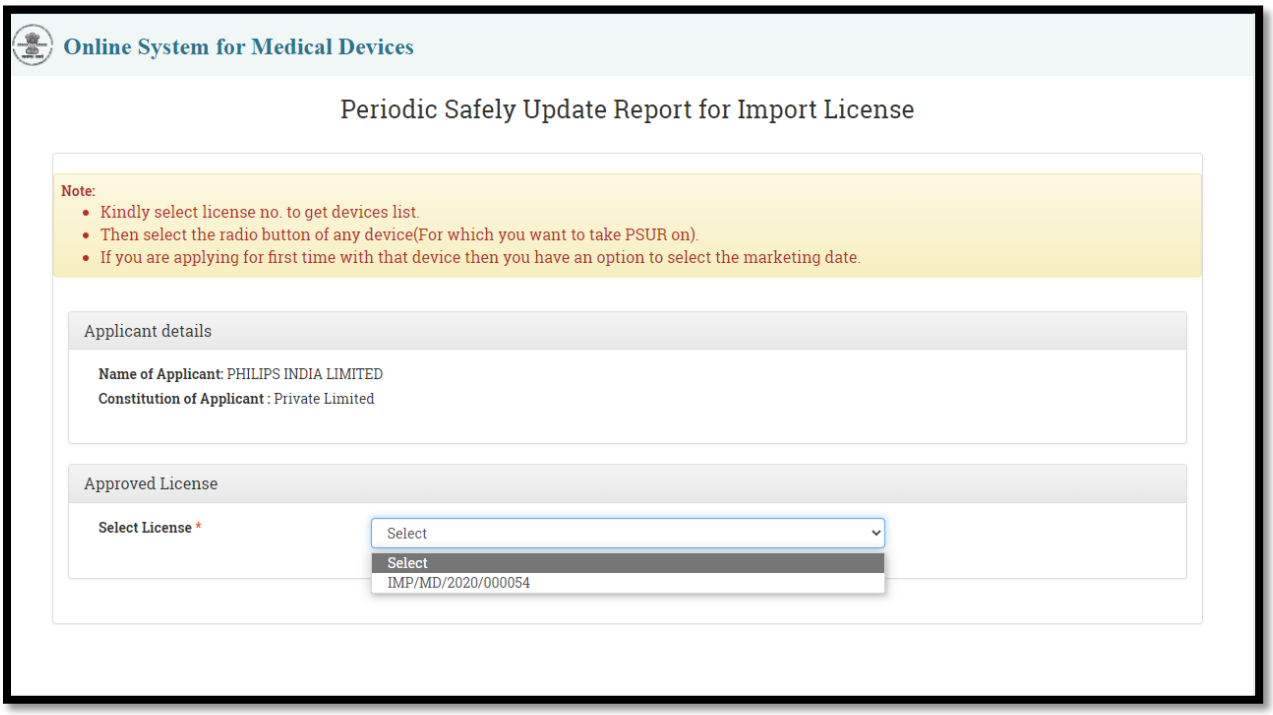

Figure 2: Select License from the drop-down

3. After selecting the Licensing type (Manufacturing/Import) form 