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COMPARISON OF ADMINISTRATIVE INFORMATION (MODULE 1) IN EAST AFRICAN COUNTRIES

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ABSTRACT

MODULE 1-ADMINISTRATIVE INFORMATION: The ICH Harmonised Tripartite Guideline on Organisation of the Common Technical Document indicates that the Common Technical Document (CTD) Module 1 should contain administrative documents specific to each region, for example, forms, labeling, etc., and that the format be specified by the relevant regulatory authorities. Module 1 summarizes information about regional administration, including a cover letter, a table of contents, an application form, information about the product, clinical and non-clinical data, pharmacovigilance work, a certificate and documents for the drug, including a GMP certificate, and a certificate of analysis of the drug substance with suitability, as well as patent information. This ASEAN Common Technical Dossier (ACTD) is a guideline of the agreed upon common format for the preparation of a well-structured Common Technical Dossier (CTD) applications that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use in the Association of South East Asian Nations (ASEAN) regions. The ACTD aims to facilitate the review process and reduce the workload of the regulatory authorities and the applicants. The contents of the dossier modules (Module 1 – 5),

Comparison for the administrative information (Module 1) differentiation in East African Countries. (Eritrea, Ethiopia, Uganda, Tanzania, and Kenya) and Manufacturing and marketing authorization & Registration status.

KEYWORDS: Module-1, CTD, ACTD, ASEAN, ICH, EMA.

INTRODUCTION

When 100 deaths from diethylene glycol poisoning were linked to the use of a sulphanilamide elixir in the USA in the 19th century, regulations in medicine were first instituted. About 10,000 infants with phocomelia and other birth defects were born as a result of the thalidomide tragedy in the year 1960s. The governments were prompted to consider enacting stricter controls for drugs as a result. Following these occurrences, other nations, particularly the USA and certain European countries, began formulating regulatory principles and restructuring their regulatory bodies.

Representatives from the European Medicines Agency (EMA), the United States Food and Drug Administration, and the Ministry of Health, Labour and Welfare in Japan created a set of guidelines in 2000 that specified the format and information that should be included in an application for the registration of a new drug that could be used in all three countries (EU, United States, and Japan) for approval of a new drug or a change to the licensing of an already-approved drug.

Common Technical Document

A collection of guidelines for a medication registration dossier is known as the Common Technical Document (CTD). Each new application dossier includes through the information on pre-clinical and clinical trials for, safety, efficacy, and well as quality standards. Each CTD is fragmented into 5 modules,

Module 1: Module 1 of the CTD describes the administrative information and prescribing information's (for examples, the application form, a table of contents, information about the product, and labellings).

Module 2: Module 2 summaries the Quality, Non-clinical and Clinical data that are provided in Module 3, Module 4, and Module 5 respectively, CTD Table of Contents, CTD Introduction, Quality Overall Summary, Nonclinical Overview, Clinical Overview, Nonclinical Written and tabulated Summaries, Clinical Summary.

Module 3: Module 3 presents the chemistry, manufacturing, and controls reports for the product presented in the dossier. This Module gives complete detail of the manufacturing of the Active pharmaceutical ingredient or the drug substance and the drug product such as manufacturer details, product development, manufacturing steps, critical process parameters and in process controls as well as details related stability of the product, drug substance, raw materials and other excipients and analytical validation process as relevant to the product.

Module 4: Module 4 also known as the Safety Module, consists of all the study reports and assessments indicating safety of the product. The data in this module pertains to non-clinical or pre-clinical studies conducted for the drug product. This Module typically includes studies related to Pharmacology, Pharmacokinetics, Pharmacodynamics, Toxicology as relevant to the drug product.

Module 5: Module 5, also known as the Efficacy module, indicates all the study reports and assessments that prove that the product shows efficacy for the target indication. This Module is the most extensive, the length of which depends on the number of clinical studies conducted (Phase 1, Phase 2, and Phase 3 study data).

ASEAN Common Technical Document

This ASEAN Common Technical Dossier (ACTD) is a guideline of the agreed upon common format for the preparation of a well-structured Common Technical Dossier (CTD) applications that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use in the Association of South East Asian Nations (ASEAN) regions. The ACTD aims to facilitate the review process and reduce the workload of the regulatory authorities and the applicants.

