Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20202013

20 NOV 2020

TO : ALL STAKEHOLDERS AND THE GENERAL PUBLIC

SUBJECT : Pilot Implementation of Food and Drug Administration (FDA) eServices Portal System for Compassionate Special Permit (CSP) Application for Drug Products

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The Food and Drug Administration (FDA), in its commitment to provide stakeholders with streamlined and improved government services, is developing the **FDA eServices Portal System** – an online platform for FDA marketing authorization applications.

The FDA wishes to invite stakeholders to use the FDA eServices Portal System through eservices.fda.gov.ph for the applications for Compassionate Special Permit. The eServices Portal is in its Pilot Implementation; hence the scope of the application is limited for the time being:

FDA eServices Portal Pilot Implementation for Compassionate Special Permit	
Transactions	Compassionate Special Permit (Named Patient Use) Compassionate Special Permit (Institutional Use)
Fees to be Paid	Based on Current Issuance on Fees and Charges (DOH Administrative Order No. 50, s. 2001)
Start of Pilot Implementation	19 November 2020
End of Pilot Implementation	19 December 2020

Please follow Annex A of this Advisory for the Guideline and Checklist of Requirements, Annex B for step-by-step guide, and Annex C for checking of application status via **FDA eServices Portal System**.

For any feedback and comments for the FDA eServices Portal System, please send it to cdrr.od@fda.gov.ph.

ROLANDO ENRIQUE D. DOMINGO, MD.
Director General

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ANNEX A
Guideline and Requirements for Compassionate Special Permit (CSP) Applications Using eServices Portal System

I. Guidelines:

1. All Compassionate Special Permit (CSP) Applications shall be accomplished using the online application form through the eServices Portal System (eservices.fda.gov.ph). Creation of account and password is no longer a requirement to obtain access to the online portal.

2. The declared e-mail address under the Contact Information is **unalterable.** The applicant shall make sure that the e-mail address is within the scope and access of the Authorized Person/s and/or Qualified Personnel handling the transaction. Thus, FDA shall not be held liable in any way for loss of access to the declared e-mail address.

3. All fields on the online application form have written warnings/pop-ups/ reminders before proceeding to the next step to ensure the accuracy of information provided.

4. The result of the application will be sent to the email address of the applicant.

5. Documentary requirements shall be in pdf with 5 MB maximum file size.

6. All information filled-out by the applicant during the process shall be reflected in the final output based on the consistency with uploaded documents. Thus, it is imperative for the client to be diligent in filling out all the required information.

II. Application and Post-Approval Commitment Requirements:

1. Named Patient Use

    a. Accomplished online Application Form
    b. Curriculum Vitae of the Prescribing Doctor
    c. Medical Abstract of Patient
    d. Medical Prescription

2. Institutional Use

    a. Accomplished online Application Form
    b. Rational for the Volume Requested
    c. Proof of NRA Approval (for emergency use drug only)
    d. Distribution Agreement (for emergency use drug only)

3. Post-commitment Reports

    a. Clinical Study Report
    b. Reconciliation Report
    c. Manufacturing Data

III. Pre-assessment

1. An FDA evaluator/assessor shall conduct pre-assessment on the submitted application and documentary requirements with regards to their completeness and correctness. Applications with incomplete or incorrect data entry and document submissions shall not be accepted and the application will not proceed to the next step of the process.

2. The Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.

3. The FDA shall inform the applicant through the registered email address the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. If the application did not pass the pre-assessment step, the FDA shall notify the reason/s for non-acceptance e.g. deficiency/ies found and prompt the applicant to apply again through the eServices Portal.

IV. Payment of Fees

1. Payment of the total application fee as indicated in the Order of Payment (OP) maybe done through Over-the-counter (OTC) payment at FDAC, On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment), based on the existing FDA issuances. Always indicate the Reference Number reflected in the OP. Clients will be informed of other available channels of payment through an FDA issuance.

2. Once the payment is made, the payment channel -LBP or Bancnet (except for OTC at FDAC) will send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts the payment in the eServices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.

3. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. This also means that the application will not proceed to the next step of the process.

4. Applicants will receive a system-generated message through the registered email address on the status of the payment made once posted or need further settlement. If full payment is made, email will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.s

V. Evaluation

1. The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.

2. The action on the application shall be Approval or Disapproval as provided by Republic Act (RA) 11032 otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act.

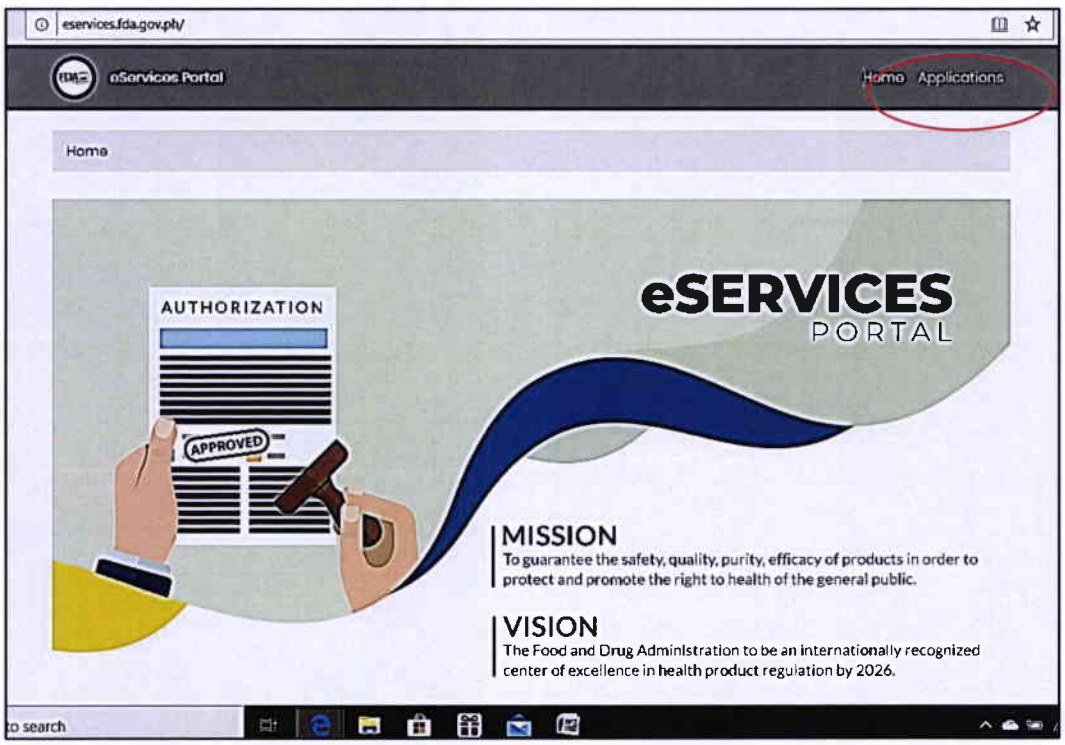
3. Evaluation shall be done within the prescribed working days and office hours. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.