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.

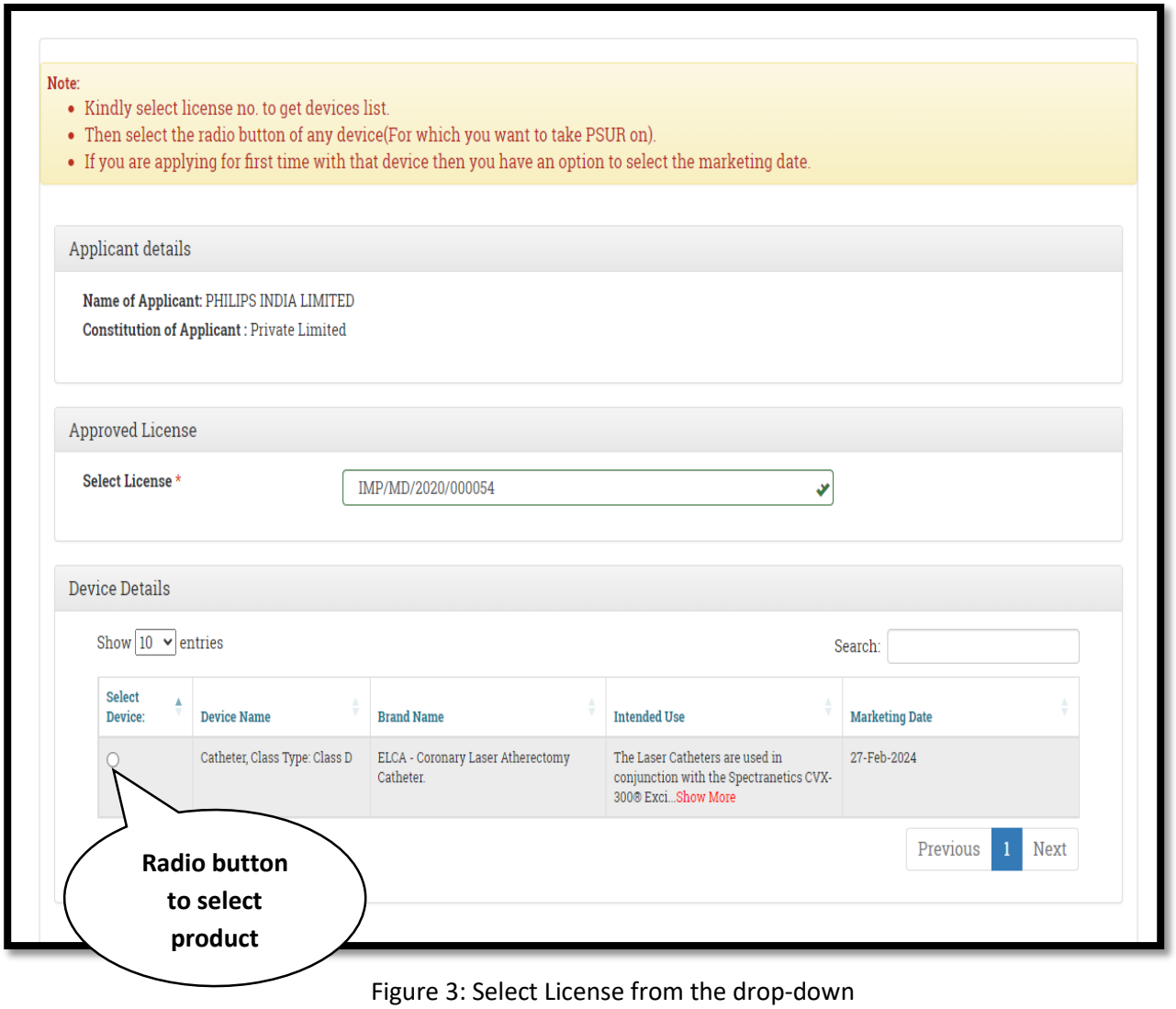

Figure 3: Select License from the drop-down

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.