ASEAN CTD Format comprised 4 parts,

- Part 1 – Table of contents, administrative information & prescribing information
- Part 2 – Quality document
- Part 3 – Non-clinical document
- Part 4 – Clinical document

Difference between CTD and ACTD Format

CTD format is a standard for registering pharmaceutical products in regulatory nations including the EU, US & Japan, whereas ACTD format is necessary for registering

pharmaceutical products in ASEAN nations (Association for South East Asians Nations).

- While ACTD format only has four parts—Part 1 for administration, Part 2 for quality and quality overall summary, Part 3 for non-clinical studies, and Part 4 for the clinical part.
- CTD format contains five modules representing Module 1 for the administrative Part, Module 2 for the quality overall summary, Module 3 for quality, Module 4 for non-clinical studies, and Module 5 for the clinical Part.

ASSOCIATION OF SOUTHEAST ASIAN NATIONS

The development of the region is important from an ASEAN [Association of South East Asian Nations] standpoint. A deal was reached in July 2009 to make it easier for countries in the ASEAN to comply with pharmaceutical laws. Different regulatory standards must be met by ASEAN nations before a medicine can be registered. The acceptance of ICH and EMA recommendations is increasing and in addition, there are conditions that are unique to each nation for successful MA approval by the Health Sciences Authority (HSA).

This ASEAN Common Technical Dossier (ACTD) serves as a template for creating well-organized Common Technical Dossier (CTD) applications that will be presented to ASEAN regulatory agencies for the registration of pharmaceuticals for human use. This guideline outlines a CTD format that, in the future, will make it easier to prepare electronic document submissions and will greatly cut down on the time and resources required to put together registration applications.

EAST AFRICAN COUNTRIES

The four regional economic communities designated by the African Union overlap with 13 nations in the East Africa area. The East African Community (EAC), the Intergovernmental Authority on Development (IGAD), the Southern African Development Community (SADC), and the Common Market for Eastern and Southern Africa (COMESA) are these regional economic groupings. The Economic Community of Great Lakes Countries, the Economic Community of Central African States, and the Indian Ocean Community are three more regional groups to which some of the nations belong.

East Africa has some of the world's fastest growing economies, developments, marketings. There are 13 nations in total: Burundi, Comoros, Djibouti, **Ethiopia, Eritrea, Kenya,** Rwanda, Seychelles, Somalia, South Sudan, Sudan, **Tanzania, and Uganda.**

METHODOLOGY

Literature review

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Collection of data by referring to respective country (Eritrea, Ethiopia, Uganda, Tanzania & Kenya) guidelines

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Contents of the Dossier (Module 1 – 5)

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Preparation of Module 01 dossier as per certain guidelines format (5 Countries)

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Comparative study of administrative information in East African countries

The dossier module contents Mod – 1: Administrative information & prescribing information, Mod – 2: CTD summaries, Mod – 3: Quality, Mod – 4: Non-clinical study reports, and Mod – 5: Clinical study reports.

Administrative Information & Prescribing Information In East-African Countries

1. **ERITREA**: **NMRA –** (NATIONAL MEDICINES REGULATORY AUTHORITY) Guideline – (THE STATE OF ERITREA, MINISTRY OF HEALTH National Medicines and Food Administration) Second edition

Contents of the module 1 (Eritrea)

MODULE 1: ADMINISTRATIVE INFORMATION		
1.1		COVER LETTER
1.2		TABLE OF CONTENTS (MODULE 1 – 5)
1.3		APPLICATION FORM
1.4		LETTER OF AUTHORIZATION & AGENCY AGREEMENT
1.5		GMP CERTIFICATE & MANUFACTURING LICENCE
1.6		CERTIFICATE OF PHARMACEUTICAL PRODUCT
1.7		REGISTRATION STATUS IN OTHER COIUNTRIES
1.8		EUROPEAN CERTIFICATE OF SUITABILITY (CEP)
1.9		LABELING
1.10		PRESCRIBING INFORMATION
	1.10.1	Summary of Product Characteristics
	1.10.2	Patient Information Leaflet
1.11		SAMPLES

