



QUICK START
FOR
DIGITAL PRODUCT REGISTRATION



For vaccines

Applicant Version

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE

DIRECTORATE GENERAL OF DRUG ADMINISTRATION

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www.dgda.gov.bd



<http://www.dgda.gov.bd/>

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Purpose of this guide

This guide shows DGDA Clients and Customers how to log in to and apply for MA Certificate for a Product Marketing Authorization.

Overview

The main steps for the Screener:

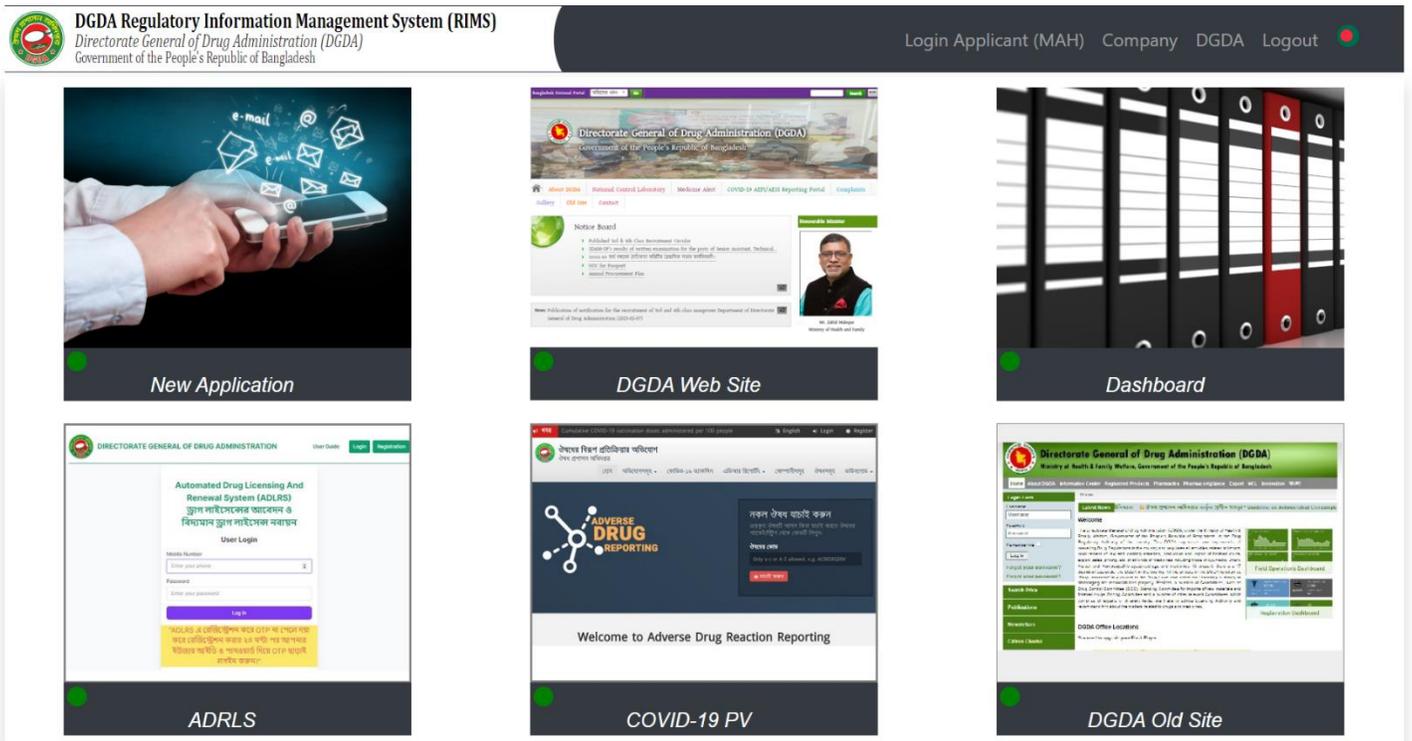
1. Go to the DGDA Application website
2. Login to the system
3. Go to the To New application
4. Monitor assigned tasks
5. Create reports

Step 1: Go to the website

The system is available on the following link:

rims.dgda.gov.bd

Please type the link in a browser to get the website.



