STANDARD OPERATING PROCEDURE

Application and processing of Pharmaceutical Import Permit.

8/23/2013
Safari Park Hotel.
Nairobi, Kenya.

The purpose of this document is to present the Standard Operating Procedures (SOP) for the above mentioned Procedures facilitated through the Kenya Electronic Single Window System (KESWS)
1. INTRODUCTION

Purpose of Document

The purpose of this document is to present the Standard Operating Procedures (SOP) facilitated through the Kenya Electronic Single Window System (KESWS) in as far as Trade in Pharmaceuticals is concerned. It is worth noting that KESWS will bring on board the following changes:

- Registered Pharmaceutical Traders will not need to come to PPB to apply for a Pharmaceutical Import Permit as this will be done through KESWS.

- Pharmaceutical Traders Registered with the PPB will have to get User ID’s and Password to enable them transact business through KESWS. This will be facilitated by Kentrade and PPB.

- The Pharmaceutical Import Permit will be generated through KESWS and as such traders can download it at a point of their convenience and make necessary attachment(s) through the KESWS for all stakeholders to view during clearance.

- Payments of FOB relevant to PPB will be done through KESWS.

- Organizations and or Persons who at one point will be involved in Donations of Pharmaceuticals will need to get Pre-Clearance from PPB Prior to arrival/departure of the Donations.
Different Scenarios exist in application for the Pharmaceutical Import Permit. These include:

- Pharmaceutical Import Permit for Products meant for Commercial Purposes
- Pharmaceutical Import Permit for Products emanating from a Prescription.
- Pharmaceutical Import Permit for Products meant for Research Purposes.
- Pharmaceutical Import Permit for Donation Products
- Pharmaceutical Import Permit for Drug Registration Samples.

The different scenarios as highlighted above differ in the below listed areas of concern:

- Requirements.
- Processes.
- Steps.
- Payment(s).

Based on the aforesaid therefore, for SOP for Pharmaceutical Import Permit meant for:

1) Commercial Purposes kindly refer to SOP 001.

2) Prescription Purposes Kindly refer to SOP 002.

3) Research Purposes Kindly refer to SOP 003.

4) Donation Purposes Kindly refer to SOP 004.

5) Drug Registration Samples Kindly refer to SOP 005.
2. **SCOPE OF THE SOP**

The SOP defines the interaction of Pharmaceutical traders in different scenarios mentioned above with Kenya Electronic Single Window System (KESWS) processes in conjunction with other stakeholders involved in trade and logistics procedures. It provides a roadmap to assist stakeholders in the use of KESWS.

The SOP explains in a stepwise manner the processes involved in:

i. Application for Pharmaceutical import Permit

ii. Processing of Pharmaceutical import permit.

iii. Approval/Rejection of Pharmaceutical Import Permit


The SOP should be used in conjunction with the KESWS user guide that provides specific details regarding use of the KESWS.

3. **Terminology used in this SOP:**

*Process* is a set of activities designed to accomplish a specific objective relevant to trade and logistics procedures. A process takes one or more inputs and turns them into outputs. Processes will be elaborated graphically through swim-lane diagrams wherein the roles and responsibilities of different organizations will be depicted.
# Process Mapping Symbols

<table>
<thead>
<tr>
<th>Process Diagram Symbol</th>
<th>Meaning</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>An activity within a process</td>
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<tr>
<td></td>
<td>Process Start and End</td>
</tr>
<tr>
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<td>Decision</td>
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<td></td>
<td>Single document or Product</td>
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<td></td>
<td>Multiple documents or products</td>
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<tr>
<td></td>
<td>Electronic Data</td>
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<tr>
<td></td>
<td>Direction of Process flow</td>
</tr>
</tbody>
</table>

Table 1: Process Mapping Symbols
1.1 APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT FOR COMMERCIAL PURPOSES.

