



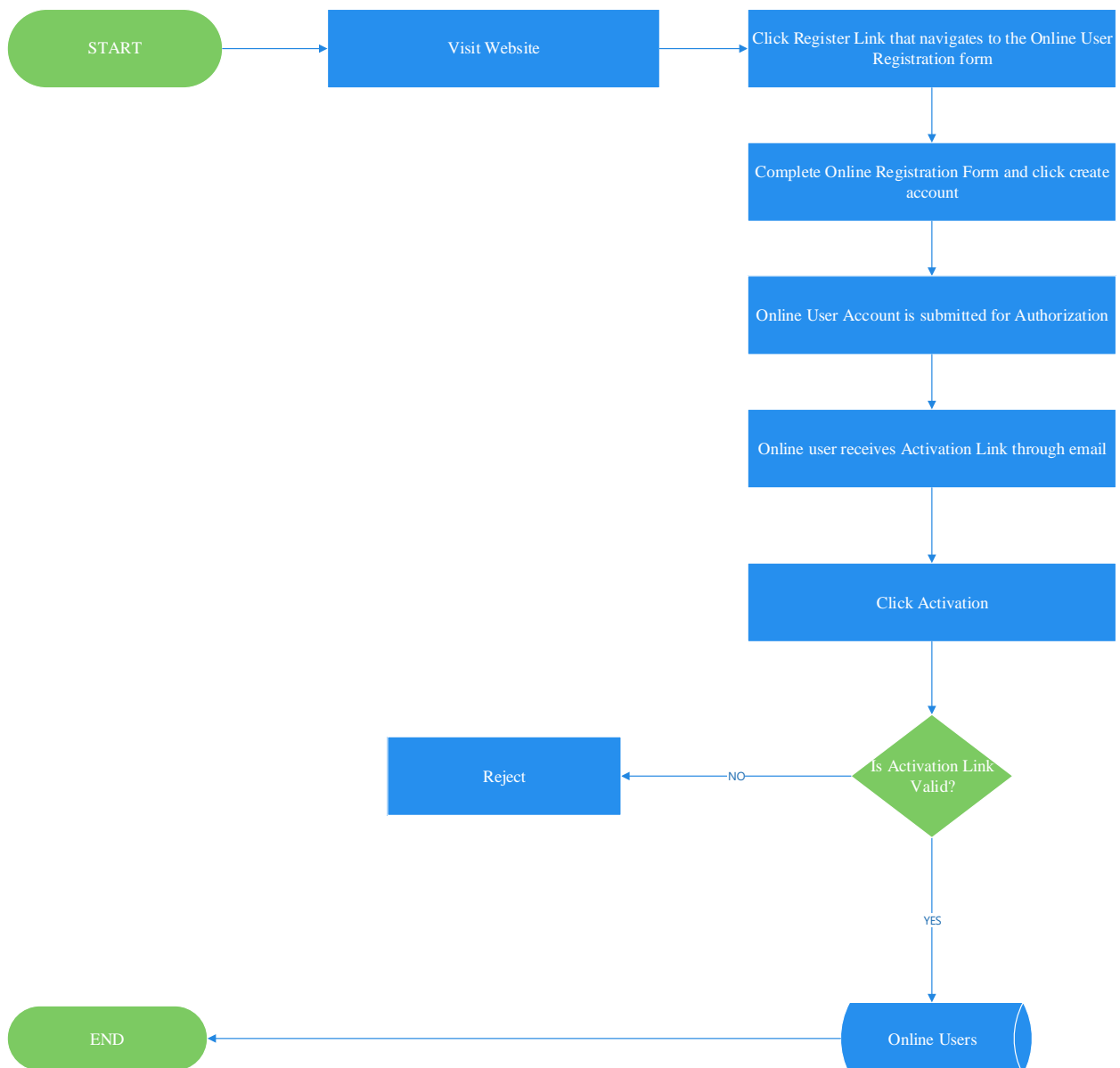
USER MANUAL FOR SECTION 75 APPLICATIONS

The Section 75 Application Medicines Module is used to apply for authorisation to import unregistered medicines. This document shows the stages to be followed when applying for authorisation letter.

1. Online Account Registration

To apply for authorisation letters and use the system to track applications and other functions you need to have a user account. The following diagram shows the registration process

Online Registration Process



To register, click the “Click here to register” link on the login page as shown below.

MCAZ ONLINE SERVICES LOGIN

Email Address

Password

Log In

[Click here to register](#) [Forgot Password](#)

Application designed and managed by Medicines Control Authority of Zimbabwe 2018

This will take you to the registration page. You need to fill in the details on the registration page. All fields are mandatory except for the Fax. The CAPTCHA is case sensitive. Once you click the “create an account” button and all information has been entered correctly, an email will be sent to the email address you entered in the email field

MCAZ Medicines Control Authority of Zimbabwe

Registration Page

MCAZ Medicines Control Authority of Zimbabwe

Login Register

MCAZ Online Services Account Registration Form

Choose at least One service from the options below

Import/Export of Registered Medicines Section 75 Medical Devices Licensing

Company Details

Company Name Street Address

Location Country

Town Telephone No.

Fax Premise No./Licence No.

Applicant Details

First Name Surname

Position In Company Phone No.