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Powered by OpenRIMS R1.0.0@2023-05-26T14:53:48Z

Step 2: Login as Applicant

As an Applicant or Customer please click on the top right on the Applicant Login as illustrated with the orange arrow here:

The screenshot shows the top navigation bar of the DGDA RIMS website. On the left is the DGDA logo and name: "DGDA Regulatory Information Management System (RIMS) Directorate General of Drug Administration (DGDA) Government of the People's Republic of Bangladesh". On the right, there is a navigation menu with the following items: "Click Here to login as an applicant" (highlighted with an orange arrow), "Login Applicant (MAH)", "Company", "DGDA", and "Logout".

Below the navigation bar are six thumbnail images representing different system components:

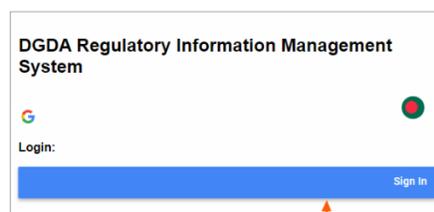
- New Application:** A hand holding a smartphone with floating email icons.
- DGDA Web Site:** A screenshot of the DGDA website's main page.
- Dashboard:** A 3D rendering of a modern office dashboard.
- ADRLS:** A screenshot of the Automated Drug Licensing And Renewal System (ADRLS) user login page.
- COVID-19 PV:** A screenshot of the Adverse Drug Reporting (ADR) system interface.
- DGDA Old Site:** A screenshot of the DGDA website's old version.

At the bottom of the page, there is a footer with the USAID logo and text: "USAID FROM THE AMERICAN PEOPLE Medicines, Technologies and Pharmaceutical Services". To the right of the USAID logo is a disclaimer: "This website is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government." Further right are links for "terms" and "privacy". On the far right, it says "Powered by OpenRIMS R1.0.0@2023-05-26T14:53:48Z".

NB! You do need a Google account to be able to submit any application.

Step 3: Select Google login

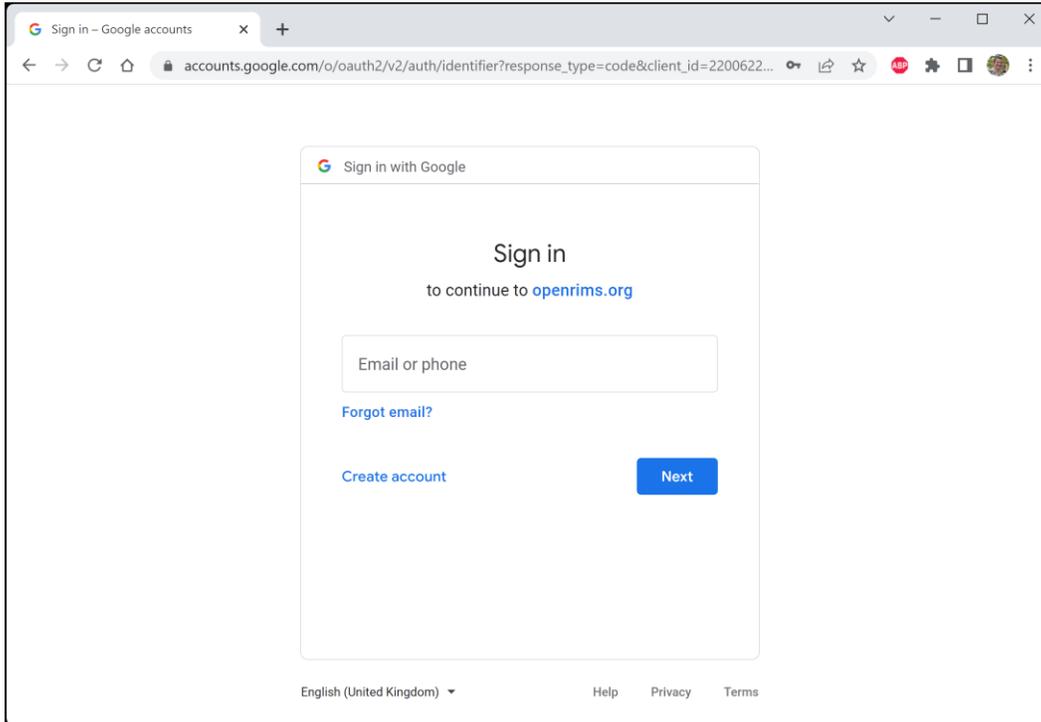
Now click the Sign in with Google button:



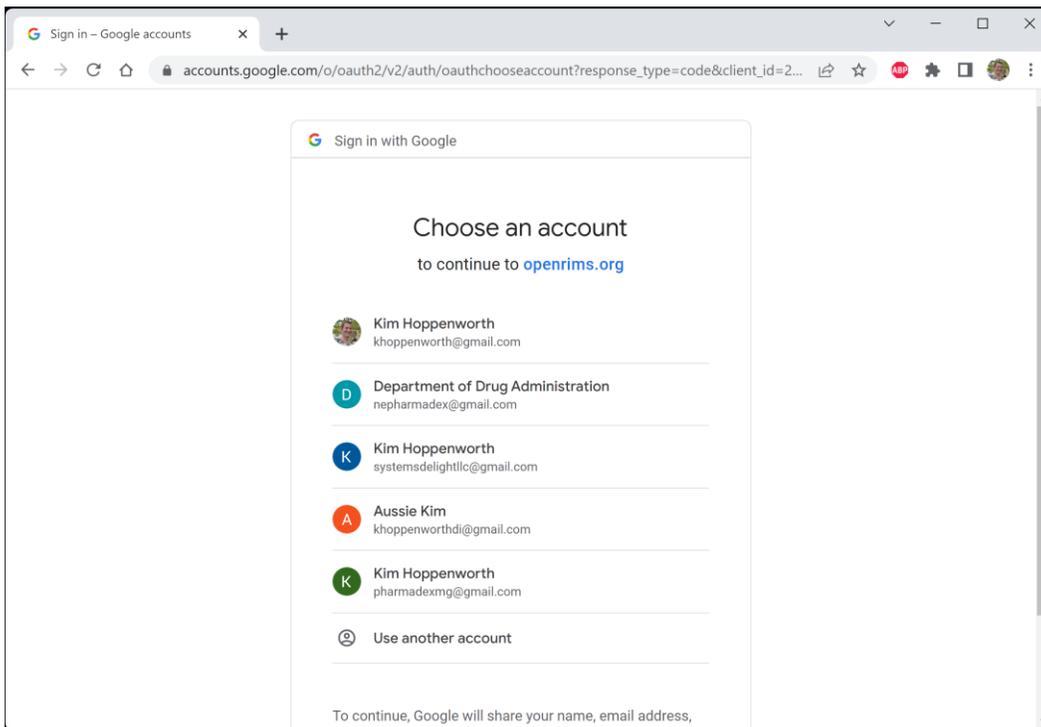
Click here to signin with google account

Step 3b: Choose Existing or new Google Login

Choose an Existing account. Or enter your information.



OR



Step 4: Go to Submit a new application.

After log in please mouse over the Submit Application tile and click the button to go to Application screen.

Submit Application!