ANNEX B

Procedure on the Use of the FDA eServices Portal System for Compassionate Business Permit (CSP) New Application

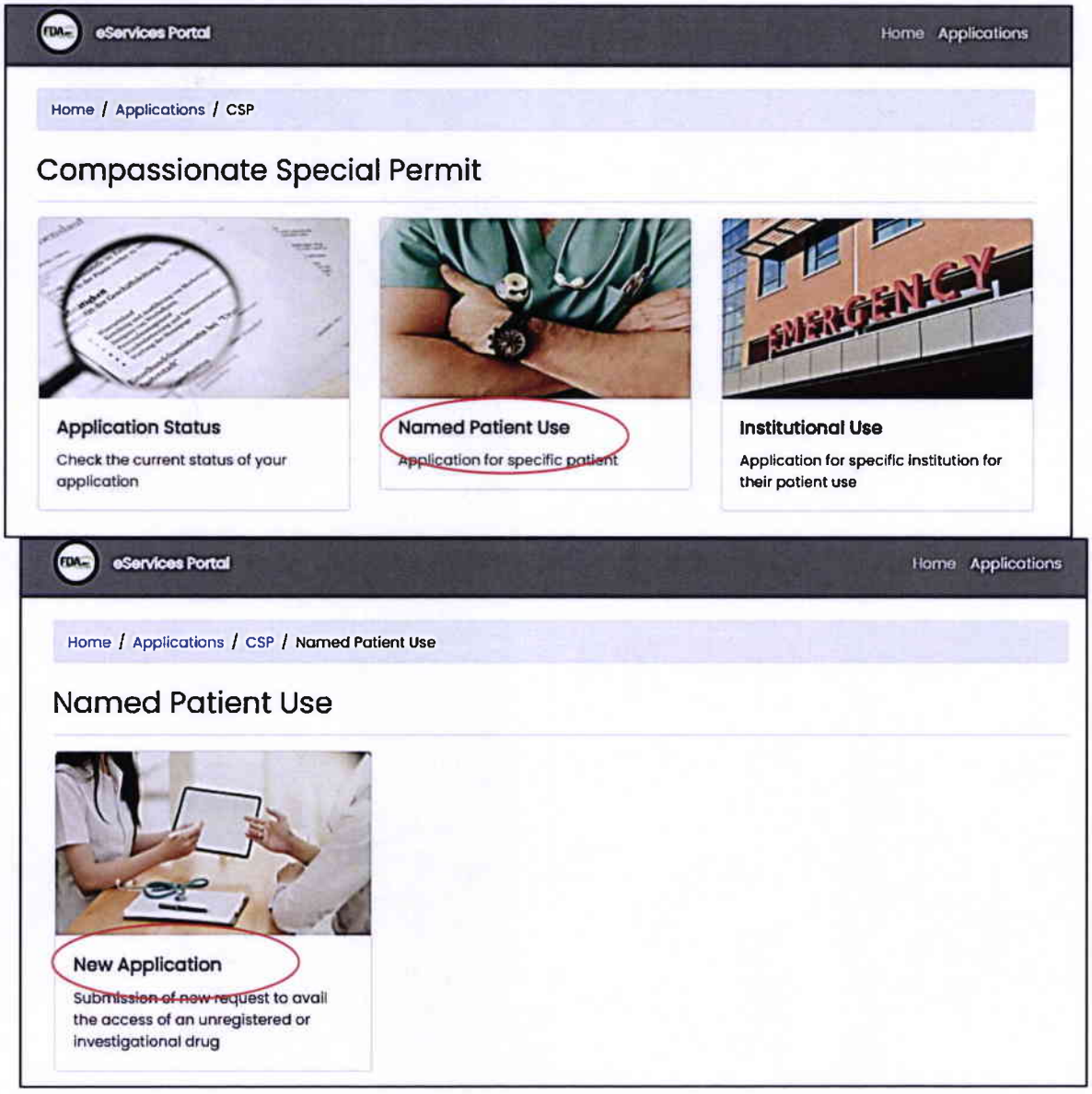
A. New CSP Application on NAMED PATIENT USE

1. Access the online portal through eservices.fda.gov.ph/and click **"Applications"** found on the upper right corner of the landing dashboard.

