GUIDELINES ON THE VERIFICATION OF APPLICATIONS FOR THE IMPORTATION AND EXPORTATION OF DRUGS AND PHARMACEUTICAL RAW AND PACKAGING MATERIALS

National Drug Authority
Rumee Towers
Plot 19, Lumumba Avenue
P. O. Box 23096
Kampala, Uganda.
Tel: +256417788100
E-mail: ndaug@nda.or.ug
Website: http://www.nda.or.ug

Safe Drugs Save Lives

Citation

These guidelines shall be cited as the *"Professional Guidelines on the Verification of Applications for the Importation and Exportation of Drugs, Pharmaceutical Raw and Packaging Materials." Doc. No. INS/GDL/038, Revision No.:1".*

Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these "**Professional Guidelines on the Verification of Applications for the Importation and Exportation of Drugs, Pharmaceutical Raw and Packaging Materials**, Doc. No. INS/GDL/038, Revision No. 1", made this 28th day of August 2023, that take effect on 6th September 2023.

Signature

Dr. Medard Bitekyerezo
CHAIRPERSON
National Drug Authority
Kampala, Uganda

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TERMS AND DEFINITIONS

Emergency Circumstance

"Emergency circumstance" shall mean a situation of serious nature that develops suddenly and unexpectedly where -

a) The authorities in Uganda, her neighbours or supranational bodies declare a public health emergency.

b) Uganda is seriously threatened by or actually confronted with a disaster, catastrophe, war or an act of God.

c) life or the quality of life or the environment may be seriously compromised.

d) a government programme would be delayed or seriously compromised unless the drug is imported.

Extraordinary Circumstance

This shall refer to an exceptional situation that is beyond or out of common order. The following situations may be considered;

a) Use in clinical trials or field trials approved by NDA by or for patients on post-trial access programs approved by NDA.

b) A confirmed market stock-out of a drug appearing on the National Formulary, with no alternative treatment of the same clinical application and pharmacologic class on the National Formulary.

c) Over-The-Counter (OTC) drug not appearing on the National Formulary and registered within the following countries/regions: USA, Japan, the European Union, United Kingdom, Switzerland, Canada, Australia, Iceland, Liechtenstein and Norway.

d) Drugs for use in specialized medical, dental and veterinary healthcare; for which there is no alternative treatment of the same clinical application and pharmacologic class on the national formulary

e) Vaccines not appearing in the National Formulary but are required for immunizing the population against disease outbreaks in communities and farms.

f) A consignment of drugs for donation or a consignment imported by or for a government ministry, department, project or program.

Notwithstanding the provisions above, importation of unregistered drugs from countries/regions with Stringent Regulatory Authorities (SRA) i.e., USA, Japan, the European Union, United Kingdom, Switzerland, Canada, Australia, Iceland, Liechtenstein and Norway may be considered as extraordinary if;

a) there are no registered alternatives for the drug in Uganda imported from countries/regions with Stringent Regulatory Authorities (SRA) i.e., USA, Japan,

the European Union, United Kingdom, Switzerland, Canada, Australia, Iceland, Liechtenstein and Norway

b) the drug is an innovator brand not registered in Uganda.

1.0 INTRODUCTION

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and the National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs. Specific to this guideline, the National Drug Authority is charged by the Act with the control of importation, exportation and sale of pharmaceuticals.

The National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations, 2014 requires that consignments of drugs to be imported into Uganda be issued verification certificates. These verification certificates are issued by NDA after applications for the importation and exportation of drugs and pharmaceutical raw and packaging materials are received and verified through the National Drug Authority Management Information System (NDAMIS).

This guideline outlines the process of receipt, screening, billing and review of applications ; the validity of verification certificates issued, the approved ports of entry and how amendments can be made.

1.1 OBJECTIVE

The objective of this guideline is to provide the applicants for verification certificates for the importation and exportation of drugs and pharmaceutical raw and packaging materials information on what is expected of them to make and support the application for a verification certificate.

The guidelines shall also provide applicants with:

a) the requirements for application for verification certificates for the importation and exportation of drugs, pharmaceutical raw and packaging materials.

b) The approved ports of entry.

c) The validity of verification certificates issued.

d) The amendment of approved verification certificates.

1.2 POLICY

These guidelines have been developed in accordance with:

Section 5(d) of the National Drug Policy and Authority Act Cap 206, which states that "*The drug authority shall be charged with the implementation of the national drug policy and, in particular, but without derogation of the foregoing, shall—control the importation, exportation and sale of pharmaceuticals."*

Section 8(3) of the National Drug Policy and Authority Act Cap 206 which states that *"no person shall import or sell any drug unless it appears on the national formulary."*

Section 8(4) of the National Drug Policy and Authority Act Cap 206 which states that "*Notwithstanding subsection (3), a drug not appearing on the national formulary may be imported and sold after authorisation by the drug authority to meet emergency or extraordinary circumstances."*

Regulation 5(1) of the National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations, 2014, which states that *"A person shall not import narcotics drugs or psychotropics substances without a permit issued by the Authority."*

Regulation 6(1) of the National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations, 2014, which states that: *"A consignment of drugs to be imported into Uganda shall before importation, be issued with a verification certificate which shall be in the format in Form 25 in the schedule to these regulations."*

Regulation 11(1) of the National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations, 2014, which states that *"For the purposes of regulation 10, the person who re-exports drugs that are refused entry into Uganda, shall make an application for verification to the Authority and the application shall be accompanied by the relevant invoices and other documents related to the drugs including the exact point of destination of the drugs and the prescribed fees"*

Regulation 21 of the National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations, 2014, which states that *"A person shall not export drugs out of Uganda without a license issued by the Authority"*

Regulation 2(2) of National Drug Policy and Authority (Fees) Regulations, 2022 which states that *"The fees paid under these Regulations to the Authority, in respect of any activity or function are non-refundable, whether an application is successful or not."*

Part 6 of the schedule (Fees for Importation and Exportation of Drugs and Surgical Instruments and Appliances) of National Drug Policy and Authority (Fees) Regulations, 2022.

1.3 SCOPE

These guidelines apply to applications for verification certificates, received through the National Drug Authority Management Information System (NDAMIS), for the importation and exportation of drugs and pharmaceutical raw and packaging materials.

2.0 REQUIREMENT FOR AN APPLICANT FOR A VERIFICATION CERTIFICATE TO HOLD AN IMPORT/EXPORT LICENSE.

2.1. An application for a verification certificate shall be made by a person duly authorised to import/export drugs into/out of Uganda, holding a valid general import or export or a limited import or export licence.

2.2 Applications for import or export licences (both general and limited) and invoices for the prescribed fees are received and generated respectively electronically through the National Drug Authority Management Information System (NDAMIS) by licensed persons under the National Drug Policy and Authority Act Cap 206).

3.0 APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF REGISTERED DRUGS

3.1 An application for a verification certificate shall be submitted electronically through the National Drug Authority Management Information System (NDAMIS) by a person duly authorised to import (import license) drugs into Uganda.

3.2 An application for a verification certificate shall be accompanied by:

a) A copy of the proforma invoice from the supplier authorised by the local agent;

b) Donation Certificate [if the drug(s) is/are a donation]; or

c) Authorisation to carry out a medical camp [if the drug(s) is/are for a medical camp]

d) For narcotics drugs and psychotropic substances and precursors, a filled application form for the authorisation for importation of narcotic drugs and psychotropic substances.

3.3 The application shall be billed the prescribed fees, after its been screened to ascertain;

a) the correctness of the importer's details, supplier information, proforma invoice and details on the attached proforma invoice (proforma invoice number, currency, unit prices, quantities) and fees option selected.

e) the attachment of the required documents i.e., the proforma invoice, donation certificate, authorisation to carry out a medical camp and for narcotics drugs and psychotropic substances and precursors, a filled application form for the authorisation for importation of narcotic drugs and psychotropic substances.

b) Authentication of proforma invoices by the appropriate representative of the manufacturer or supplier and pharmacist-in-charge of the importing entity.

