PharmaDex Software Applicant

User Manual

January 2016

Contents

Accronyms and Abbreviations

API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical (Classification)
BP	British Pharmacopeia
CTD	Common Technical Document
DGDA	Directorate General of Drug Administration
INN	International Non-proprietary Name
IS	Information System
MedRA	Medical Dictionary for Regulatory Activities
MSH	Management Sciences for Health
NRA	National Regulatory Authority
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Introduction

Ensuring the quality, safety, and effectiveness of health products is a complex task for national medicine regulatory authorities (NRAs), as is ensuring that these products meet and comply with international standards and guidelines. Regulation of medicines, vaccines, medical devices, and other health products involves pre-marketing evaluation, marketing authorization, and post-marketing surveillance, all of which require effective management of information systems.

Despite efforts to improve regulatory information management in low- and middle-income countries, many countries still face challenges in developing an information system (IS) for the entire pharmaceutical regulatory process, including registration, licensing, inspection, quality control, pharmacovigilance, and medicine information. Implementation of an information management system that supports regulatory business processes and information flow can lead to improved efficiency and transparency by making NRA databases available and by providing timely information to stakeholders.

What is PharmaDex?

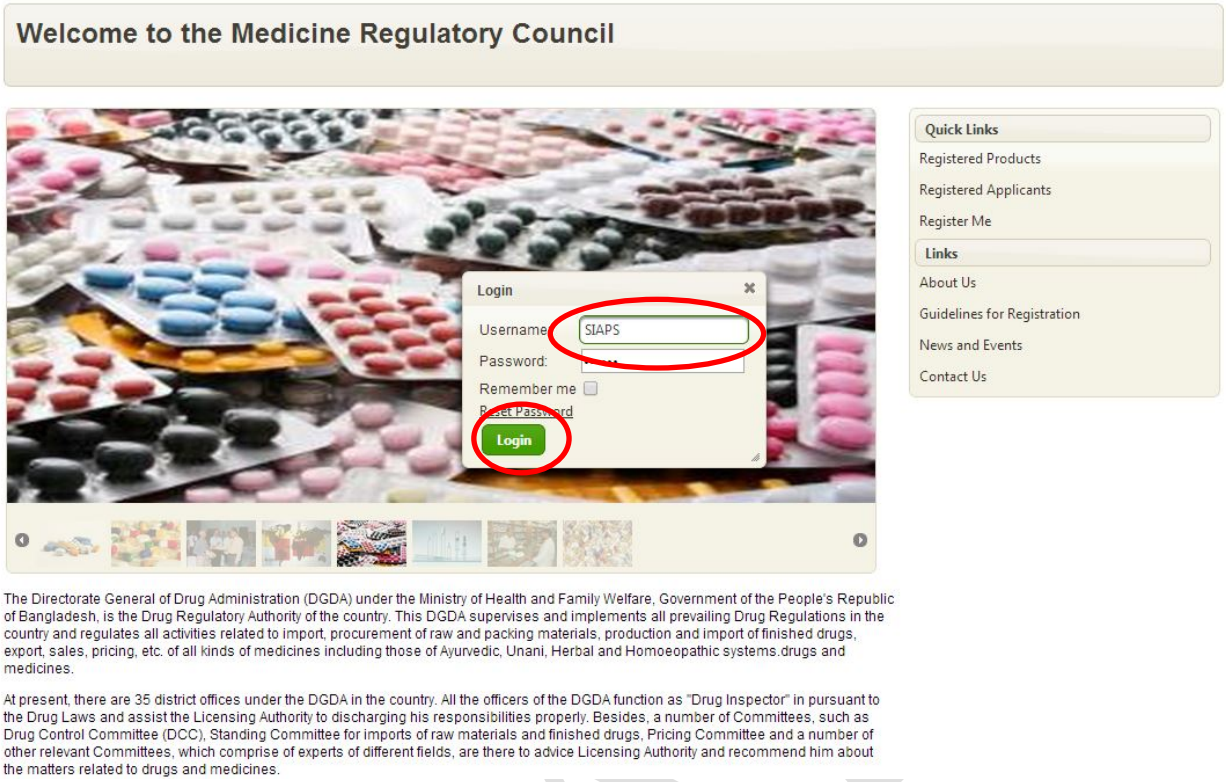
PharmaDex is a web-based integrated IS solution that facilitates management, documentation, dissemination, and sharing of regulatory information. Key features include—

- **Designed as a web-based system**—allows for online application and information sharing with the regulated industry and consumers
- **Provides modular structure**—helps NRA departments integrate and coordinate their work, from product registration, licensing, pre- and post-marketing inspections, to quality control, pharmacovigilance, and administration
- **Includes built-in document tracking and management system**—facilitates archival, documentation, management, and retrieval of dossiers; and provides a platform to develop electronic document management systems
- **Supports submission in Common Technical Document (CTD) format**—allows dossiers to be submitted as non-eCTD electronic submissions
- **Uses international standard dictionaries**—provides standard terminologies and dictionaries with built-in International Nonproprietary Names (INN), Anatomical Therapeutic Chemical (ATC) classification system, and the Medical Dictionary for Regulatory Activities (MedDRA)
- **Provides one-stop access to regulatory approval package**—enables access to product approval history, approval letter, and approved product information.
- **Enhances performance monitoring**—monitors built-in key performance metrics and generates activity reports for the NRA
- **Provided as an open source platform and non-proprietary database** — PharmaDex is freely available for NRAs in developing countries.

Accessing PharmaDex

To log in, go to the homepage and click on the door in the upper right corner.

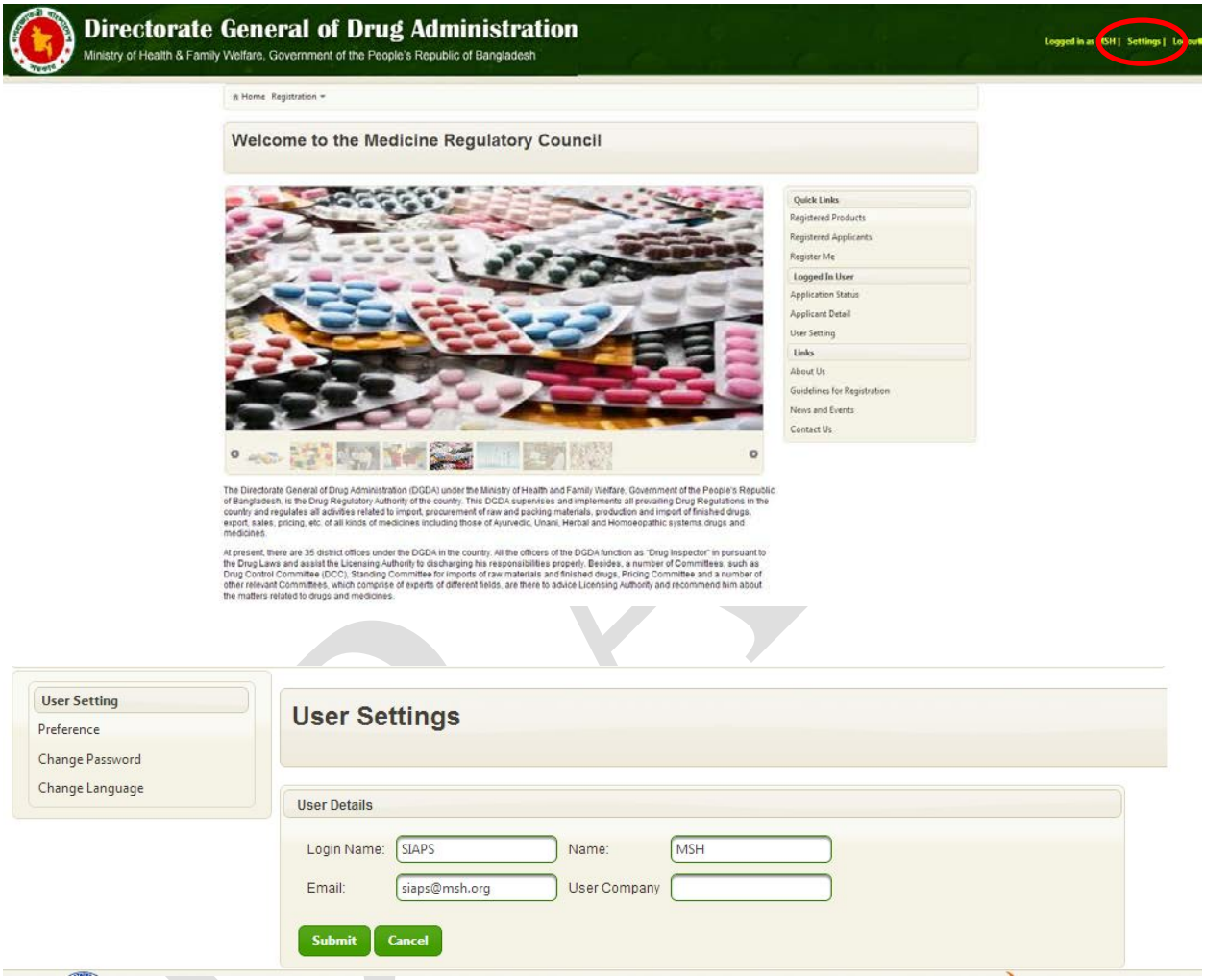
Enter in your username and the temporary password that was emailed to you, and then click "Login."