<table>
<thead>
<tr>
<th>SOP Number: 001</th>
<th>Title: APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT FOR COMMERCIAL PURPOSES.</th>
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<tbody>
<tr>
<td>Revision No:</td>
<td>Effective Date: 31/10/2013</td>
</tr>
<tr>
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<td>PPB</td>
</tr>
<tr>
<td>Approved By:</td>
<td>PPB</td>
</tr>
</tbody>
</table>

A. OVERVIEW:

The SOP explains in a stepwise manner the process of application, evaluation, approval and issuance of pharmaceutical import permit.

Once approved, a Pharmaceutical Import Permit with a number is generated. The Importer can download and print at a location of their convenience if he/she so wishes.

It is the responsibility of the importer to monitor the status of the application via the KESWS System.

It is the responsibility of PPB to give timely update on the status of the application via the KESWS System.
B. RESPONSIBILITIES:

1) The Registered Pharmaceutical trader is responsible for application of the pharmaceutical import permit via the KESWS.

2) KESWS is responsible for distributing the application to PPB.

3) PPB is responsible for processing and approving/rejection/Holding the application.

4) The Registered Pharmaceutical trader is responsible for checking on the status of the application.

5) PPB is responsible for a timely update on the status of the application.

6) PPB is responsible for Issuance of the Pharmaceutical Import Permit.

7) PPB is responsible for Inspection of the consignment once they arrive. The PPB IO is responsible for inspection & subsequent approval, Holding/Query or Rejection of the consignment at POE once it arrives.

C. REQUIREMENTS

C.1 Approved IDF.

C.2 Registration certificates of the pharmaceutical products.

C.3 Valid Retention certificate of the Pharmaceutical products.

C.4 Proforma Invoice/Invoice.

C.5 Valid Wholesale dealer’s Licence issued by PPB.

D. DEFINITIONS

1) PPB- Pharmacy and Poisons Board.

2) KESWS- Kenya Electronic Single Window System.

3) IDF- Import Declaration Form.

4) EXIM-Exporter / Importer/Registered trader.

5) PFI- Proforma Invoice.
6) CO- Checking Officer.
7) VO- Validating Officer.
8) IO- Inspecting Officer.
9) SOP- Standard Operating Procedure.
10) ID- Identification.
11) OGA- Other Government Agency.
12) POE- Ports of Entry/Exit.
E. PROCEDURE:

E.1 Process Flow (Swim-Lane) Chart.

F. STEPS
The steps below describe the Process of application of a Pharmaceutical Import Permit and its processing; details of interaction are available in the KESWS user guide.

1) Apply for a Pharmaceutical Import Permit- PO1
The Registered Pharmaceutical trader selects the PPB as the OGA and makes application for a Pharmaceutical Import Permit in KESWS. The system
will provide an option to select Pharmaceutical Products retained by him or her and or authorised by principle agent in the Kenyan market.

Applicant has to fill up all the other tabs which capture information on Header/Consignee, Exporter/Consignor, Goods/Item others, transport, FOB, Consignment Type, Document Type (Permit) & Process required for the Request. System displays the online form appropriately based on the selections. Exim can update/remove/delete/cancel the application as he/she deem fit before submission. Search mechanisms are available to enable Exim search for the relevant retained pharmaceutical products specific to the EXIM.

2) Submit Application- PO2

The Registered Pharmaceutical trader updates the application and submits to PPB via KESWS.

3) Unique Reference Number Generation- PO3

KESWS generates a unique reference number which will be used in all subsequent trade docs.

4) Update of Application for Pharmaceutical Import Permit.-PO4

At the PPB, the Checking officer one (CO-1) verifies the information on the application and can thus put the status as either:

- On-hold/query
- Reject
- Approve

If CO-1 is satisfied, he/she will advise the trader to make payment and this will be confirmed by CO-2 attached at accounts/Finance Department. If satisfied, this case will be rerouted to VO. The VO can also either:

- Approve
- Hold/Query
- Reject.
5) Approval of the Application of Pharmaceutical Import Permit.-PO5

The VO reviews the application and updates the status of the request as approved.

The system generates the permit reference number if the application is approved.

6) Issuance of the Pharmaceutical Import Permit.-PO6

Once the VO has put the status as approved, the Exim can print the permit at any point of his/her convenience for his/her reference. This approval status will be available for all stakeholders to view in KESWS.
1.1 APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT FOR PRESCRIPTION PURPOSES.

