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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINE ON

IMPORT AND EXPORT OF HEALTH PRODUCTS AND TECHNOLOGIES

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For clarifications, comments, or suggestions, please contact:

The Chief Executive Officer
Pharmacy and Poisons Board
P.O. Box 27663 – 00506, Nairobi
Telephone: 0709770100
Email: info@pharmacyboardkenya.org
Website: www.pharmacyboardkenya.org

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Prepared by:

Sign.....

Date.....18/1/2022.....

Reviewed by: Head, EIU:

Sign.....

Date.....26/1/2022.....

Checked by: HQM

Sign.....

Date.....28/1/2022.....

Authorized by: Chief Executive Officer

Sign.....

Date.....31/1/2022.....

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Abbreviations and acronyms

API	Active Pharmaceutical Ingredient
BD	Base Document
COA.	Certificate of Analysis
COC	Certificate of conformity
cGMP.	Current Good Manufacturing Practice
DDA	Dangerous Drug Authorization
EU	European Union
Exim.	Exporter/Importer
FPP	Finished Pharmaceutical Product
FOB.	Free on Board
HPT's.	Health Products and Technologies
Hs Code.	Harmonized system Code
ICH	International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
iCMS	Integrated custom management system
IDF.	Import declaration form
KRA.	Kenya Revenue Authority
Kentrade.	Kenya Trade Network Agency
KEBS.	Kenya Bureau of Standards
LTR.	Local technical representative
MA.	Market Authorization
MAH.	Market Authorization Holder
NOC.	No objection Certificate
NPP's	Narcotics, Psychotropics and precursor chemicals
NMRA.	National medicine regulatory authority
PD	Product Dossier
PHIS	Pharmaceutical Health Information System
PI	Product Information
PVoC.	Pre-export verification of conformity to standards
PRIMS	Physical Readiness Information System
PPB.	Pharmacy and Poison's Board

PGA. Partner Government Agency

For purposes of this guideline, BD and IDF are used interchangeably. Similarly, No objection certificate and letter of no objection are used interchangeably.

Glossary of terms

The definitions provided below apply to the words and phrases used in this guideline. The following definitions are provided to facilitate interpretation of the guideline.

Active pharmaceutical ingredient (API)

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Airway Bill

The air waybill is a contract of carriage between the shipper and air carrier. It is issued by the air carrier and serves as a receipt for the shipper.

Batch number/Lot Number

A distinctive combination of numbers and/or letters which specifically identifies a batch or lot and from which the product history can be determined.

Bio-equivalence

The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of action when administered at the same molar dose under similar conditions in an appropriately designed study.

Bonded warehouse

Bonded warehouses are secured, government-approved warehouse facilities in which imported goods are stored without payment of duty until they are removed and entered for consumption.

Bulk product

Any product that has completed all processing stages up to, but not including, final packaging.

Bill of landing

A bill of lading is a contract of carriage between the shipper and the steamship company (carrier). It certifies ownership and receipt of goods by the carrier for shipment. It is issued by the carrier to the shipper.

Certificate of Pharmaceutical Product (COPP)

A WHO-type certificate as defined in the WHO Certification Scheme on the quality of Pharmaceutical products moving in the international commerce.

Custom Clearing Agent

A person who carries on the business of arranging for the customs clearance of goods and who deals with the customs for and on behalf of another person or company.

Clearance

Means the accomplishment of the Customs formalities necessary to allow goods to enter home use, to be exported or to be placed under another customs procedure

Commercial invoice

A commercial invoice is a bill for the merchandise from the seller to the buyer. It should include basic information about the transaction: description of the goods, delivery and payment terms, order date, and number. The overseas exim needs the commercial invoice to clear goods from the PGA (where applicable), customs, prove ownership, and arrange payment. Governments in importing countries also use commercial invoices to determine the value of the goods for assessment of duties.

Dosage form

This is the pharmaceutical-technological form in which a medicinal substance is made available. Pharmaceutical may be administered in solid form (e.g.

tablets, powers), in semi-liquid form (e.g. ointments, pastes), in liquid form (e,g. drops, injectables, infusions) or in gaseous form (inhalation).

Excipient

Is any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient.

Entry

Entry is the act of filing the necessary documentation with the customs officer to secure the release of imported merchandise

Exim

An individual or company or similar legal entity importing or exporting or seeking to import or export a health product and technology

Export

To take or cause to be taken out of the customs territory or into an export processing zone.

Exchange Rate

An exchange rate is the number of units of a given currency that can be purchased for one unit of another currency.

Finished pharmaceutical product (FPP)

A finished dosage form of a pharmaceutical product which has undergone all stages of manufacture, including packaging in its final container and labelling.

Generic product

Is a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference

medicinal product has been demonstrated by appropriate bioavailability studies.