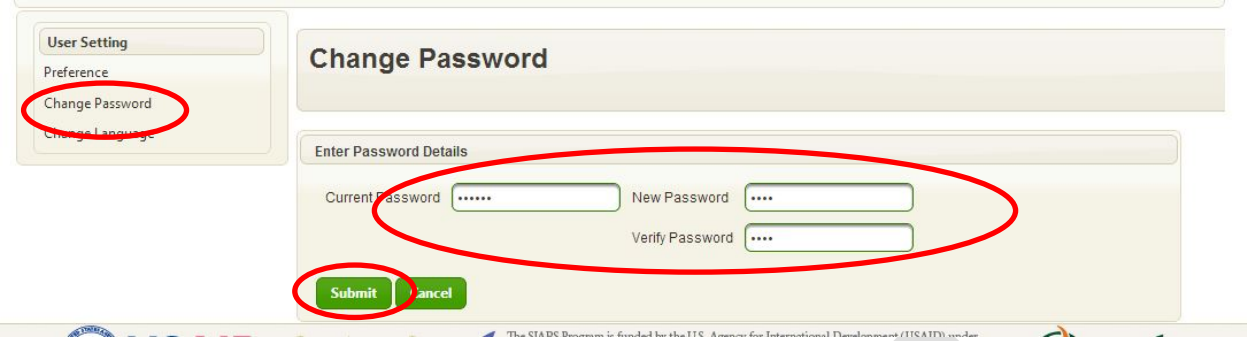
Once you login, you will see your username in the upper right corner.

Changing User Settings

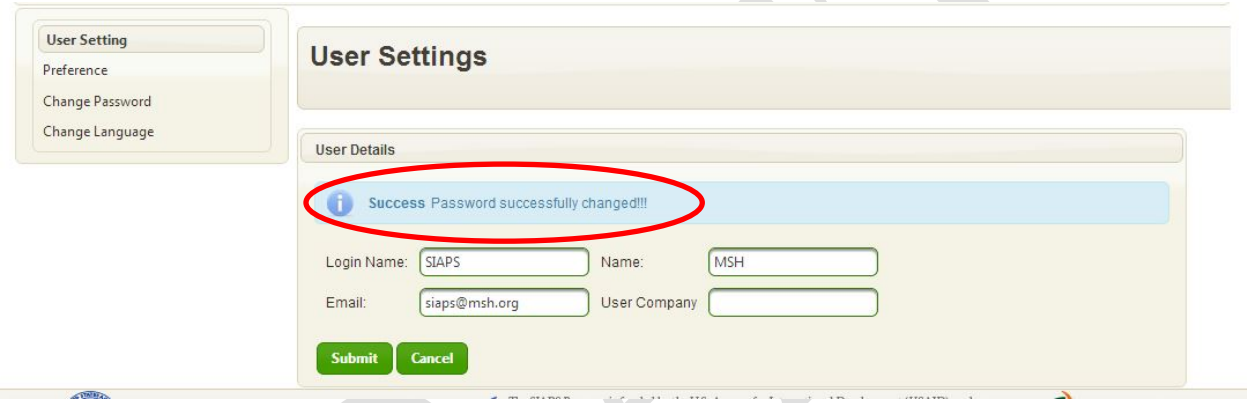
Once logged in, you can change your password and language settings by clicking on “Settings” in the upper right corner.



Enter in your current password (the one that was emailed to you) and a new password. Hit “Submit” once finished.



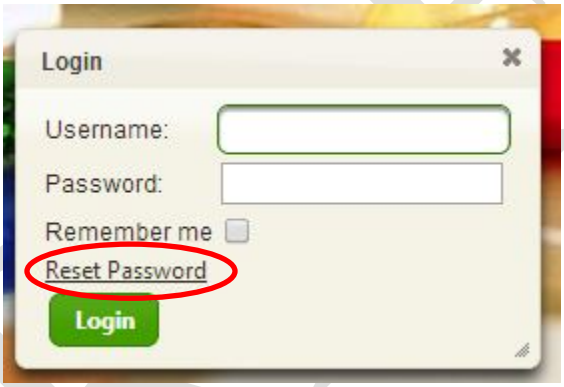
You will receive a notification that your password has been successfully changed.



Resetting Password

If you have forgotten your password, you can reset it. To do so, go to the homepage and click the door in the upper right corner.

Click on "Reset Password."

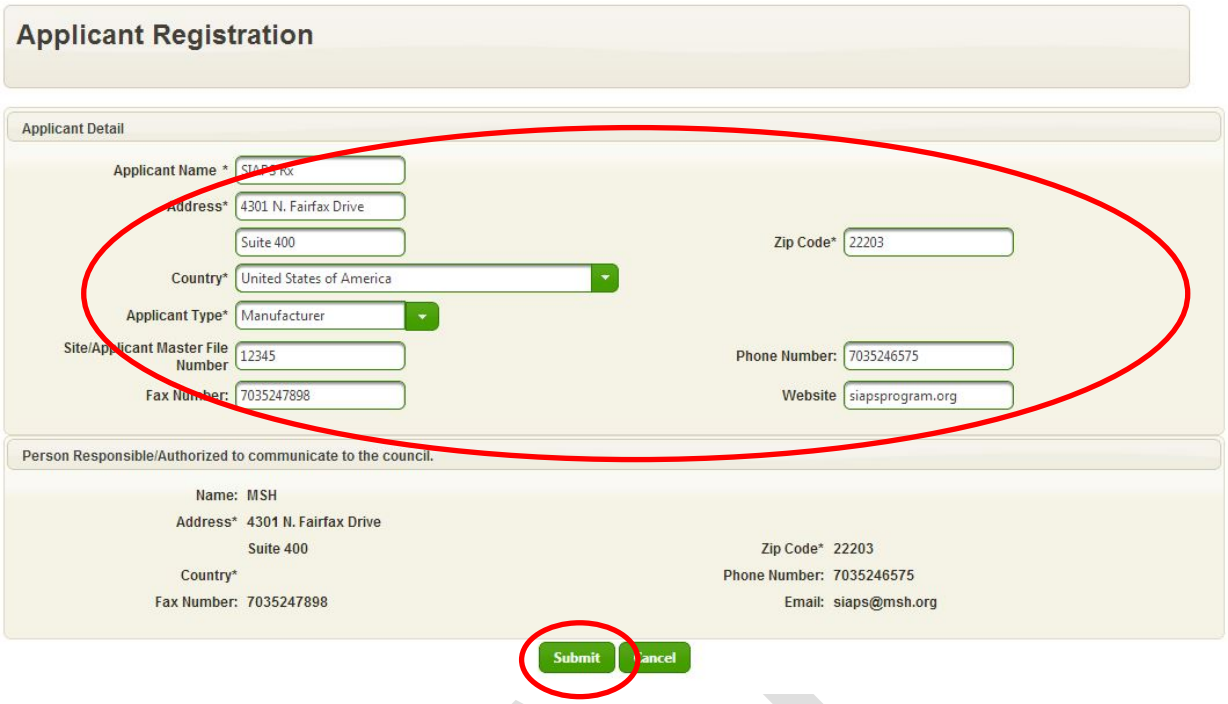


Enter in the email address you used when you registered for PharmaDex and hit "Reset." A new password will be emailed to you. To change your password, follow the instructions in Chapter 5 on changing passwords.

Registering Applicants

After logging into PharmaDex, if you are not associated with an applicant you will need to register an applicant before registering any products. To do this, click on "Registration," "Registration Forms," and "Applicant Registration Form."

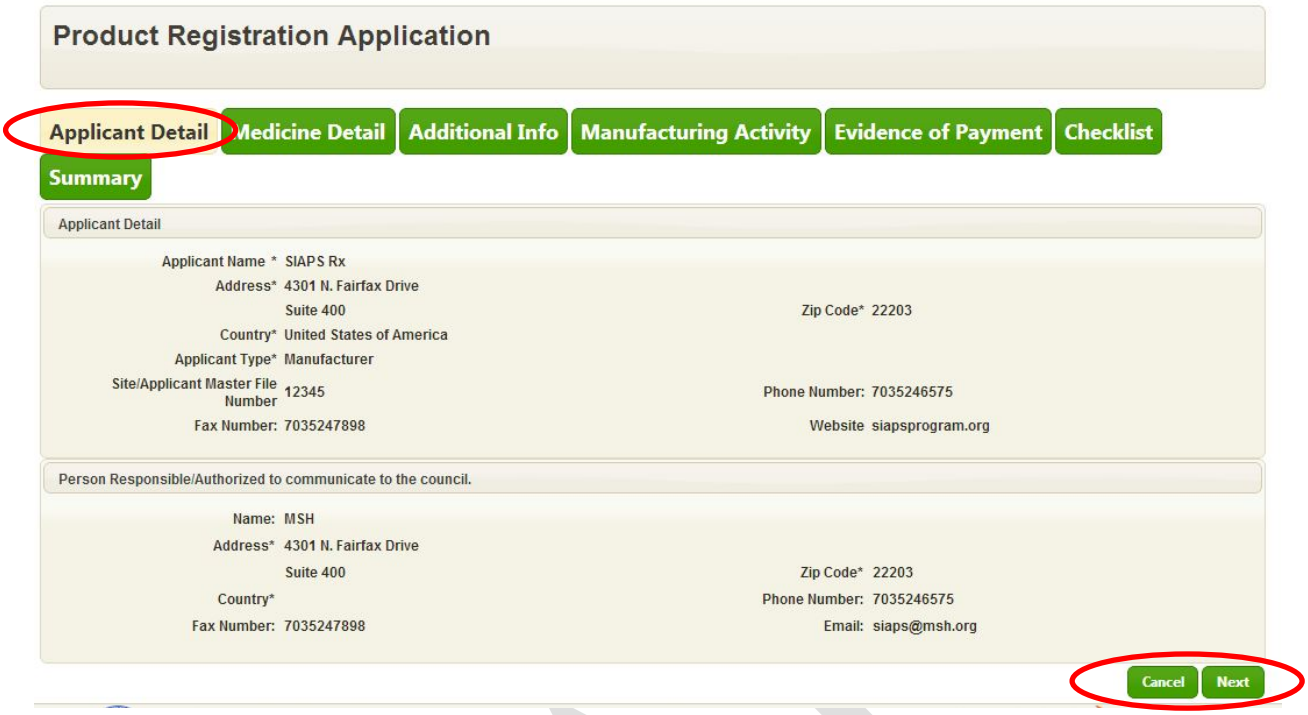
Fill in the required information and hit "Submit."