Email Address

Password Confirm Password

3BN93P Your Captcha HERE

Create an Account

Remember to tick here

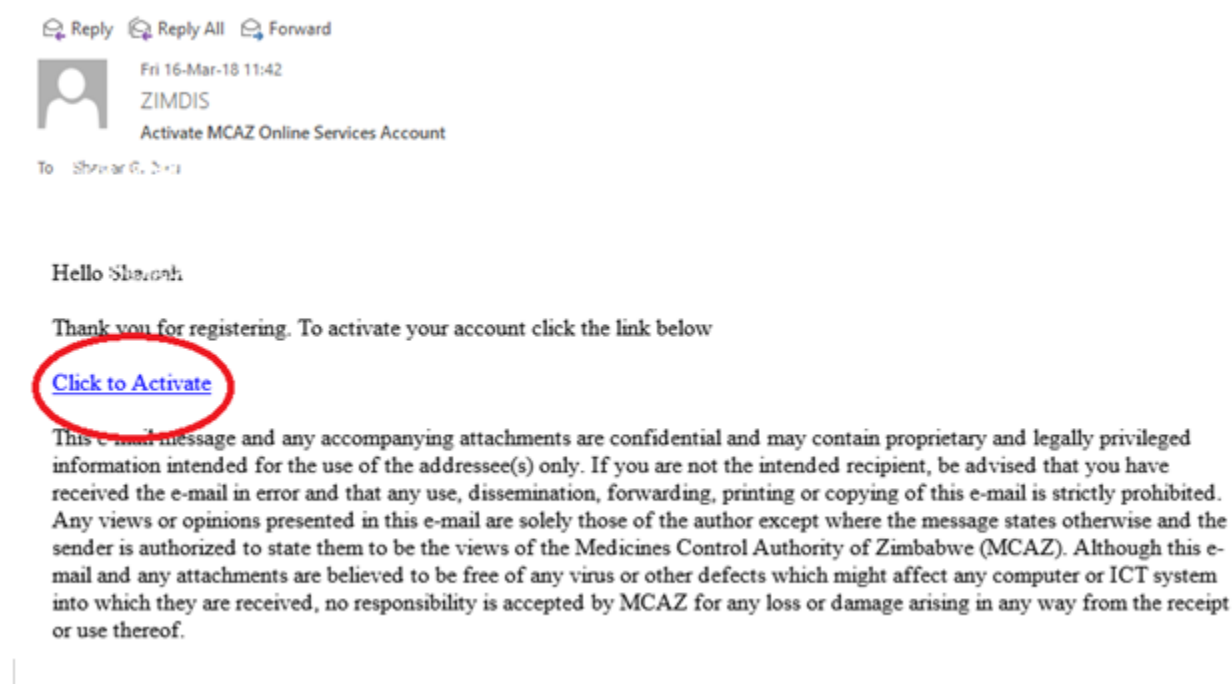
Trading name

Email address you can access



Medicines Control Authority of Zimbabwe

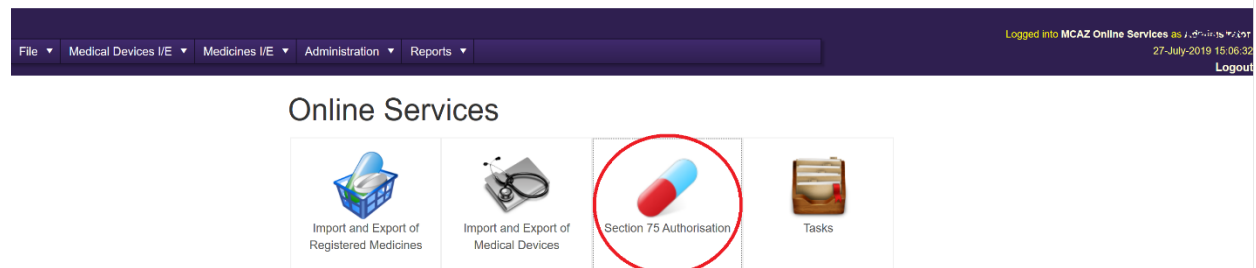
The email that is sent will have an activation link. You need to click that link for your account to be activated. If you don't activate your account, you will not have access to the system. The activation email and link are depicted below



When your account has been activated, login with your user credentials. The first page you see will have all processes you have access to. Click the “Section 75 Authorisation” button.



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2. Application for Section 75 Authorisation

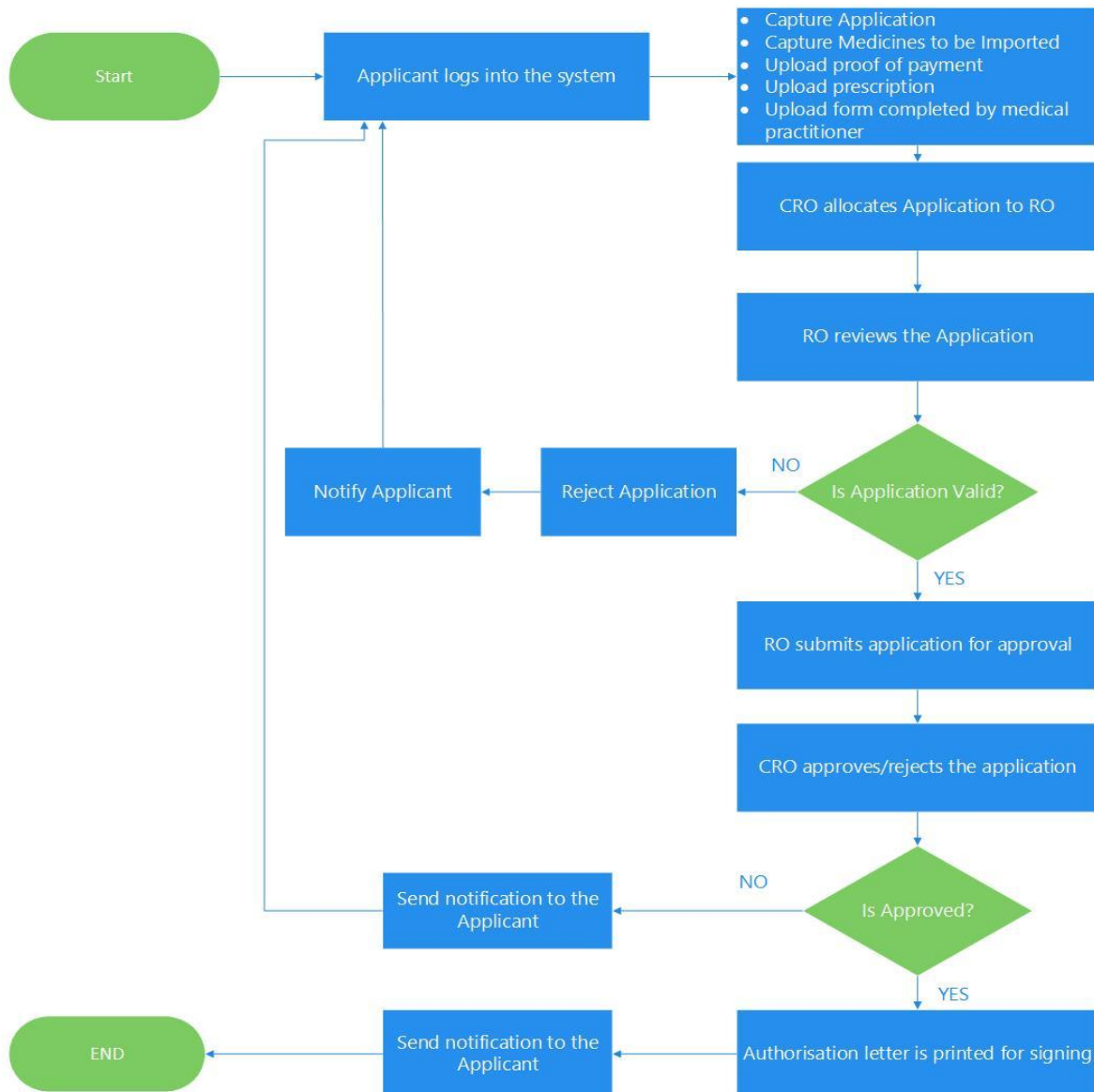
There are 3 types of applications under section 75, i.e.

- i. **Application for Prescription,**
- ii. **Application for Institutions and**
- iii. **Application for Bulk Importation**

i. Application for Prescription

The following diagram shows the process flow for Application for Prescription.

Application Process for UM Prescription



After clicking the “Section 75 Authorisation” button you will be directed to the Section 75 dashboard. Click the “Application for Prescription” icon as shown below

Section 75 Dashboard

Application designed and maintained by Medicines Control Authority of Zimbabwe 2019

When you have clicked the icon, you will be directed to the “Request for Authority to Import Unregistered Medicines for Prescriptions” page. Fill in all the information required accurately and click “Save Application” once done. This is shown below:

REQUEST FOR AUTHORITY TO IMPORT AN UNREGISTERED MEDICINES FOR PRESCRIPTIONS

SECTION A: PATIENT DETAILS

Premise Application No. N/A

First Name Surname

Street Address Area

Town Category

SECTION B: MEDICAL PRACTITIONER COMMENTS

Name Of Medical Practitioner Physical Address

Clinical condition Medicines previously used

Any additional information Outcome of treatment(in brief) with medicines mentioned above

*Progress report(including adverse drug reactions if any) Medical Practitioner Qualifications

The next stage is to add medicines and this is done by clicking the “Add Medicines” button as shown below.

SECTION B: MEDICAL PRACTITIONER COMMENTS

Name Of Medical Practitioner	DR BLESSINGS BONDAMAKARA 64 HO	Physical Address	67 Queen Elizabeth Road Grosvenor
Clinical condition	Kidnaji	Medicines previously used	Telmesatan
Any additional information	yes	Outcome of treatment(in brief) with medicines mentioned above	death
*Progress report(including adverse drug reactions if any)	bulging eyes	Medical Practitioner Qualifications	PharmD

Save Application

UNREGISTERED MEDICINES TO BE IMPORTED

+ Add Medicines

Drag a column header and drop it here to group by that column

Brand Name	Generic Name	Strength	PackSize	Dosage Form	Total Quantity	Manufacturer
There are no medicines to display						

New Drugs

A pop up that allows you to add medicines will appear and you can add your medicines from the list provided. On the drop down provided ensure to select an entry which has generic name, strength, manufacture and country. If the medicine is not there, then add your medicines using the “Add New” button. Save your medicines once done and then close the popup. This is shown below