<table>
<thead>
<tr>
<th>SOP Number: 002</th>
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A. OVERVIEW:

The SOP explains in a stepwise manner the process of application, evaluation, approval and issuance of pharmaceutical import permit.

Once approved, a Pharmaceutical Import Permit with a number is generated. The Importer can download and print at a location of their convenience if he/she so wishes.

It is the responsibility of the importer to monitor the status of the application via the KESWS System.

It is the responsibility of PPB to give timely update on the status of the application via the KESWS System.
B. RESPONSIBILITIES:

B.1 The Registered Pharmaceutical trader is responsible for application of the pharmaceutical import permit via the KESWS.

B.2 KESWS is responsible for distributing the application to PPB.

B.3 PPB is responsible for processing and approving/rejection/Holding the application.

B.4 The Registered Pharmaceutical trader is responsible for checking on the status of the application.

B.5 PPB is responsible for a timely update on the status of the application.

B.6 PPB is responsible for Issuance of the Pharmaceutical Import Permit.

B.7 PPB is responsible for Inspection of the consignment once they arrive. The PPB IO is responsible for inspection & subsequent approval, Holding/Query or Rejection of the consignment at POE once it arrives.

C. REQUIREMENTS

C.1 Valid Wholesale dealer's Licence for the importer issued by PPB.

C.2 Valid Prescription.

C.3 Pfi/Invoice.

D. DEFINITIONS

D.1 PPB- Pharmacy and Poisons Board.


D.3 IDF- Import Declaration Form.

D.4 EXIM-Exporter / Importer/Registered trader.

D.5 PFI- Proforma Invoice.

D.6 CO- Checking Officer.
D.7 VO- Validating Officer.
D.8 IO- Inspecting Officer.
D.9 SOP- Standard Operating Procedure.
D.10 ID- Identification.
D.11 OGA- Other Government Agency.
D.12 INN- International Non-Propriety Name.
D.13 Docs- Documents.
D.14 POE- Ports of Entry/Exit.
**E. PROCEDURE:**

**E.1** Process Flow (Swim-Lane) Chart.

**F. STEPS**

The steps below describe the Process of application of a Pharmaceutical Import Permit and its processing; details of interaction are available in the KESWS user guide.
F.1 Apply for a Pharmaceutical Import Permit- PO1

The Registered Pharmaceutical trader selects the PPB as the OGA and makes application for a Pharmaceutical Import Permit in KESWS by typing into the system the Brand name of the product, its INN, its formulation, its strength, its batch number, manufacture and Expiry dates.

Applicant has to fill up all the other tabs which capture information on Header/Consignee, Exporter/Consignor, Goods/Item others, transport, FOB, Consignment Type, Document Type (Permit) & Process required for the Request. System displays the online form appropriately based on the selections. Exim can update/remove/delete/cancel the application as he/she deem fit before submission.

F.2 Submit Application- PO2

The Registered Pharmaceutical trader updates the application and submits to PPB via KESWS.

F.3 Unique Reference Number Generation- PO3

KESWS generates a unique reference number which will be used in all subsequent trade docs.

F.4 Update of Application for Pharmaceutical Import Permit.-PO4

At the PPB, the Checking officer one (CO-1) verifies the information on the application and can thus put the status as either:
- On-hold/query
- Reject
- Approve

If CO-1 is satisfied, he/she will approve the application and this will be rerouted to VO. The VO can also either:
- Approve
- Hold/Query
- Reject.
F.5 Approval of the Application of Pharmaceutical Import Permit.-PO5

The VO reviews the application and updates the status of the request as approved.

The system generates the permit reference number if the application is approved.

F.6 Issuance of the Pharmaceutical Import Permit.-PO6

Once the VO has put the status as approved, the Exim can print the permit at any point of his/her convenience for his/her reference. This approval status will be available for all stakeholders to view in KESWS.
1.1 APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT FOR RESEARCH PURPOSES.