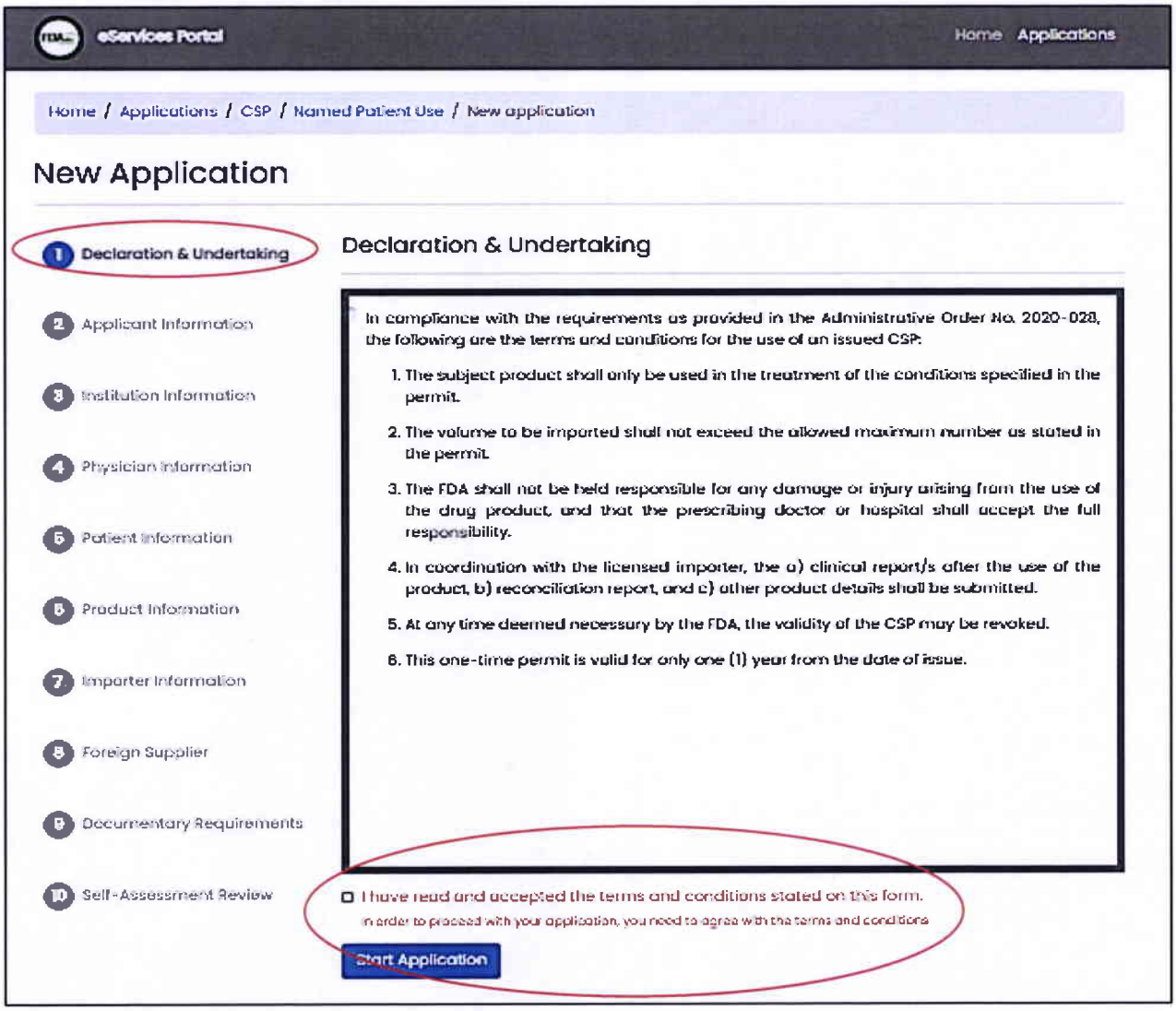


2. Click on the **Compassionate Special Permit**.

3. Click on the **Named Patient Use** and **New Application**.



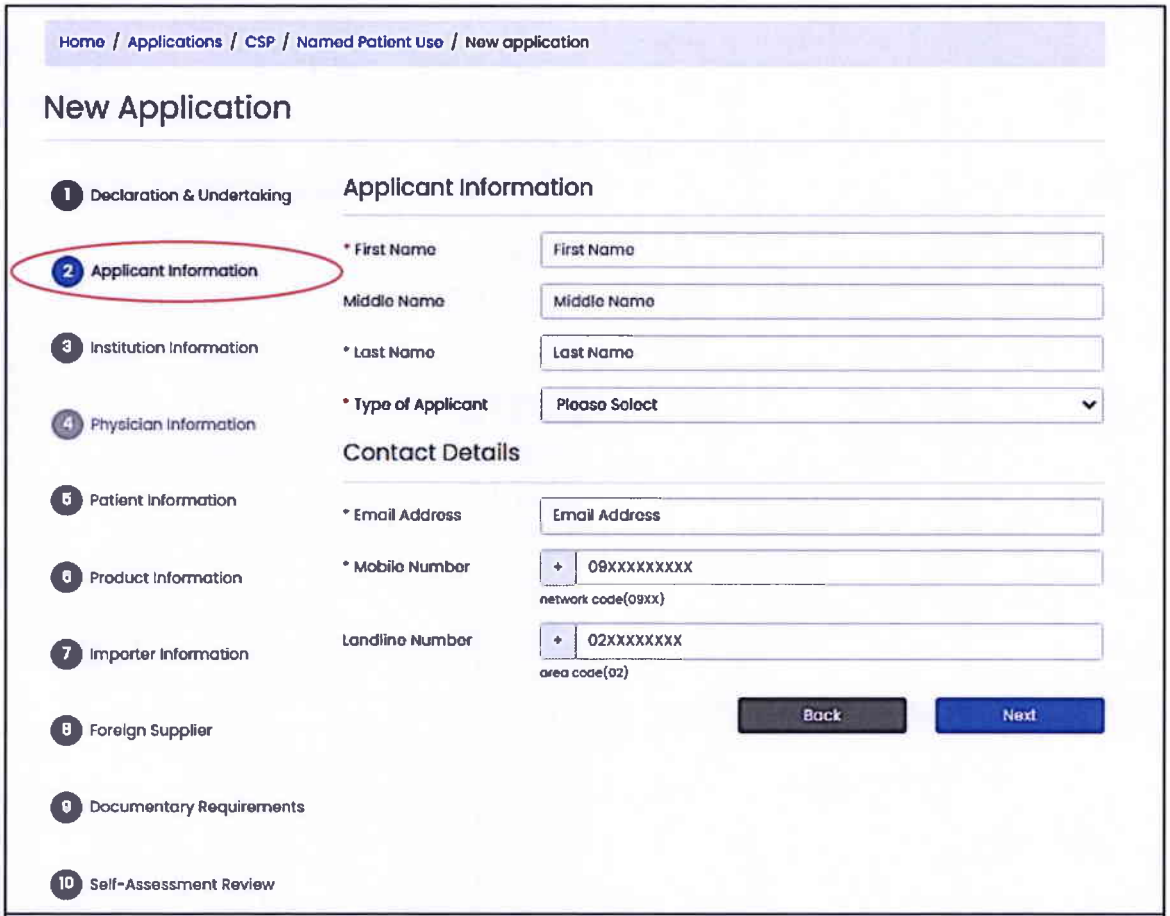
4. Read carefully the **"Declaration and Undertaking"** before proceeding with the application process. Make sure to check the box found and click **"Start Application"**.