Capture Medicines

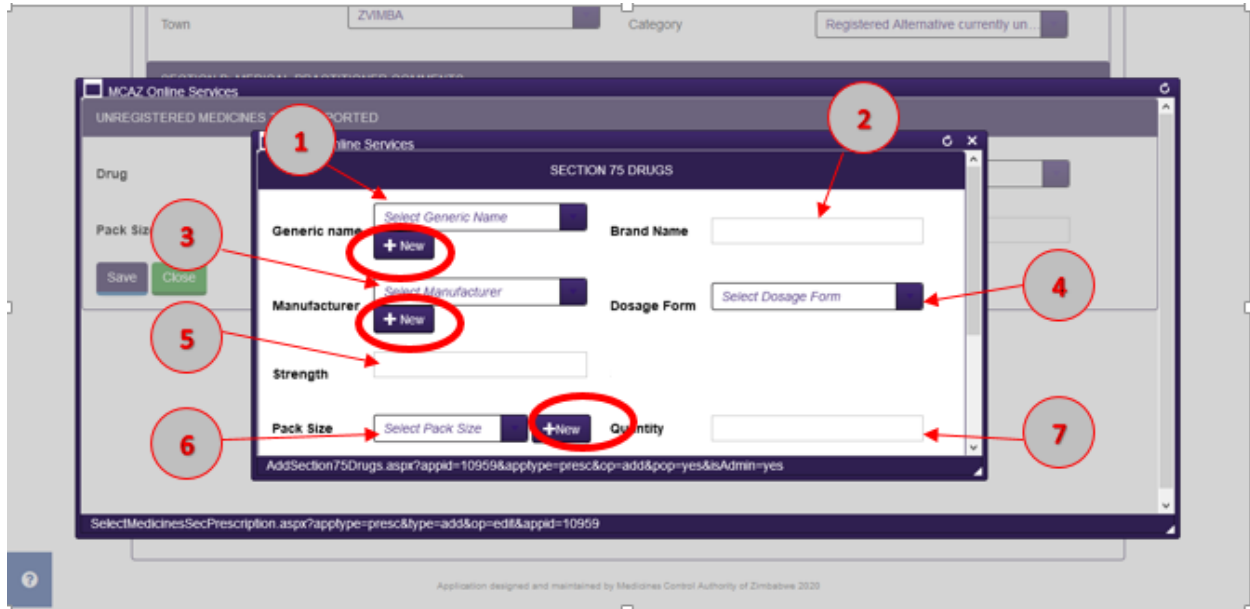
UNREGISTERED MEDICINES TO BE IMPORTED

Drug	Select Medicines	+New	Manufacturer	Select Manufacturer
Pack Size	Select Pack Size	+New Packsize	Quantity	

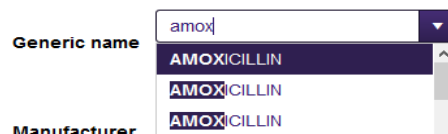
Save **Close**


SelectMedicinesSecPrescription.aspx?apptype=presc&type=add&appid=4

If you have clicked the “Add New” drug button then the following popup will be available for you to add a drug that is not on the list. Add the New information in the provided fields. Also, if the generic name, manufacturer and pack size you want is not available from the provided lists then click the respective “Add New” buttons next to each item you want to add. The respective popups will be shown for you to add the information you need. Click save then close once done. This is shown below



1. **Generic name** – type in the field the generic name only of the medicine you wish to import then a drop down with suggestive names similar to the generic name you typed will appear in like this

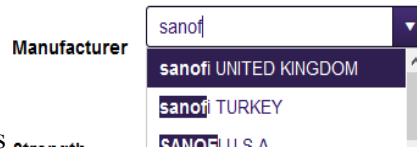


- If there is no match click on new button encircled in the main picture above the type the generic name press save and close
- Try again to type in the generic name in the generic name field it should be now appearing in the drop down ,if it is not appearing refresh the page by clicking this  on the top right of the pop up


2. **Brand name** – if the medicine you wish to add has a brand name just type it in the brand name field ,if the medicine you wish to add has no brand name you can leave the field blank .

- Please do not repeat typing in the generic name in the brand name field

- 3. Manufacturer-** type in the field the manufacturer of the medicine you wish to import then a drop down with suggestive names similar to the manufacturer