2. **ETHIOPIA: EFDA** – (ETHIOPIAN FOOD AND DRUG ADMINISTRATION) Guideline – (FOOD, MEDICINE, AND HEALTH CARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA) (FMHACA)

Contents of the module 1 (ETHIOPIA)

MODULE 1: ADMINISTRATIVE INFORMATION		
1.1		COVER LETTER
1.2		TABLE OF CONTENTS OF THE APPLICATION INCLUDING MODULE 1 (MODULES 1 – 5)
1.3		APPLICATION FORM
1.4		AGENCY AGREEMENT
1.5		GOOD MANUFACTURING AND CERTIFICATE OF PHARMACEUTICAL PRODUCT
1.6		CERTIFICATE OF SUITABILITY (CEP) if any
1.7		PRODUCT INFORMATION
	1.7.1	Summary of Product Characteristics
	1.7.2	Labelling information (immediate and outer label)
	1.7.3	Patient Information Leaflet (PIL)
1.8		EVIDENCE FOR AN APPLICATION FEE

3. **UGANDA**: **NDA** – (NATIONAL DRUG AUTHORITY) Guideline – (Guidelines on submission of documentation for Marketing Authorization of a Pharmaceutical product for Human Use)

Contents of the module 1 (UGANDA)

MODULE 1: ADMINISTRATIVE INFORMATION		
1.1		COMPREHENSIVE TABLE OF CONTENTS FOR ALL MODULES
1.2		COVER LETTER
1.3		COMPREHENSIVE TABLE OF CONTENTS
1.4		QUALITY INFORMATION SUMMARY (QIS)
1.5		PRODUCT INFORMATION
	1.5.1	Prescribing Information (Summary of Product Characteristics)
	1.5.2	Container labelling
	1.5.3	Patient Information Leaflet (PIL)
	1.5.4	Mock-ups and specimens
1.6		INFORMATION ABOUT THE EXPERTS
1.7		APIMFs AND CERTIFICATES OF SUITABIITY TO THE MONOGRAPHS OF THE EUROPEAN PHARMACOPOEIA
1.8		GOOD MANUFACTURING PRACTICE
1.9		REGULATORY STATUS WITHIN EAC AND IN COUNTRIES WITH SRAs
	1.9.1	List of countries in EAC and countries with SRAs in which a similar application has be submitted
	1.9.2	Evaluation reports from EAC-NMRA

	1.9.3	Evaluation reports from SRAs
	1.9.4	Manufacturing and Marketing authorization
1.10		PAEDIATRIC DEVELOPMENT PROGRAM
1.11		PRODUCT SAMPLES
1.12		REQUIREMENT FOR SUBMISSION OF A RISK MITIGATION PLAN
1.13		SUBMISSION OF RISK MANAGEMENT (RMP)

4. **TANZANIA**: **TMDA** – (TANZANIA MEDICINES AND MEDICAL DEVICE AUTHORITY) Guideline – (Guidelines on submission of documentation for registration of Human Pharmaceutical Products)

Contents of the module 1 (TANZANIA)

MODULE 1: ADMINISTRATIVE INFORMATION		
1.1		COMPREHENSIVE TABLE OF CONTENTS FOR ALL MODULES
1.2		COVER LETTER
1.3		COMPREHENSIVE TABLE OF CONTENTS
1.4		APPLICATION FORM
1.5		PRODUCT INFORMATION
	1.5.1	Prescribing information (Summary of Product Characteristics)
	1.5.2	Container labelling
	1.5.3	Patient Information Leaflet (PIL)
	1.5.4	Mock-ups and specimens
1.6		INFORMATION ABOUT EXPERTS
1.7		CERTIFICATES OF SUITABILITY OF MONOGRAPHS OH THE EUROPEAN PHARMACOPOEIA (CEP) or EAC-APIMF
1.8		GOOD MANUFACTURING PRACTICE (GMP)
1.9		GOOD CLINICAL PRACTICE (GCP) or GOOD LABORATORY PRACTICE (GLP)
1.10		REGULATORY STATUS
	1.10.1	Registration status from countries with Stringent Drug Regulatory Authorities (SDRAs)
	1.10.2	Registration status in EAC Partner States
	1.10.3	List of countries in which a similar application has been submitted
	1.10.4	Statement on whether an application for the product has been previously rejected, withdrawn or repeatedly deferred in the EAC Partner states
1.11		EVIDENCE OF API AND/OR FPP PREQUALIFIED BY WHO
1.12		MANUFACTURING AND MARKETING AUTHORIZATION
1.13		PRODUCT SAMPLES