4.0 REVIEW OF AN APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF REGISTERED DRUGS

4.1 After payment of the prescribed fees, the application supported by a proforma invoice, shall be verified by reviewing the;

a) Current registration status (as per the current version of the Register) on the date of technical verification;

b) Current Good Manufacturing Practice (cGMP) compliance status of the manufacturing facility on the date of technical verification;

c) The letter of approval from NDA for variations for drugs that have just undergone variations that are not yet updated in the current version of the Register; and

d) For narcotics and psychotropic drugs and precursors the correctness of importer's details, supplier and manufacturer's information and conversions of salts to bases in the application for the permit for the importation of narcotic drugs or psychotropic substances.

e) Authorisation by the Local Technical Representative (LTR) for the drug(s)

5.0 APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF PHARMACEUTICAL RAW AND PACKAGING MATERIALS

5.1 An application for a verification certificate shall be submitted electronically through the National Drug Authority Management Information System (NDAMIS), by a person duly authorised to manufacture drugs (manufacturing license) in Uganda.

5.2 An application for a verification certificate should be accompanied by:

a) A copy of the proforma invoice from the supplier.

b) For narcotics drugs and psychotropic substances and precursors, a filled application form for the authorisation for importation of narcotic drugs and psychotropic substances.

5.3 The application shall be be billed the prescribed fees, after it's been screened to ascertain;

a) the correctness of the importer's details, supplier information, proforma invoice, details on the attached proforma invoice (proforma invoice number, currency, unit prices, quantities) and reason for import/export;

b) the attachment of required documents (proforma invoice and for narcotic drugs and psychotropic substances, a filled application form)

c) Authentication of proforma invoices by the appropriate representative of the manufacturer or supplier and pharmacist-in-charge of the importing entity.

6.0 REVIEW OF AN APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF PHARMACEUTICAL RAW AND PACKAGING MATERIALS

6.1 After payment of the prescribed fees, the application, supported by a proforma invoice, shall be verified by reviewing the;

a) Current registration status of the product the material is being imported for (as per the current version of the Register), on the date of technical verification;

b) Current Good Manufacturing Practice (cGMP) compliance status of the manufacturing facility on the date of technical verification;

c) For narcotics drugs and psychotropic substances, the correctness of importer's details, supplier and manufacturer's information and conversions of salts to bases in the application for the permit for the importation of narcotic drugs or psychotropic substances; and

d) The correctness of the prescribed fees option selected being either pharmaceutical raw materials or bulk product for primary packaging, secondary packaging for Buy Uganda Build Uganda and non-Buy Uganda Build Uganda products.

7.0 APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE EXPORTATION OF REGISTERED DRUGS

7.1 An application for a verification certificate shall be submitted electronically through the National Drug Authority Management Information System, by a person duly authorised to;

a) manufacture (manufacturing license) and export (export license) drugs out of Uganda
b) export (export license) drugs out of Uganda.

7.2 The application shall be billed the prescribed fees, after it's been screened to ascertain;

a) the correctness of the exporter's details, supplier information, proforma invoice and details on the attached invoice (proforma invoice number, currency, unit prices, quantities) and fees option selected

b) the attachment of required documents (proforma invoice, donation certificate for donations)

c) Authentication of proforma invoices by the appropriate representative of the manufacturer or supplier and pharmacist-in-charge of the exporting entity.

8.0 REVIEW OF AN APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE EXPORTATION OF REGISTERED DRUGS

8.1 After payment of the prescribed fees, the application supported by proforma invoice shall be verified by reviewing the:

a) Current registration status (as per the current version of the register) on the date of technical verification;

b) Current Good Manufacturing Practice (cGMP) compliance status of the manufacturing facility on the date of technical verification;

c) Variation approval from NDA for variations for drugs that have just undergone variations that are not yet updated in the current version of the Register; and

d) Certificates of Analysis for each batch/lot

e) For purposes of re-export of drugs (export of drugs not manufactured in Uganda), a copy of the Imported Goods Authorisation Report issued by NDA at the Port of Entry into Uganda.

f) For purposes of the re-export of drugs that have not been allowed into Uganda, supporting documents including written communication from the Director Inspectorate & Enforcement/Chief Inspector of Drugs concluding/closing outstanding issues, import permit issued by the competent authority in the destination country.

9.0 APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE EXPORTATION OF PHARMACEUTICAL RAW AND PACKAGING MATERIALS

9.1 An application for a verification certificate, shall be submitted electronically through the National Drug Authority Management Information System, by a person duly authorised to manufacture pharmaceutical raw and packaging materials in Uganda.

9.2 The application shall be billed the prescribed fees, after it's been screened to ascertain;

a) the correctness of the exporter's details, supplier information, proforma invoice and details on the attached invoice (proforma invoice number, currency, unit prices, quantities) and import/export reason

b) the attachment of certificates of analysis for each batch/lot of the materials

c) Attachment of documents attesting to the compliance status of Compliance status of the manufacturing facility to international best practices

d) the attachment of required documents (proforma invoice, certificates of analysis/test reports, compliance certificates)

e) Authentication of proforma invoices by the appropriate representative of the manufacturer or supplier and pharmacist-in-charge of the exporting entity.

10.0 REVIEW OF AN APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE EXPORTATION OF PHARMACEUTICAL RAW AND PACKAGING MATERIALS

10.1 After the payment of the prescribed fees, the application supported by a proforma invoice shall be verified by reviewing the;

a) Compliance status of the manufacturing facility to international best practices on the date of technical verification.

b) Certificate of Analysis for each batch/lot of the materials

11.0 APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF DRUGS UNDER EMERGENCY OR EXTRA-ORDINARY CIRCUMSTANCES

11.1 An application for a verification certificate shall be submitted electronically through the National Drug Authority Management Information System (NDAMIS) by a person duly authorized to import (Import License) drugs into Uganda.

11.2 An application for a verification certificate should be accompanied by:

a) A copy of the proforma invoice from the supplier.

b) Donation Certificate for donated drugs.

c) Authorization to conduct a medical camp for drugs to be used in a medical camp

d) Evidence of cGMP compliance of the manufacturer. The manufacturer should have GMP certification issued by either NDA, the National Medicnes

Regulatory Authorities of the following countries/regions: USA, the European Union, United Kingdom, Switzerland, Canada, Australia, Iceland, Liechtenstein and Norway or prequalified by the World Health Organisation.

e) Documented evidence/justification describing the emergency or extraordinary circumstance. (refer to Terms and Definitions)

f) For narcotics drugs and psychotropic substances and precursors, a filled application form for the authorisation for importation of narcotic drugs and psychotropic substances.

g) Clinical Trial Certificate for drugs for use in clinical trials

h) Evidence of registration of the drug(s) in the country of origin or emergency use approval of the drug by the competent authority in the country of origin, by a supranational body and any other regulatory authority if not registered

11.3 The application shall be billed the prescribed fees after being /screened to ascertain;

a) the correctness of the importer's details, supplier information, proforma invoice, details on the attached proforma invoice (proforma invoice number, currency, unit prices, quantities) and selection of prescribed fees;

b) the attachment of the required documents (proforma invoice, donation certificates for donated drugs, justification / evidence supporting the application whilst the considering the terms and definitions of emergency and extraordinary circumstance in this document, GMP certificates, Clinical Trial Certificates drugs for clinical trials , Certificates of Registration in the country of origin, Emergency Use Approvals in the country of origin, any other regulatory Authority or by supranational bodies such as the World Health Organization).

12.0 REVIEW OF AN APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF DRUGS UNDER EMERGENCY OR EXTRAORDINARY CIRCUMSTANCES

12.1 After payment of the prescribed fees, the application, supported a by proforma invoice, shall be verified by reviewing the;

a) Current Good Manufacturing Practice (cGMP) compliance status of the manufacturing facility on the date of technical verification. The GMP certification shall be issued by either NDA, the National Medicines Regulatory Authorities of the following countries/regions: USA, the European Union, United Kingdom, Switzerland, Canada, Australia, Iceland, Liechtenstein and Norway or prequalified by the World Health Organisation;

b) the authenticity and relevance of the required documents (proforma invoice, donation certificates for donated drugs, justification / evidence supporting the application whilst the considering the terms and definitions of emergency

and extraordinary circumstance in this document, GMP certificates, Clinical Trial Certificates drugs for clinical trials, Certificates of Registration in the country of origin, Emergency Use Approvals in the country of origin, any other regulatory Authority or by supranational bodies such as the World Health Organization).

c) For narcotics drugs and psychotropic substances, the correctness of importer's details, supplier and manufacturer's information and conversions of salts to bases in the application for the permit for the importation of narcotic drugs or psychotropic substances.

