TRAINING MANUAL

Integrated Regulatory Information Management System (IRIMS)
IRIMS Software - Overview

Integrated Regulatory Information Management System (IRIMS) is globally recognized online computer based information management system for the Health Regulatory Bodies / Authorities to process the business with automated processes.

IRIMS includes the following features.

- Online fee challan generation
- Online application for new drug registration
- Online application for renewal of existing registered drug
- Online application for post registration changes of existing registered drug
- Online data submission of 2-D barcode on IRIMS software
- Mobile application for the verification of 2-D barcode
ONLINE FEE CHALLAN SYSTEM

This is a first step of IRIMS software you can generated online computer based challan and can submit it in any branch of ABL

Note: The existing challans will also be acceptable up to next 03 months in this system but the verification of existing challan from the DRAP Accounts are mandatory.
Online fee challan system is used to submit fee for product registration, renewal, PRVC and other purposes where fee is mandatory to process the case. The online challan system is shown as below.
Input the values for the fields displayed as below. Fill all the relevant fields.

| COMPANY NAME | ABCDEFG |
| CITY         | ISLAMABAD |
| EMAIL        | ABC@ABC.COM |
| DIVISION     | Drug Licensing |
| PAYMENT HEAD | Drug Registration, Controlled Drugs, Pharmacy Services, Quality Assurance, Health & GTC, Medical Devices, Biological Drugs |
| FEE HEAD     | Biological Drugs |
| FEE          | 50000.00 |
Select the corresponding payment head.
Select the fee head from drop down list.
Once the fee head is selected the “Fee” field is automatically populated with the corresponding fee. Press “Generate Slip” button
When the “Generate Slip” is pressed the following slip will be generated containing the fee details as provided. Print the generated slip and submit in bank.
PRODUCT REGISTRATION, RENEWAL AND PRVC IN IRIMS SOFTWARE
The following Login screen is used to Login into IRIMS. Use the username and password already assigned on DRIS software. If not already assigned then use the Register link on the following screen.
If the Company is not already registered then click Register link on previous screen a new screen will appear as follows. Fill the required fields and press the register button. For manufacturers enter DML number and For importers enter DSL. Company prefix (GCP) and GLN (for each site) will be required prior to the registration in the IRIMS. GCP and GLN will be provided by the GS-1 Pakistan. Then press register button your information will be received in DRAP after verification computer generated username and password will be forwarded on your official email (as provided in this form).

Note: Only use the official email of the company.
PROCEDURE FOR REGISTRATION OF A NEW PRODUCT
Use the login screen previously shown to login IRIMS. Provide the username and password already given, once the username and password is verified the system will take you to the company Dash Board showing the information about the company license, products and the batches entered. On the left hand side you have several options to choose from, e.g. if you want to register a new product go to “NEW Tasks” then select “Product Registration”
When “New Product Registration “ is selected you will be taken to the following screen, enter the values in the fields shown below and press save. By pressing “Add more” button under “Fee Detail” you can enter multiple fee details.
Once the “Save” button is pressed on the “Application Details” you will be taken to next step for entering “Manufacturer” details. Enter the details here and press “Save” button.
Now Enter the details of the composition of product and press “Save”
Enter the packaging detail of the product and press “Save” button. Here you can add multiple pack sizes by Pressing the “Add More” button.
On the last screen enter the references or skip this. By selecting the skip option provide brief description of the Skip reason and press “Save” button.
Once the details of the product registration are entered the following screen is displayed. Here you have 3 options in the dropdown list “1) Edit Details 2) Submit Application 3) Print”. You can edit and print the details entered and can submit but by pressing “Submit Application“ the details will be no more editable.
Once the product details are completed the newly entered product will be listed under the “Pending Tasks” as shown below. The status option shows the status of the application. The Status “Draft” means that the product details are entered but not yet submitted you can still edit the product details by pressing the folder option at the last of the listing of product as shown on the next screen.
To edit the product details select “Edit Details” from the “Options” drop down list as shown below.
HOW TO ENTER THE BATCH INFORMATION OF A REGISTERED PRODUCT
HOW TO ENTER A BATCH INFORMATION