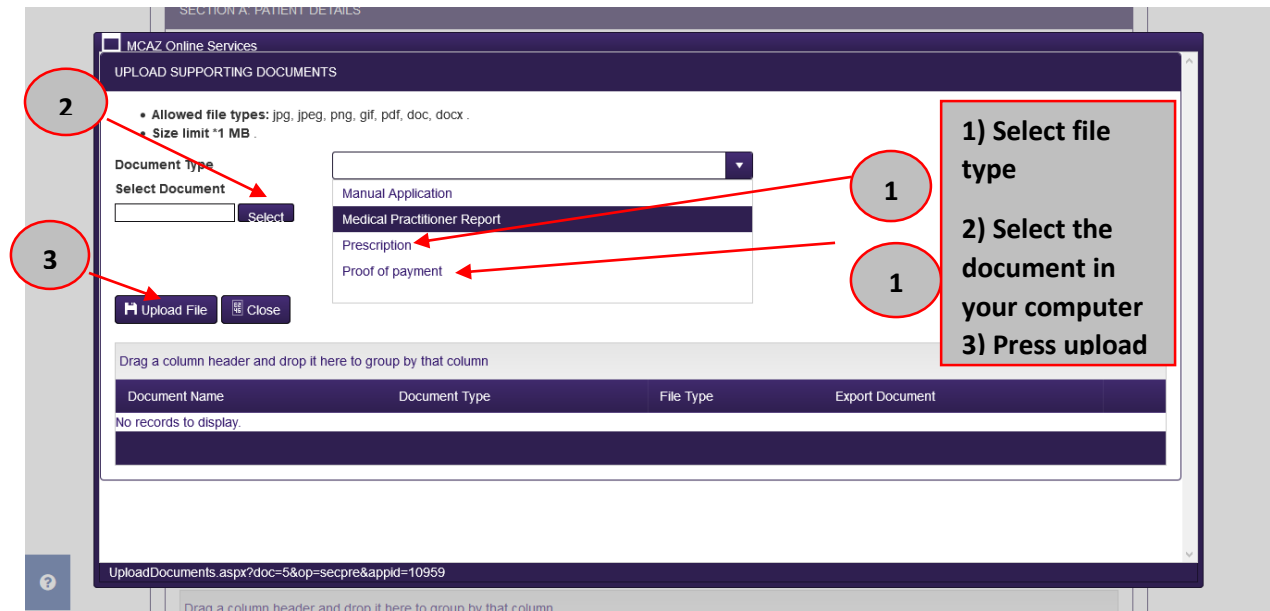


you typed will appear in like this

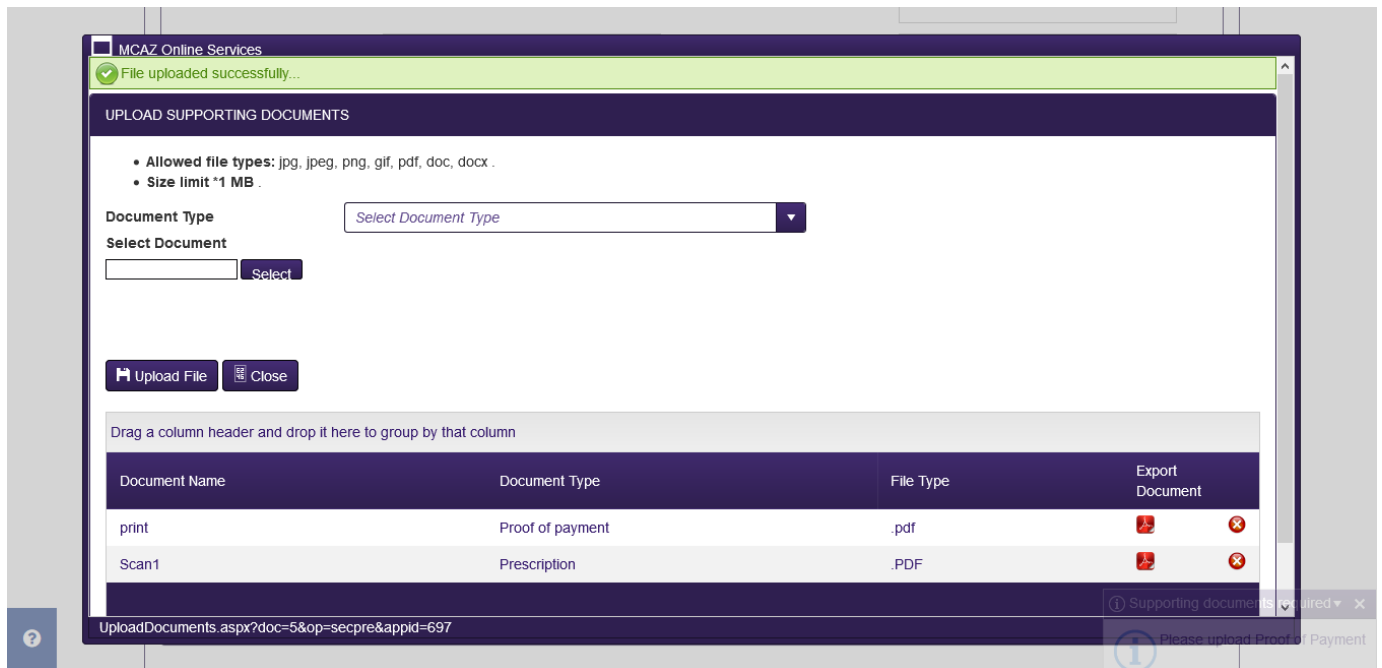
- If there is no match click on new button encircled in the main picture above,
 - then type the manufacturer name ,street address & country press save and close
 - Try again to type in the manufacturer name in the manufacturer field, it should be now appearing in the drop down ,if it is not appearing refresh the page by clicking this  on the top right of the pop up screen.
- 4. Dosage form-**type in the dosage form in the field then select from the dosage form appearing from the drop down.
- Please select dosage that are singular such as Tablet ,Injection ,Capsule etc
- 5. Strength-** type in the strength in the field
- if your medicines does not have strength please use –
- 6. Pack size-** type in the field the pack size of the medicine you wish to import then a drop down with suggestive names similar to the manufacturer you typed will appear in like this
- If there is no match click on new button encircled in the main picture above,
 - then type in the pack size press save and close
 - expected pack sizes should be in this format 30 tablets ,30 capsules, 10 vials, 10 ampoules etc
- 7. Quantity-** type in the quantity in the field. If you have included pack size the quantity will be the number of units of the pack size required. For example, 6 x 30- quantity being **6 and not 180**

3 x 100- quantity being **3 and not 300**

When you are returned to the main application page, you can now upload your supporting documents. These are the Prescription and Proof of Payment. To do this click the “Upload Supporting Documents” button that will now be visible next to the “Save” button which will produce pop up as shown below



All the documents you successfully upload will be listed in the grid below the “Upload File” button. If you have uploaded the wrong document, click the delete icon on the right side of each document as shown below.



Click the “Close” button once finished. If you have uploaded all required documents, the “Submit for Authorisation” button will be available. Click it to send your application for review as shown below



Application loaded successfully... SECTION B. MEDICAL PRACTITIONER COMMENTS

Name Of Medical Practitioner: Dr Zimudzi Kudzai Alexander Not ... Physical Address: Not Provided

Save Application Upload Required Document **Submit for Authorisation**

UNREGISTERED MEDICINES TO BE IMPORTED

+Add Medicines

Print Proforma Invoice

Drag a column header and drop it here to group by that column

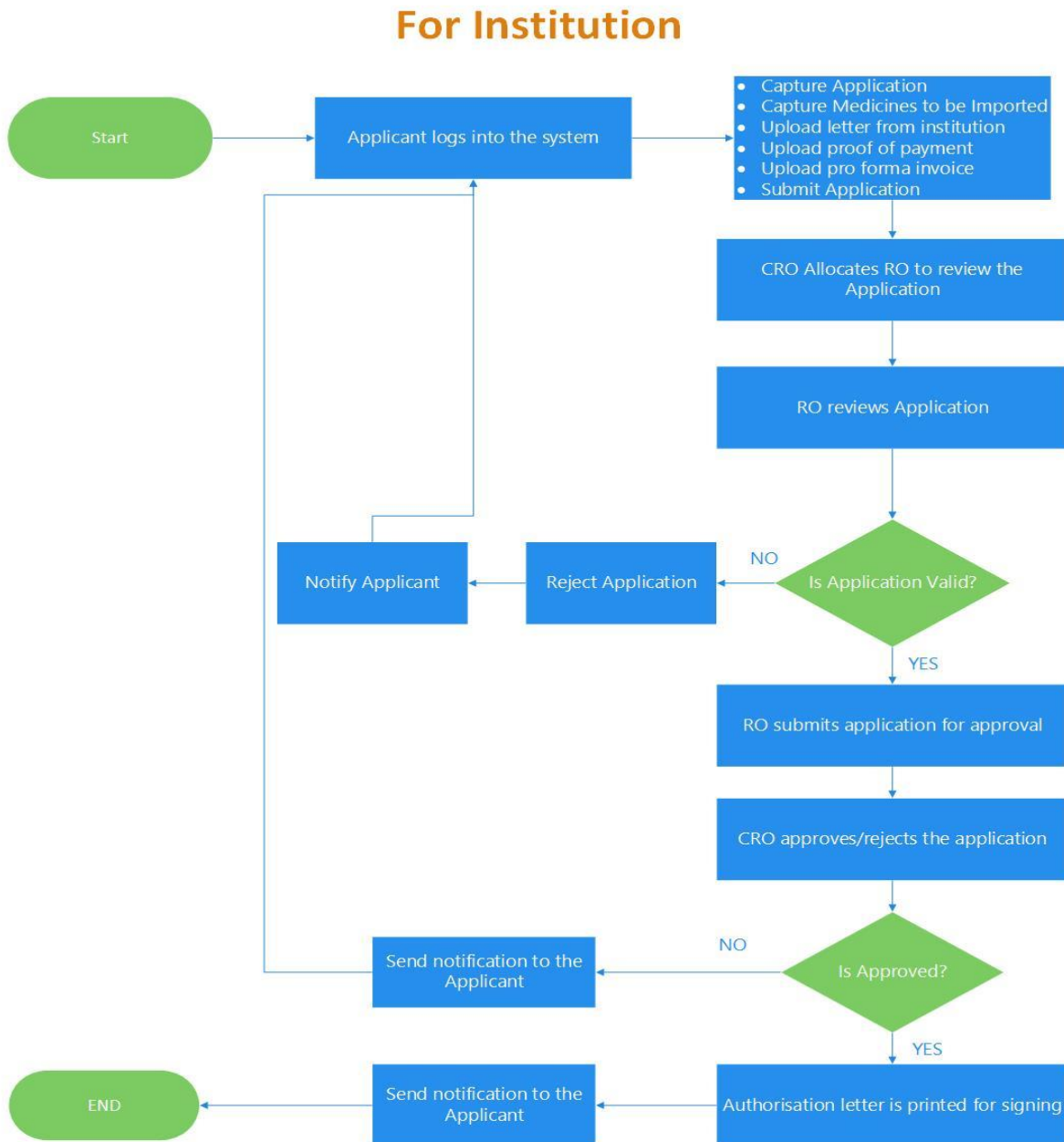
Brand Name	Generic Name	Strength	PackSize	Dosage Form	Total Quantity	Manufacturer
N/A	VENLAFAXINE	150MG	500 TABLETS	CAPSULE	5600	CONSILIENT

New Drugs



ii. Application for Institutions

The following chart shows the process flow for Application for Institutions process



To apply for this type of authorisation while on the Section 75 dashboard, click the “Application for Institutions” icon. This is shown in the diagram below

Section 75 Dashboard

Application for Prescription
Application for Institutions
Application for Bulk

Applications for Prescription (Capturing) (0)
Applications for Prescription (Pending Review) (0)
Applications for Prescription (Approved) (0)
Applications for Prescription (Rejected) (0)

Applications for Institutions (Capturing) (0)
Applications for Institutions (Pending) (0)
Applications for Institutions (Approved) (0)
Applications for Institutions (Rejected) (0)

Applications for Bulk Importation (Capturing) (0)
Applications for Bulk Importation (Pending) (0)
Applications for Bulk Importation (Approved) (0)
Applications for Bulk Importation (Rejected) (0)

Application designed and maintained by Medicines Control Authority of Zimbabwe 2019

You will then be directed to the “Request for Authority to Import Unregistered Medicines for Institutions” page. Select the name of your premise. There are two checkboxes that are ticked by default, that is, “MCAZ Licensed?” and “On Behalf of”.