13.0 APPROVED SOURCES FOR THE IMPORTATION OF DRUGS UNDER EMERGENCY OR EXTRAORDINARY CIRCUMSTANCES

13.1 The drugs shall be sourced from:

a) manufacturers that are inspected and approved by National Drug Authority for compliance to current Good Manufacturing Practices, or

b) manufacturers that are inspected and approved for compliance to current Good Manufacturing Practices by National Medicines Regulatory Authorities (NMRAs) of the following countries/regions: USA, Japan, The European Union, United Kingdom, Switzerland, Canada, Australia, Iceland, Liechtenstein and Norway.

c) sources prequalified by World Health Organization.

13.2 Notwithstanding the provisions of 11.0, 12.0 and 13.0 above, National Drug Authority shall reserve the right to perform due diligence and grant or decline importation requests in consideration of safety, efficacy and quality; and in consideration of new information about drug products that may arise from time to time.

14.0 VALIDITY OF A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF DRUGS UNDER EMERGENCY OR EXTRAORDINARY CIRCUMSTANCES

14.1 Upon successful application, a verification certificate shall be issued.

14.2 The verification certificate shall be valid for a period of 12 months from the date of issue.

15.0 PORTS OF ENTRY

15.1 The importation of all consignments of drugs should be done through the approved ports of entry, which are:

a) Entebbe International Airport

b) Malaba One Stop Border Post

c) Busia One Stop Border Post

d) Nakawa

16.0 CONDITIONS FOR AMENDMENT OR REPLACEMENT OF VERIFICATION CERTIFICATE

Note: A used verification certificate whether fully or partially exhausted, may be amended. Other than the submission of a police letter reporting loss, there are no other conditions whatsoever that a certificate maybe amended if the applicant doesn't submit the original copy of the verification certificate issued. If the applicant is unable to provide the original copy, they will be required to re-apply for the issuance of another verification certificate.

16. 1 If an applicant has misplaced the original verification certificate, hasn't fully utilized it at the time of expiry, errored during the application process or any other justifiable cause, wishes to amend or replace an approved or issued verification certificate, he/she may submit any such request, in writing, to the Director Inspectorate and Enforcement/Chief Inspector of Drugs. The letter should state the area(s) the applicant wants amended.

REFERENCES

National Drug Policy and Authority (Fees) Regulations 2022

The National Drug Policy and Authority Act, Cap. 206

National Drug Policy and Authority (Importation and Exportation of Drugs Regulations), 2014

APPENDIX 1: USER MANUAL FOR NDAMIS APPLICATION FOR A VERIFICATION CERTIFICATE

Stepwise guide for making an online application for Verification Certificate in NDAMIS

1. Type portal.nda.or.ug in your browser and a page will be displayed as below. Then click "*APPLY ONLINE*".

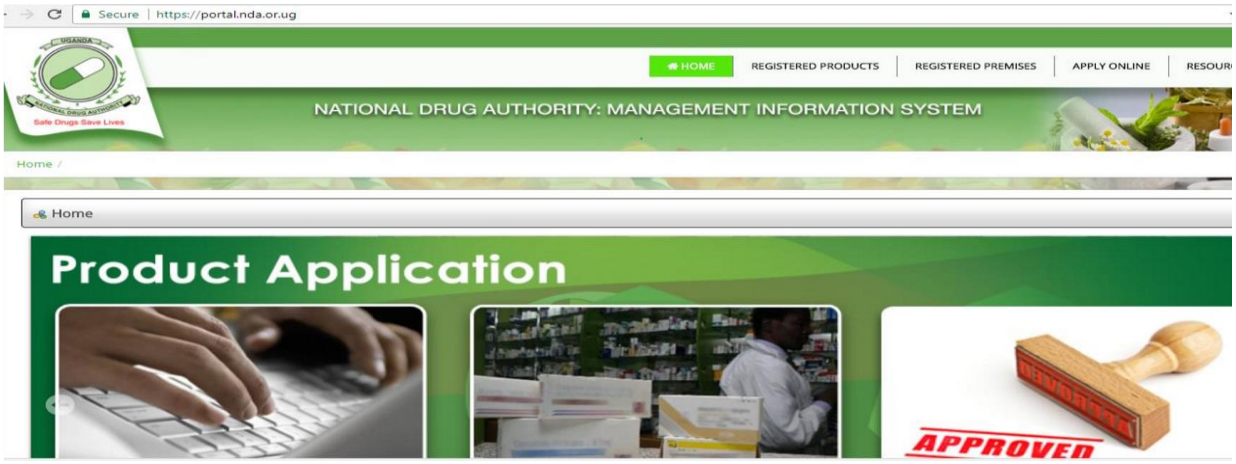

Figure 1: **ONLINE APPLICATION PAGE**

Input your User Credentials and Click on the *"Login"* tab. **Always uncheck "*Remember me*"** whenever logging in. *Avoid sharing your user credentials.*

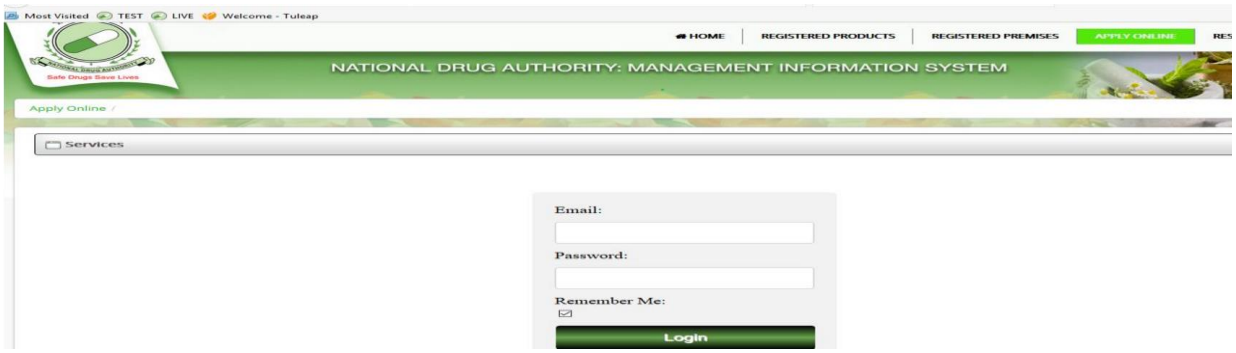

Figure 2: **INPUT LOGIN PAGE**

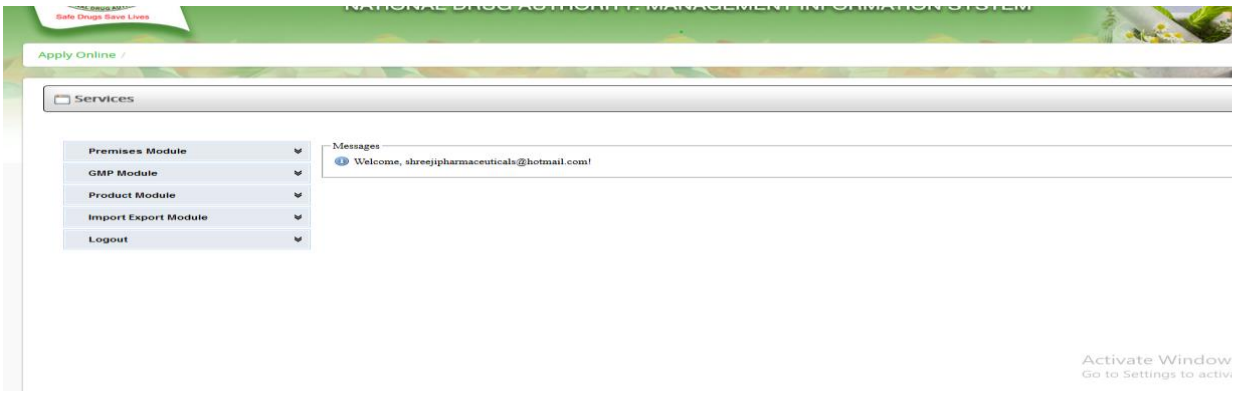

Figure 3: **SCREENSHOT SHOWING SUCCESSFULLY LOGIN**

2. On logging in, click on "*Import and Export Module*", then "*Certificate Application"*. Choose *"New Application*" and a page such as the one below will be displayed for you to input your application details.

