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THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GOOD RELIANCE PRACTICES

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TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma - Tanzania, Tel: +255 (26) 2961989/2061990/ +255(22) 2450512/2450751/2452108, Email: info@tmda.go.tz, Website: www.tmda.go.tz, Toll free: 08001100834

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Abbreviations and Acronyms

AVAREF	-	African Vaccine Regulatory Forum
CEP	-	Certificates of Suitability to the monographs of the European Pharmacopoeia
CMA	-	Conditional Marketing Authorization
CPQ	-	Confirmation of API Prequalification
COVID-19	-	Corona Virus Disease 2019
EAC	-	East Africa Community
EMA	-	European Medicines Agency
EU	-	European Union
GCP	-	Good Manufacturing Practices
GMP	-	Good Clinical Practices
HSSP	-	Health Sector Strategic Plan
ICH	-	International Council for Harmonization
IEC	-	International Electrotechnical Commission
ILAC		International Laboratory Accreditation Cooperation
ISO	-	International Organization for Standardization
MHLW/PMDA		Japanese Ministry of Health, Labour and Welfare /Pharmaceuticals and Medical Devices Agency
NEHCIPTZ		National Essential Health Care Intervention Package in Tanzania
NRA	-	National Regulatory Authority
OECD	-	The Organisation for Economic Co-operation and Development
PIC/S	-	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
QCL	-	Quality Control Laboratory
RA	-	Regulatory Authority
SRA		Stringent Regulatory Authority
TMDA		Tanzania Medicines and Medical Devices Authority
WHO		World Health Organization
USFDA		United States Food and Drugs Administration

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Finally, I would like to thank the management of TMDA for their valuable support in the development of these guidelines.

Dr. Yonah H. Mwalwisi
Director of Human and Veterinary Medicines

Foreword

This document has been crafted by the Tanzania Medicines and Medical Devices Authority (TMDA) to outline reliance model and approach the Authority is planning to ensure access to quality, safe and efficacious medicines and other health technologies for the well-being of the community.

This guidance document shall be read in conjunction with the current laws and regulations used within TMDA jurisdiction. Irrespective of the requirements of this guidance document, TMDA has the right to request additional information or define conditions not specifically described in this document that are deemed necessary for establishing the quality, safety and efficacy of the product.

The guidance is intended to clarify the key principles of reliance, reliance models, procedures and pathways to be implemented by the Authority to accelerate the regulatory decision that ensures medical products are easily accessible and available to the needs of the country. The guidance apply to all regulatory functions performed by TMDA for all products that fall within the global definition of medicines and other health technologies that appears in different global frameworks for medical products and TMDA regulations.

We expect that this document will enhance the acceleration of the Authority's decision and in turn ensure access and availability to essential medical products with required quality standards to protect the public.

Moreover, the document intends to facilitate the working relationship between the TMDA and other NRAs subject to medical product regulations and reduce the duplication of work done by other competent authorities. This will eventually complement the efforts made by collaborative and harmonization initiatives to promote reliance on regulatory decision-making to support the millennium development goal for improving people's lives. Furthermore, this initiative will ultimately increase access to essential medical products that are needed for the well-being of the community and covering the National Essential Health Care Intervention Package at the national and regional levels.

Adam M. Fimbo
DIRECTOR GENERAL

Glossary of Terms

The following terms are defined for the purpose of this guideline:

Abridged regulatory pathways

Abridged regulatory pathways are regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely or primarily based on the application of reliance. The expectation is that the use of reliance would save resources and shorten timelines compared to standard pathways, while maintaining regulatory oversight standards.

Assessment

For the purpose of this document, the term “assessment” covers the outcome of any evaluation conducted for a regulatory function (e.g. evaluation conducted for a clinical trial application, evaluation of an initial authorization for a medical product or any subsequent post-authorization changes, evaluation of safety data, evaluation conducted as part of an inspection, etc.)

Authority

Refers to the Tanzania Medicines and Medical Devices Authority.

Competency

Reliance requires that national authorities build the necessary competencies for critical decision-making for proper implementation of the regulatory framework. In most cases, they need to have several critical tools for implementation, such as information-sharing arrangements or information platforms, among others. Conversely, authorities being relied on should have and maintain competencies and performance in the given area, and they should prove the use of internationally accepted standards. The competencies should be benchmarked through transparent processes that develop trust in the capacities of these reference authorities.

Consistency

Reliance on a specific process/evaluation/decision should be established for a specific and well-defined category of products/practices and should also be predictable. Thus, it is expected that reliance shall be applied consistently for all products/practices in the same predetermined category.

Equivalence of regulatory systems

Implicates strong similarity between two regulatory systems that are mutually established and documented through objective evidence. Equivalence can be established using criteria and approaches such as similarity of the regulatory framework and practices, adherence to the same international standards and guidelines, experience gained in the use of assessments for regulatory decision-making, joint activities, and exchanges of staff. It is expected that equivalent regulatory systems will result in similar standards and levels of regulatory oversight or “levels of control”.

International standards and guidelines

The term includes relevant WHO standards and guidelines, as well as any other relevant internationally recognized standards (e.g., International Organization for Standardization or pharmacopoeial standards) and guidelines (e.g., International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use [ICH] or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme [PIC/S]).

