





INSPECTION GUIDELINE	
TITLE:	AUTHOR:
GUIDELINES FOR INSPECTION OF IMPORTED MEDICAL DEVICES, FOOD SUPPLEMENTS, MEDICAL COSMETICS, HERBAL PRODUCTS AND OTHER BORDERLINE PRODUCTS	KEBS AND PPB
	NO. OF APPENDICES:
AUTHORIZATION: This Inspection Procedure is issued under the authority of:	
<i>Signature</i>	<i>Signature</i>
MANAGING DIRECTOR (KEBS)	REGISTRAR (PPB)
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RECORD OF CHANGES

No	Date (dd-mm-yyy)	Details of changes		Authorization
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1.0 PURPOSE

This guideline provides a framework for handling imported medical devices, food supplements, medical cosmetics, herbal products and other borderline products by both KEBS and PPB

2.0 SCOPE

This guideline shall apply to imported medical devices, food supplements, medical cosmetics, herbal products and other borderline products.

3.0 TERMINOLOGY

3.1 Definition of terms used

For the purpose of this procedure the following terms shall be applied in addition to those already defined in KEBS QM and PPB Inspection Manual/ Regulations

3.1.1 Borderline product

This is a production which does not fall into the category of Food Supplement, Medical Devices, Herbal Product, Medical Cosmetics and is neither a medicinal product nor a Medical Cosmetics but has a health-related function.



3.1.2 Food/Dietary/Nutritional Supplement or Nutraceutical Products

A product other than tobacco intended to supplement the diet and shall include all of the following characteristics:

- a) Contains concentrated source of one or more of the following: vitamins, minerals, amino acids, essential oils, natural substances of plants or animal origin, enzymes, substances with nutritional or physiological functions or contains any combination of these
- b) Is intended to be taken orally in the form of tablet, capsule, powder, soft gel, granules or liquids
- c) Is not presented for use as a conventional food or as a sole item of a meal of the diet
- d) Is labeled as a food supplement and has NO medical claims on it

3.1.3 Herbal Products

Any labeled preparation in pharmaceutical dosage form that contains one or more substances of natural origin as active ingredients that are derived from plants.

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3.1.4 **Inspection:**

Is examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgment, with general requirements.

3.1.5 **Medical Devices:**

A medical device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means."

3.1.6 **Medical Cosmetics**

Medical Cosmetics are substances or preparations that contains the qualities of a pharmaceutical product designed for cleansing, perfuming, soothing, treating, preventing or alleviating disease or symptoms of a pathological condition or that affect the structure or function of the human body

3.1.7 **Pharmaceutical Products**



A pharmaceutical product means a substance or a mixture of substances which can be used for any of the following purposes: -

- a) Treating, preventing, or alleviating symptoms of a diseases
- b) Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition
- c) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporary and whether by way of terminating, reducing, Postponing, or increasing or accelerating the operations of that function.

3.2 **Abbreviations and acronyms**

- 3.2.1 KEBS – Kenya Bureau of Standards
- 3.2.2 PPB – Pharmacy and Poisons Board of Kenya
- 3.2.3 PVoC – Pre-Export Verification of Conformity
- 3.2.4 CoC – Certificate of Conformity
- 3.2.5 NCR – Non-Conformity Report
- 3.2.6 ISM – Import Standardization Mark

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- 3.2.7 ISO – International Organization for Standardization
- 3.2.8 IEC – International Electro Technical Commission.
- 3.2.9 NCR – Non – Conformity Report
- 3.2.10 UCR- Unique Consignment Reference

4.0 REFERENCES

This procedure makes reference to the following documents, which form part of the QMS documentation



- 4.1 ISO 9001:2015, Quality Management Systems-requirements
- 4.2 ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection
- 4.3 ISO/IEC 17000:2004 Conformity assessment - Vocabulary and general principles
- 4.4 The Standards Act Cap 496, Laws of Kenya
- 4.5 Legal Notice Number 78 of July 2005 CAP 496, Laws of Kenya
- 4.6 Pharmacy and Poisons Act, Chapter 244, Laws of Kenya.
- 4.7 Legal Notices 191 and 192 of 2010 Chapter 244 of the Laws of Kenya
- 4.8 Legal Notice 1879, 1880 and 1881 of 2014 Chapter 244, Laws of Kenya
- 4.9 The PVoC Manual.

5.0 INSPECTION REQUIREMENTS

5.1 Pre –Export Verification of Conformity

- 5.1.1 To initiate importation of any product under this inspection framework, an importer shall apply and obtain UCR number from Kenya Electronic Single Window System;
- 5.1.2 The importer, through the exporter, shall then submit an inspection request to KEBS appointed inspection agent operating in the country of supply using the UCR as the reference for the consignment and pay requisite fees for the same.
- 5.1.3 KEBS appointed inspection agent shall undertake inspection in the country of supply as provided for in the PVoC Manual and issue a CoC for products meeting the requirements of the relevant Kenya Standards or approved specification. Products not meeting the requirements of the relevant Kenya Standards or approved specifications shall be issued with a Non- Conformity Report (NCR) and shall not be eligible for exportation to Kenya.
- 5.1.4 The Inspection agent shall provide CoC/NCR data to KEBS
- 5.1.5 KEBS make CoC data available to PPB through Kenya Electronic single window

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- 5.1.6 The importer upon receipt of the CoC from the Inspection Agent, shall apply for an import permit from PPB.
- 5.1.7 PPB shall process the import permit.
- 5.1.8 The importer shall process the IDF using the import permit issued by PPB.
- 5.1.9 The importer shall produce the PPB import permit and CoC to PPB and KEBS for clearance of cargo at the port of entry.

5.2 Handling of Goods Arriving Without CoC

- 5.2.1 The importers shall apply and obtain a UCR number from Kenya Electronic Single Window System;
- 5.2.2 The importer shall submit a request for certification to the KEBS at the port of entry upon payment of the 15% CIF destination inspection fee.
- 5.2.3 KEBS shall undertake destination inspection and issue a local CoC for products meeting the requirements of the relevant Kenya Standards or approved specification. Products not meeting the requirements of the relevant Standards shall be rejected and destroyed or re-shipped at a cost to the importer.
- 5.2.4 KEBS shall make available local CoC data to PPB through Kenya Electronic single window
- 5.2.5 The importer shall apply for PPB import permit.
- 5.2.6 PPB shall process the import permit.
- 5.2.7 The importer shall process the IDF using the import permit issued by PPB.
- 5.2.8 The importer shall produce the PPB import permit and local CoC to PPB and KEBS for clearance of cargo at the port of entry.

6.0 ISM REQUIREMENTS

- 6.1 These products are covered by ISM requirements.
- 6.2 To obtain the ISM, the importers shall apply for ISM in line with the guidelines for ISM published by KEBS on www.kebs.org.
- 6.3 KEBS shall process and issue the ISM to the importer for affixing on the products before placing them on the market.