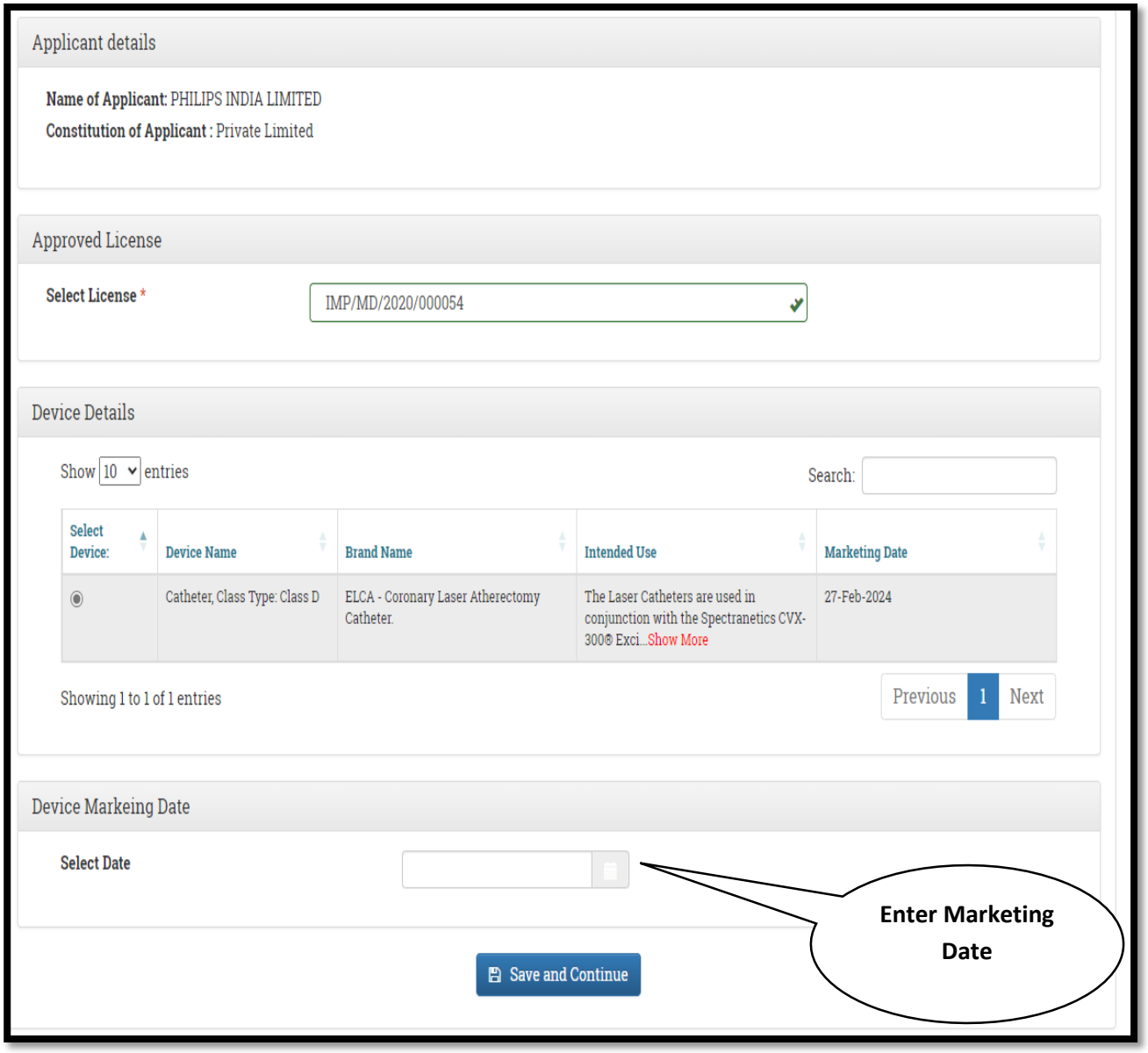

Figure 4: Entering Device Marketing Date

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.

6. 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.