Applicant Registration
Applicant Detail
Applicant Name *
Address*
4301 N. Fairfax Drive
Suite 400
Zip Code*
22203
Country*
United States of America
Applicant Type*
Manufacturer
Site/Applicant Master File Number
12345
Phone Number:
7035246575
Fax Number:
7035247898
Website
siapsprogram.org
Person Responsible/Authorized to communicate to the council.
Name: MSH
Address* 4301 N. Fairfax Drive
Suite 400
Zip Code* 22203
Country*
Phone Number: 7035246575
Fax Number: 7035247898
Email: siaps@msh.org
Submit
Cancel

Registering Products

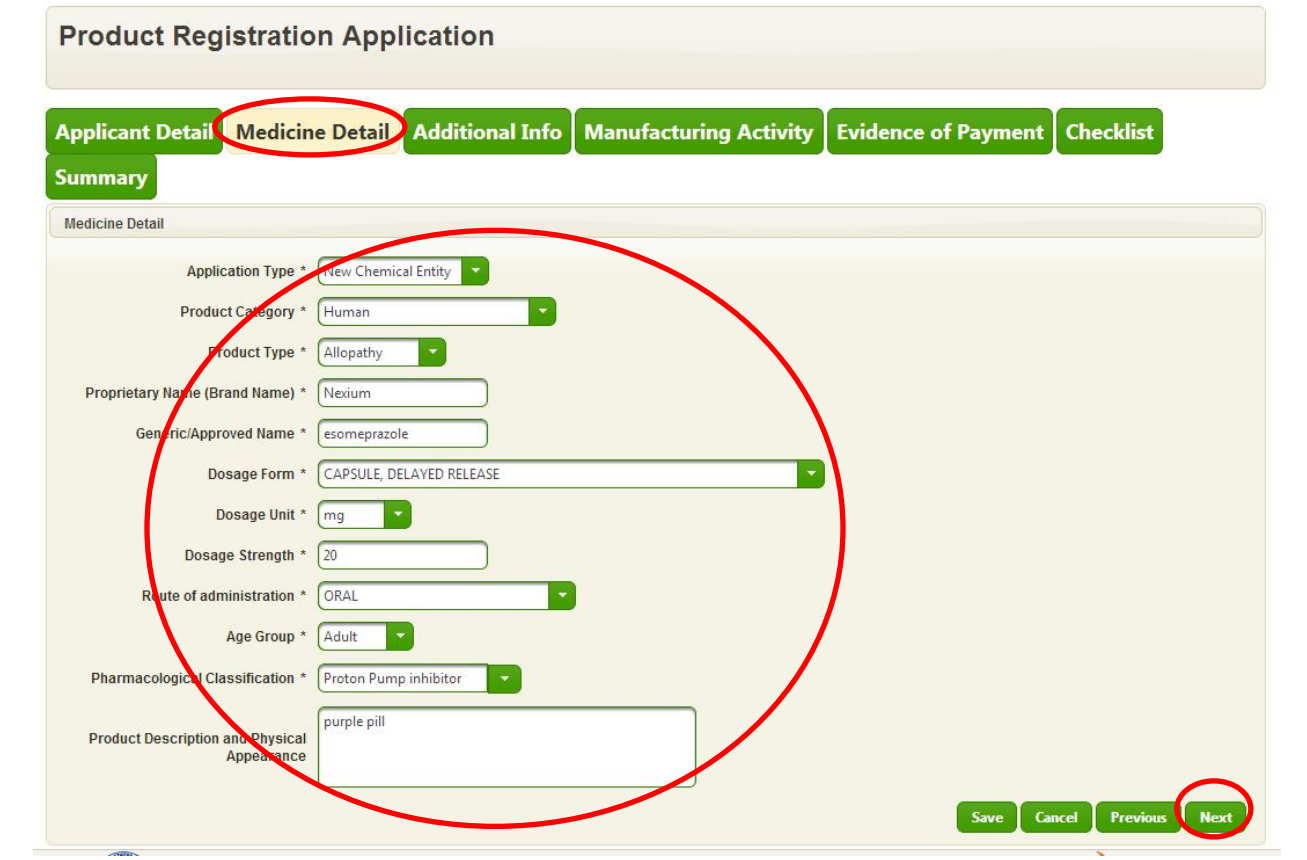
In order to register a product, you must have a valid user name to access the system and you must be the person responsible for the applicant. After registering an applicant, you can begin to register products. To do so, go to the following menu options show below click on "Registration" > "Registration Forms" > "Product Registration Form."

The first page you see contains information about the applicant. The system will automatically populate your profile. Click on "Next" to proceed or "Cancel" to cancel.



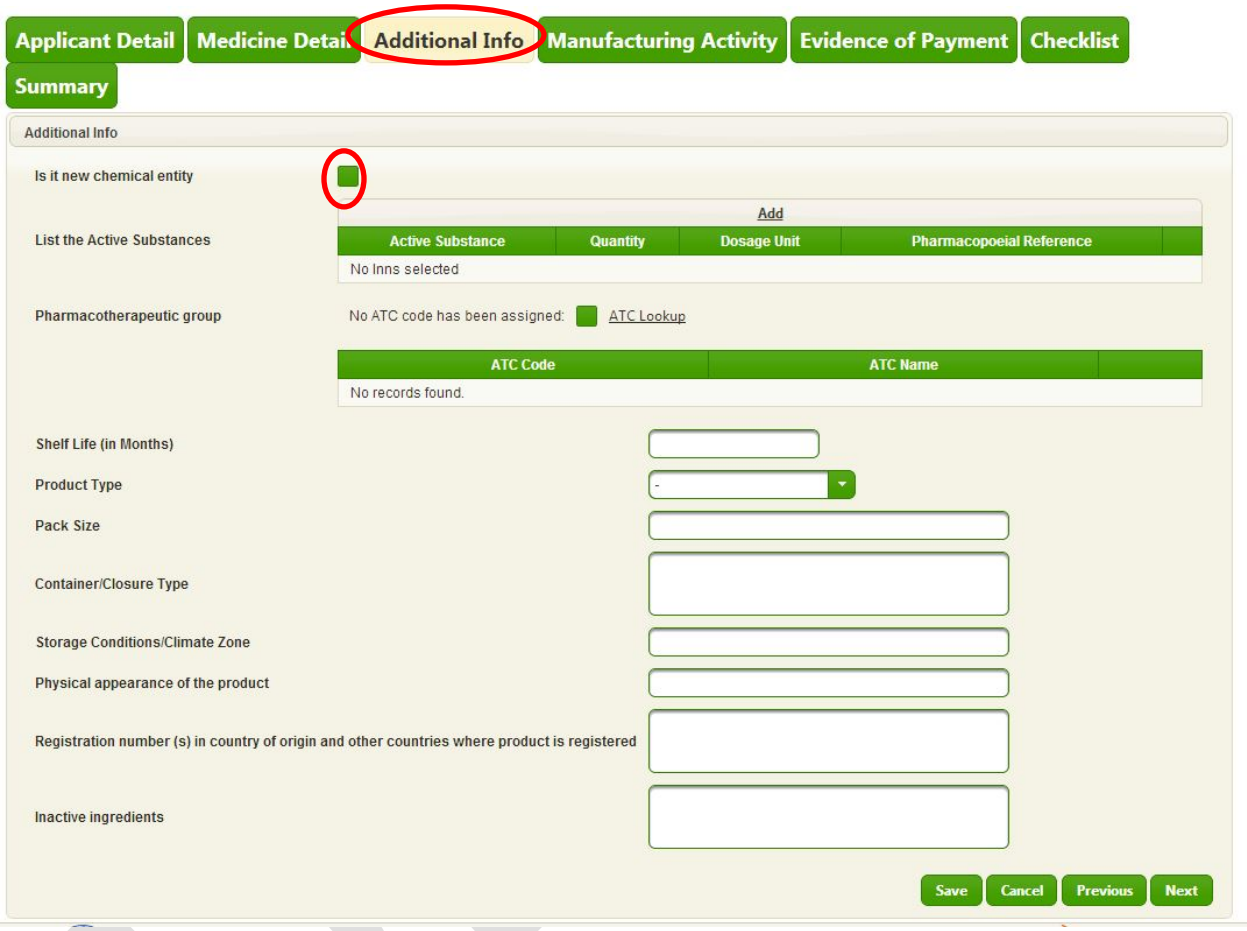
Medicine Detail

On the "Medicine Detail" tab, fill in the required fields with as much information as possible and click "Next" to continue.