<table>
<thead>
<tr>
<th>SOP Number: 003</th>
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A. OVERVIEW:

The SOP explains in a stepwise manner the process of application, evaluation, approval and issuance of pharmaceutical import permit.

Once approved, a Pharmaceutical Import Permit with a number is generated. The Importer can download and print at a location of their convenience if he/she so wishes.

It is the responsibility of the importer to monitor the status of the application via the KESWS System.

It is the responsibility of PPB to give timely update on the status of the application via the KESWS System.
B. **RESPONSIBILITIES:**

B.1 The Registered Pharmaceutical trader is responsible for application of the pharmaceutical import permit via the KESWS.

B.2 KESWS is responsible for distributing the application to PPB

B.3 PPB is responsible for processing and approving/rejection/Holding the application.

B.4 The Registered Pharmaceutical trader is responsible for checking on the status of the application.

B.5 PPB is responsible for a timely update on the status of the application.

B.6 PPB is responsible for Issuance of the Pharmaceutical Import Permit.

B.7 PPB is responsible for Inspection of the consignment once they arrive.

The PPB IO is responsible for inspection & subsequent approval, Holding/Query or Rejection of the consignment at POE once it arrives.

C. **REQUIREMENTS**

C.1 Ethical Committee Approval.

C.2 PPB Expert Committee on Clinical Trial Approval.

C.3 PFI/Invoice.

D. **DEFINITIONS**

D.1 PPB- Pharmacy and Poisons Board.


D.3 IDF- Import Declaration Form.

D.4 EXIM-Exporter / Importer/Registered trader.

D.5 PFI- Proforma Invoice.

D.6 CO- Checking Officer.
D.7 VO- Validating Officer.
D.8 IO- Inspecting Officer.
D.9 SOP- Standard Operating Procedure.
D.10 ID- Identification.
D.11 OGA- Other Government Agency.
D.12 POE- Ports of Entry/Exit.

E. PROCEDURE:

E.1 Process Flow (Swim-Lane) Chart.

APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT

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<td></td>
<td></td>
</tr>
</tbody>
</table>

- Start
  - Submit Application for permit
    - Receive as advised
      - No
        - Valid?
          - Yes
            - Make Payment for permit
          - No
            - Approve Application
              - Issue Permit
                - End
  - Evaluate Application
    - Confirm Payment
F. STEPS
The steps below describe the Process of application of a Pharmaceutical Import Permit and its processing; details of interaction are available in the KESWS user guide.

F.1 Apply for a Pharmaceutical Import Permit- PO1
The Researcher will have to get a User ID and Password from PPB in conjunction with KESWS.

The Researcher then selects the PPB as the OGA and makes application for a Pharmaceutical Import Permit in KESWS by typing in either the Name or the code of the Pharmaceutical product under research.

Applicant has to fill up all the other tabs which capture information on Header/Consignee, Exporter/Consignor, Goods/Item others, transport, Consignment Type, Document Type (Permit) & Process required for the Request. System displays the online form appropriately based on the selections. The Researcher can update/remove/delete/cancel the application as he/she deems fit before submission.

F.2 Submit Application- PO2
The Researcher updates the application and submits to PPB via KESWS.

F.3 Unique Reference Number Generation- PO3
KESWS generates a unique reference number which will be used in all subsequent docs.

F.4 Update of Application for Pharmaceutical Import Permit.-PO4
At the PPB, the Checking officer one (CO-1) verifies the information on the application and can thus put the status as either:
- On-hold/query
- Reject
- Approve
If CO-1 is satisfied, he/she will approval the case and this will be rerouted to VO for approval.

The VO can also either:
- Approve
- Hold/Query
- Reject.

**F.5 Approval of the Application of Pharmaceutical Import Permit.-PO5**

The VO reviews the application and updates the status of the request as approved.

The system generates the permit reference number if the application is approved.

**F.6 Issuance of the Pharmaceutical Import Permit.-PO6**

Once the VO has put the status as approved, the Exim can print the permit at any point of his/her convenience for his/her reference. This approval status will be available for all stakeholders to view in KESWS.
1.1 APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT FOR DONATION PURPOSES.