Good Manufacturing Practice (GMP)

Part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Hs Codes

The Harmonized commodity description and coding system generally referred to as harmonized system or simply HS is a multipurpose international product nomenclature developed by the World Customs Organization (WCO)

Health Product and technologies

Means the meaning assigned to it in the Pharmacy and poison's Act, CAP 244.

International Non-proprietary Name (INN)

INN is a unique name that is globally recognized and is public property.

In-vitro diagnostic medical device

A device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body, solely or principally to provide information for diagnostic, monitoring or compatibility purposes. It includes reagents, calibrators, control materials, specimen receptacles, software and related instruments, apparatus or other articles

Importation

The act of bringing or causing any goods to be brought into customs territory from a foreign country or from an export processing zone.

Import/Export Permit

Authorization issued by the Pharmacy and poison's Board (the Board) for the importation or exportation of goods subject to restriction.

Label

Is a descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a packaging of any medicinal product.

Local Technical Representative (LTR)

A person or company with sufficient pharmaceutical expertise that is incorporated within the Country and who will be responsible for facilitating communication with the applicant and when the product is registered shall assume all legal responsibilities.

Manufacturer

Any process carried out in the course of making a product or medicinal substance and includes packaging, blending, mixing, assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product, but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as a vehicle for administration.

Market Authorization Holder (MAH)

Is a person who holds authorization to place a medicinal product in the Country and is responsible for that product.

Market authorization

Means approval to market a medicinal product in the Country.

Medical device

Any instrument, apparatus, laboratory equipment, reagent, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article that is intended by the manufacturer to be

used, alone or in combination, in human beings or animals for one or more of the following specific purpose(s):

a) diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury;
b) investigation, replacement, modification or support of the anatomy or of a physiological process;
c) supporting or sustaining life;
d) control of conception;
e) disinfection of medical devices;
f) providing information for medical or diagnostic purposes by means of in-vitro examination or specimens derived from the human body or other animal; and which
g) does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

National Medicines Regulatory Authority

A National body that has the legal mandate to set objectives and administer the full spectrum of medicines regulatory activities.

Packaging Materials

Any material used to protect an active pharmaceutical ingredient or finished pharmaceutical product during storage and transport but excluding labels

Patient Information Leaflet (PIL)

Packages insert which contains information for patient's understanding of how to safely use a medicinal product.

Packing List

A packing list is a document used in international trade. It provides the exporter, international freight forwarder, and ultimate consignee with information about the shipment, including how it's packed, the dimensions

and weight of each package, and the marks and numbers that are noted on the outside of the boxes.

Promotion

Promotion refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

Proforma Invoice.

A proforma invoice is a provisional invoice sent to the prospective buyer, usually in response to the latter's request for a price quotation. A quotation usually describes the product, and states the price at a specific delivery point, the time of shipment, and the terms of payment. A proforma invoice is also needed by the buyer to obtain a foreign exchange or import permit.

Substandard Product

This is an authorized product that fails to meet either its quality standards or its specifications or both according to the market authorization specifications.

Transhipment

The movement, either directly or indirectly, of goods from an aircraft, vessel arriving in Kenya from a foreign place, to an aircraft, vessel or vehicle departing to a foreign destination.

Transit

The movement of goods imported from a foreign place through Kenya to a foreign destination.

Unauthorized Product

A product that is not in compliance with the National regulations and legislation, being unknown to the authorities and which therefore requires regulatory action.

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AUTHOUR:

Pharmacy and Poisons Board

CONTRIBUTORS

Dr. Allan Wambua; Trade Affairs Unit;

Dr. Washington Oyoo; Inspectorate Department;

Mr. Job Kandie: Trade Affairs Unit;

Ms Mary Kendi: Trade Affairs Unit;

Ms Lucy Mugambi: Inspectorate Department;

Ms Myra Angote: Trade Affairs Unit;

INTRODUCTION

1.1 Background

Health is a fundamental right enshrined in the Kenyan Constitution. Indeed, Article 43(1) of the Constitution prescribes the right to every Kenyan to access highest attainable standards to health.

The international covenant on economic social and cultural rights (ICESCR) of the UN economic and social Council affirms this position. In its general comment No.14 of the right to the highest attainable standards of health (Article 12 of the Covenant), it avers that health is a fundamental human right indispensable for the exercise of other human rights. It outlines that every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.

As a result, availing health products and technologies is integral to realization of the above fundamental rights. Globalization and increased transnational flow of goods and services coupled with improved communication and technological advances in IT infrastructure are key enablers towards this realization.

Trade is simply the exchange of goods and services while international trade allows the exchange of the same across National Borders. International trade allows manufactures, distributors and business community to import and or export goods or components from foreign market into their markets. This can

be motivated by lack of these products, access at reasonable cost, value addition among other factors.

The availability of HPT's is sometimes limited due to finite economic resources, difficulty in meeting norms and regulatory standards in their production, market authorization, and logistical challenges in their supply

chain. As a consequence, Governments through their medicine regulatory authorities need to be alert and put measures in place to prevent penetration of substandard and suspected falsified HPT's which pose hazards to public health. In light of this, investments and close collaboration between custom authority(KRA) and the Board is deemed crucial to ensure safe, efficacious and quality HPTs to patients.