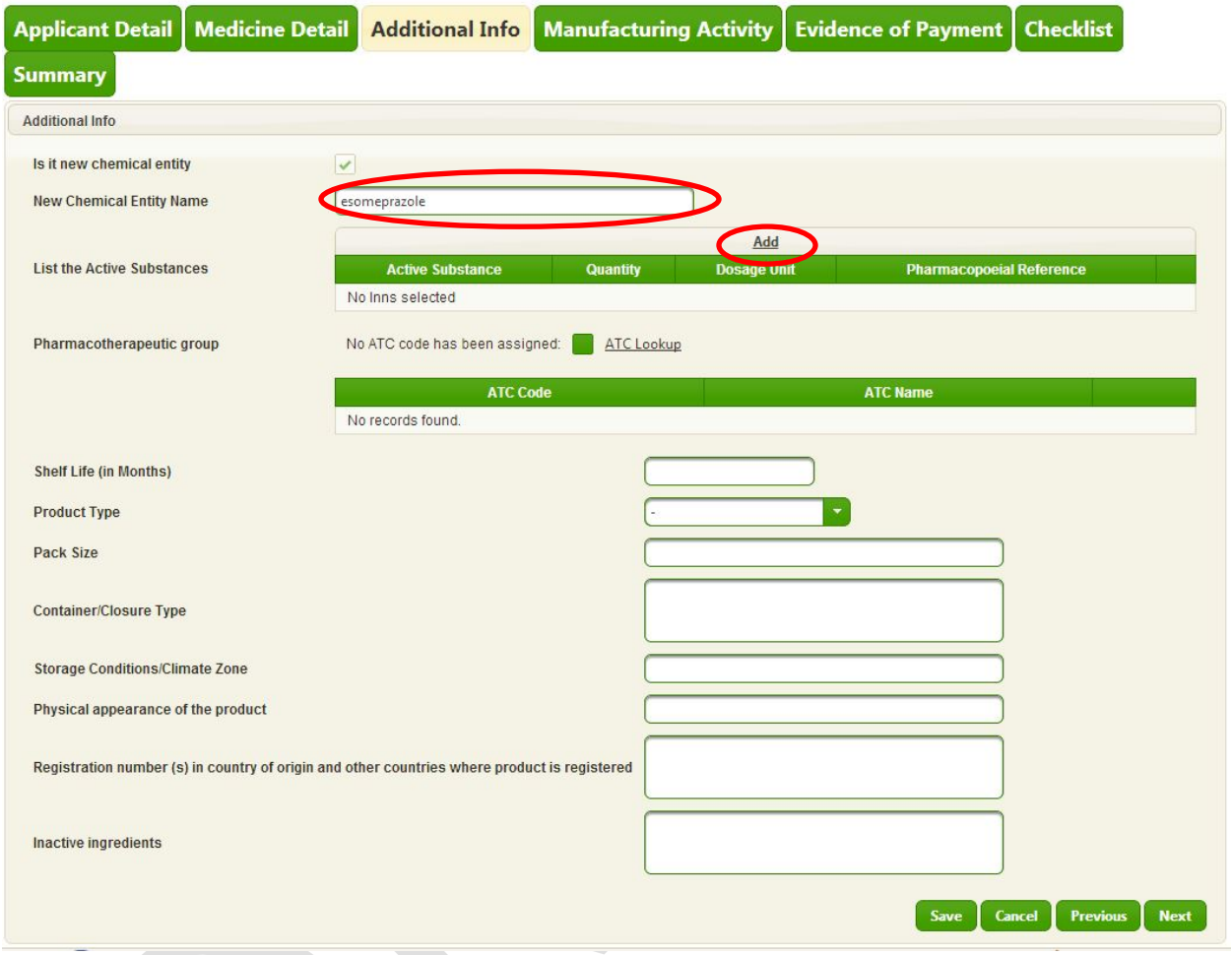
Additional Product Information

On the "Additional Info" tab, if the product is a new chemical entity, check the box and type in the product's name. If it is not a new chemical entity, leave the box unchecked.