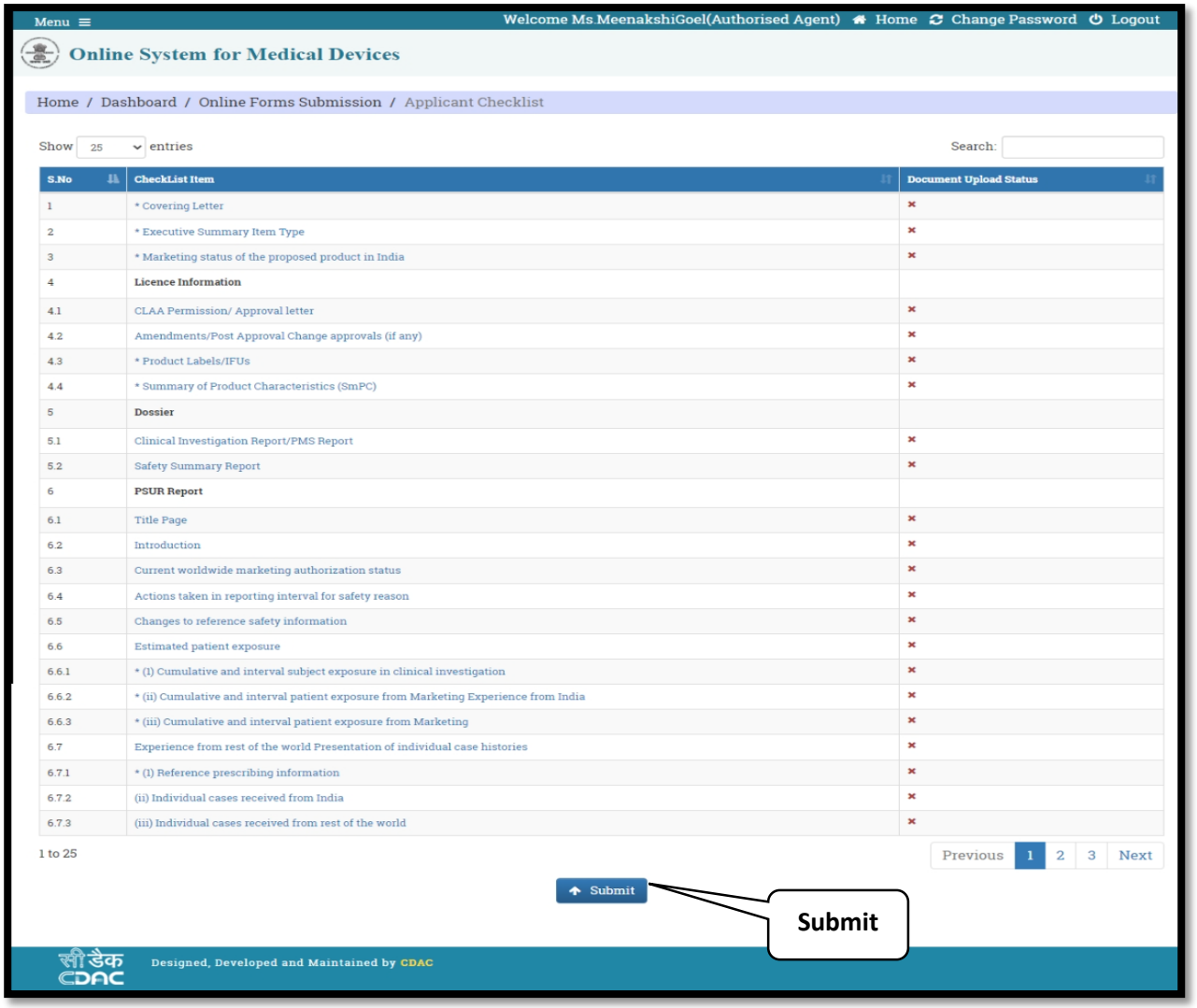

Figure 5: Submission of checklist

7. 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.

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

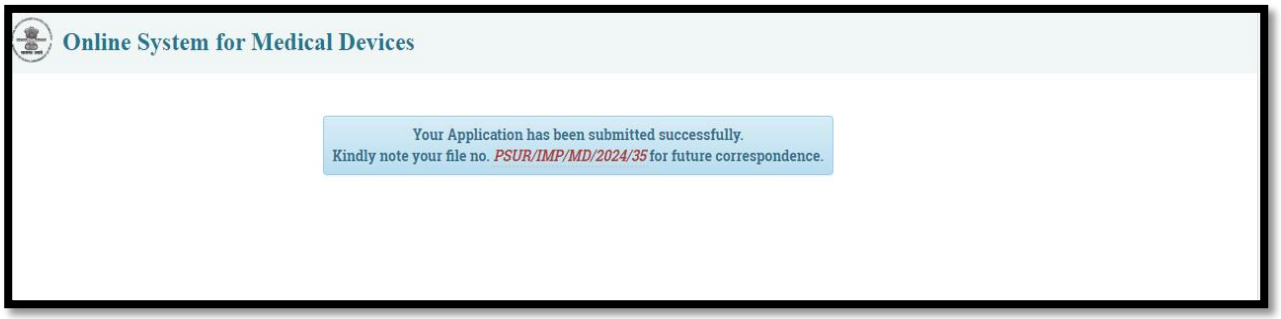

Figure 8: File has been submitted successfully