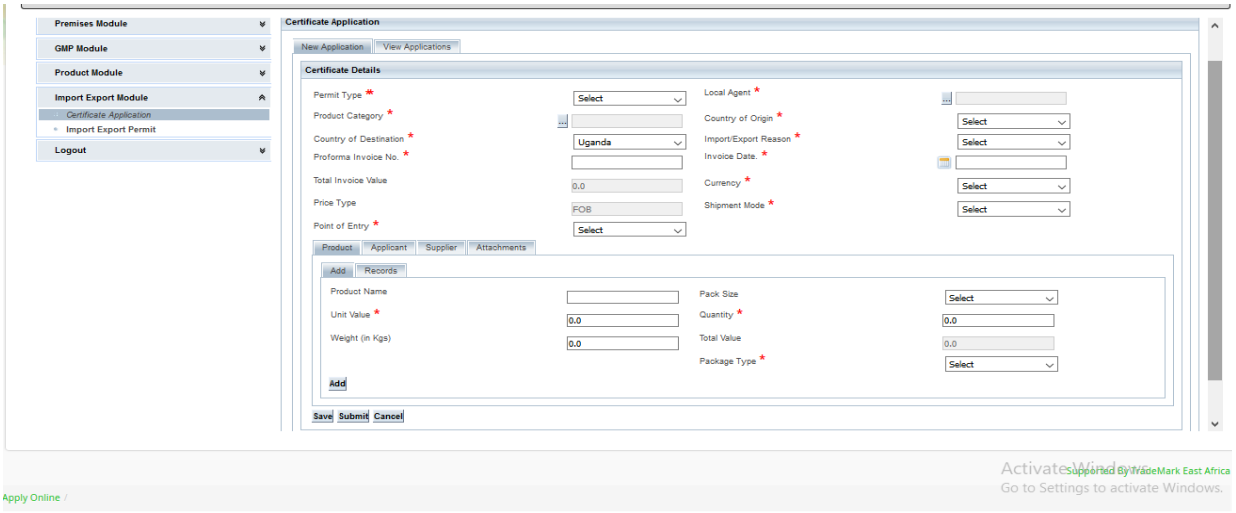

Figure 4: **IMPORT/EXPORT APPLICATION PAGE**

3. Click on the drop-down to select the appropriate "*Permit type*" depending on what type of import or export application you intend to make. For example; "*Import Verification Certificate*" for importation of registered products; "*Export Verification Certificate*" for exports of registered products; "*Special Case Import/Export Verification certificate"* for medical devices, unregistered products and donations of unregistered drugs, drugs for clinical or field trials, "*Raw material import Verification Certificate*" for importation of raw materials for registered products, etc.

4. To input details of local agent, click the green tab next to "*Local agent*" **Then type in the first letter of the premise name and select premise category**, then click

on search. Select the premise which is applying for importation (as displayed in the screen short below) or press cancel to go to the previous screen.

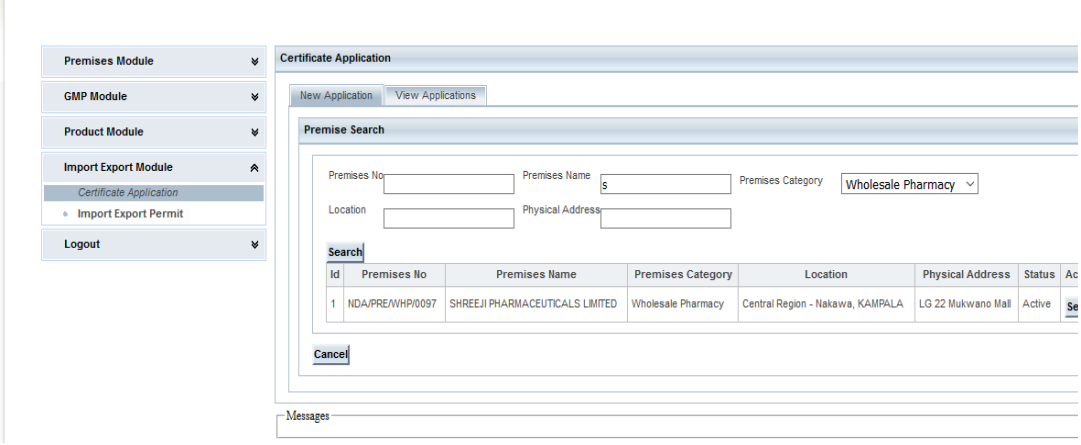

Figure 5: **SELECTING THE LOCAL AGENT/ PREMISE**

Note:

i. Before applying for a verification certificate, ensure that your premises are active*, (i.e. you must be licensed for that year in case it is a pharmacy, external store or medical device and for institutions you must also apply for renewal and be approved to transact any business in that year*) and after you can apply to have an Annual import / export permit or A provisional Import /export permit.

ii. "*Local agent*" refers to the Local Technical Representative of the product in Uganda, for the case of registered products or the Institution / Premise that is importing.

iii. Local agent or applicants who are not licensed to import or export with either an annual permit or a provisional import/export permit will not proceed when they select their details under "*Local agent*". The system will display an error reading "*No valid licence found*".

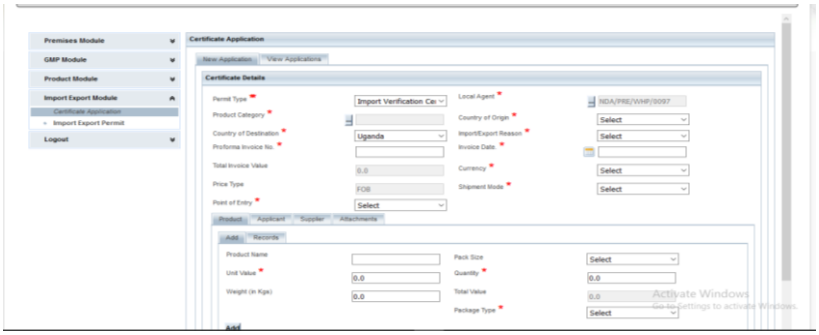

Figure 6: **SELECTED PERMIT TYPE AND PREMISE**

5. To select product category, click on the dotted button (…) to search if u are looking for a drug or medical device as seen on the screenshot below:

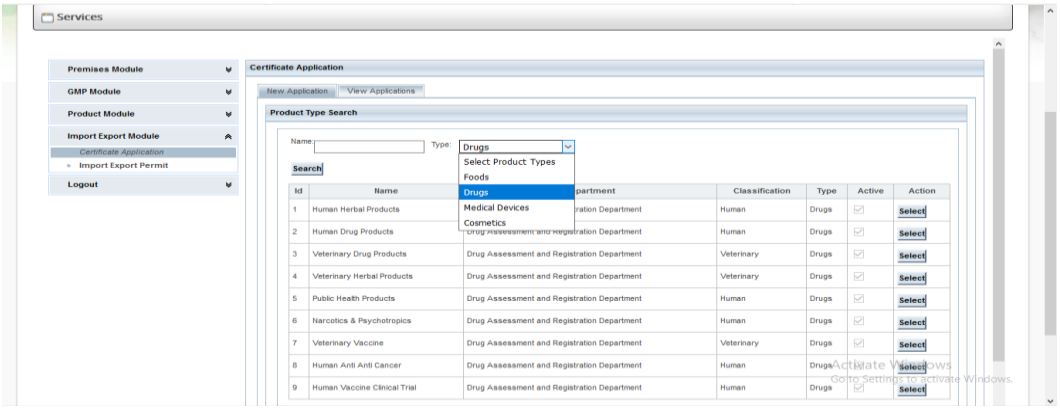

Figure 7: **SELECTING THE PRODUCT CATEGORY I.E DRUGS OR MEDICAL DEVICES**

6. Click on the drop-down under “type” and click on Drugs or Medical devices to select and click the Search icon. Select the correct type of product depending on your import. For example: If you intend to import human drugs, go to the drop down and click on Drugs and then click search button and select Human Drug Products.
7. Country of Origin refers to the country where the drugs or goods are coming from. To select, click on the drop-down arrow, scroll to the correct country and select by clicking on it.
8. Select *“Import/Export Reason”* by clicking on the drop-down and select the corresponding reason by clicking on it. For example;
    i. Commercial, if you are importing for business i.e. 2%.
    ii. Exempted, if you are exporting, importing vaccines for both human and veterinary use, importing pharmaceutical raw and packaging materials and importing human anti-cancer drugs.
    iii. Donations, choose “*Donation below 1000 USD*” or “*Donations below 5000 USD*” or “*Donations above 5000 USD*” depending on the total invoice value.
9. Enter the *“Proforma Invoice number”* and *“Invoice Date”* as indicated on the Proforma invoice in the respective entry fields.

Note: Total invoice value is auto-generated by the system as the products are entered and added.