The “MCAZ Licensed?” checkbox should be ticked if you are an importer who is registered with MCAZ and un-tick if you are a public institution or a non-profit making organization that is not Licensed by MCAZ. Also, if you are importing in behalf of another institution, then make sure the “On Behalf of” checkbox is selected. Then choose the name of the institute you are importing in behalf of. If you are importing on behalf of a public institution or a non-profit making organization un-tick the checkbox on the extreme right. This is shown below

Application loaded successfully

MCAZ Medicines Control Authority of Zimbabwe

REQUEST FOR AUTHORITY TO IMPORT UNREGISTERED MEDICINES FOR INSTITUTIONS

Application No. **APP-SEC75-INST-2020-00442** Application Status **Capturing**

Importer MCAZ Licensed? On Behalf of MCAZ Licensed?

UNREGISTERED MEDICINES TO BE IMPORTED

Drag a column header and drop it here to group by that column

Brand Name	Generic Name	Strength	Manufacturer	Dosage Form	PackSize	Total Quantity
There are no medicines to display						

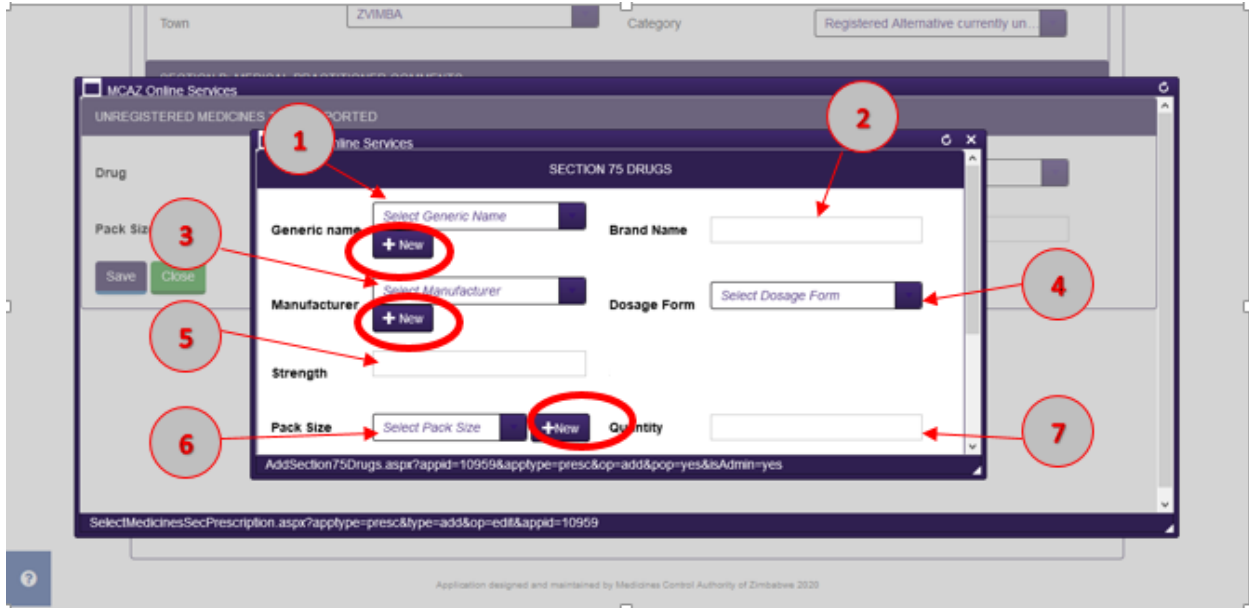
At this point you will then be able to add medicines by clicking the “Add Medicines” button as depicted below

The screenshot shows the MCAZ web application interface. At the top, there is a navigation menu with options: File, Medical Devices I/E, Medicines I/E, Administration, and Reports. The user is logged in as Administrator on 27-July-2019 at 16:56:29. The main content area is titled 'REQUEST FOR AUTHORITY TO IMPORT UNREGISTERED MEDICINES FOR INSTITUTIONS'. It displays 'Application No. 1' and 'Application Status Capturing'. The 'Importer' field contains 'PHARMACEUTICAL & CHEMICAL PRODUCTS'. There are checkboxes for 'MCAZ Licensed?' and 'On Behalf of'. A 'Save Application' button is present. Below this, a section titled 'UNREGISTERED MEDICINES TO BE IMPORTED' features a '+ Add Medicines' button circled in red. A table with columns 'Brand Name', 'Generic Name', 'Strength', 'Manufacturer', 'Dosage Form', 'PackSize', and 'Total Quantity' is shown, with the message 'There are no medicines to display'.

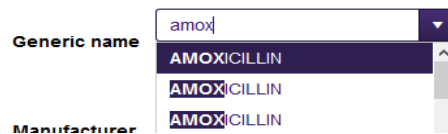
The pop up to add medicines is then visible to you. Select your medicine from the drop down list. Ensure to select an entry which has generic name, strength, manufacture and country .If it isn't available then click the “Add New” button to add your unregistered drug. This is shown below


The screenshot shows a pop-up window titled 'Capture Medicines'. It contains a form for 'UNREGISTERED MEDICINES TO BE IMPORTED'. The 'Drug' field has a dropdown menu with a '+ New' button circled in red. The 'Manufacturer' field is empty. The 'Pack Size' and 'Quantity' fields are also empty. There are 'Save' and 'Close' buttons at the bottom. The URL at the bottom of the window is 'SelectMedicinesSecInstitution.aspx?type=add&appid=1'.

If you click the “Add New” button then you can add a new drug. You need to enter the Generic name, Brand name, Manufacturer, Dosage form and strength of the drug in the popup as below. Click save to add the drug information and click close once done.



1. **Generic name** – type in the field the generic name only of the medicine you wish to import then a drop down with suggestive names similar to the generic name you typed will appear in like this



- If there is no match click on new button encircled in the main picture above the type the generic name press save and close
- Try again to type in the generic name in the generic name field it should be now appearing in the drop down ,if it is not appearing refresh the page by clicking this  on the top right of the pop up

2. **Brand name** – if the medicine you wish to add has a brand name just type it in the brand name field ,if the medicine you wish to add has no brand name you can leave the field blank .



Medicines Control Authority of Zimbabwe


- Please do not repeat typing in the generic name in the brand name field

3. **Manufacturer-** type in the field the manufacturer of the medicine you wish to import then a drop down with suggestive names similar to the manufacturer