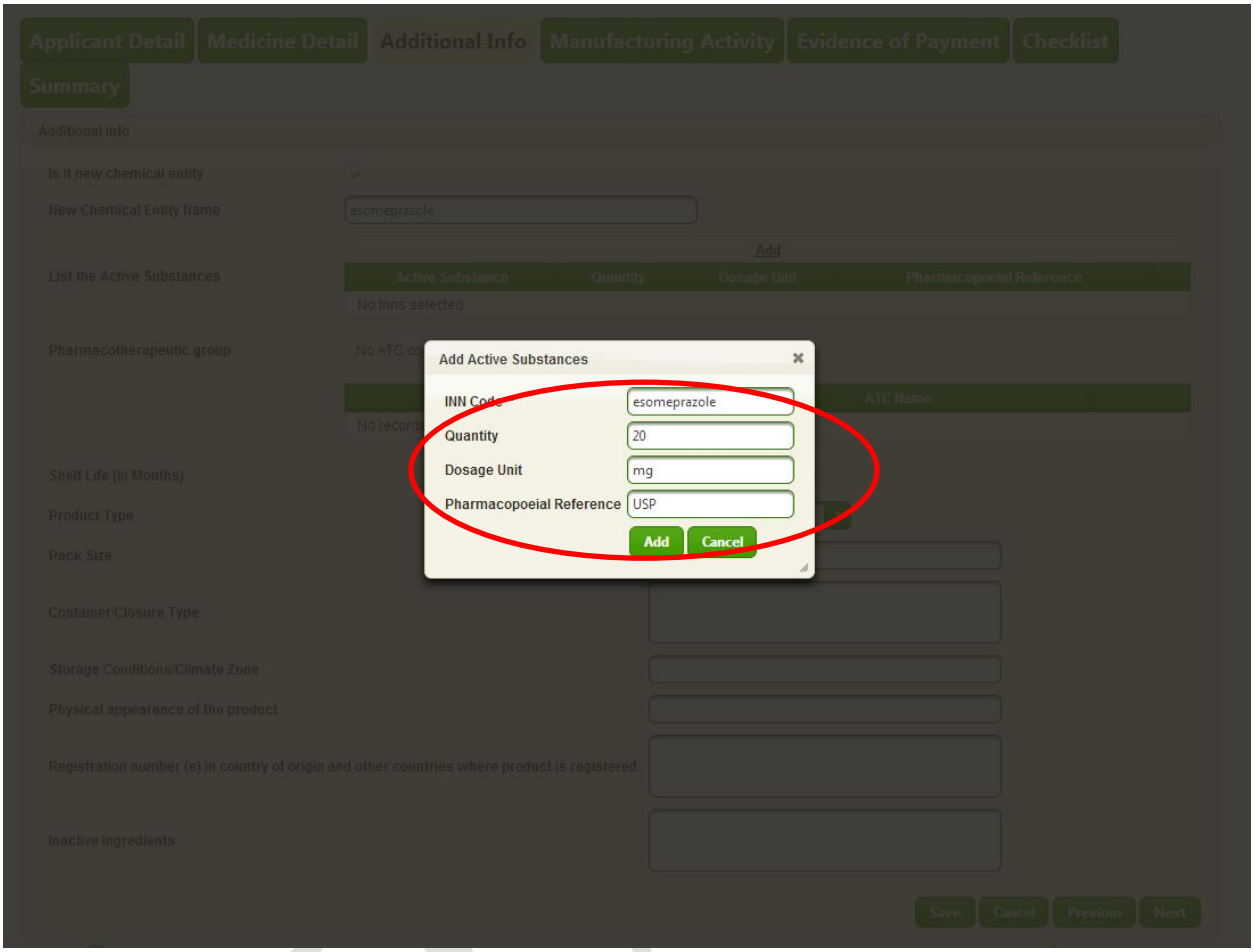


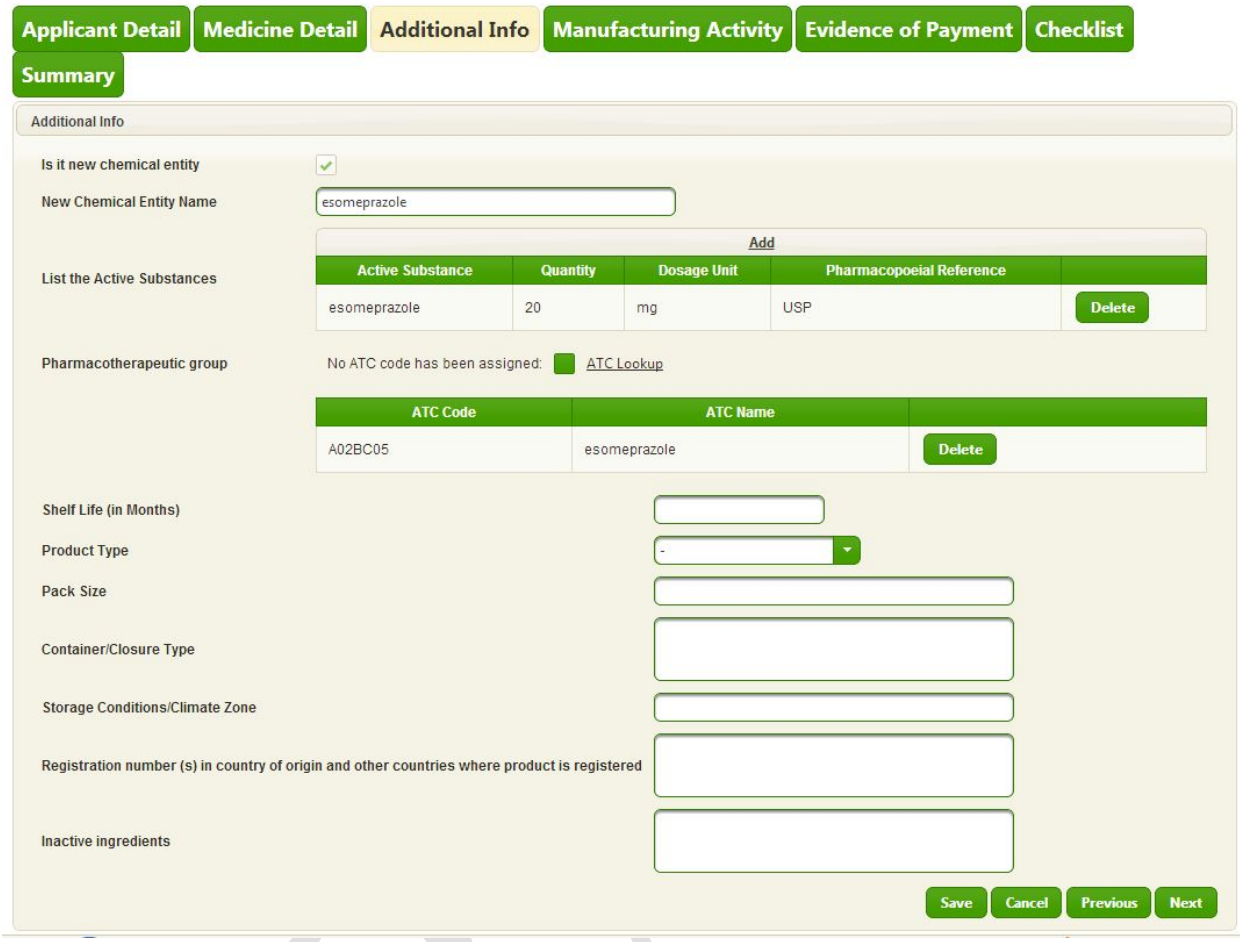
Active Substance

To add the Active Substance(s), click on "Add."



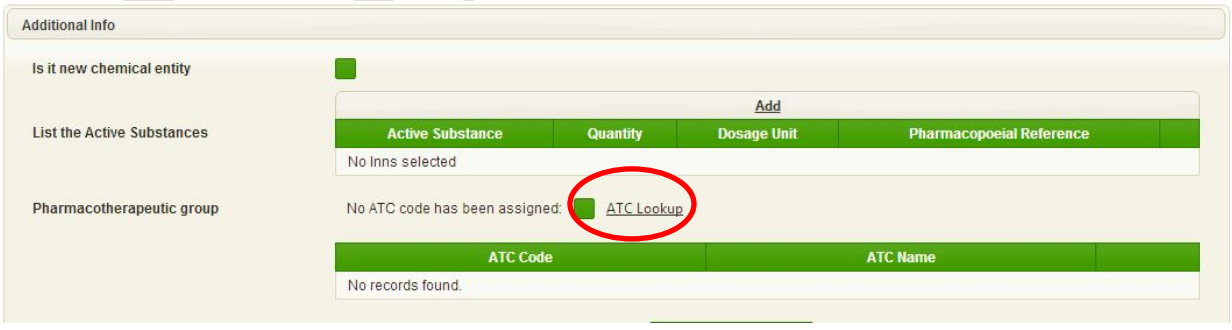
Begin typing in the INN, and a list will automatically populate based on what you type. Select the correct INN code, and enter in the quantity (i.e. how much of that active substance), followed by the dosage unit (g, mg, etc.) and the pharmacopeia reference that was used (USP, BP, etc.). Click "Add" once finished and the ATC code will appear.

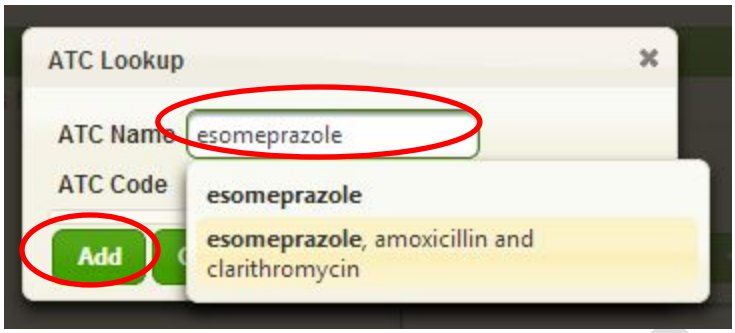

Applicant Detail
Medicine Detail
Additional Info
Manufacturing Activity
Evidence of Payment
Checklist
Summary
Additional Info
Is it new chemical entity
New Chemical Entity Name
esomeprazole
List the Active Substances
Add
Active Substance
Quantity
Dosage Unit
Pharmacopoeial Reference
No Inns selected
Pharmacotherapeutic group
Add Active Substances
INN Code
esomeprazole
Quantity
20
Dosage Unit
mg
Pharmacopoeial Reference
USP
Add
Cancel
Shelf Life (in Months)
Product Type
Pack Size
Container/Closure Type
Storage Conditions/Climate Zone
Physical appearance of the product
Registration number (s) in country of origin and other countries where product is registered
Inactive ingredients
Save
Cancel
Previous
Next



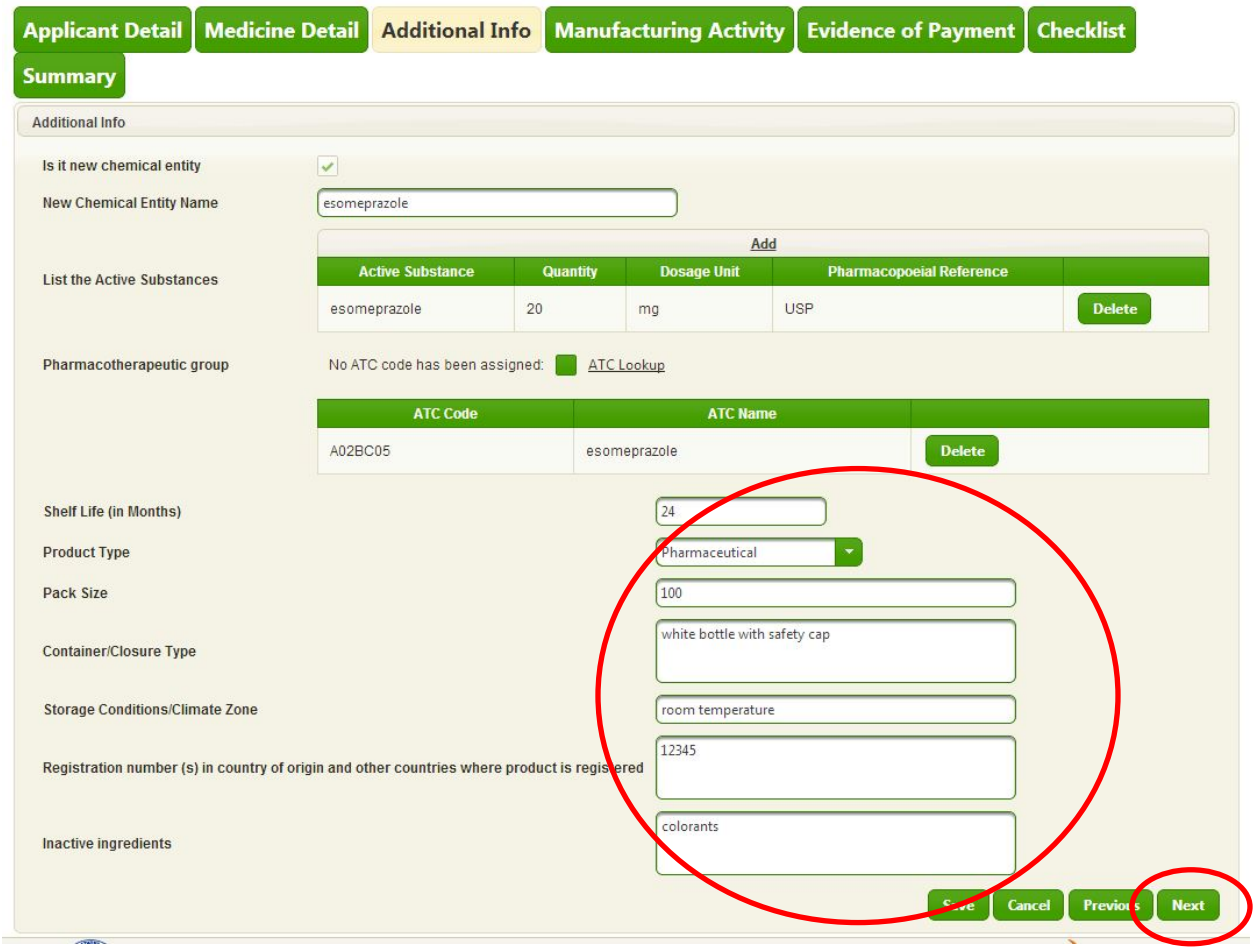
ATC Code

If no ATC code has been assigned, then you can click “ATC Lookup” and search that way. Click “Add” once finished.