10. Choose *"Currency"* by clicking on the drop-down list for that tab and click on the correct currency type as indicated on the Proforma invoice i.e. USD, UGX, and POUNDS etc.
11. Still using the drop-down lists on the respective areas, choose the *"Point of Entry"* and the corresponding *"Shipment Mode".*
12. To enter products, click on the tab for *"Product"* and enter required information. As shown in the screen short below

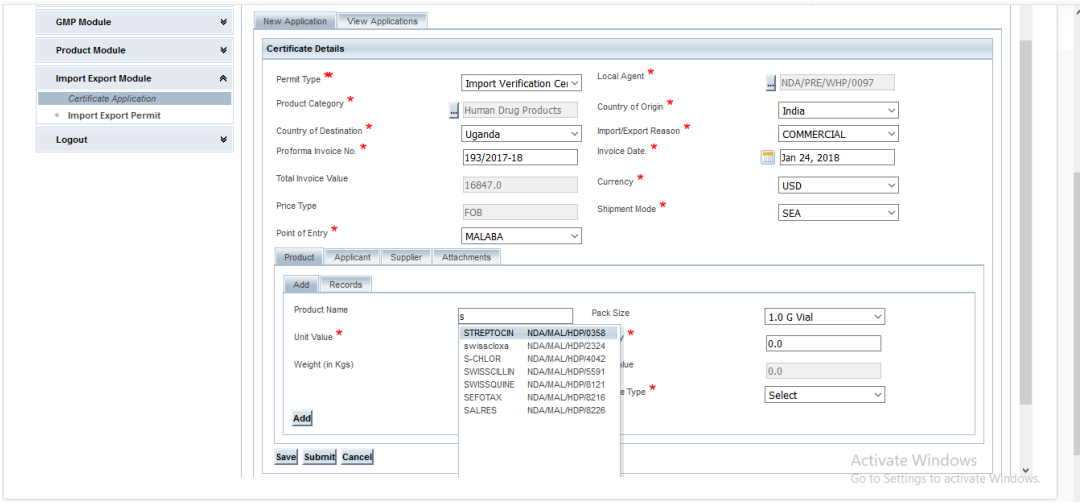

Figure 8: **SEARCHING FOR THE REGISTRED PRODUCT ON THE REGISTER**

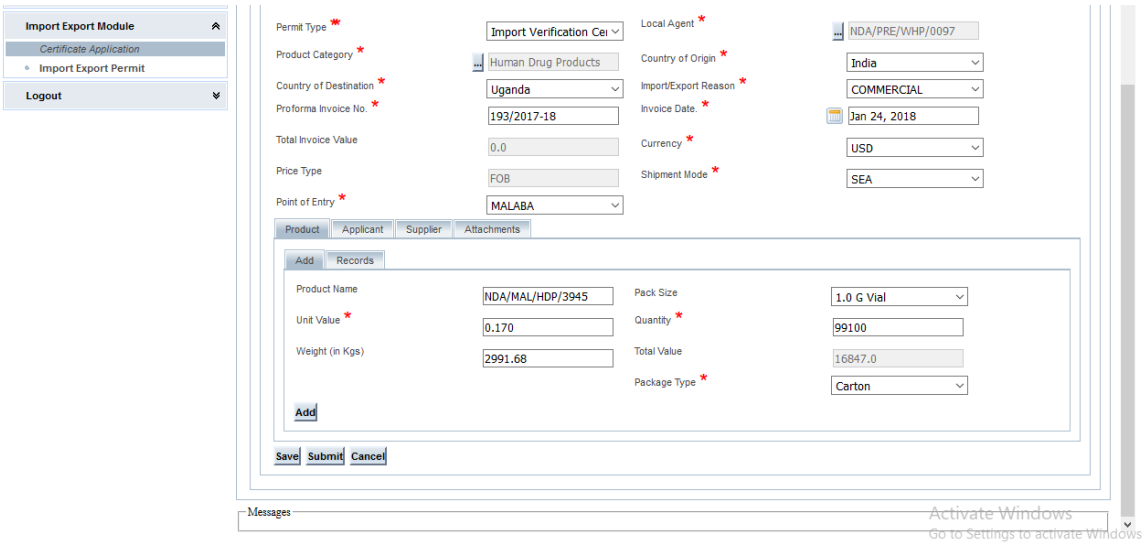

Figure 9: **IMPORT VERIFICATION APPLICATION (FOR REGISTURED DRUGS)**

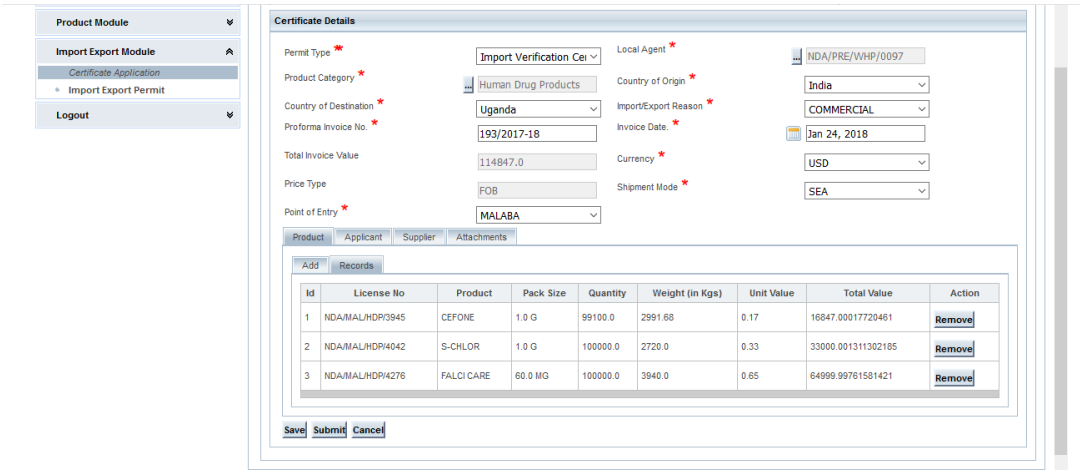

Figure 10: **ADDING THE SELECTED REGISTERED PRODUCTS**

13. Note that:
    i. The drug product will not be added unless all fields marked with an asterisk have been filled.
    ii. **Ensure that you input the weight of each product that you add**
    iii. For a correct Total Invoice Value to be generated, the Unit value entry has to precede the Quantity entry i.e. (Enter the Product name, pack size, unit value, quantity, weight, and package type …**in that order**). Please ensure that the Total invoice value indicated in the field corresponds to the value on the **PROFORMA INVOICE**.

Note: APPLICATION FOR IMPORTATION / EXPORTATION OF AN UN-REGISTURED DRUG OR MEDICAL DEVICE

i. The application type of the certificate should be Special Case Import Verification or Special Case Export Verification.
ii. The same procedure of Import Verification will be followed after the selection of the **Special Case Import /Export Verification**
iii. When it comes to adding the product, type the brand name of the product, then proceed to the manufacturer details. In case it's the first time you are importing from that manufacturer, click new and the screenshot below will be displayed. Type in the name of the manufacturer, select either large or small scale, select whether the industry deals in finished or API Products, select the country of the manufacturer, type the postal address, location, and physical address of the manufacturer, click on the Telephone details tab, select the telephone type and type the telephone number and click ADD. Do the same for the Email details tab. After filling

in the details click **Add Manufacturer.** This will add the manufacturer to your product details and will take you to another screen.