5. KENYA: **PPB – (THE PHARMACY AND POISONS BOARD)** Guideline – Guidelines on Medicines Evaluation and Registration.

Contents of the module 1 (KENYA)

MODULE 1: ADMINISTRATIVE INFORMATION		
1.1		COMPREHENSIVE TABLE OF CONTENTS FOR ALL MODULES
1.2		COVER LETTER
1.3		APPLICATION FORM
1.4		PRODUCT INFORMATION
	1.4.1	Prescribing information (Summary of Product Characteristics)
	1.4.2	Container labelling
	1.4.3	Patient Information Leaflet (PIL)
	1.4.4	Mock-ups and specimens
1.5		INFORMATION ABOUT THE EXPERTS
1.6		CERTIFICATES OF SUITABILITY OF MONOGRAPHS OH THE EUROPEAN PHARMACOPOEIA (CEP) or PPB-APIMF
1.7		GOOD MANUFACTURING PRACTICE (GMP)
1.8		GOOD CLINICAL PRACTICE (GCP) or GOOD LABORATORY PRACTICE (GLP)
1.9		REGULATORY STATUS
	1.9.1	Registration status from countries with Stringent Drug Regulatory Authorities (SDRAs)
	1.9.2	Registration status in PPB Partner States
	1.9.3	List of countries in which a similar application has been submitted
	1.9.4	Statement on whether an application for the product has been previously rejected, withdrawn or repeatedly deferred in the PPB Partner states
1.10		EVIDENCE OF API AND/OR FPP PREQUALIFIED BY WHO
1.11		MANUFACTURING AND MARKETING AUTHORIZATION
1.12		PRODUCT SAMPLES

SUMMARY

- A brief description of CTD, ACTD format, and comparison of administrative information (Module 1) among East-African countries as per their country guidelines have been discussed in this dissertation.
- CTD comprised of 5 modules; Module – 1: Administrative information & prescribing information, Module – 2: CTD summaries, Module – 3: Quality, Module – 4: Non-clinical study reports, and Module – 5: Clinical study reports. ACTD comprises 4 Parts namely; Part I: Table of contents, administrative information & prescribing information, Part II: Quality document, Part III: Non-clinical document, and Part IV: Clinical document.

- The differentiation of administrative & prescribing information dossier modules in East-African countries like **Eritrea, Ethiopia, Uganda, Tanzania and Kenya** as per their respective country guidelines. The dossier contents regarding administrative & prescribing information have been reconstituted briefly according to their country guidelines. Major contents like Summary of product characteristics, Patient Information Leaflet & Quality Information Summary have been explained accordingly.

CONCLUSION

- Since there are different drug approval processes around the world, it is crucial, especially for generic manufacturers, to carefully assess the market need, development costs, target regions, and regulatory requirements prior to the development of drugs.
- From the comparative analysis of administrative information in East African countries that the administrative information systems within the area exhibit substantial differences. Some nations have advanced significantly, but others are languishing behind. By comparing the administrative information (Module 1), we can better understand the differences between Module 1 in East African countries like Eritrea, Ethiopia, Uganda, Tanzania & Kenya. The major contents like manufacturing and marketing authorization & Registration status exhibit the majority of differences in comparison with the listed East African countries.
- To conclude, the comparative analysis in East African countries like Eritrea, Ethiopia, are the region's has huge population, rapid economic development, and high prevalence of diseases. The registration procedure for pharmaceutical businesses operating in the area has been made easier because of the East African community's efforts to harmonize regulatory criteria for pharmaceutical goods across member nations. As such, registering a dossier in these nations may be a crucial part of a company's strategy for accessing the African market.

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