2.0 Legal Mandate.

The Board is mandated in law under CAP 244 of the Pharmacy and Poison's Act to control the importation and exportation of health products and technologies. This is outlined in section 3B subsection 2 (b) of the functions of the Board.

The Act further provides for formulation of rules and regulations pertaining to importation and exportation under section 44 subsection 1 (ff).

The rules give provision for importation of part 1 poison, restriction on the importation or manufacture of specified drugs, exportation of drugs and poisons and exemptions.

3.0 Scope of the Guideline

This guideline describes the processes, format, means and general requirements for the application and submission of import and export permits of HPTs. The information herein therefore aims to provide and promote understanding of, and compliance with, importing/exporting laws, regulations, and procedures for HPT's.

4.0 Documentations critical for Import/Export processing and clearance

The below listed documents shall be critical for issuance of an import/ export permit and clearance of a HPT consignment by the Board.

These documents include:

i. Proforma invoice;
ii. Commercial invoice;

iii. Packing List/Packing note;
iv. Certificate of Origin;
v. Bill of Lading;
vi. Airway Bill;
vii. Entry;
viii. Certificate of analysis (COA);
ix. Certificate of conformity (COC);
x. Batch/Lot Release certificate;
xi. PVoC certificate;
xii. Audit/Inspection reports;
xiii. Certificate of pharmaceutical products (COPP);
xiv. Market authorization certificates;
xv. Emergency use authorization certificates (EUA);
xvi. Compassionate use authorization letter (CUA);
xvii. Free sale certificates;
xviii. Certificate of exportability;
xix. Certificate of business/entity registration/incorporation/business name;
xx. Wholesale dealer licences and or similar establishment licences by the Board or other Government Institutions;
xxi. Donation Certificate;
xxii. Cosmetic certificates;
xxiii. Batch release certificates (for vaccines);
xxiv. Letters of concurrence from National competent authorities;

5.0 Permit

This is an import/export authorization granted by the Board for import or export of HPT's. It assigns an investment value to an exim and a commitment to the Board by the exim for provision of the stated HPT's.

5.1 Types of Import Permits

There are 13 types of permits. These include;

i. Commercial medicine import permit;
ii. Medical device import permit;
iii. Narcotics, Psychotropics and precursor chemicals import permit (Commercial);
iv. Narcotics, Psychotropics and precursor chemicals import permit (Raw materials)
v. Raw materials import permit;
vi. Prescription drug import permit;
vii. Clinical trials import permit;
viii. Drug registration sample(s) import permit;
ix. Priority import permit;
x. Donation import permit;
xi. Bonded medical products import permit;
xii. Promotional material import permit;
xiii. Export permit;

5.1.1 Commercial medicine import permit.

This type of permit covers pharmaceutical products being imported for commercial purposes. This will include finished pharmaceutical products in various dosage forms such as medicines, food supplements, herbal products, cosmetics[1] and borderline products.

It attracts a payment of 0.75% FOB.

5.1.1.1 Requirements for issuance of commercial medicine import permit.

a) Proforma/commercial invoice;
b) Product registration/retention certificate or emergency use authorization certificate or compassionate use authorization letter/Certificate of pharmaceutical product or any other authorization the Board determines fit to assure quality, safety

[1] Guidelines for inspection of imported medical devices, food supplements, medical cosmetics, herbal products and other borderline products, KEBS-PPB 2017-06-06;

and efficacy of the product(s) including audit reports or listing letters;

c) Batch release certificates or letters of Concurrence from the NMRA's (in case of vaccines);

d) Wholesale dealers' licence;

5.1.2 Medical device import permit.

This type of permit covers the importation of medical devices and invitro-diagnostics being imported for commercial purposes.

It attracts a payment of 0.75% FOB.

5.1.2.1 Requirements for issuance of medical device import permit.

a) Proforma invoice/commercial invoice;

b) Product registration/retention certificate or emergency use authorization certificate, compassionate use authorization letter;

c) Certificate of business incorporation/Business name certificate;

5.1.3 Narcotics, Psychotropics and precursor substances Permit (NPP's) (Commercial).

This type of permit covers importation of NPP's being imported for commercial purposes.

It attracts a payment of 0.75% FOB.

5.1.3.1 Requirements for issuance of NPP's Permit (Commercial)

a) Proforma/commercial invoice;

b) Product registration/retention certificate or emergency use authorization/compassionate use authorization letter or Certificate of pharmaceutical product or any other authorization the Board determines fit to assure quality, safety and efficacy of the product(s) including audit reports or listing letters;

c) Dangerous drug(s) authorization (DDA) permit;

d) Wholesale dealers license (in case of pharmaceuticals) or Certificate of business incorporation or business name certificate (in case of precursor chemicals);

5.1.4 Narcotics, Psychotropics and precursor substances Permit (NPP's) (Raw materials).

This type of permit covers importation of NPP's being imported for local production purposes.