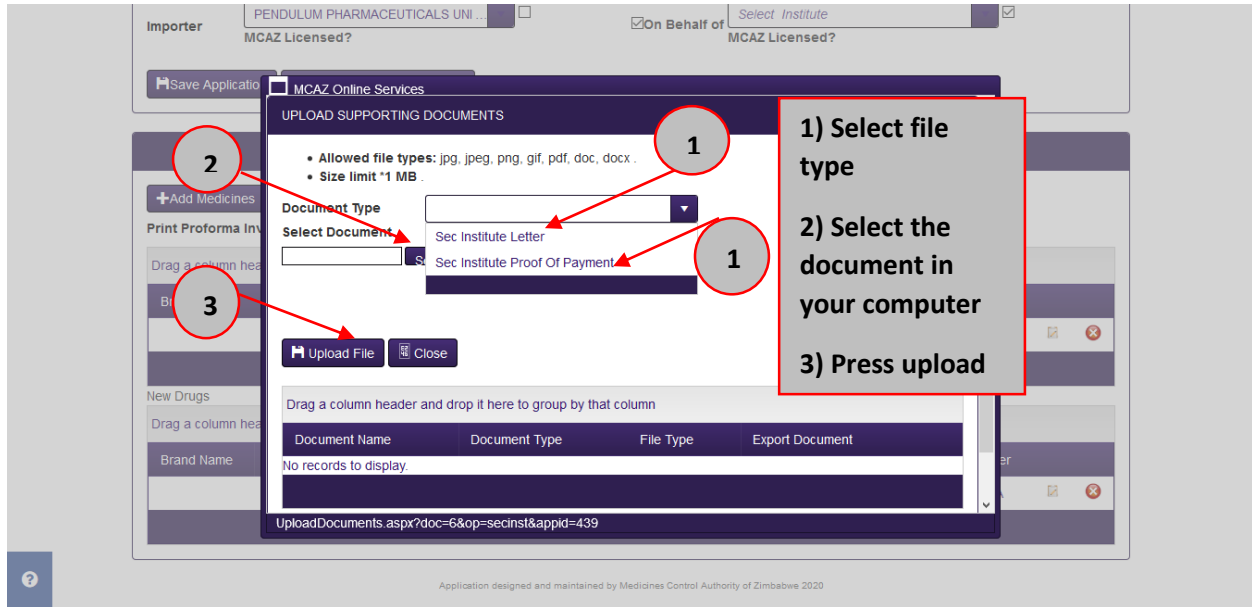
Manufacturer

- sanofi UNITED KINGDOM
- sanofi TURKEY
- SANOFI U.S.A

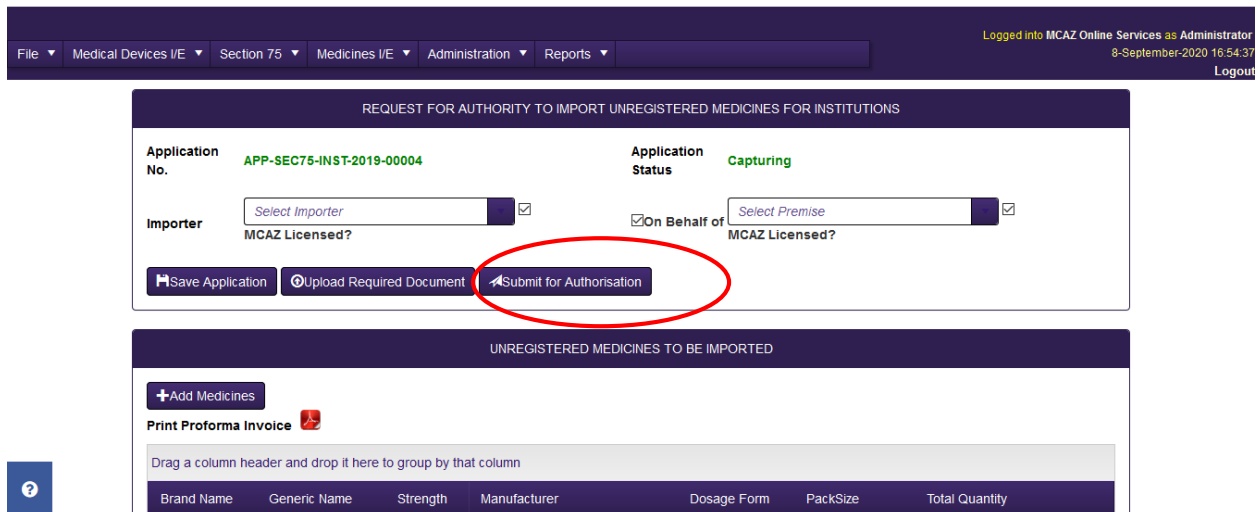
you typed will appear in like this

- If there is no match click on new button encircled in the main picture above,
 - then type the manufacturer name ,street address & country press save and close
 - Try again to type in the manufacturer name in the manufacturer field, it should be now appearing in the drop down ,if it is not appearing refresh the page by clicking this  on the top right of the pop up screen.
4. **Dosage form-**type in the dosage form in the field then select from the dosage form appearing from the drop down.
 - Please select dosage that are singular such as Tablet ,Injection ,Capsule etc
 5. **Strength-** type in the strength in the field
 - if your medicines does not have strength please use –
 6. **Pack size-** type in the field the pack size of the medicine you wish to import then a drop down with suggestive names similar to the manufacturer you typed will appear in like this
 - If there is no match click on new button encircled in the main picture above,
 - then type in the pack size press save and close
 - expected pack sizes should be in this format 30 tablets ,30 capsules, 10 vials, 10 ampoules etc
 7. **Quantity-** type in the quantity in the field. If you have included pack size the quantity will be the number of units of the pack size required. For example, 6 x 30- quantity being **6 and not 180**
3 x 100- quantity being **3 and not 300**

Close the add medicines popup when you are done to be redirected to the main application page. At this point the “Upload Supporting Documents” button will be visible to you. Click this button to upload all required documents. These are the Institute Letter and the Institute Proof of Payment. To upload the specific documents you need, select the appropriate document in the “Document Type” dropdown list. Then click the “Select” button to retrieve the document from your device. After you have selected the appropriate document from your device, click the “Upload File” button to upload the document. Repeat this procedure for all types of documents. This is depicted below



Click the “Close” button once finished. If you have uploaded all required documents, the “Submit for Authorisation” button will be available. Click it to send your application for review as shown below



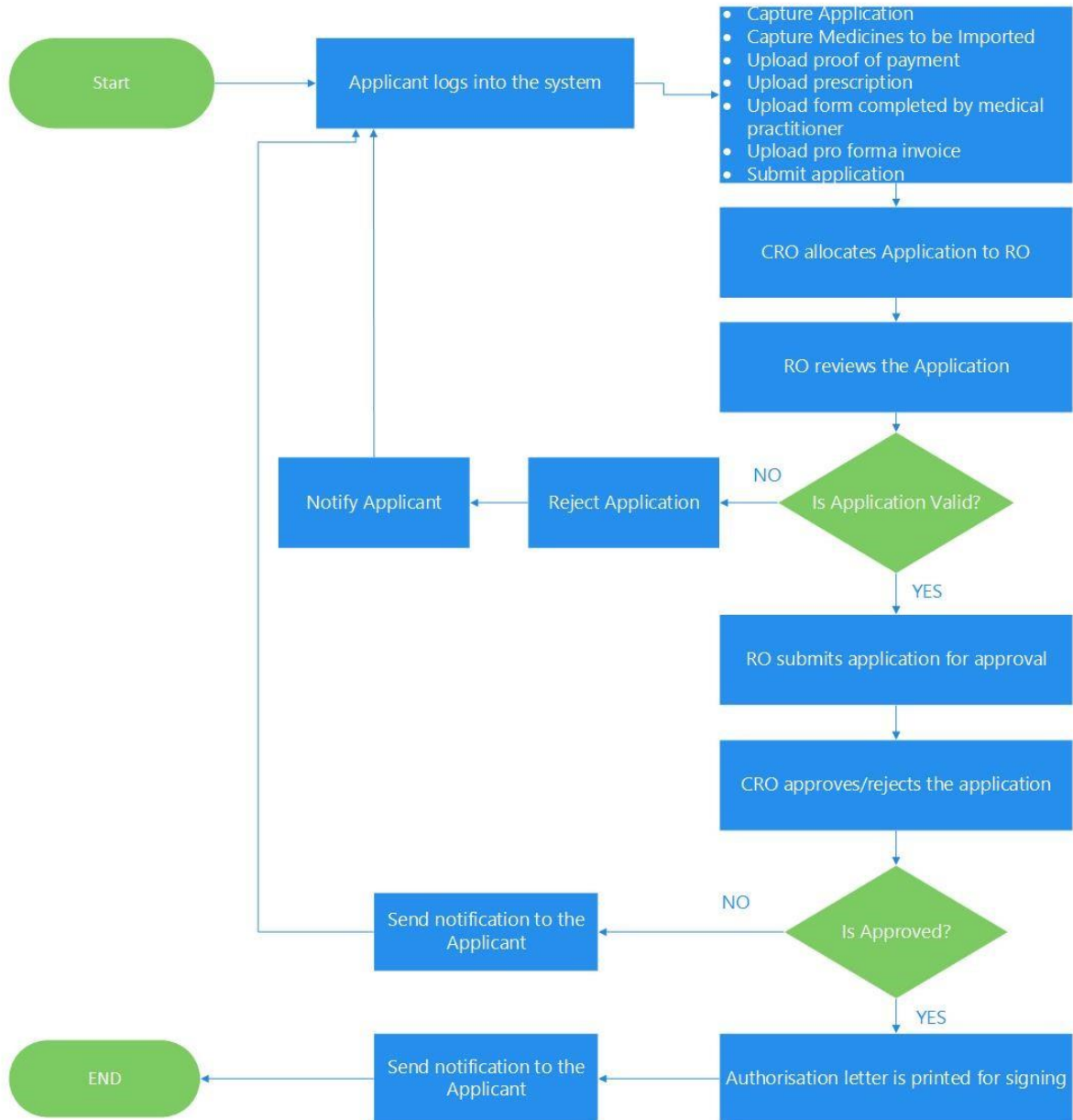


Medicines Control Authority of Zimbabwe

iii. Application for Bulk

The following chart shows the process flow for Application for Institutions process