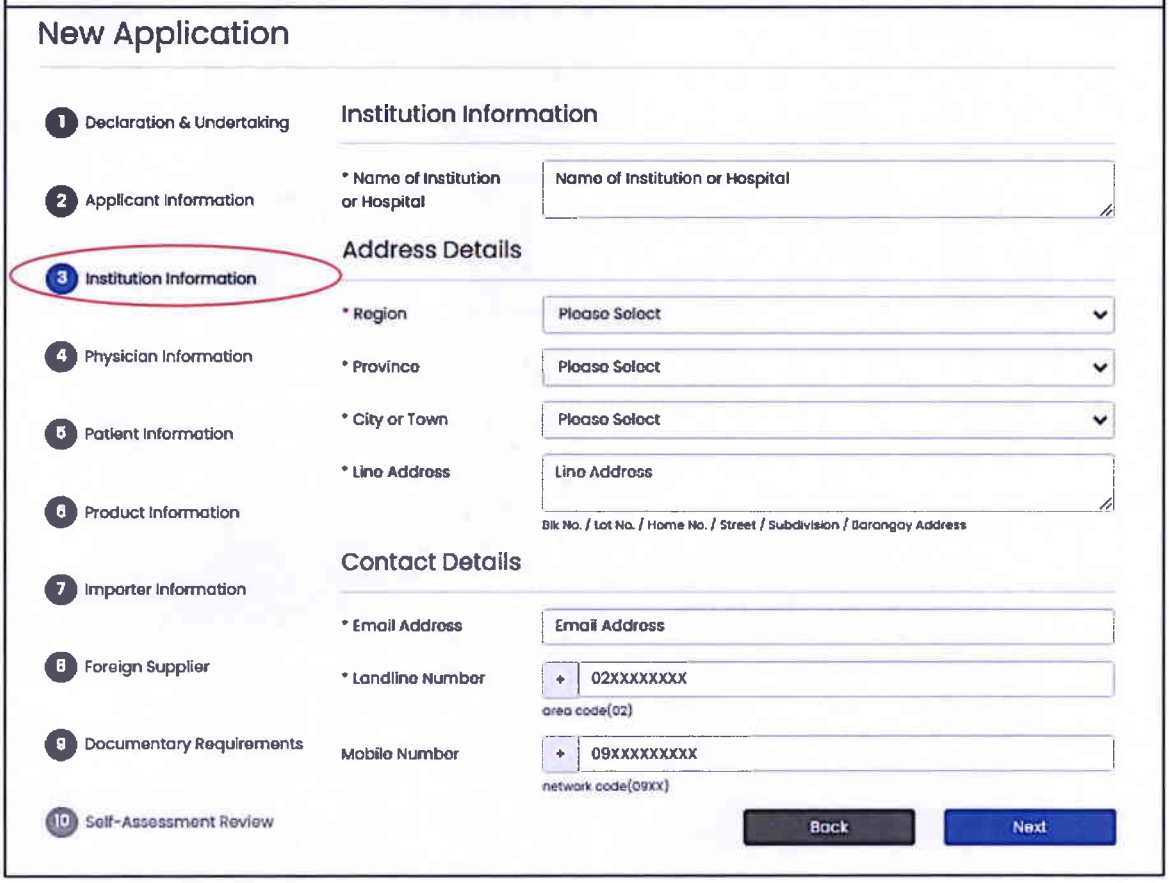


5. Fill-out all the information accurately. The e-mail address shall be official and the applicant shall make sure that it is within his/her scope.

   Please take note that all the fields marked with asterisk (*) are required to be filled-out.

   All necessary information must be provided.