It does not attract any payment.

5.1.4.1 Requirements for issuance of NPP's (Raw materials)

a) Proforma invoice/commercial invoice;
b) Material safety data sheet/Certificate of analysis (COA);
c) Certificate of business incorporation or business name registration certificate;
d) Manufacturer's license issued by the Board or Wholesale dealer's license;

Note: Before issuance of any of the NPP's permit above, the Board may wish to ascertain the rational use of the product. In this regard, the Board shall undertake audit of the importing entity and the utilization of the same including third party audits who might have been sold or have requested for such a supply. Where the Board is not satisfied with the audit findings, the Board shall decline such issuance and its decision shall be final.

5.1.5 Raw materials import permit

This type of permit covers the importation of raw materials (API's), excipients, packaging material, labels, literature inserts, chemicals, reference and working standards, culture and medias, manufacturing equipments, spares, parts and tools being imported by a licensed manufacturing facility.

The finished products, or process-inputs, from these categories of products must be registered or registrable by the Board.

These permit does not attract any payment.

5.1.5.1 Requirements for issuance of a Raw material import permit

a) Proforma invoice/commercial invoice;
b) Pharmacopeial specifications (where applicable);
c) Manufacturing license from the Board or Product registration/retention certificate (in case of culture medias or similar products) or Wholesale dealer's license;
d) Batch certificate of analysis (where applicable);

5.1.6 Prescription Drug Import permit

This type of permit covers importation of medicines for personal use.

The quantity of the medicine in this type of application is limited to 3-month supply, however, this can vary in some situations such as pandemics or other justifiable situations. This type of permit caters for returning patients who have being receiving treatment abroad or are in long term treatment and must continue to get refills based on their doctor's review.

This type of permit does not attract payment.

Note: It is the responsibility of the patient/guardian/duly registered medical doctor and or the Hospital to appoint a pharmaceutical company with a wholesale dealers license to make the permit application.

5.1.6.1 Requirements for issuance of a prescription import permit.

a) Proforma invoice/commercial invoice;
b) Prescription from a duly registered medical doctor/ or a letter of duty of care of a medical doctor to the stated

patient/compassionate use authorisation letter;

c) Wholesale dealers license;

5.1.7 Clinical trials import permit

This type of permit covers importation of investigational medicinal products (IMP), medical devices, reagents and chemicals being imported for clinical trials and research studies.

The application does not attract payment.

Note. The import/export and storage of IMP should comply with the regulatory requirement to ensure integrity and accountability of the products.

5.1.7.1 Requirements for issuance of a clinical trials import permit.

a) Proforma/commercial invoice;

b) Expert committee on clinical trials approval letter (ECCTA) (in case of a clinical trial), or NACOSTI authorization certificate in case of the other scientific research studies; and or Institutional ethical research committee (ERC) approval;

c) Registration of the institution where such research is being undertaken;

5.1.8 Samples import permit

This permit covers importation of medicine and medical device samples being imported for evaluation, registration, investigation and quality tests. The quantity is limited to either quality laboratory test requirements, the Board's samples for evaluation requirements, or any other quantity that may be preferred by an investigating agency or government institution.

It does not attract any payment.

5.1.8.1 Requirements for issuance of samples import permit

a) Proforma/commercial invoice/non-commercial invoice detailing the medicines or medical devices are for product evaluation/registration/investigation/quality tests. The declared value should be for custom purposes only.
b) Wholesale dealer's license (in case of medicines) or certificate of incorporation or business name certificate (in case of medical devices, food supplements/borderline products) and or;
c) Certificate of analysis/conformity;

5.1.9 Priority import permit

This type of permit covers the importation of oncology medicines, anti-malarial medicines, anti-retroviral medications and anti-tuberculosis medicines.

This type of permit does not attract payment.

5.1.9.1 Requirements for issuance of priority import permit

a) Proforma/commercial invoice;
b) Product registration/retention certificate;
c) Wholesale dealers license;

5.1.10 Donation import permit

This type of permit covers importation of HPT's donated to various institutions and organizations in the Country.

It does not attract payment.

5.1.10.1 Requirements for issuance of Donation permit

a) There should be an expressed need for such donation;
b) Proforma invoice/invoice detailing/itemizing the products being donated, their Batch Numbers and expiry dates;

c) Quality statement of the donated HPTs by the donor or COPP (where applicable)/Product registration certificate from the Country of Origin/compliance to ISO13485 certificate (where applicable)/Certificate of analysis detailing product specificity and selectivity and any other quality attribute that might be determined appropriate by the Board /Certificate of conformity or product registration/retention locally (a letter of No objection from the MAH/LTR should be sought;
d) Donation certificate;
e) The recipient organization registration certificate and or current licensure from the professional regulatory authority;
f) Packing list;

Note: In some situations, in case of used-medical devices; the Board may request for provision of test report on the suitability of the medical device(s) being donated;

HPTs being donated into the Country for a medical camp should provide that medical camp authorization by the Medical Board and or County Government.