My Tasks

Application Tracking

Reports

Click Here for New application Submission

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terms privacy

OpenRIMS R1.0.0@2023-04-24T18:16:13Z

Step 5: Add a new Application

Apply for new application:

Applications | New applications | Modifications | De-registration | Exit

Application Type

| Name | Additional information |
|--|---|
| <input type="checkbox"/> Product Export Certification | Receive a certificate to import a medicine by the standard procedure. |
| <input checked="" type="checkbox"/> Product Registration for Introduced Vaccine and Biosimilar Product | Registration Procedure for Introduced Vaccine and Biosimilar Product |

Click Here to add new application

Applications

Search

Add

| Scheduled | Days | Generic Name | Category |
|-----------|------|--------------|----------|
|-----------|------|--------------|----------|

By clicking on ADD button a new form will come up.

Step 6: Fill up the forms.

New application form will appeared like below:

Product Registration for Introduced Vaccine and Biosimilar Product

1 of 6

Applicant Information

Applicant Name: test
 Designation: test
 Contact number: test
 Email address: test

Company Information

Company Name: test
 Company Type: APH Manufacturer (selected)

Manufacturer_Site_Address

People's Republic of Bangladesh / Dhaka / Dhaka

Postal Code: 2321234
 Country: Bangladesh
 License Number: test432
 GMP Certification No.: test1543
 GMP Inspection Date: 6/4/2023
 Web Address: test.com

Payment Information

Payment Date: 6/4/2023
 Payment Mode: Chalan (selected)
 Chalan Number: test65432
 Bank and Branch Name: test
 Evidence of payment (upload a pdf file): Upload a file (test.pdf)

Product Information

SmPC_Template: Summary Product Characteristics (SmPC) uploaded
 SmPC_Upload: SmPC Upload uploaded
 Sample and Testing submitted to NCL: Not Submitted (selected)
 Product Group: Vaccine (selected)
 Application Type For Vaccine Registrations: Registration/IVA (selected)
 Product Category: Human (selected)
 Generic Name: test1234
 Brand Name: tube
 Excipient Name: testy
 Label Claim: test
 Diluent Name: test
 Name of the Reference Product (Innovator Brand): test
 Physical Appearance: solution
 Dosage Form: IV (selected)
 Dosage Strength: test
 Indication: test
 Side Effects: test
 Shelf life (in Months): 12
 Pack Size (for example 5 x 10's): 23
 Container/Closure Type: Vial (selected)
 Storage Conditions: test

Terms and Conditions

Information provided are true to the best of my knowledge and will take full responsibility. Yes

Product Registration for Introduced Vaccine and Biosimilar Product

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1. This is the 1st Application form.
2. Fill up all sections with all the necessary information.
3. Click on the "Next" button.
4. Fill up the second section with all the necessary information.
5. Click on the "Next" button.
6. Repeat steps 4 and 5 for the remaining 3 sections.
7. Once you have filled up all 6 sections, click on the "Submit" button.

Important: Make sure to upload the chalan slip and SmPC form and other relevant uploads in the designated sections.

Step 7: Submission

Last step before submission:

Applications New applications Modifications De-registration Exit

Product Registration for Introduced Vaccine and Biosimilar Product

testtube

CTD Module 1

CTD Module 2

CTD Module 3

CTD Module 4

CTD Module 5

→ Click here to check or verify the given informations.

Save Cancel Submit

Check back the declaration

MAH Self Check List

All Required Documents Compiled and Submitted

Yes No N/A Notes

Product Registration for Introduced Vaccine and Biosimilar Product

To Save temporarily → Save Cancel Submit

Click Here to submit the application

Step 8: Acknowledgement Receipt

User will get an acknowledgement receipt after successful application submission.

Applications New applications Modifications De-registration Exit

User will get an acknowledgement printable slip after successful application submission.

Receipt for Submission of Application to DGDA

Submitted Date

June 4, 2023

Application Processing

Additional information

Generic Name

references

office

Print

Ok

Click on the "Print" button to print the acknowledgement receipt as a PDF file.

END OF DOCUMENT