Legal basis

Reliance should be coherent with national legal frameworks and supported by clear mandates and regulations that aim to achieve efficient implementation.

Mutual recognition agreement

According to a definition issued by the Organization for Economic Co-operation and Development (OECD), a mutual recognition agreement is a principle of international law whereby states party to such agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process that allows conformity assessments carried out in one country to be recognized in another country.

Recognition

The recognition is routine acceptance of the regulatory decision of another regulator or trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition should be based on evidence of conformity that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Reference regulatory authority

Refers to a national or regional authority, or a trusted institution such as WHO prequalification (WHO PQ), EMA, or USFDA, whose regulatory decisions or work products are relied upon by another regulatory authority to inform its own regulatory decisions

Regional regulatory system

A system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework but not necessarily under a common legal framework. The common framework must at least ensure equivalence among the members in terms of regulatory requirements, practices and quality assurance policies. The system or regional body may have enforcement powers to ensure compliance with the common regulatory framework.

Regulatory reliance

Regulatory reliance is the act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to regulatory work performed by another regulatory or trusted institution for purposes of reaching its own regulatory decisions.

Reliance

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Sameness of product

For this document, ‘the sameness of the product’ means that two products have identical essential characteristics (i.e., the product being submitted to the relying authority and the product approved by the reference regulatory authority should be essentially the same). All relevant aspects applicable to drugs, medical devices, in vitro diagnostics, biocidal and tobacco products have to be considered to confirm that the product is the same or sufficiently similar (e.g., same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same active pharmaceutical ingredient suppliers, the same quality of all excipients, etc.). Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same.

Unmet medical need

The definition of unmet medical need varies between countries and constituents. Even if many definitions may look similar, different constituents may apply different sets of criteria (such as epidemiology/prevalence, the burden of disease, existence or not of treatment, etc.) depending on the context of use. Two examples of the definitions used by EU and US regulators are given below.

- **European Commission:** Commission Regulation 507/2006 on the conditional marketing authorization (CMA) for medicinal products for human use provides for four conditions for CMA to apply: positive risk/benefit balance, likelihood to provide comprehensive clinical data, unmet medical need and benefit to public health. For this purpose, unmet medical need means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorized in the Community or, even if such a method exists, in relation to which the medicinal product concerned will be of a major therapeutic advantage to those affected. [EC]

- **US FDA:** In FDAs guidance for industry, an unmet medical need is defined as a condition whose treatment or diagnosis is not addressed adequately by available therapy. An unmet medical need includes an immediate need for a defined population (i.e., to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs). [FDA]

Stringent Regulatory Authority

In this guideline, stringent regulatory authority refers to:

- member of ICH before 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency of Japan;

- an ICH observer before 23 October 2015, namely: The European Free Trade Association, as represented by Swissmedic and Health Canada; or

- a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement before 23 October 2015 including Australia, Iceland, Liechtenstein and Norway.

Work-sharing

Work sharing is a process by which the regulatory authority of two or more jurisdictions shares activities to accomplish a specific regulatory task. The opportunities for work-sharing include, but are not limited to, jointly assessing applications for authorization of clinical trials, marketing authorizations or good practices inspections, joint work in the post-

marketing surveillance of medical product quality and safety, joint development of technical guidelines or regulatory standards, and collaboration on information platforms and technology. Work-sharing also entails the exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other NRAs.

Joint activity is a form of work-sharing whereby a regulatory task is conducted by two or more NRAs in collaboration to share their assessments, benefit from each other's expertise and discuss any shortcomings of the data evaluated. For example, a joint assessment is a procedure in which the same application is submitted simultaneously to two or more NRAs so that they conduct their evaluations in parallel and share their scientific assessments (e.g., the different modules for quality, nonclinical and clinical data can be assigned to different NRAs for review). The NRAs participating in a joint assessment can combine their lists of questions or deficiencies with the manufacturer and base their respective independent regulatory decisions on the outcome of these assessments. Similarly, a joint inspection is one in which two or more NRAs share the activities and assessments performed during an inspection.

1. Introduction

The Tanzania Health Sector Strategic Plan (HSSP V, 2021 – 2026) considers medical products and other health technologies among the key elements of health systems. It is therefore important to ensure that, the medical products of established quality, safety and efficacy are available to meet the health care requirements and cover the National Essential Health Care Intervention Package in Tanzania (NEHCIPTZ) that are needed for prevention, diagnosis and treatment of specific diseases and that are also recommended for procurement at the national level.

To meet this need, it is important to ensure that the country has a robust regulatory system that will facilitate access to quality-assured existing and new health products. This also includes promoting transparency to regulatory decisions and should provide greater focus on accelerating the equitable deployment of and access to innovative medical products.

A well-designed and operated regulatory system not only improves product availability, enabling the achievement of national disease program priorities but also unlocks capital that is currently tied up in inventory for reinvestment in healthcare. TMDA is continuing to strengthen the regulatory system to achieve accelerated and more equitable access to products and tools reflecting public health best practices.