See other provisions in the donation guidelines.

5.1.11 Bonded medical products import permit

This permit serves to facilitate importation of HPT's being brought into a customs bonded warehouse.

The permit does not attract any payment.

5.1.11.1 Requirements for issuance of Bonded medical products import permit

a) Proforma/commercial invoice;
b) Customs bonded warehouse license;
c) Wholesale dealer's license;

d) Board's letter allowing importation of HPT(s) into that Bonded warehouse;
e) DDA (in case of NPP's);

5.1.12 Promotional material import permit

This type of permit serves to facilitate importation of HPT's or other products for health-related information promotional purposes such as physician samples, scientific conferences, healthcare workers training, product detailing items with health-related information, health-related scientific exhibitions and fairs, tournament and sports, tools and equipments accompanied by specialist-engineers coming for equipment repair and or maintenance (a letter on this repair and maintenance should be provided).

This type of permit serves to offer temporary entry of HPT's for the above stated events. In such situations, this should be declared to the Board before entry and the same served before exit.

This type of permit does not attract any payment.

5.1.12.1 Requirements for issuance of promotional import permit

a) Proforma invoice/non-commercial invoice cum packing list itemizing the products being imported, their Batch/lot numbers (where applicable). For Physician samples, they should be embossed as such on the secondary packs.
b) Wholesale dealer's license or registration certificate of the recipient organization in Kenya;
c) In case of exhibitions/fairs, a letter confirming allocation/participation of an entity in that exhibition/fair;

Medicinal products being imported for promotional purposes should be registered and or retained.

5.1.13 Export Permit

This type of permit serves to facilitate export of HPT's out of the Kenyan territory. It does not attract any payment.

5.1.13.1 Requirements for issuance of export permit.

a) Proforma/commercial invoice;
b) Certificate of analysis/certificate of conformity/local product registration/retention certificate;
c) Wholesale dealer's license (in case of pharmaceuticals or certificate of incorporation/business name registration certificate in case of medical devices/food supplements/borderline products/ herbal products);
d) DDA (in case of NPP's);

In situations where a local product is not manufactured for the local market, either or some of the below list of certificates may be requested by the Board:

a) Free sale certificate (medical devices/borderline products/food supplement/cosmetics/herbal products);
b) Certificate of pharmaceutical product (COPP) (in case of pharmaceuticals);
c) Import authorization from the foreign NMRA or National competent authority;

6.0 Information determined as critical for issuance of an import/export permit

During the application of an import/export permit, the below information will be considered mandatory for successful evaluation of an import/export permit. This information includes:

a) Application regime:
b) Importers name and their full address;
c) Exporters name and their full address;
d) Mode of transport;
e) Port of entry or exit (as per the Gazette notice for entry/exit of HPT's);
f) Country of origin;
g) Country of supply;
h) Purpose of import;
i) Product trade name;
j) Product generic/INN name;
k) Product strength and unit of measure;
l) Product unit pack size;
m) Product unit package type;
n) Product unit pack size price in foreign currency;
o) Product total quantity;
p) Currency;
q) Product Hs Code;
r) Unit price of the product;
s) Total FOB in foreign currency;
t) Any other information the Board may determine fit for regulatory oversight;

6.1 Access into the application system

The import/export permit application process is an online based activity. As a result, exim will be required to:

1. Obtain login credentials for the online system;
2. Ensure his/her company KRA PIN is activated;

6.2 Login Credentials.

It shall be the responsibility of the exim to obtain the requisite login credentials from KRA for interaction with the integrated custom management system (iCMS), Kenya Trade Network Agency (Kentrade) for interaction with the Trade

Facilitation Platform (TFP) of Kenya National Electronic Single Window System (eSW), and The Pharmacy and Poisons Board (PPB) for the PPB regulatory information management system (PRIMS) system. The application procedures for the login credentials are available in each PGA websites.

6.3 PIN Activation and OPT-IN

It shall be the responsibility of the exim to ensure that their company PIN is activated in the systems above and where necessary opted-in for visibility of the company to all relevant PGA's.

7.0 Application procedure for an import/export permit

7.1 Creation of a Base Document (BD)

The procedure for applying for an import permit begins with creation of a base document (BD). This is done in the integrated custom management system(iCMS) of KRA (www.kra.go.ke). The importer will be required to obtain login credentials from KRA by filling the application form in the KRA website.

7.1.1 Key sections to note while applying for the BD

7.1.1.1 Hs Code/Tariff

This is an integral element of the base document and the import permit and shall facilitate in mapping the BD/IDF to the right partner government agency regulatory pathway.

