GUIDELINES FOR VERIFICATION OF APPLICATIONS FOR IMPORTATION OF DRUGS FOR EMERGENCY OR EXTRAORDINARY CIRCUMSTANCES

National Drug Authority
Rumee Tower
Plot 19, Lumumba Avenue
P. O. Box 23096
Kampala, Uganda.
Tel: +256 - 0414 - 255665/347391/2
E-mail: ndaug@nda.or.ug
Website: http://www.nda.or.ug

Doc. No.: INS/GDL/038	Revision Date: 02 Oct 2018	Review Due Date: 05 Oct 2021
Revision No.: 0	Effective Date: 05 Oct 2018	

Authorization of these guidelines

	Authorized by
Title	Secretary to the Authority
Name	Donna Kusemererwa
Signature	
Date	03 Oct 2018

TABLE OF CONTENTS

1.0 BACKGROUND

The National Drug Policy and Authority Act (NDP/A) (Cap 206) mandates National Drug Authority to regulate the manufacture, importation, exportation, sale and supply of drugs. Section 8(3) of the NDP/A act requires that no drug shall be imported or sold unless it appears on the national formulary. However notwithstanding section 8(3) of the Act as indicated above, section 8(4) provides that a drug not appearing on the national formulary may be imported and sold after authorisation by the National Drug Authority to meet emergency or extraordinary circumstances.

1.1 Policy

1.1.1 The National Drug Policy and Authority Act (NDP/A) (Cap 206), section 2(d) states one of the functions of National Drug Authority as "*to improve Government regulation and control on manufacture, production, importation, exportation, marketing and use of drugs*".

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

1.1.3 Section 8(4) of the National Drug Policy and Authority Act (NDP/A) (Cap 206) states that: "*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*".

1.2 Objective

This Guideline provides a framework within which importation applications will be handled under section 8(4) of the Act, so as to enable the population of Uganda to have access to drugs at all times.

1.3 Scope

Applications for importation of drugs to meet emergency and extraordinary circumstances received by NDA through the National Drug Authority Management Information System (NDAMIS).

2.0 REVIEW OF APPLICATIONS

Review and consideration of applications for importation of drugs to meet emergency or extraordinary circumstances shall be carried out against the following criteria:

2.1 Emergency circumstance

This shall refer to a circumstance declared or communicated by an authorized Government Authority/Ministry/Department; which is urgent or unforeseeable or a situation which is not caused by dilatory conduct where the population of Uganda is seriously threatened by or actually confronted with a natural disaster, catastrophe, war or an act of God.

2.2 Extraordinary circumstance

This shall refer to importation of a drug not on the national formulary undertaken within the context of the following circumstances:

a) Drugs for use in clinical trials or field trials approved by NDA or for patients on post-trial access programs approved by NDA.
b) 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) drugs 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.

2.3 Notwithstanding the provisions of 2.1 and 2.2 above, National Drug Authority shall reserve the right to perform due diligence and grant or decline importation requests under section 8(4) in consideration of safety, efficacy and quality; and in consideration of new information about drug products that may arise from time to time.

3.0 APPROVED SOURCES

The above drugs shall be sourced from:

a) Manufacturers that are inspected and approved by National Drug Authority for compliance to Good Manufacturing Practices, or
b) Manufacturers that are inspected and approved for compliance to Good Manufacturing Practices by national medicines regulatory authorities (NMRA) 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 Organisation.
d) Manufacturers located within East African Community member states, with a valid certificate of compliance with Good Manufacturing Practices issued by the National Medicines Regulatory Agency.

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	Akampurira Moses	First Issue

End of Document