DRUG NATIONAL AUTHORITY

Guidelines on Submission of Documentation for Marketing Authorisation of a Pharmaceutical Product for Human Use that is Prequalified by World Health Organization or Approved by a Stringent Regulatory Authority

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Writing, Reviewing, Checking, Approval and Authorisation of these Guidelines

These guidelines were written and reviewed by the National Drug Authority (NDA) Secretariat.

They were checked by the Committee on National Formulary during their fourth meeting held on 15th July 2015.

They were approved by the fifth Drug Authority during their 52nd meeting held on 2nd of September 2015.

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	NDA Secretariat	Committee on National Formulary (CNF)	The Authority
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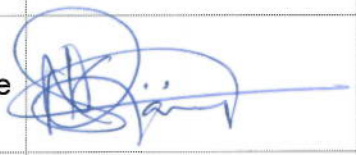
Signature			
Date	4th September 2015	4th January 2016	6th January 2016

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1.0 Introduction

1.1 National Drug Authority recognizes the scientific evaluation of drugs by Stringent Regulatory Authorities (SRAs) and the World Health Organization (WHO).

1.2 Where an applicant shares with NDA information on a drug that has been approved by WHO or SRA, NDA will consider such a drug for registration using an abridged evaluation process.

2.0 Objective of these guidelines

2.1 The objective of these guidelines is apply an abridged procedure for a pharmaceutical product for human use that is prequalified by the World Health Organization or approved by a stringent regulatory authority so as to shorten the registration timelines for products falling in this category.

3.0 Policy

These guidelines are developed in accordance with:

a) the National Drug Policy and Authority Act Cap 206, section 35(1)(a) states that:

"the drug authority may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug". Section 35(3) "If, on application made in the prescribed manner and on payment of the prescribed fee, the Authority is satisfied that the drug or preparation in respect of which the application is made has not been registered; and that the use of the drug or preparation is likely to prove beneficial, the Authority shall register the name and description of that drug or preparation".

b) National Drug Policy and Authority Registration Regulations, 2014, No.29, section 4(1) and (2) state that:

"(1) All products shall be registered in Uganda before sale or distribution.

(2) A person who intends to manufacture, import or export a product shall, prior to the manufacture, importation or exportation of the product, apply to the Authority for registration of the product".

4.0 Scope of these guidelines

These guidelines apply to pharmaceutical products for human use that are prequalified by World Health Organization or approved by a stringent regulatory authority.

5.0 Definitions

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

"Stringent Regulatory Authority" (SRA) means a regulatory authority which is:

a) a member of the International Conference on Harmonisation (ICH) (as specified on www.ich.org); or

b) an ICH observer, being the European Free Trade Association (EFTA), as represented by SWISSMEDIC, and Health Canada (as may be updated from time to time); or

c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).

6.0 Abbreviations and Acronyms

CTD	Common Technical Document
EFTA	European Free Trade Association
ICH	International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
SRA	Stringent Regulatory Authority
WHO	World Health Organisation

7.0 Documentation to be Submitted for WHO Prequalified Products

7.1 A covering letter, which should include:

a) A statement indicating that the information submitted is true and correct; and

b) A statement confirming that for WHO prequalification, the drug, including but not limited to composition/formulation, strength, manufacturing, specifications, packaging, product information, will at the time of submission and after registration in all respects, be the same as the drug prequalified by WHO.

7.2 Complete application (dossier) in CTD format, as per National Drug Authority Guidelines on Submission of Documentation for Marketing Authorisation of a Pharmaceutical Product for Human Use, Doc. No.: DAR/GDL/004.

7.3 Evidence of WHO prequalification and a copy of the marketing authorization, or the equivalent thereof, issued by the WHO prequalification team to demonstrate that the product is prequalified as per WHO requirements.

7.4 A copy of the current WHO-type certificate of a pharmaceutical product issued and fully completed, including answers to each question.