Home / Applications / CSP / Named Patient Use / New application
New Application
1 Declaration & Undertaking
2 Applicant Information
3 Institution Information
4 Physician Information
5 Patient Information
6 Product Information
7 Importer Information
8 Foreign Supplier
9 Documentary Requirements
10 Self-Assessment Review
Applicant Information
* First Name
First Name
Middle Name
Middle Name
* Last Name
Last Name
* Type of Applicant
Please Select
Contact Details
* Email Address
Email Address
* Mobile Number
+
09XXXXXXXXX
network code(09XX)
Landline Number
+
02XXXXXXXX
area code(02)
Back
Next


New Application
1 Declaration & Undertaking
2 Applicant Information
3 Institution Information
4 Physician Information
5 Patient Information
6 Product Information
7 Importer Information
8 Foreign Supplier
9 Documentary Requirements
10 Self-Assessment Review
Institution Information
* Name of Institution or Hospital
Name of Institution or Hospital
Address Details
* Region
Please Select
* Province
Please Select
* City or Town
Please Select
* Line Address
Line Address
Blk No. / Lot No. / Home No. / Street / Subdivision / Barangay Address
Contact Details
* Email Address
Email Address
* Landline Number
+
02XXXXXXXX
area code(02)
Mobile Number
+
09XXXXXXXXX
network code(09XX)
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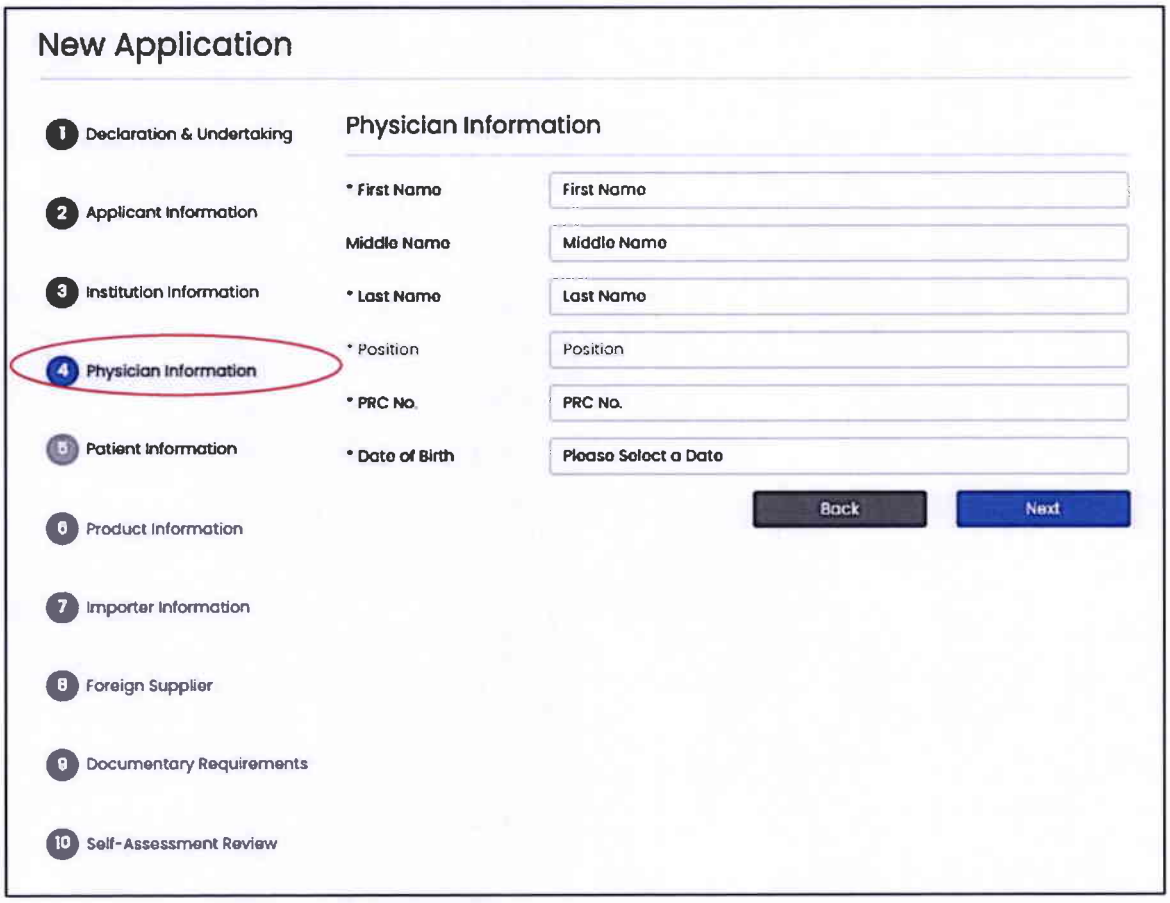
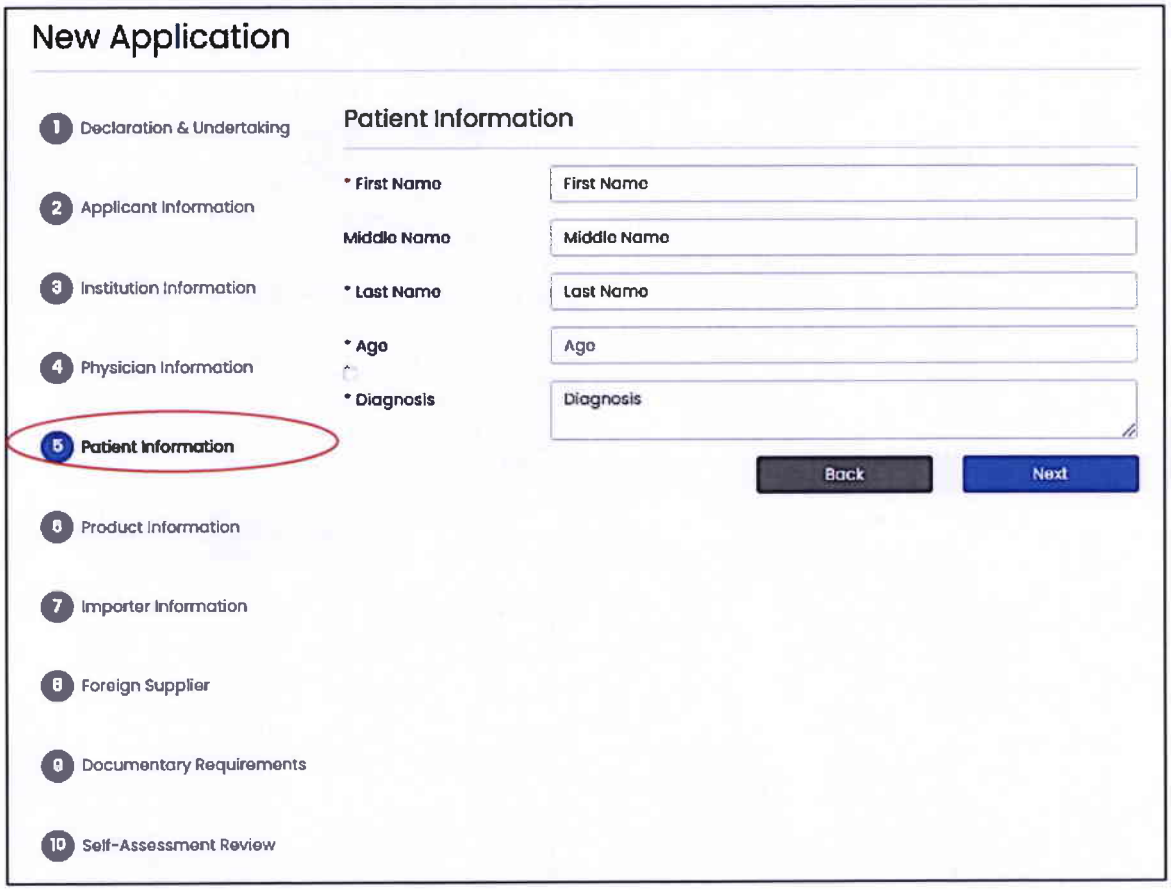
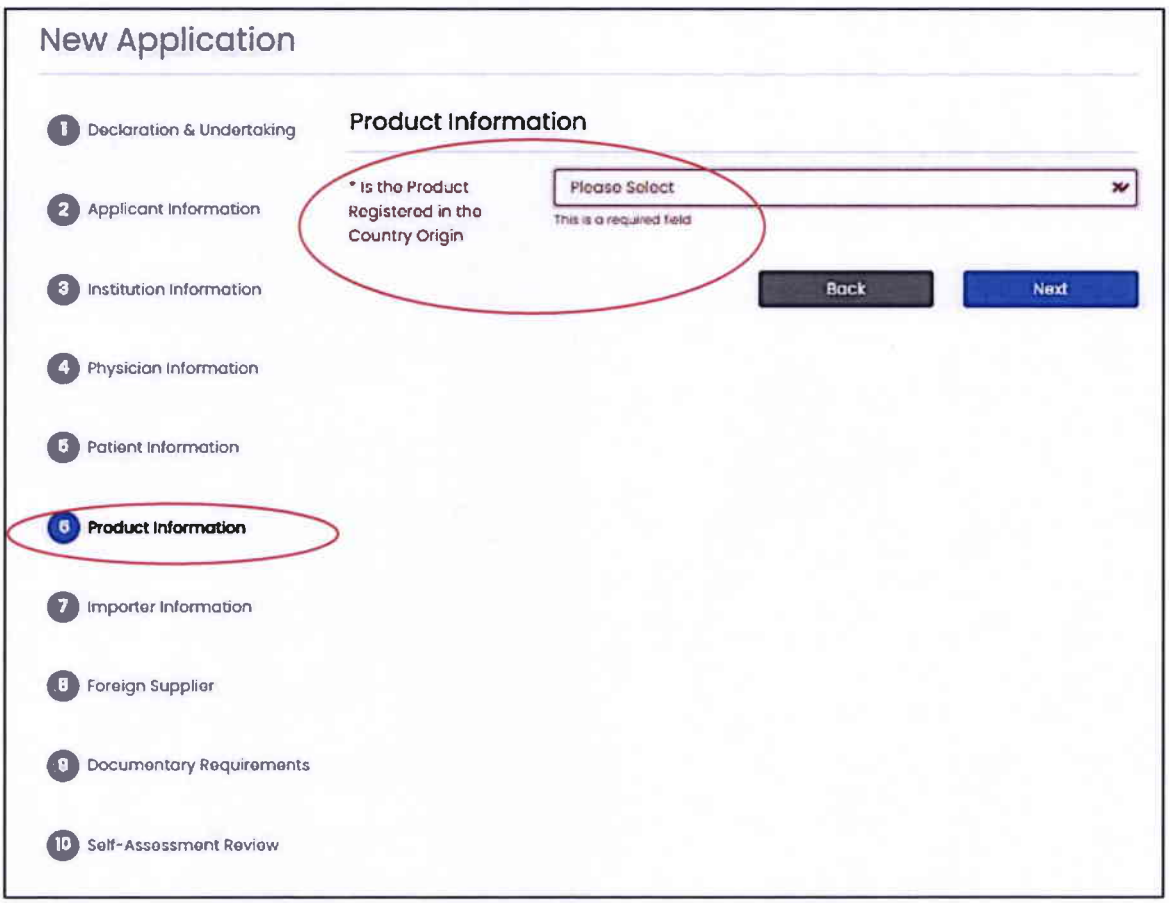