<table>
<thead>
<tr>
<th>SOP Number: 004</th>
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A. OVERVIEW:

The SOP explains in a stepwise manner the process of application, evaluation, approval and issuance of pharmaceutical import permit.

Once approved, a Pharmaceutical Import Permit with a number is generated. The Importer can download and print at a location of their convenience if he/she so wishes.

It is the responsibility of the importer to monitor the status of the application via the KESWS System.

It is the responsibility of PPB to give timely update on the status of the application via the KESWS System.
B. RESPONSIBILITIES:

B.1 The Registered Organisation or its agent is responsible for application of the pharmaceutical import permit via the KESWS.

B.2 KESWS is responsible for distributing the application to PPB.

B.3 PPB is responsible for processing and approving/rejection/Holding the application.

B.4 The Registered Organisation or its agent is responsible for checking on the status of the application.

B.5 PPB is responsible for a timely update on the status of the application.

B.6 PPB is responsible for Issuance of the Pharmaceutical Import Permit.

B.7 PPB is responsible for Inspection of the consignment once they arrive. The PPB IO is responsible for inspection & subsequent approval, Holding/Query or Rejection of the consignment at POE once it arrives.

C. REQUIREMENTS

C.1 Certificate of Analysis (COA) of those products.

C.2 Donation Certificate From the Donating Organisation/Person.

C.3 Registration Certificate of the recipient Organisation with relevant authorities.

C.4 Packing list detailing product names, manufacture & Expiry dates, formulation, strength, quantity and Batch Numbers.

C.5 Invoice/PFI.
D. DEFINITIONS

D.1 PPB- Pharmacy and Poisons Board.
D.3 IDF- Import Declaration Form.
D.4 EXIM- Exporter / Importer/Registered trader.
D.5 PFI- Proforma Invoice.
D.6 CO- Checking Officer.
D.7 VO- Validating Officer.
D.8 IO- Inspecting Officer.
D.9 SOP- Standard Operating Procedure.
D.10 ID- Identification.
D.11 OGA- Other Government Agency.
D.12 COA- Certificate of Analysis.
D.13 POE- Ports of Entry/Exit.
E. PROCEDURE:

E.1 Process Flow (Swim-Lane) Chart.

APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT

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<tr>
<th>IMPORTER</th>
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<th>PAYMENT AGENT</th>
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<tbody>
<tr>
<td>Start</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submit Application for permit</td>
<td>Evaluate Application</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rectify as advised</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Make Payment for permit</td>
<td>Confirm Payment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approve Application</td>
<td>Issue Permit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>End</td>
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</table>
F. STEPS
The steps below describe the Process of application of a Pharmaceutical Import Permit and its processing; details of interaction are available in the KESWS user guide.

F.1 Apply for a Pharmaceutical Import Permit- PO1
The Donor/Recipient organization or their agent will have to get a User ID and Password from PPB in conjunction with KESWS.

The Donor/Recipient organisation or their agents then selects the PPB as the OGA and makes application for a Pharmaceutical Import Permit in KESWS by typing in the names of the products being donated, their batch numbers, their quantity, their manufacture and Expiry dates, and manufacturer.

The applicant has to fill up all the other tabs which capture information on Header/Consignee, Exporter/Consignor, Goods/Item others, transport, Consignment Type, Document Type (Permit) & Process required for the Request. System displays the online form appropriately based on the selections. The Researcher can update/remove/delete/cancel the application as he/she deems fit before submission.

F.2 Submit Application- PO2
The Researcher updates the application and submits to PPB via KESWS.

F.3 Unique Reference Number Generation- PO3
KESWS generates a unique reference number which will be used in all subsequent docs.

F.4 Update of Application for Pharmaceutical Import Permit.-PO4
At the PPB, the Checking officer one (CO-1) verifies the information on the application and can thus put the status as either:
- On-hold/query
- Reject
- Approve
If CO-1 is satisfied, he/ she will approval the case and this will be rerouted to VO for approval.

The VO can also either:
- Approve
- Hold/Query
- Reject.

**F.5 Approval of the Application of Pharmaceutical Import Permit.-PO5**

The VO reviews the application and updates the status of the request as approved.