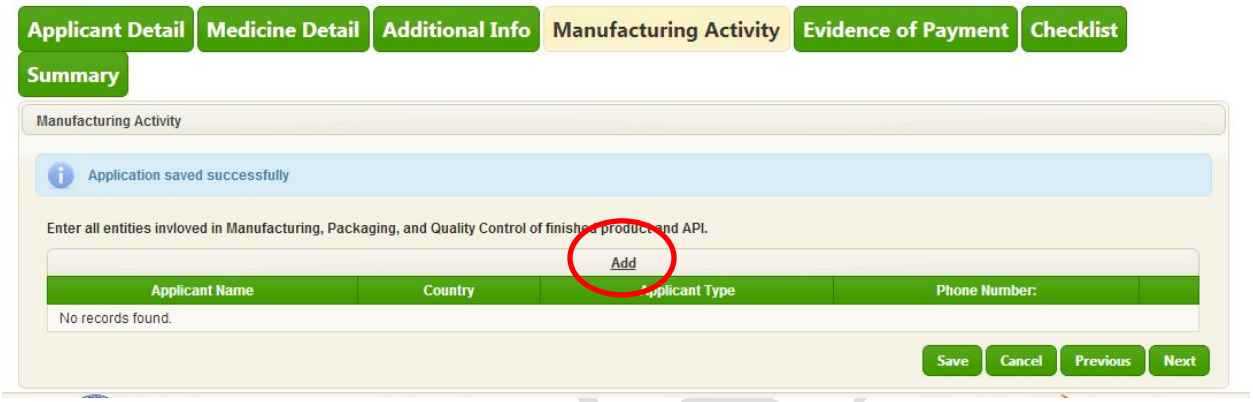
Fill in the rest of the information on the page and hit "Next" to continue. At any point, you can click "Save" to save your application, but your application will automatically be saved when you advance to the next page.

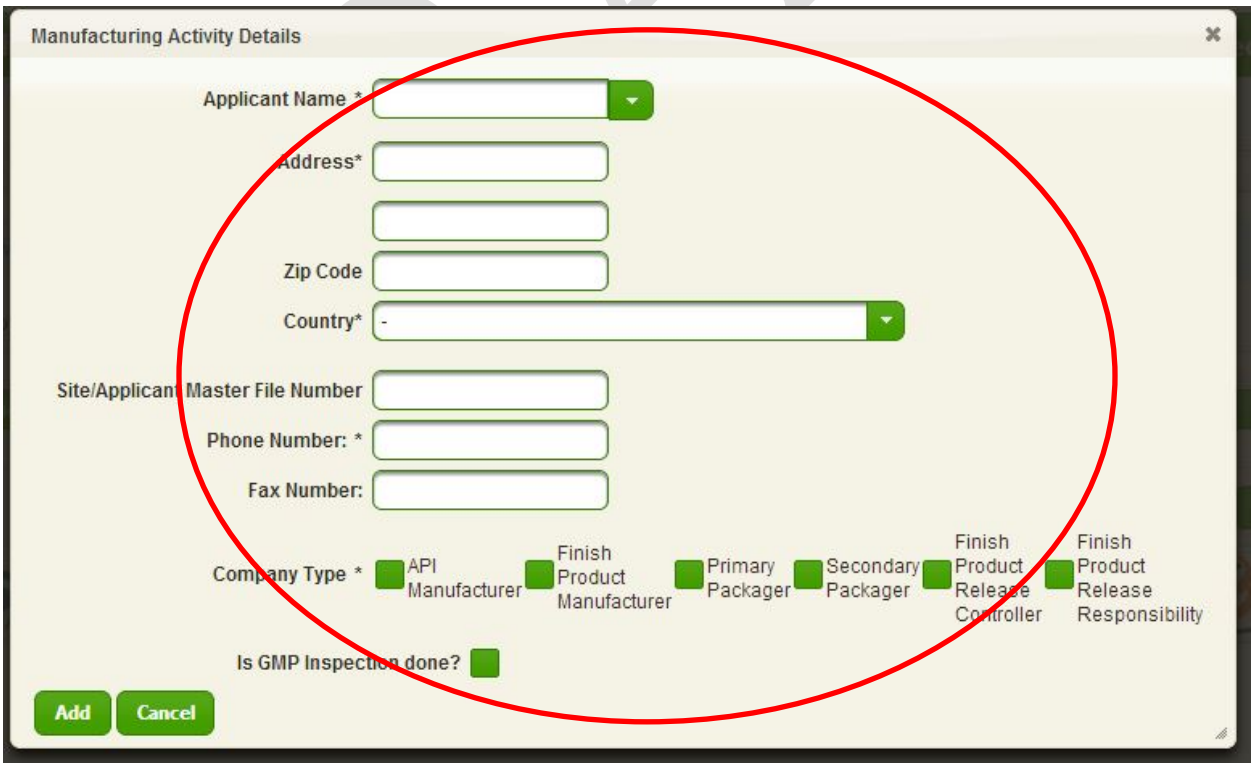


Manufacturing Activity

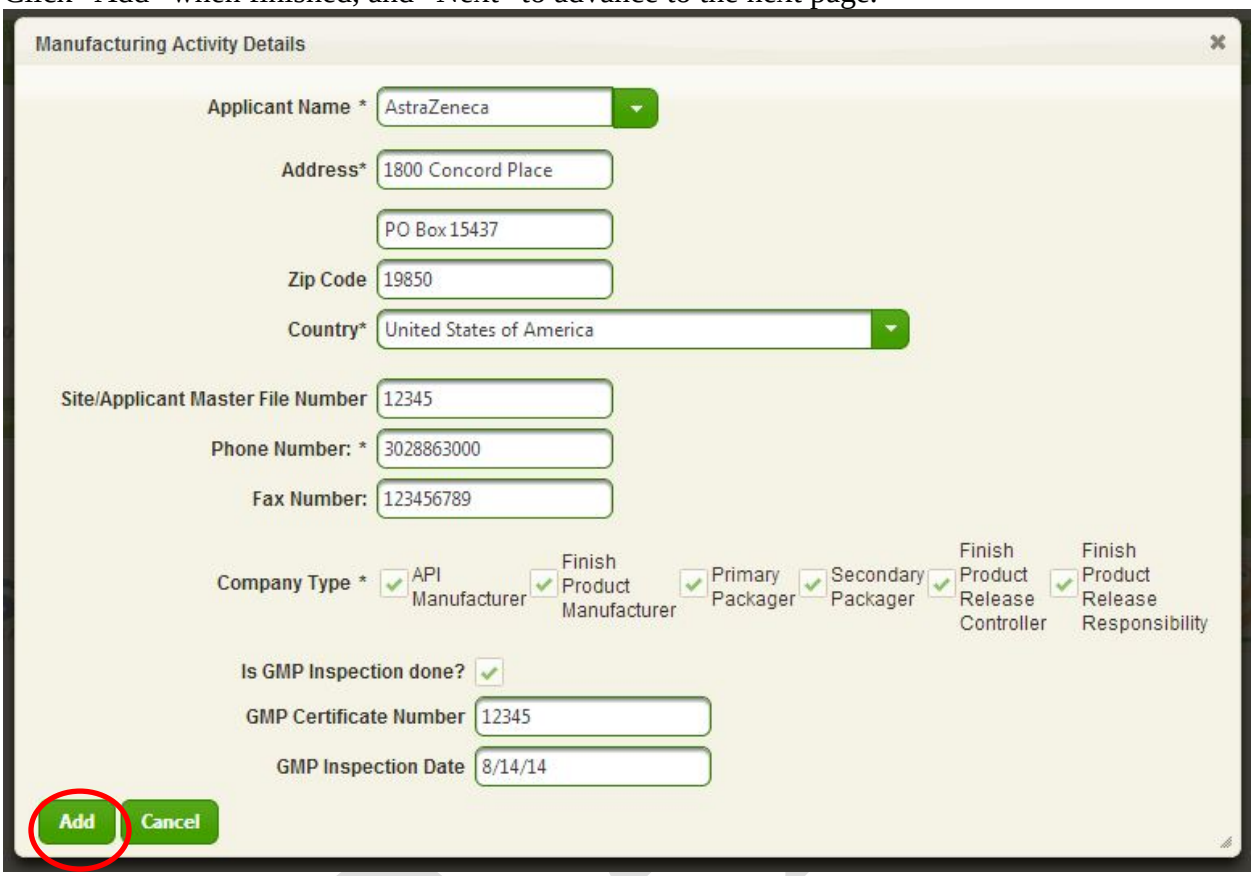
To add a manufacturer, click "Add" and fill in the information in the required fields. Check the appropriate company type(s) and if a GMP inspection was performed, check the box and enter in the GMP certificate number and date of inspection.