New Application
1 Declaration & Undertaking
2 Applicant Information
3 Institution Information
4 Physician Information
5 Patient Information
6 Product Information
7 Importer Information
8 Foreign Supplier
9 Documentary Requirements
10 Self-Assessment Review
Physician Information
* First Name
First Name
Middle Name
Middle Name
* Last Name
Last Name
* Position
Position
* PRC No.
PRC No.
* Date of Birth
Please Select a Date
Back
Next

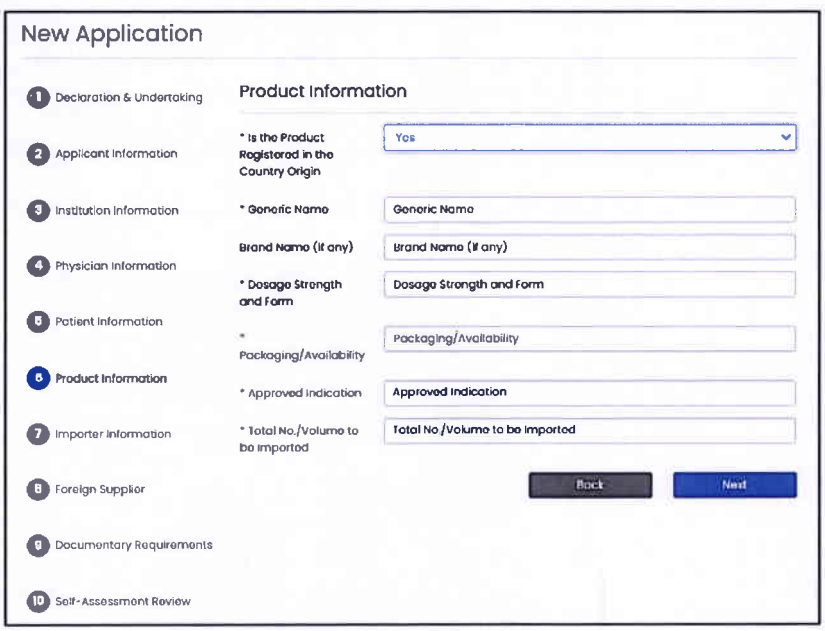

New Application
1 Declaration & Undertaking
2 Applicant Information
3 Institution Information
4 Physician Information
5 Patient Information
6 Product Information
7 Importer Information
8 Foreign Supplier
9 Documentary Requirements
10 Self-Assessment Review
Patient Information
* First Name
First Name
Middle Name
Middle Name
* Last Name
Last Name
* Age
Age
* Diagnosis
Diagnosis
Back
Next

6. Select from the drop-down button the answer for *"Is the Product registered in the Country of Origin?"*



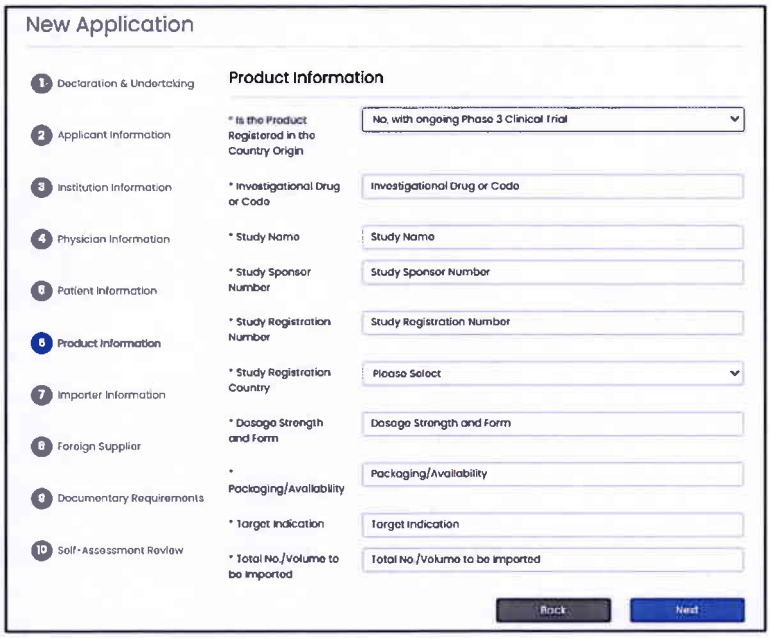
If the applicant chooses **YES**, he/she needs to identify the following;

a. Generic Name of the product
b. Dosage strength and form
c. Packaging/Availability
d. Approved Indication
e. Total No./Volume to be Imported