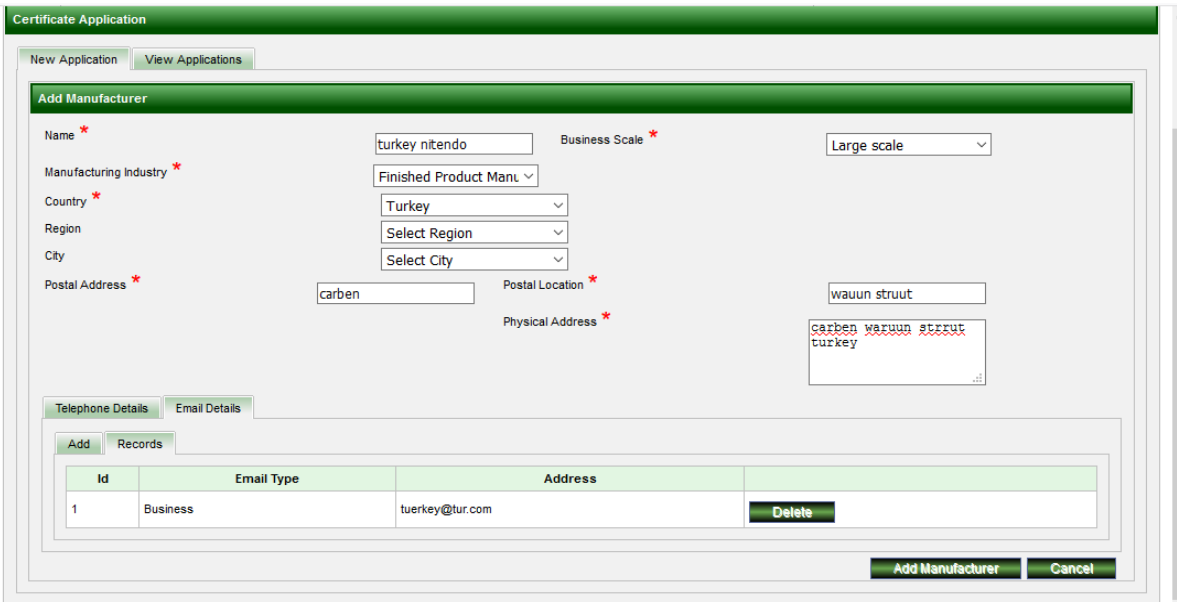

Figure 11: **ATTACHING MANUFACTURER DETAILS TO THE PRODUCT**

iv. After adding the manufacturer, input all the details as displayed in the screenshot below i.e. (Generic name of the Product, Description, Unit Value, Quantity, Weight in Kg's, Package Type …**Strictly In that Order**), as shown below,

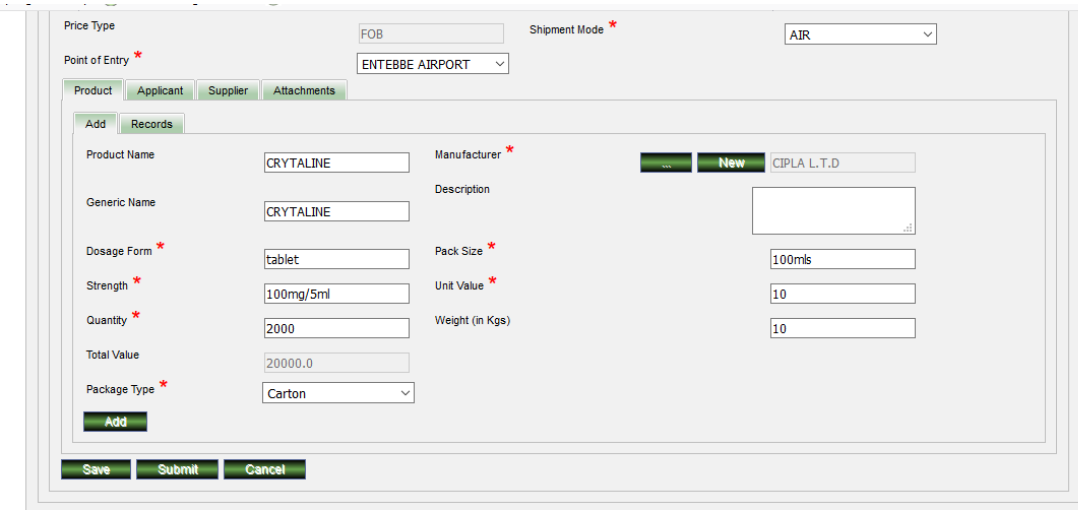

Figure 12: **ADDING UN-REGISTERED PRODUCT DETAILS**

v. then click **Add**, check under records and the product will be added as shown below

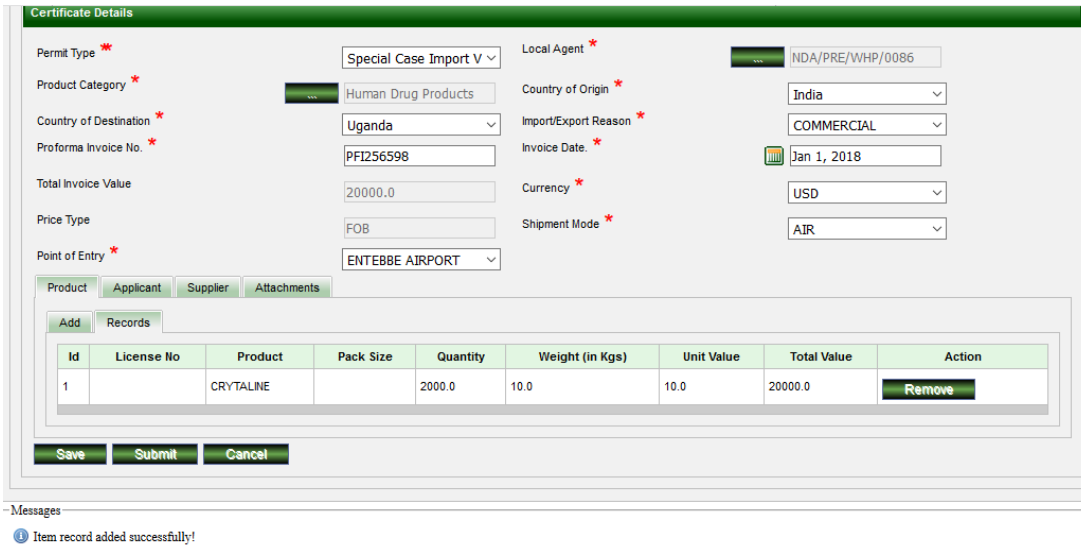

Figure 13: **ADDING THE UN-REGISTERED PRODUCT DETAILS ON THE APPLICATION**

Note: In case you have more than one product on the Proforma Invoice with the same manufacturer details, first add one product, complete the whole application by filling in the supplier details and attaching the Proforma Invoice, then submit the application. After that, click on view applications search for the application you have input and click edit, then you can add the other products by only searching the manufacturer details. In this case you click the dotted search button **(…)**, type the manufacturers name that you in put at first and click search, you will be able to select the manufacturer you input. as shown below

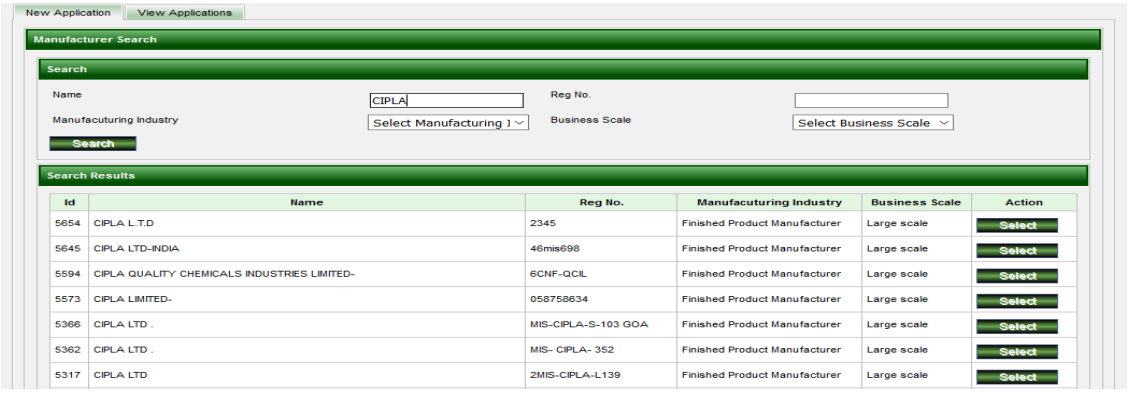

Figure 14: **SEARCHING FOR THE MANUFACTURER**

14. After every complete product entry, click on *"Add"* tab to save product entry. To delete a product entry, click on *"Records"* and then click *"Remove"* against the product you intend to remove. You will then be asked to confirm the removal for which you click *"yes"* to confirm.