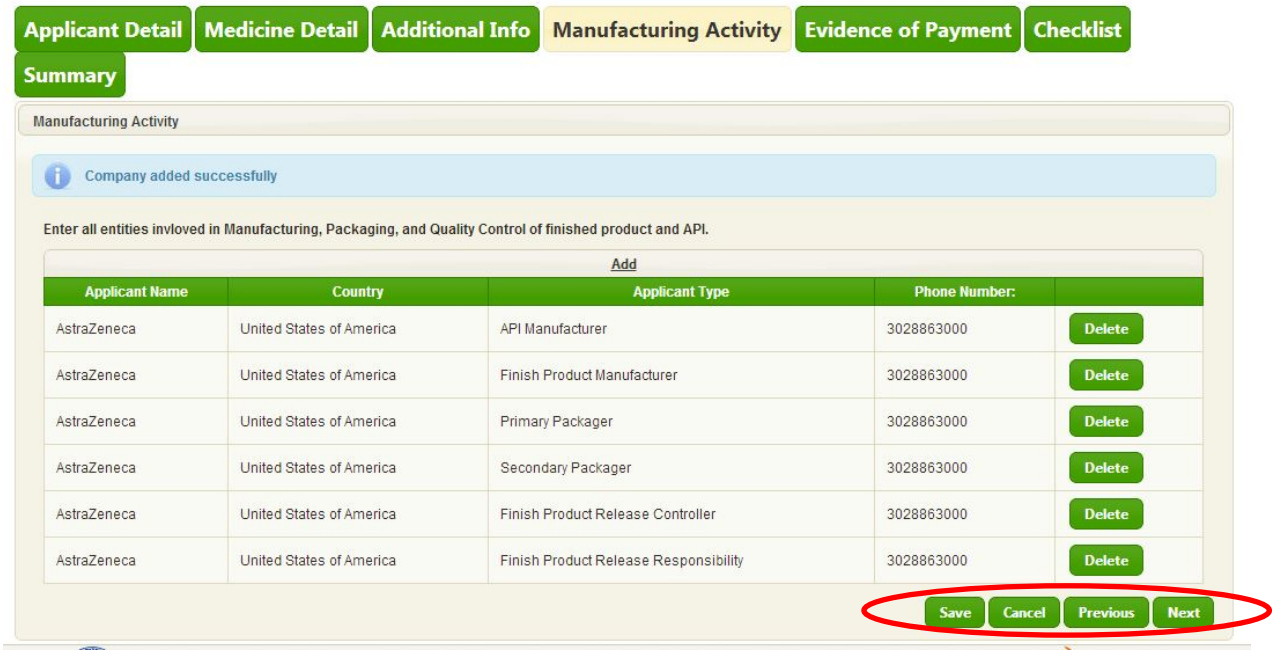
Note: You need to have at least one Finished Product Manufacturer specified in order to submit the application.





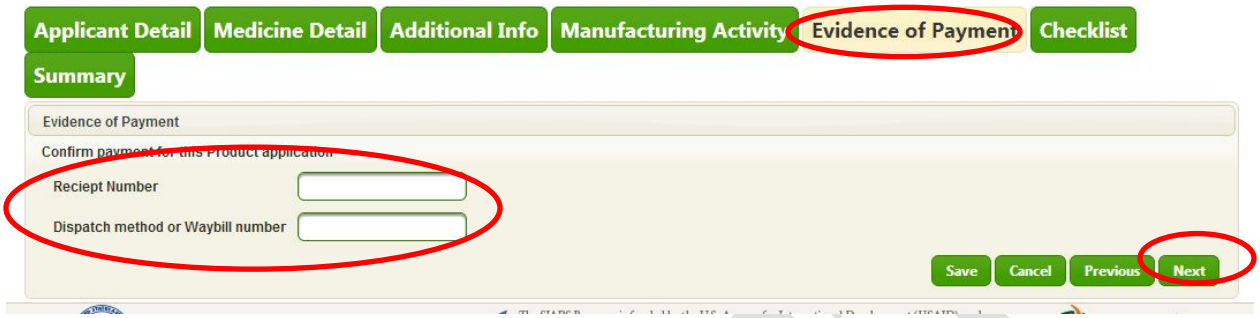
Click “Add” when finished, and “Next” to advance to the next page.