7.5 Stability data for Zone IV(b).

7.6 Labelling that meet NDA requirements.

7.7 Evidence of compliance with NDA GMP requirements. The applicant should fill in the GMP document review form and submit together with the application for registration along with applicable fees.

7.8 The latest WHO approved product information (summary of product characteristics (SmPC), or an equivalent thereof, the patient information leaflet (PIL), or equivalent thereof, and the labelling).

7.9 A list of the WHO approved manufacturer(s) of the product, including manufacturers of intermediates, primary packaging sites and release-testing sites, with the physical address of the manufacturing site(s) (and unit if applicable).

7.10 A list of the WHO approved manufacturer(s) of the active pharmaceutical ingredient(s) (API(s)) used in the manufacture of the product, with the physical address of the manufacturing site(s) (and unit if applicable).

7.11 Sample(s) of the product in market packaging(s). Attach the respective certificate of analysis.

7.12 A copy of the currently approved drug specifications (release and shelf-life), dated and signed or certified by authorized personnel, with the analytical test procedures.

7.13 A copy of the currently approved drug specifications (release and shelf-life), dated and signed or certified by authorized personnel, with the analytical test procedures.

7.14 The Quality Information Summary (QIS) as per NDA registration guidelines.

7.15 Any variations that are not country (Uganda) specific should be submitted to the WHO for approval and NDA should be updated of the change (after approval).

8.0 Documentation to be Submitted for Products Approved by a Stringent Regulatory Authority

8.1 A covering letter, which should include:

a) a statement indicating that the information submitted is true and correct;

b) a statement confirming that for an SRA approved product , the drug, including but not limited to composition/formulation, strength, manufacturing, specifications, packaging, product information, will, at the time of submission and after registration, in all respects be the same as the drug registered with the reference SRA; and

c) a statement indicating that the product is actually on the market of the reference SRA's country or region.

8.2 Complete application (dossier) in CTD format, as per National Drug Authority Guidelines on Submission of Documentation for Marketing Authorisation of a Pharmaceutical Product for Human Use, Doc. No.: DAR/GDL/004.

8.3 Evidence of approval of the drug by an SRA. A copy of the marketing authorization, or the equivalent thereof, issued by the reference SRA to demonstrate that the product is registered or licensed in accordance with the reference SRA requirements. If applicable, a copy of the latest renewal of the marketing authorization should also be provided.

8.4 A copy of the current WHO-type certificate of a pharmaceutical product issued and fully completed, including answers to each question, by the reference SRA.

8.5 Stability data for Zone 1V b.

8.6 Labelling that meet NDA requirements.

8.7 Evidence of compliance with NDA GMP requirements. The applicant should fill in the GMP document review form and submit together with the application for registration.

8.8 The latest SRA-approved product information (summary of product characteristics (SmPC), or an equivalent thereof, the patient information leaflet (PIL), or equivalent thereof, and the labelling). Provide a web link to the SRA-approved product information, preferably on the website of the SRA itself, if available.

8.9 A list of the SRA-approved manufacturer(s) of the product, including manufacturers of intermediates, primary packaging sites and release-testing sites, with the physical address of the manufacturing site(s) (and unit if applicable).

8.10 A list of the SRA-approved manufacturer(s) of the active pharmaceutical ingredient(s) (API(s)) used in the manufacture of the product, with the physical address of the manufacturing site(s) (and unit if applicable).

8.11 A tabular listing of the batches manufactured for the market of the reference SRA's region or country since approval or during the past five years, whichever is shorter. The table should include at least the batch number, batch size (number of units), date of manufacture and pack type/size. Also provide a copy of the most recent product quality review, prepared according to the requirements of the reference SRA.

8.12 Sample(s) of the product in market packaging(s). Attach the respective certificate of analysis.

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Document Revision History

Date	Revision No.	Document No.	Author(s)	Changes made and reasons for revision
6th Jan 2016	0	DAR/GDL/027	Apollo Angole Michael Mutyaba Eunice Nakimuli	First issue

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