application process for I/E of UM bulk



To apply for this type of authorisation while on the Section 75 dashboard, click the “Application for Bulk” icon. This is shown in the diagram below

The screenshot shows the MCAZ Section 75 Dashboard. The top navigation bar includes the MCAZ logo and the text 'Medicines Control Authority of Zimbabwe'. Below the navigation bar, there is a 'File' dropdown menu and a 'Medicines I/E' dropdown menu. The user is logged in as 'SG JURU' on '30-July-2019 5:03:40'. The dashboard is titled 'Section 75 Dashboard' and features a grid of application icons. The 'Application for Bulk' icon is circled in red. The grid includes icons for 'Application for Prescription', 'Application for Institutions', 'Applications for Prescription (Capturing)', 'Applications for Prescription (Pending Review)', 'Applications for Prescription (Approved)', 'Applications for Prescription (Rejected)', 'Applications for Institutions (Capturing)', 'Applications for Institutions (Pending)', 'Applications for Institutions (Approved)', 'Applications for Institutions (Rejected)', 'Applications for Bulk Importation (Capturing)', 'Applications for Bulk Importation (Pending)', 'Applications for Bulk Importation (Approved)', and 'Applications for Bulk Importation (Rejected)'. A 'Tasks' and 'Messages' tab is visible, with the 'Messages' tab active, showing 'No records to display.' The footer of the dashboard states 'Application designed and maintained by Medicines Control Authority of Zimbabwe 2019'.

This will take you to the “Request for Authority to Import Unregistered Medicines for Bulk” page. Fill in the required information and click “Save”. Note that you cannot change the Application Fees field.

The screenshot shows the 'REQUEST FOR AUTHORITY TO IMPORT AN UNREGISTERED MEDICINES FOR BULK' form. The form is titled 'REQUEST FOR AUTHORITY TO IMPORT AN UNREGISTERED MEDICINES FOR BULK' and has an 'Application Status' of 'Capturing'. The form includes the following fields: 'Importer' (Select Importer/Exporter), 'Mode Of Transport' (Select Mode Of Transport), 'Approximate date of arrival' (text input), 'Supplier' (Select Supplier), 'Port Of Entry' (Select Port Of Entry), and 'Application Fees' (text input with a value of '\$40.00'). The 'Save' button is circled in red. Below the form, there is a section titled 'UNREGISTERED MEDICINES TO BE IMPORTED' with a table structure.

After saving you will now be able to add medicines. Click the “Add Medicines” Button to add your medicines as shown below

Applications loaded successfully.

MCAZ Medicines Control Authority of Zimbabwe

Logged into MCAZ Online Services as SG JURU 30-July-2019 5:39:01 Logout

File Medicines I/E

REQUEST FOR AUTHORITY TO IMPORT AN UNREGISTERED MEDICINES FOR BULK

Application No: APP-SEC75-BULK-2019-00003 Application Status: Capturing

Importer: PHARMACEUTICALS OF ZIMBABWE Supplier: NITON PHARMACEUTICALS

Mode Of Transport: Road Port Of Entry: BEITBRIDGE BORDER POST

Approximate date of arrival: 31/Jul/2019 Application Fees: \$40.00

Save

UNREGISTERED MEDICINES TO BE IMPORTED

+Add Medicines

Drag a column header and drop it here to group by that column

Brand Name	Generic Name	Strength	Manufacturer	Total Quantity	CostOfConsignment
There are no medicines to display					

Application designed and maintained by Medicines Control Authority of Zimbabwe 2019

The popup to add medicines will be shown where you must add all the medicines that need to be imported. Click “Save” to add each drug that you want, then click “Close” to close the popup and return to your application. This is shown below

Capture Medicines

UNREGISTERED MEDICINES TO BE IMPORTED

Drug: Select Medicines Manufacturer: Select Manufacturer

Total Cost: Quantity:

Pack Size: Select Pack Size +New Packsize

Save Close

SelectMedicinesSecBulkApplication.aspx?type=add&appid=3

When you are returned to the main application page, you can now upload your supporting documents. These are the Pro Forma invoice and Proof of Payment. To do this click the “Upload Supporting Documents” button that will now be visible next to the “Save” button as shown below

REQUEST FOR AUTHORITY TO IMPORT AN UNREGISTERED MEDICINES FOR BULK

Application No: APP-SEC75-BULK-2019-00002 Application Status: Capturing

Importer: MARK ROBERTSON & COMPANY (PVT) LTD Supplier: APOTHECARY PRODUCTS (PVT) LTD

Mode Of Transport: Air-Freight Port Of Entry: R.G.MEDICINE INTERNATIONAL AIRP

Approximate date of arrival: 31/Jul/2019 Application Fees: \$40.00

Buttons: Save, Upload Supporting Documents (highlighted), Print Proforma Invoice

UNREGISTERED MEDICINES TO BE IMPORTED

+ Add Medicines

Drag a column header and drop it here to group by that column

Brand Name	Generic Name	Strength	Manufacturer	Total Quantity	CostOfConsignment
Teating Sec	TELEMOPTAN	1 mg		56 8	
Teating Sec	TELEMOPTAN	12mg		45678	

The page to upload supporting documents will popup. To upload the specific documents you need, select the appropriate document in the “Document Type” dropdown list. Then click the “Select” button to retrieve the document from your device. After you have selected the appropriate document from your device, click the “Upload File” button to upload the document. Repeat this procedure for all types of documents. This is depicted below

UPLOAD SUPPORTING DOCUMENTS

- Allowed file types: .jpg, .jpeg, .png, .gif, .pdf, .doc, .docx
- Size limit: *1 MB

Document Type: Sec Bulk Profoma Invoice (dropdown menu open showing options: Sec Bulk Profoma Invoice, Sec Bulk Proof Of Payment)

Select Document: [Text Input] [Select]