15. Enter the details of the **Applicant (If and only if the Local Agent / Premise Importing / Exporting is different from the Applicant and you are Importing Registered Drug Products)**. This is done by clicking on the *"Applicant"* tab and filling in all the necessary fields. i.e. as seen in the screenshots below. Always ensure you input the Right **Tin Number**

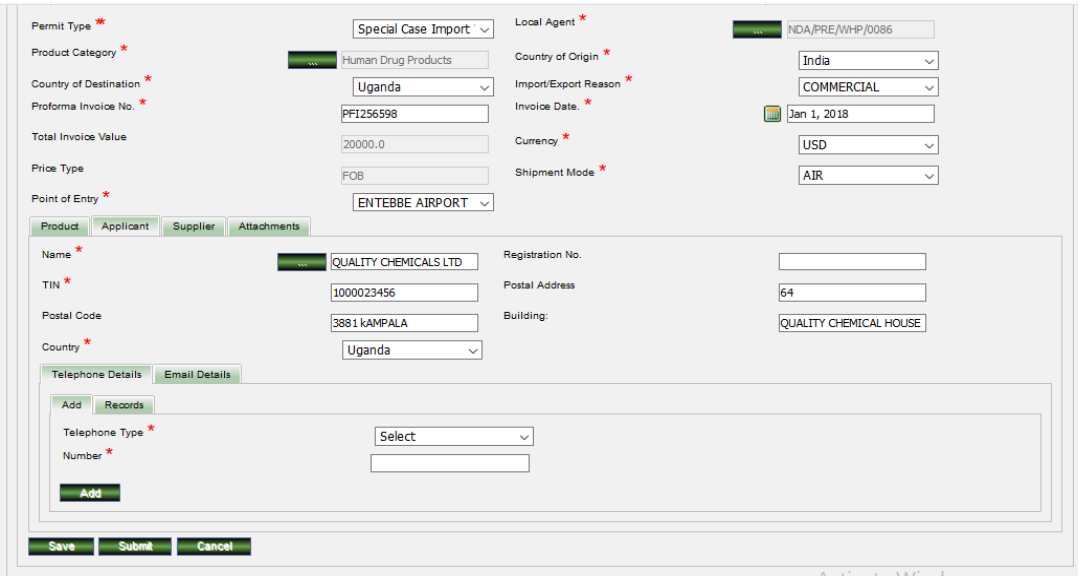

Figure 15: **LOCAL AGENT DIFFERENT FROM APPLICANT DETAILS. THIS ONLY APPLIES WHEN IMPORTING REGISTRED PRODUCTS**

16. Click on **Supplier tab** and enter the details of supplier as they appear on the Proforma invoice as seen in the screen short below. In case it's not the first time you are in putting the supplier details on the system, you don't have to input fresh details, just search with the dotted search button for the supplier **(…)**. In put the name and then select the searched supplier

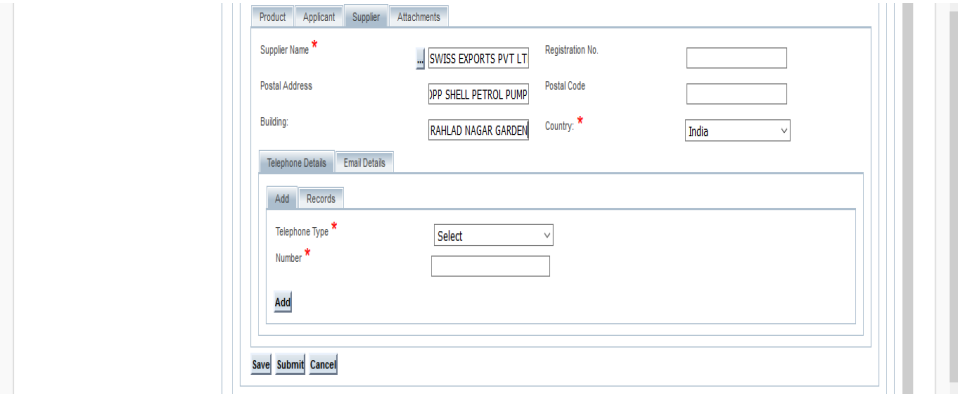

Figure 16: **SUPPLIER DETAILS. ENSURE YOU INPUT THE EMAIL AND PHONE NUMBER AS WELL**

17. Finally, make the necessary attachments. Click on the *"Attachments"* tab, select attachment type by clicking on the drop-down list of the *"attachment type"* and click on the respective attachment. Then, click on the ***"+Add"*** to browse for the intended attachment and click on open, and then on the green *"Add"* button for the addition of the attachment. Ensure you attach all the documentation that you feel will be needed by the verification team to avoid any quarries to do with documentation.

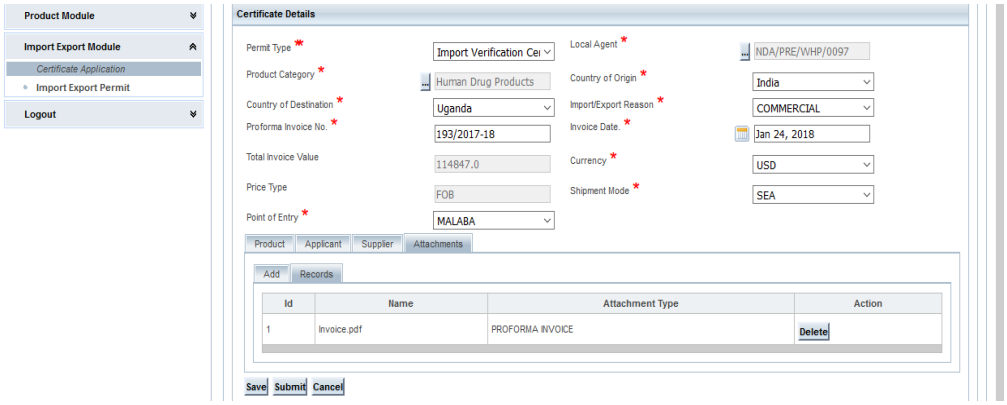

Figure 17: **PROFORMA INVOICE ATTACHEMNTS**

18. Once you are satisfied with all the information entered, click on the *"Submit"* button at the bottom of the page and the application will be received by NDA. You will see a pop-up message on the screen indicating that your application has successfully been submitted. (As shown in the screenshot below). You may as well save your application in case it's not complete. But it can only be saved if the supplier and at least one of the product details are filled in.

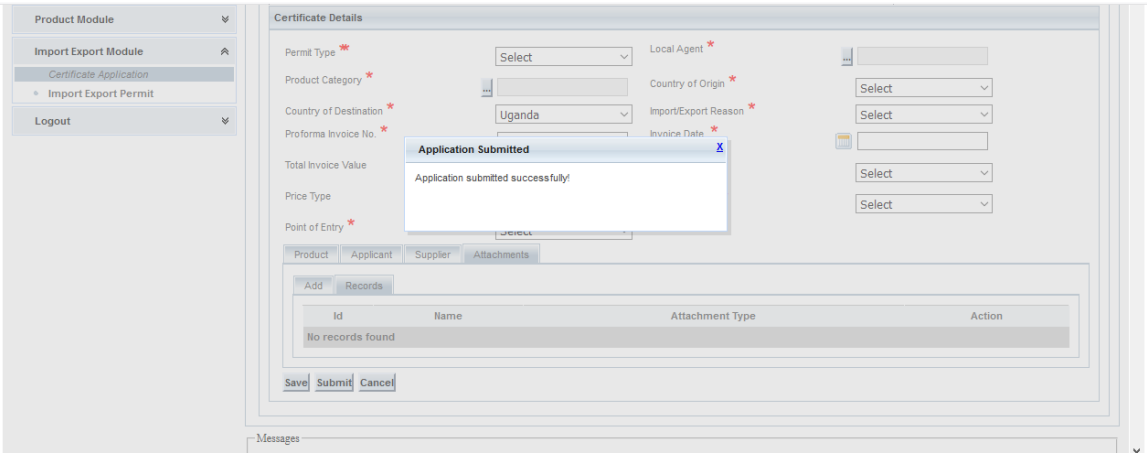

Figure 18: **SUBMITTED APPLICATION**

19. Once the application has been captured/submitted, you can be able to view it, and its status will be *"Pending verification"*. To view application, click on *"Certificate application"* and then on *"View Application"* which will lead you to a screenshot such as the one below. Record the application number received by email with which you can continue to track the progress of the application.