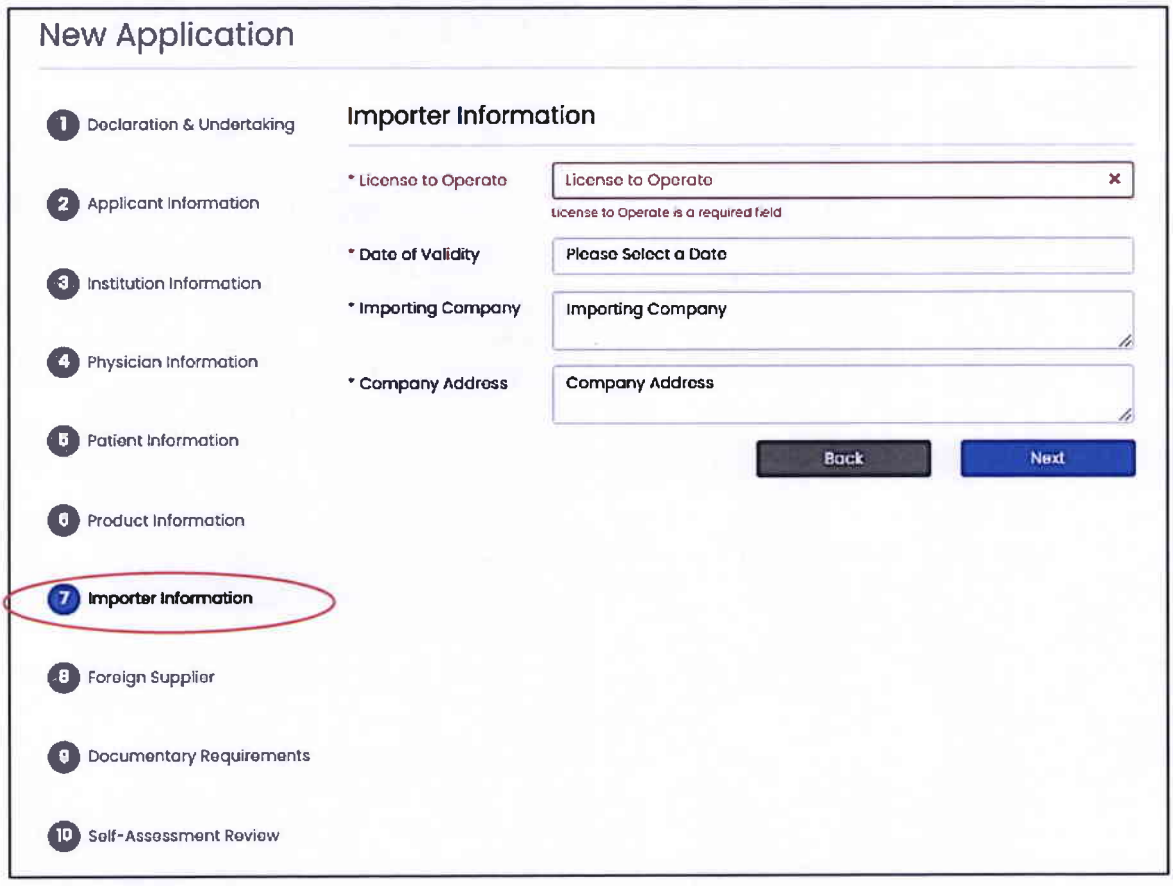


If the applicant chooses **NO, WITH ONGOING PHASE 3 CLINICAL TRIAL**, he/she needs to identify the following;

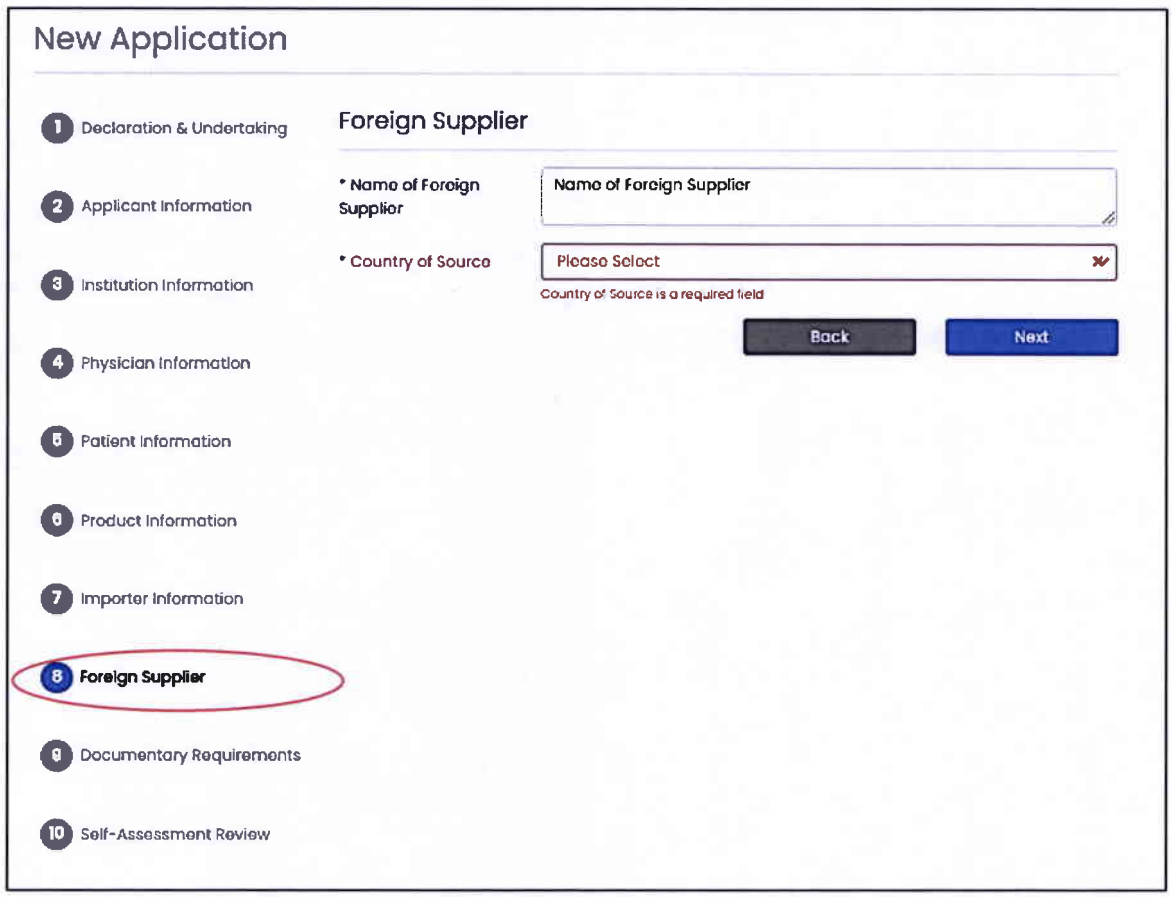
a. Investigational Drug or Code
b. Study Name
c. Study Sponsor Number
d. Study Registration Number
e. Study Registration Country
f. Dosage Strength and Form
g. Packaging/Availability
h. Target Indication
i. Total No./Volume to be Imported



7. Fill-out the **Importer Information**.



8. Fill-out the **Foreign Supplier** tab and choose from the drop-down button of the **Country of Source**.



9. Upload all the necessary documents.