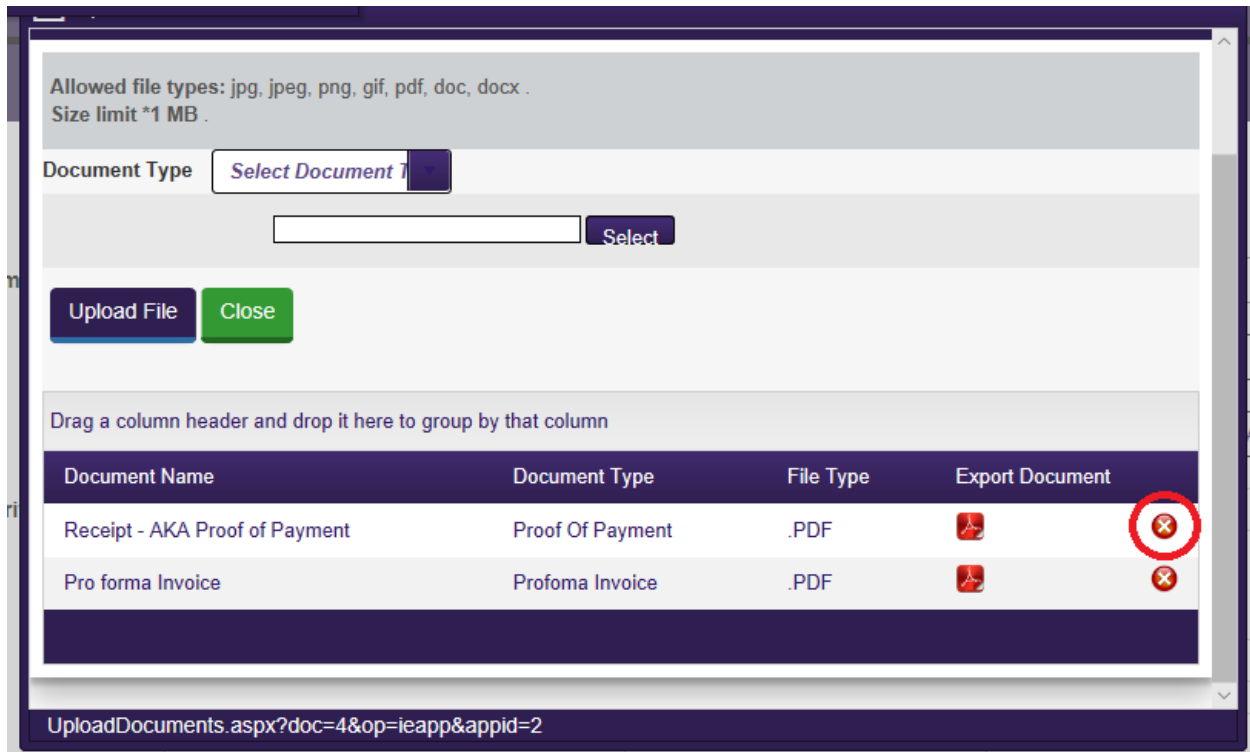
[Upload File] [Close]

Drag a column header and drop it here to group by that column

Document Name	Document Type	File Type	Export Document
No records to display.			

UploadDocuments.aspx?doc=7&op=secbulk&appid=2

All the documents you successfully upload will be listed in the grid below the “Upload File” button. If you have uploaded the wrong document, click the delete icon on the right side of each document as shown below.



Allowed file types: jpg, jpeg, png, gif, pdf, doc, docx .
Size limit *1 MB .

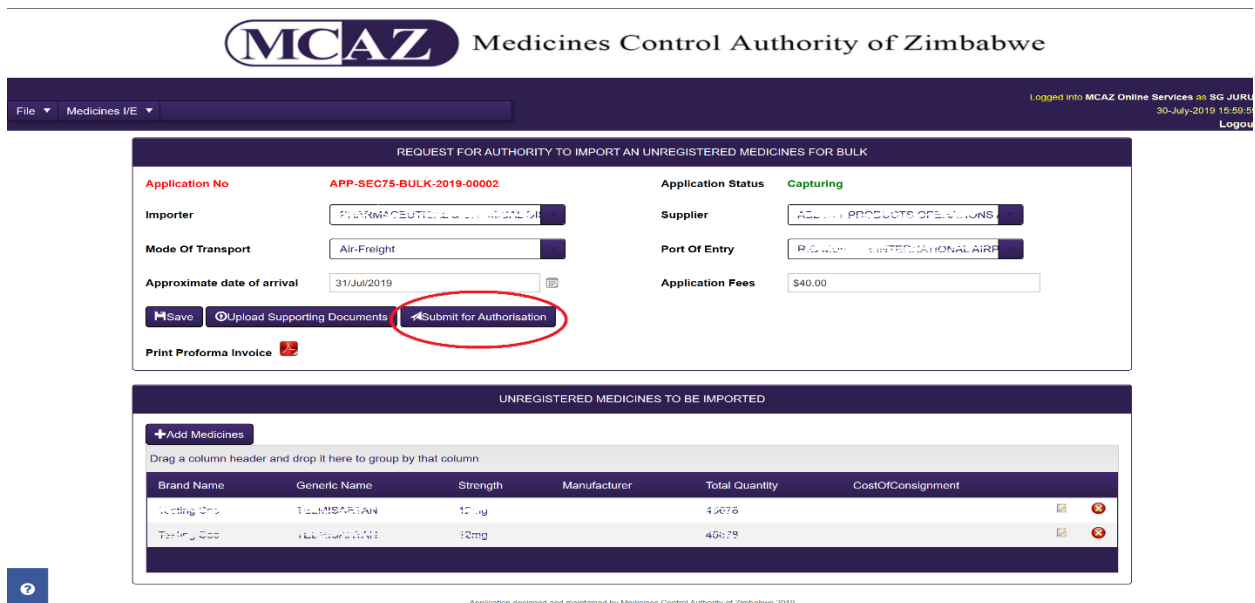
Document Type

Drag a column header and drop it here to group by that column

Document Name	Document Type	File Type	Export Document	
Receipt - AKA Proof of Payment	Proof Of Payment	.PDF		
Pro forma Invoice	Profoma Invoice	.PDF		

UploadDocuments.aspx?doc=4&op=ieapp&appid=2

Click the “Close” button once finished. If you have uploaded all required documents, the “Submit for Authorisation” button will be available. Click it to send your application for review as shown below



MCAZ Medicines Control Authority of Zimbabwe

File Medicines I/E Logged into MCAZ Online Services as SG JURU 30-July-2019 15:59:5 Logout

REQUEST FOR AUTHORITY TO IMPORT AN UNREGISTERED MEDICINES FOR BULK

Application No: APP-SEC75-BULK-2019-00002 Application Status: Capturing

Importer: PHARMACEUTICALS INTERNATIONAL Supplier: ADELPHI PRODUCTS OPERATIONS

Mode Of Transport: Air-Freight Port Of Entry: PORT OF ENTRY - LIMITED INTERNATIONAL AIRP

Approximate date of arrival: 31/Jul/2019 Application Fees: \$40.00

Print Proforma Invoice

UNREGISTERED MEDICINES TO BE IMPORTED

+Add Medicines

Drag a column header and drop it here to group by that column

Brand Name	Generic Name	Strength	Manufacturer	Total Quantity	CostOfConsignment		
Toradol Tabs	TOLUMSARICAN	10mg		40676			
Toradol Tabs	TOLUMSARICAN	12mg		40678			

Application designed and maintained by Medicines Control Authority of Zimbabwe 2019

Once your application has been approved, you will see the notification on your dashboard. This will be under the “Applications for Bulk Importation (Approved)” icon. Your application process will have been successful. If your application has been rejected, you will also get a notification under “Applications for Bulk Importation (Rejected)” icon. The reasons for rejection will also be listed. This will help you to resolve any issues that caused the rejection. Once these are rectified you can go through the application process successfully. The diagram below shows where the notifications will appear.

The screenshot displays the MCAZ Section 75 Dashboard. At the top, the MCAZ logo and name are visible. Below the header, a navigation bar shows 'File' and 'Medicines I/E'. The user is logged in as 'SG JURU' on '30-July-2019 16:10:20'. The dashboard is titled 'Section 75 Dashboard' and features a grid of 16 application status tiles. The tiles are arranged in a 4x4 grid. The tiles are: 'Application for Prescription', 'Application for Institutions', 'Application for Bulk', 'Applications for Prescription (Capturing)', 'Applications for Prescription (Pending Review)', 'Applications for Prescription (Approved)', 'Applications for Prescription (Rejected)', 'Applications for Institutions (Capturing)', 'Applications for Institutions (Pending)', 'Applications for Institutions (Approved)', 'Applications for Institutions (Rejected)', 'Applications for Bulk Importation (Capturing)', 'Applications for Bulk Importation (Pending)', 'Applications for Bulk Importation (Approved)', and 'Applications for Bulk Importation (Rejected)'. The 'Applications for Bulk Importation (Approved)' tile is circled in red. To the right of the dashboard is a 'Messages' table with columns: Subject, Notes, From, AssignedDate, DueDate, and Action Status. The table is currently empty, displaying 'No records to display.'

Subject	Notes	From	AssignedDate	DueDate	Action Status
No records to display.					