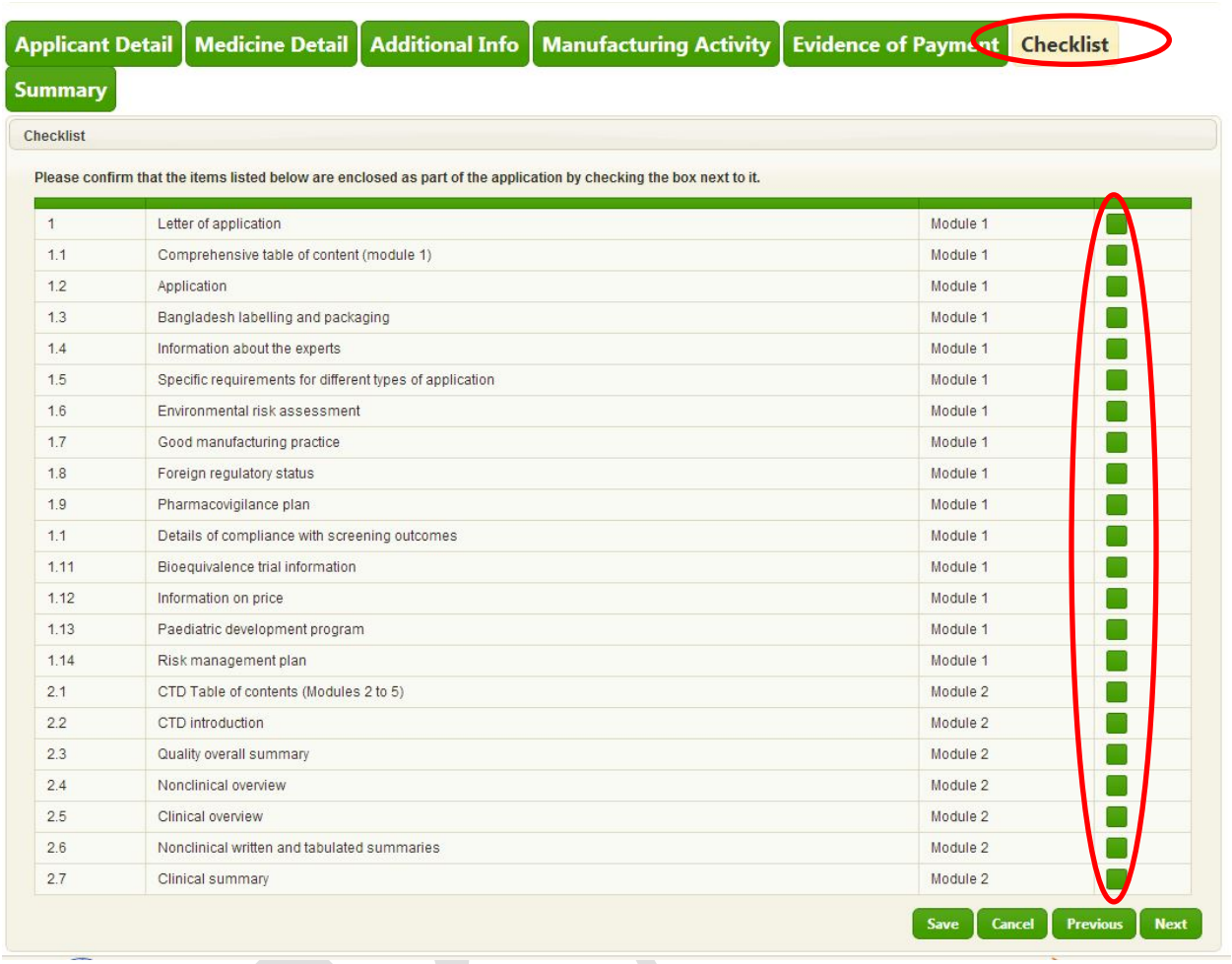


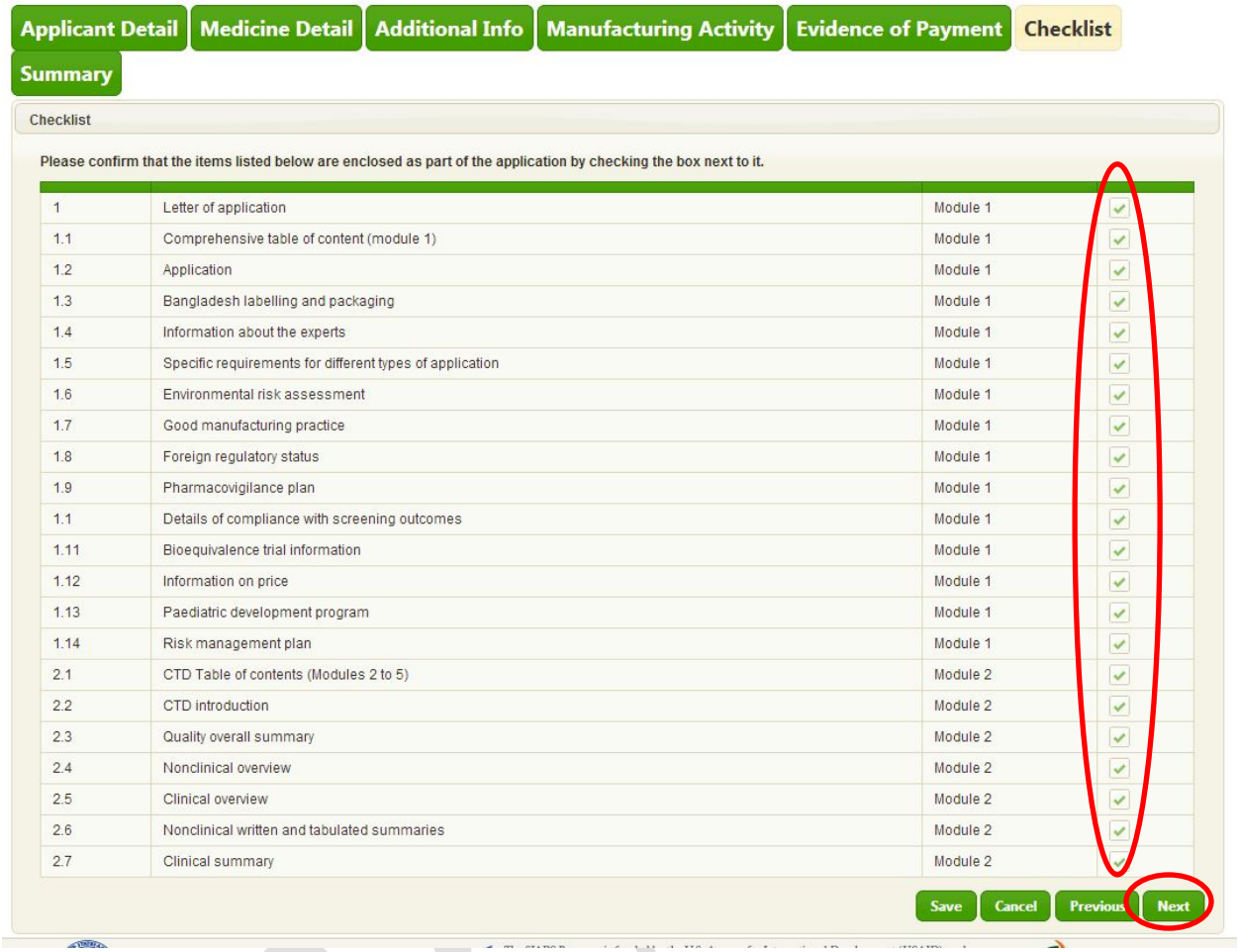
Payment Info

On the “Evidence of Payment” page, enter in the receipt number and the dispatch method or waybill number. Hit “Next” when finished.



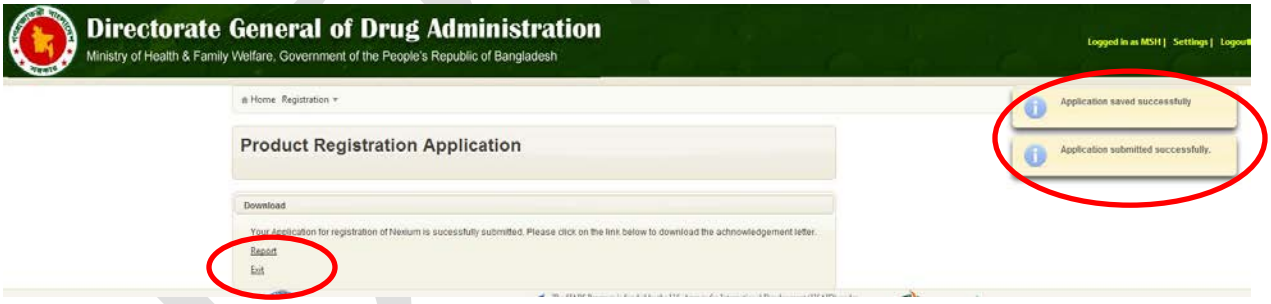
On the “Checklist” tab, ensure that all parts of the application are included and check the boxes as appropriate. Click “Next” when finished.


Applicant Detail
Medicine Detail
Additional Info
Manufacturing Activity
Evidence of Payment
Checklist
Summary
Checklist
Please confirm that the items listed below are enclosed as part of the application by checking the box next to it.
1 Letter of application Module 1
1.1 Comprehensive table of content (module 1) Module 1
1.2 Application Module 1
1.3 Bangladesh labelling and packaging Module 1
1.4 Information about the experts Module 1
1.5 Specific requirements for different types of application Module 1
1.6 Environmental risk assessment Module 1
1.7 Good manufacturing practice Module 1
1.8 Foreign regulatory status Module 1
1.9 Pharmacovigilance plan Module 1
1.1 Details of compliance with screening outcomes Module 1
1.11 Bioequivalence trial information Module 1
1.12 Information on price Module 1
1.13 Paediatric development program Module 1
1.14 Risk management plan Module 1
2.1 CTD Table of contents (Modules 2 to 5) Module 2
2.2 CTD introduction Module 2
2.3 Quality overall summary Module 2
2.4 Nonclinical overview Module 2
2.5 Clinical overview Module 2
2.6 Nonclinical written and tabulated summaries Module 2
2.7 Clinical summary Module 2
Save
Cancel
Previous
Next



On the "Summary" tab, you can view all of the information you have provided. If you would like to change anything, click "Previous" to go back and make the appropriate changes. When done, go back to the "Summary" tab and hit "Submit."

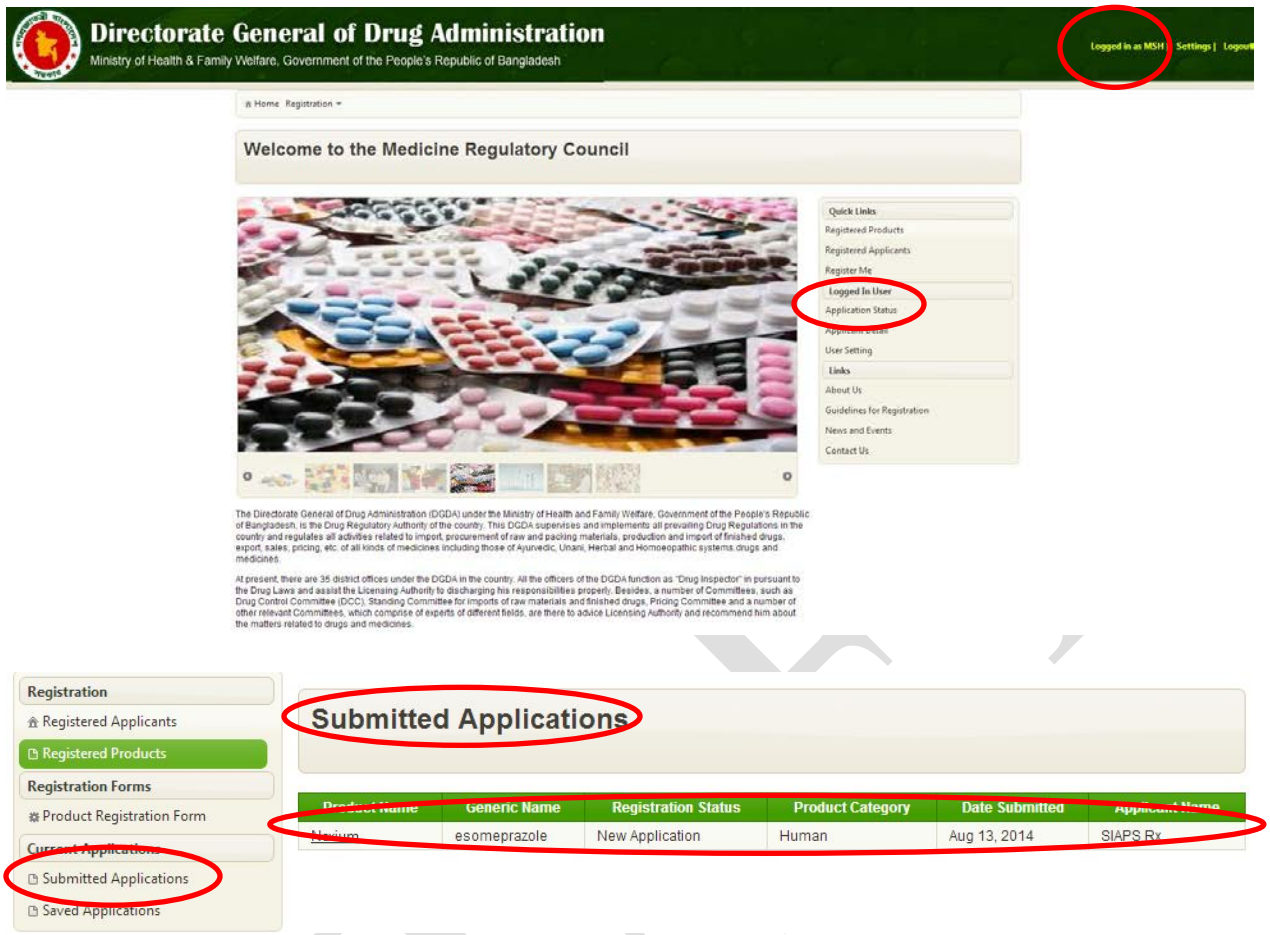
You will be directed to a new page and receive a notification that your application has been submitted. To view the acknolwedgement letter, you can go to the letters tab below and click on download button.



You can continue to register other products by repeating the same steps above.

Viewing Status of Applications

To view the status of applications you have submitted, log in and click on “Application Status.” From here, you can view submitted and saved applications as well as any products that have already been registered.



Viewing Saved Applications

During the process of filling out the product registration information you can save the information and access it at a later point. You will have to login to the system and go to the registration page or access the menu Registration > Current Application > Saved application.