It shall be the responsibility of the exim to pick the right Hs Code/Tariff in respect to the nature of his/her consignment. Where necessary and in doubt, the exim is required to seek tariff classification/ruling from the tariff department of KRA.

Choosing the wrong Hs Code/tariff shall amount to mis-declaration and shall be handled as per the related provisions in the respective Act.

For avoidance of doubt, the Hs Code that shall be applicable shall be as per the current EAC CET Tariff Book.

7.1.1.2 BD information and details

The exim is informed that the information put on the BD shall be similarly required in the permit application without any alteration or deviation.

7.2 Import permit creation and application

Upon successful creation and submission of a BD/IDF, the importer shall be expected to take note of the auto-generated BD number.

The client will be expected to login into the Trade facilitation platform (TFP) of the National Single Window system(eSW) and synchronize the BD/IDF to the import permit by first:

a) Creating a Unique consignment reference number (UCR). In doing so, the importer shall ensure all the mandatory sections highlighted in asterisks are filled. The exim shall ensure he/she chooses the right regime. For purposes of this guideline, **regime** includes either: **Import, export, re-export, transhipment, transit**.

b) Choosing the appropriate type of import permit as explained above and proceeding to ensure that similarly the mandatory sections marked in asterisks are filled up. This shall include the choosing the **right mode of transport** as either: **Air, Sea, Road or Rail** and declaring the commensurate **port of entry/exit** and **custom's freight station**. Additionally, he/she shall be expected to make the right attachments as highlighted above. (See section requirements for issuance of the chosen type of permit above).

Before submitting the application, the client shall be expected to review his/her application for correctness in the summary page. If the application is satisfactory, the client shall submit the application online to the Board for evaluation and ensure payment is done (where applicable).

All exim(s) of HPT products shall ensure that such products obtain regulatory approvals such as MA or import/export permit approvals prior placing them in any port for clearance. Also visit the Board website or the below website for illustration: www.infotradekenya.go.ke

7.3 Payment for the import permit.

Upon submission of an import permit application, the client will be expected to make payment.

Only three (3) types of import permits shall be subject to payment. These are:

a) Commercial medicine import permit;
b) Medical device import permit;
c) Narcotics, Psychotropics and precursor substances import permit (commercial);

The import permit service fee shall be paid at **a rate of 0.75% FOB**. These fees might be revised time and again after stakeholder consultation and in reference to gazette notice.

7.3.1 Import permit payment procedure

Upon submission of an import permit that requires payment, the importer shall receive an auto-system generated invoice in the company email. The payment invoice shall outline the below areas:

a) The import permit application number;
b) The amount to pay in foreign currency;

c) The amount to pay in local currency based on CBK forex rate of the material day;
d) The MPESA pay bill number for the Board;

After payment, the system shall update the payment records of the related import permit application. Applications whose payment are done through other payment methods such as electronic funds transfer (EFT), swiping via PDQ machine, cheques and pre-payments shall be updated accordingly upon verification by the finance team and the same availed to the trade department electronically for subsequent action.

The evaluation process of the import permit application commences after payment is done and updated accordingly.

7.3.2 Underpayments

During permit application evaluation, where it is discovered that an importer under-declared the total value of the consignment, the Board shall calculate the extra-amount to be paid by the importer and input it into the import permit application. As a consequence, the importer shall receive an email containing the invoice for the top-up.

Importers are advised to avoid such actions as much as possible as it amounts to professional misconduct of the responsible person in the concerned company unless such mistakes are system generated.

7.4 Evaluation of import/export permits

The evaluation of import/export permits shall be on a first-in first out basis (FIFO).
There shall be two (2) levels of evaluation. These shall include: First evaluators level and second evaluators level.

The first evaluation level shall form the screening and review of the application for adequacy. Applications which successfully go through the first level of

evaluation shall proceed to the second level of evaluation for review and final decision determination based on the provided information.

7.4.1 Evaluation Outcomes

During the evaluation process, various outcomes may be determined. These outcomes include:

1. Approved-Pending release;
2. Approval to progress to the final determination;
3. Referred back for amendment;
4. Queried;
5. On-hold;
6. Application decline;

7.4.1.1 Evaluation Outcomes Communication to Exim

These shall be available in the track status section of the system or via an email communication or text message upon subscription.

Successful screening at the first evaluators level shall communicate to the exim that the application is in approval process. Unsuccessful screening shall indicate that the application has been referred back for amendment, queried, put on-hold or application declined.

Successful evaluation at the second evaluators level shall communicate to the exim that the application is approved-pending release. This shall signal the end of the permit evaluation process and start of the port activities upon arrival of the consignment at the port of entry/exit. This shall require the Board inspector(s) at the port to verify and inspect the consignment as per the port activities (See port of entry/exit inspections).

Referred back for amendment shall communicate to the exim that the application requires correction and this outcome can originate

from either of the evaluation levels back to the exim. On providing the required details and resubmitting the application, the application shall go back to the first evaluation but shall retain its initial application number which gives it an edge over the rest in light of FIFO.