The system generates the permit reference number if the application is approved.

**F.6 Issuance of the Pharmaceutical Import Permit.-PO6**

Once the VO has put the status as approved, the Donor/Recipient organization or their agent can print the permit at any point of his/her convenience for his/her reference. This approval status will be available for all stakeholders to view in KESWS.
1.1 APPLICATION FOR PHARMACEUTICAL IMPORT PERMIT FOR DRUG REGISTRATION PURPOSES.

<table>
<thead>
<tr>
<th>SOP Number: 005</th>
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It is the responsibility of the importer to monitor the status of the application via the KESWS System.

It is the responsibility of PPB to give timely update on the status of the application via the KESWS System.
B. RESPONSIBILITIES:

B.1 The Registered Pharmaceutical trader is responsible for application of the pharmaceutical import permit via the KESWS.
B.2 KESWS is responsible for distributing the application to PPB
B.3 PPB is responsible for processing and approving/rejection/Holding the application.
B.4 The Registered Pharmaceutical trader is responsible for checking on the status of the application.
B.5 PPB is responsible for a timely update on the status of the application.
B.6 PPB is responsible for Issuance of the Pharmaceutical Import Permit.
B.7 PPB is responsible for Inspection of the consignment once they arrive. The PPB IO is responsible for inspection & subsequent approval, Holding/Query or Rejection of the consignment at POE once it arrives.

C. REQUIREMENTS

C.1 Certificate of Analysis (COA) of those products.
C.2 Valid Wholesale dealer’s licence issued by PPB.
C.3 Invoice of No commercial Value and Indicating that the products are for Registration Purposes only.
C.4 Research Dossiers of those products.
D. DEFINITIONS

D.1 PPB- Pharmacy and Poisons Board.
D.3 IDF- Import Declaration Form.
D.4 EXIM-Exporter / Importer/Registered trader.
D.5 PFI- Proforma Invoice.
D.6 CO- Checking Officer.
D.7 VO- Validating Officer.
D.8 IO- Inspecting Officer.
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<td>Valid?</td>
</tr>
<tr>
<td></td>
<td>Make Payment for permit</td>
<td>Confirm Payment</td>
</tr>
<tr>
<td></td>
<td>Approve Application</td>
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F. STEPS
The steps below describe the Process of application of a Pharmaceutical Import Permit and its processing; details of interaction are available in the KESWS user guide.

F.1 Apply for a Pharmaceutical Import Permit- PO1
The Registered Pharmaceutical trader selects the PPB as the OGA and makes application for a Pharmaceutical Import Permit in KESWS by typing in the names of the products being imported, their batch numbers, their quantity, their manufacture and Expiry dates, and manufacturer and site.

The applicant has to fill up all the other tabs which capture information on Header/Consignee, Exporter/Consignor, Goods/Item others, transport, Consignment Type, Document Type (Permit) & Process required for the Request. System displays the online form appropriately based on the selections. The Registered Pharmaceutical trader can update/remove/delete/cancel the application as he/she deems fit before submission.

F.2 Submit Application- PO2
The Researcher updates the application and submits to PPB via KESWS.

F.3 Unique Reference Number Generation- PO3
KESWS generates a unique reference number which will be used in all subsequent docs.

F.4 Update of Application for Pharmaceutical Import Permit.-PO4
At the PPB, the Checking officer one (CO-1) verifies the information on the application and can thus put the status as either:
- On-hold/query
- Reject
- Approve

If CO-1 is satisfied, he/ she will approval the case and this will be rerouted to VO for approval.
The VO can also either:
- Approve
- Hold/Query
- Reject.

**F.5 Approval of the Application of Pharmaceutical Import Permit. - PO5**

The VO reviews the application and updates the status of the request as approved.

The system generates the permit reference number if the application is approved.

**F.6 Issuance of the Pharmaceutical Import Permit. - PO6**

Once the VO has put the status as approved, the Donor/Recipient organization or their agent can print the permit at any point of his/her convenience for his/her reference. This approval status will be available for all stakeholders to view in KESWS.