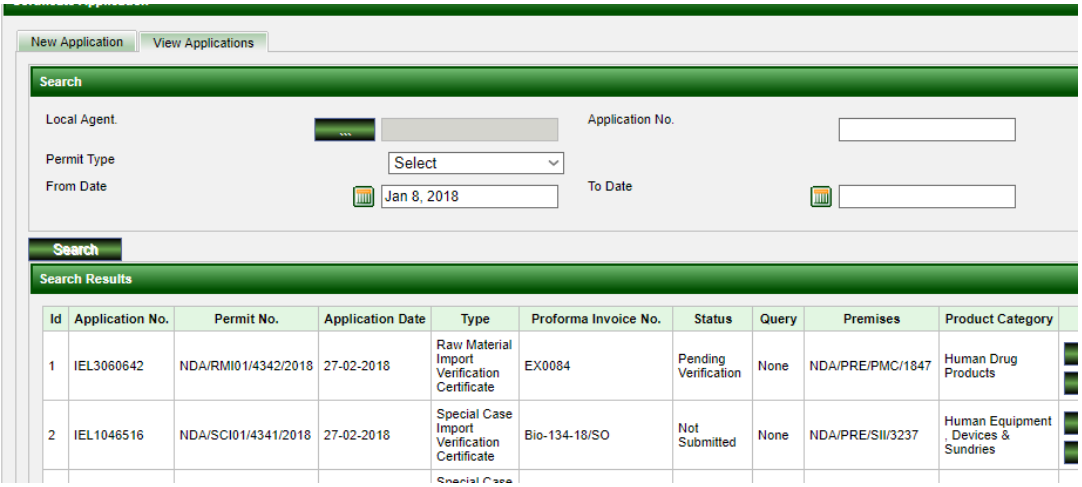

Figure 19: **VIEWING AN APPLICATION**

20. Select *"from date"* by clicking on calendar icon and choosing date depending on when the application was made, then click the *"Search"* button at which point you can see application details. To view the more detailed specifics of the application, click on the *"View"* button under the "Action" column. After seeing the status of your application, you may select "Cancel review" to exit.

21. In case you are queried, search for the application and it will have options of Edit and view under Action. As shown in the screen short below.

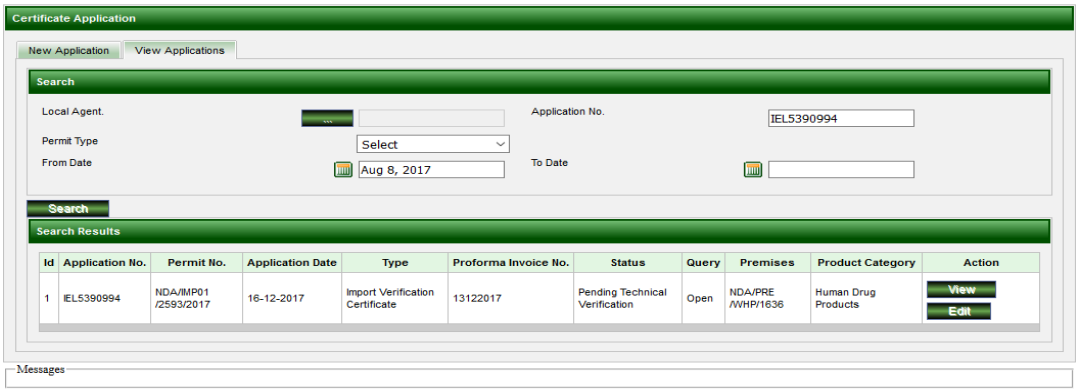

Figure 20: **VIEWING A QUERRIED APPLICATION**

22. To view the query, click “View” under the “Action column, click on query response as seen in the screen short below:

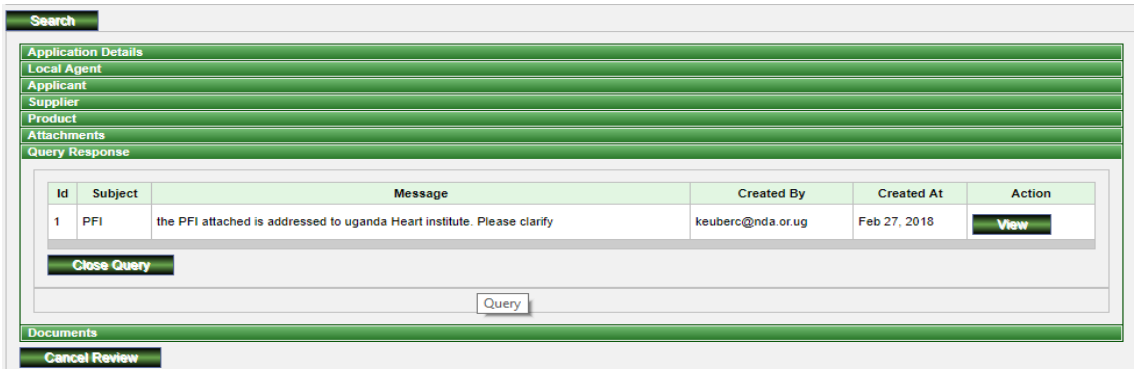

Figure 21: **VIEWING THE QUERY**

23. To respond to the query, click on view and you will be able to reply to the query as seen in the screen short below

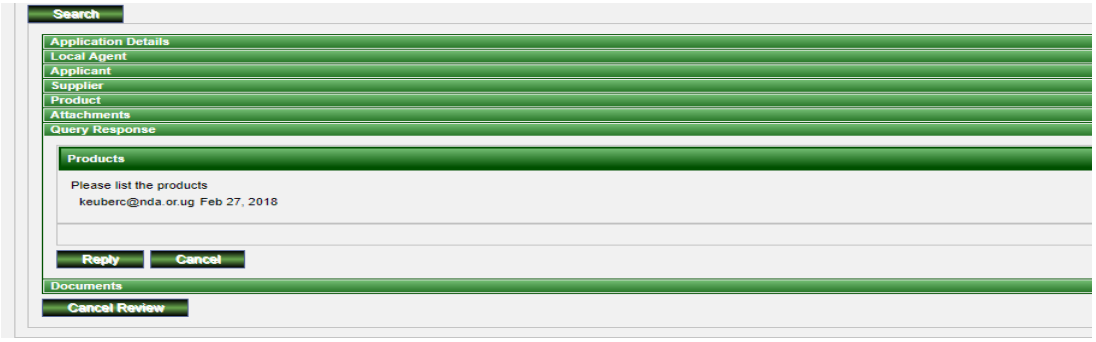

*Figure 22:***REPLYING TO THE QUERY**

24. If the query requires addition/removal of an attachment or amendment of the application, Click the “Edit” button under the Action column” and proceed to edit the application accordingly and click *“Submit”.* ***When you are done replying the query, ensure that you close the query so that the application is available for NDA staff action***

25. Once you are done with your work in NDAMIS, you should logout by clicking on the “*Logout*” icon in the top right corner of the page.

Do not hesitate to Contact our NDA TEAM for any inquiries or help needed for this online application process

End

APPENDIX 2: RECOMMENDED FORMAT OF PROFORMA INVOICE

	National Drug Authority Plot No. 19 Lumumba Avenue, P.O. Box 23096, Kampala, Uganda. email: ndaug@nda.or.ug; website: www.nda.or.ug Tel: +256417788100	Doc. No.: INS/FOM/450 Revision No.: 0 Effective Date: 10 Jan 2023 Page 1 of 1
Recommended Format of a proforma invoice		

<Exporter's name, address, telephone, E-mail>

Proforma Invoice				
Date: Exporter reference no.			Proforma invoice #:	
Consignee			**Shipping information**	
Company Name: Name/Department: Address: City/State/Postal Code: Country: Phone No.:			Shipment mode: Number of pieces: Total Gross Weight: Total Net Weight: Carrier/Vessel flight no: Port of loading: Port of discharge: Terms of delivery: Country of origin:	
Description of goods (Trade name, Generic name, Registration no.)	Pack size		F O B	**Sub-total**
Currency _____			**Total Value**	

Banking information: _____

Purpose of supply: _____

I declare that the information mentioned above is true and correct to the best of my knowledge.

Signature: _____ Stamp: _____

Name: _____ Date: _____

Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Changes made and reasons for revision
02. Oct. 2018	0	INS/GDL/038	*Author* Moses Akampurira	First Issue of Document
28 August 2023	1	INS/GDL/038	*Author* Mark Barigye Reviewers Denis Mwesigwa Victoria Kwesiga Dora Namyalo Peter Ssali	1. Guidelines for verification of Applications for importation of drugs for emergency or extraordinary circumstances revised to include guidance on the Verification of Applications for the Importation and Exportation of Drugs and, Pharmaceutical Raw and Packaging Materials 2. Appendix for Stepwise guide for making an online application for Verification Certificate in NDAMIS added to the guidelines 3. Format for proforma invoice added to guideline

End of Document