Queried shall communicate to the exim to provide more information in respect to addition of more attachments only. Once this is done, the same shall be available to the evaluator for subsequent action.

On-hold outcome shall communicate to the exim the information requested by the evaluating officer. The application shall however not be editable to the exim;

Application declined shall communicate to the exim that the application has been rejected in total or cancelled. Application which suffers this outcome will have no further recourse.

7.5 Utilization of an Import/Export permit

An import /export permit granted to an exim shall be used for one occasion only and shall not be transferable to any third party.

Once an import/export permit is issued, they cannot be altered.

7.6 Amendment of an approved import permit

Amendment of an approved permit is possible subject to such authorization by the Board.

In requesting for such an amendment, the exim shall provide reasons for such amendment for review by the Board.

Amendment shall not require payment.

7.7 Validity of an import/export permit

Import/export permits shall have a validity period of one year from the date of issue. However, such validity can be extended by one to three months upon approved extension request by the exim.

Narcotics, Psychotropics and precursor substance permits shall have a validity period of six months.

The above notwithstanding, an approved import/export permit may be revoked at any time by the Board. Reasons for revocations may include:

a) Unauthorised change of particulars on the issued permit;
b) Erasing or overwriting details or particulars on the issued permit;

7.8 Records

Upon issuance of import/export authorization by the Board, the exim shall be expected to retain the such records for a period of 5 years from the date of importation. Such storage can be in either form of hard copy or electronic.

Stored import/export records shall be easily accessible and availed for review to the Board inspector for any post-import/export audit/investigation.

8.0 Turnaround times (TATs)

The TATs of the import permit applications shall be as per the Board's current Service Charter timelines.

9.0 Ports of Entry

The entry/exit of HPT's shall be through the gazetted ports of entry/exit.

9.1 Port of Entry/Exit Activities

The owner of the consignment or their nominated clearing agents shall be notified of arrival of the consignment by airline/ship ground handlers for subsequent port activities.

This shall include, filling a customs entry, declaration and custom assessments. Where health products and technologies are detected, such an entry/declaration/consignment shall be routed/assigned to the Board for inspection, verification and advise to the customs authority officials on whether to release or not to release the consignment. This shall be done in the designated systems in place at the time such as iCMS of customs, cargo-release system of Kentrade or any other system determined as appropriate by the Board in agreement with the other port users.

Consignment inspection and verification is two phased:

9.1.1 Phase one.

Document verification.

This will entail the verification of the following particulars/documents;

i. Regime code of the permit issued by the Board (Import/Export/re-export);
ii. Commercial Invoice and the declared value (FOB) in relation to what was declared during permit requisition;
iii. Importer (This should be the Market Authorization Holder/Local technical
    a. Representative or the registered recipient entity in cases of donations);
iv. The imported HPT's in relation to their MA or Board's authorization;
v. Certificate of analysis/Conformity (COA's/CoC's/PVoC's) of the products;
vi. Quantities of products imported versus those authorised during permit acquisition;
vii. Alignment of unique consignment number (UCR) of the permit to IDF/BD;
viii. Alignment of the particulars of the Entry (declaration) to those in permit, IDF/BD, airwaybill/bill of landing & and Release order;

9.1.2 Phase two.

Consignment inspection

This will include the following activities;

i. Actual product presentation through organoleptic examination;
ii. Products physically present versus those on the invoice and permit;
iii. Physical Product label claim versus that on the invoice & permit;
iv. Product labelling characteristics as declared to the Board during product registration (dossiers) and as presently secured on the Board database;
v. Storage conditions as per the declared climatic zones in dossiers;
vi. Patient information leaflet (PIL);
vii. Manufacturing site in country of origin;
viii. Quantities of the products imported versus those allowed in the permit and those on invoice;
ix. Batch numbers, manufacture and expiry dates of the products;
x. Minilab tests (Raman spectroscopy), based on a risk-based approach;

Note: Spelling errors, low-quality printing, volume disparities in ampoules and other defects may be signs of a substandard or falsified product. The external package should be intact and should not show any signs of damages or infiltrations that may change the inner content. If such is detected during port inspections and verifications, further regulatory actions may be taken.

During inspection, if an inspector determines more clarity is needed as to ascertain quality, safety and efficacy of a HPT, he/she shall draw sample in line with the sampling procedure of the Board, for minilab tests or full laboratory tests and investigations. Consequently he/she shall quarantine the consignment in appropriate warehouse as determined appropriate by the Board. The same shall be communicated to the customs officers and the owner or their nominated clearing agent in the system as either the consignment has been placed on-hold, or queried or to be released under quarantine. This shall await the minilab

tests or laboratory test report or investigation report for subsequent decision.

If the inspection outcome is successful, the inspector shall remove hold (default hold) and signal a No-Objection status for release of the consignment to the custom officials.