In order to enter the batch information of already registered product, login to the system on the company Dash Board select “Our Products” the list of registered product will be displayed as follows. Press the “Batch” button at the end of product. New Screen will appear.
Press the “New Batch” button.
When the “New Batch” button is press the following screen will be displayed. Fill the fields as shown below and press “Save“ button.
How to enter serials of a product.
To enter Serials press the “Serials” button on the “Product Batches” screen shown below.
All the already entered serials will be displayed as below. To enter new serials press “Add New Serials”
From the options drop down list select “Add More Serials” a new screen will appear.
On the screen displayed below enter the serials details and press “save” button.
RENEWAL OF THE ALREADY REGISTERED PRODUCT
For the renewal of the already registered product on the Dash board under “New Tasks” select “Renewal Application”
Once the renewal option is selected the following screen will be displayed. You can select the registered product by pressing the folder icon at the end of the product listing.
When the folder option of the registered product is selected then the following screen is displayed here select “Renewal Request” from the “Options” drop down list.

Note: You can edit the product details by selecting the “Edit” option from the option drop down list as shown below.
Once the Renewal option is selected the following screen is displayed. Enter the details and press “Save”.
All the renewal applications submitted will be listed under “Pending Tasks → Renewal Application”
POST REGISTRATION VARIATION CHANGES (PRVC)
Post Registration Variation Changes (PRVC) option is available on company main Dash Board. Under New Tasks, PRVC/Reg. Transfer as shown below.

![Post Registration Variation Changes (PRVC) option](image)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Registration No</th>
<th>Origin</th>
<th>Reg. Status</th>
<th>Batches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Company</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FzadA3443, 12mg, aerosol</td>
<td>063434</td>
<td>Domestic</td>
<td>Unregistered</td>
<td>4</td>
</tr>
<tr>
<td>Test 1, 60ml, capsule</td>
<td>210311</td>
<td>Domestic</td>
<td>Registered</td>
<td>0</td>
</tr>
<tr>
<td>Test 2, 250mg, aerosol</td>
<td>123450</td>
<td>Domestic</td>
<td>Unregistered</td>
<td>0</td>
</tr>
<tr>
<td>Test 3, 40ml, tablet</td>
<td>RPHD-1100112</td>
<td>Domestic</td>
<td>Registered</td>
<td>0</td>
</tr>
<tr>
<td>Testprod-N, 20mg, aerosol</td>
<td>500555</td>
<td>Domestic</td>
<td>Unregistered</td>
<td>0</td>
</tr>
<tr>
<td>Testprod-V, 300mg, tablet</td>
<td>900222</td>
<td>Domestic</td>
<td>Unregistered</td>
<td>0</td>
</tr>
</tbody>
</table>

Displaying all 6 products.
Click New Tasks → PRVC/Reg, a new screen will be displayed shown below. Select the options dropdown list and then select “PRVC request”
Once the “PRVC request” is selected the following screen will be displayed. Fill the fields and press Next button. Fill all those fields as asked by the software.
When the required fields are filled press the submit button.
All the PRVC submitted applications will be listed under Pending Tasks PRVC / Transfer Applications as shown below
MOBILE APP FOR BARCODE SCANNING

• Mobile app for barcode scanning is used to scan the barcodes printed on pharmaceutical products. This app is available on Google Play Store by the name “DRAP Barcode Scanner” and is easily downloadable.
• Download and install to get start.
• Companies can verify their barcodes and submission of data in DRAP using this app prior to marketing.
About

Developed by MIS Division

Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulation & Coordination
Government of Pakistan
Support:

Scanning:

Auto focus feature in your smart phone is necessary in most cases.

Focus on a 2D barcode, depending on the camera and app version, you may need to try focusing from different distances, start from 1.5 feet and go close until app read it. Most of the time, best distance is 4–8 inches.

Use Flash if no adequate light is available.

Use low FPS if camera preview is too dark.

This app will not give results for bar-codes other than 2D data matrix.

Result:

First portion of result is decoded from bar-codes other than 2D data matrix.
In case of any query regarding IRIMS Software you can contact at support@dra.gov.pk