10.0 Risk Based Approach in permit issuance and port activities

In a rapidly globalizing world economy, increased transnational flow of goods, services and consignments, and harmonization of regulatory requirements, the Board shall embrace risk-based approach in its activities (where applicable). In this regard, the Board shall configure various parameters in its online system(s) in an endeavour to actualize this requirement and trigger various interventions or actions.

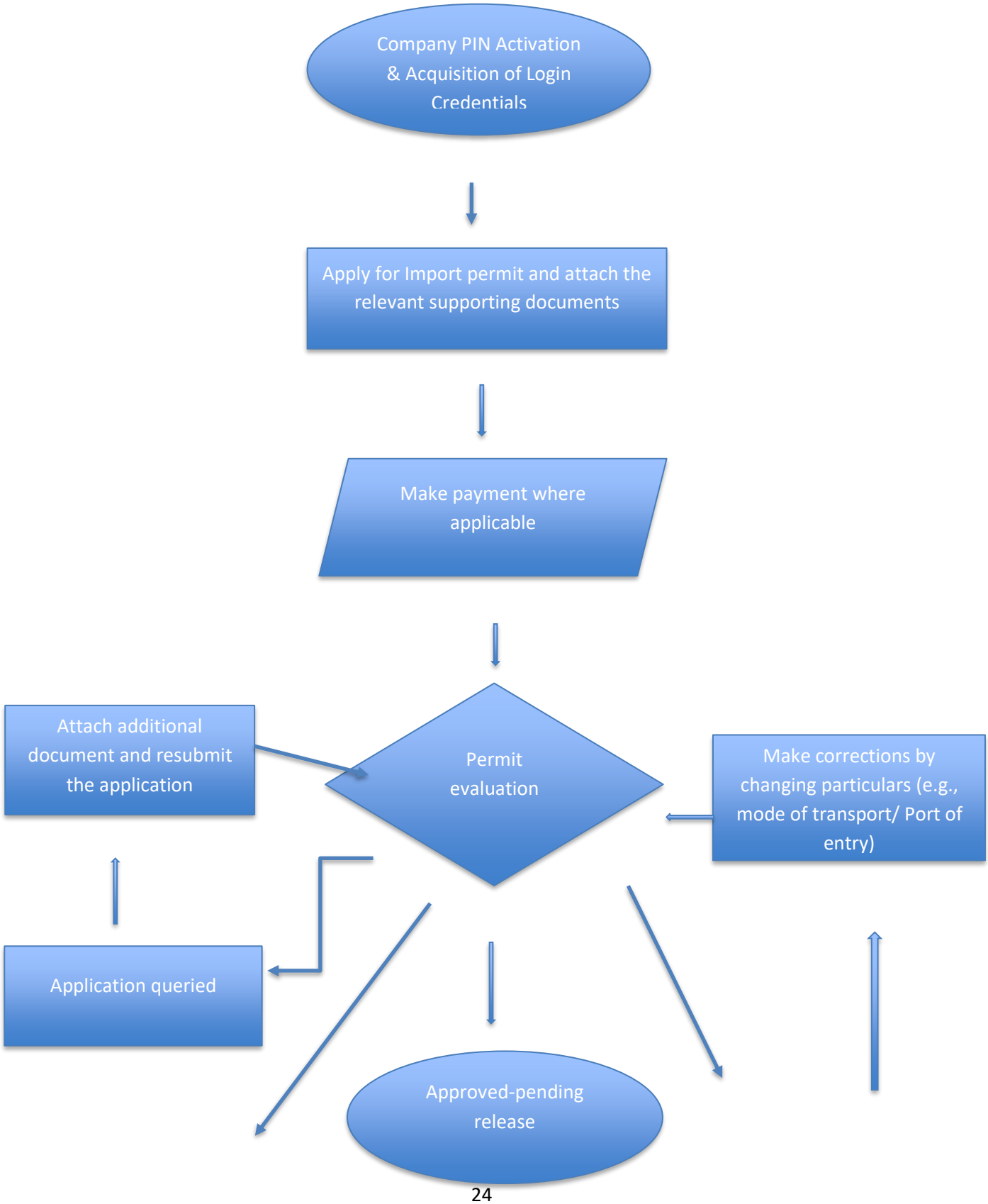
The parameters may include:

a) A company KRA PIN;
b) Hs Code(s);
c) Country of Origin;
d) Country of Supply;
e) Port of entry;
f) Product trade name;
g) Product generic/INN name;
h) Type of permit;
i) Importer name;
j) Exporter name;

The configuration of the above parameters may be informed by decisions from:

a) Quality safety efficacy (QSE) committee of the Board;
b) GDP/cGMP reports of the Board;
c) PMS/Pharmacovigilance reports of the Board;
d) WHO product advisories;
e) Other NMRA's advisories;

Process Flow Diagram (Importation/Exportation);



REVISION HISTORY

Revision No:	Date	Author(s)	Section(s) revised	Description of change	Approvals
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