Disease program strategies can be directly enabled by transforming and adapting good regulatory practices to support the multi-decision needs, allowing for the accessibility of medical products. Countries often require a sustainable mechanism to support the development or strengthening of regulatory capacities to perform various regulatory functions related to medical product regulations. Investments in good regulatory practices should be adapted to each country's context, including their preparedness and readiness to introduce new health products and innovative health service solutions. Cross-cutting interventions include those that integrate the availability of medical products and other health commodities across all priority diseases and support coordinated regulatory capacity.

Building on the collective lessons learned to date from COVID-19, TMDA needs to enhance its mechanisms to accelerate regulatory decisions on the quality, safety, and efficacy of medical products to ensure their availability and accessibility. This can be achieved by implementing good regulatory practices and applying reliance practices. Regardless of the model used, adopting reliance will facilitate timely decisions on the quality, safety, and efficacy of medical products.

To address current challenges and innovations in the field, the TMDA should consider adopting critical approaches for effective, efficient, and transparent regulatory systems. Such systems are an essential component of overall healthcare systems and can contribute to desired public health outcomes and investments in innovation. Inefficient

regulatory systems can create barriers to accessing safe, effective, and quality medical products.

Implementing a reliance approach in the regulatory environment can improve regulatory efficiencies for various functions related to medical product regulations, leading to timely decisions on the quality, safety, and efficacy of medical products. This approach can also facilitate the efficient use of available resources and reduce work duplication by recognizing regulatory decisions made by other NRAs.

This guidance outlines the purpose, scope, principles, and approaches to regulatory reliance, as well as the context within which it has been developed and the pathway for achieving a good reliance. The guidelines have been developed specifically to manage regulatory activities for which decisions have been made by other NRAs. The guidelines also aim to provide approaches to optimize the use of available resources and expertise, reduce work duplication and speed up the volume of priority medical products. As the majority of normal or routine regulatory procedures for essential medical products can take days to be approved, having a guideline in place to deal with applications that meet the criteria for the reliance pathway is vital.

2. Purpose

The purpose of the guidelines is to provide a coordinated and consistent mechanism to promote a more efficient approach to regulatory oversight, thereby promoting access to quality-assured, effective, and safe medical products.

To accomplish this, the guideline:-

a) Serves as a comprehensive operational plan to address the context of reliance in supporting regulatory practices, procedural documents, and other guidance integration;

b) Defines the reliance operations structure and assigns essential tasks to all functions involved in the regulation of medical products;

c) Provides mechanisms for coordination and cooperation of the Authority with other regulatory authorities within the region or globally;

d) Integrates reliance operations to ensure consistency with nationally recognized regulatory policy and guidance;

e) Develops a common understanding of risk management and establish a system to monitor those risks to ensure early action;

f) Clarifies the roles, principles, and key approaches for regulatory reliance to be used by the TMDA concerning the availability of priority medical products according to the country's needs;
g) Establishes a minimum level of reliance on other regulatory authorities.

3. Scope and Applicability

This guideline applies to reliance activities in the field of regulatory oversight of medical products needed for priority diseases and other health products that are deemed necessary for the benefit of the public. The guideline covers all regulatory activities, including the regulatory system, marketing authorization and registration, vigilance, market surveillance and control, licensing establishments, inspections of regulatory compliance, oversight of clinical trials, and release of product lots.

4. Principles of Good Reliance Practices

The adopted principles of reliance are in line with the WHO recommendations to optimize innovative and more effective forms of collaboration to make the best use of available resources and expertise to avoid duplication to ensure the safety, quality and efficacy of locally used products.

4.1 The sovereignty of decision making

Reliance is a sovereign decision. The Authority decides when and how to use reliance and in which circumstances. The decision to use reliance and how best to do so rests with the TMDA. In applying reliance in daily practice, the TMDA shall maintain independence, sovereignty, and accountability in regulatory decision-making.

4.2 Legal basis

The Authority applies reliance procedures in coherence with Section 5 (2)(f) of the Tanzania Medicines and Medical Devices Act, Cap 219 and its regulations made under thereof, which aims at efficient decision-making.

4.3 Transparency

The TMDA shall use the approach of relying on regulatory decisions made by another regulatory authority while remaining transparent regarding the standards, processes, and approaches adopted to implement reliance measures. In addition, the basis and rationale for relying on a specific entity may be disclosed and understood by all parties.

The TMDA shall engage with all stakeholders, including the industry, to ensure the appropriateness and awareness of the reliance processes. The Authority is committed to transparency through the publishing and sharing of regulatory information to facilitate information exchange among interested parties.

4.4 Competency

The authority has the necessary competencies for important decision-making processes and the proper implementation of the reliance guidelines. These competencies are established through transparent processes that develop trust in the capacities of competent and dedicated staff, who can effectively utilize information from foreign sources in the local context.

4.5 Consistency

The Authority reliance decision shall be established for the specific and well-defined category of products and practices. The scope of regulatory activities where reliance may be practiced has been clearly defined and the process for practicing reliance is transparent and predictable. Thus, the expectation is that reliance is applied consistently for products/processes in the same predetermined categories.

5. Reliance Pathways

The authority employs reliance pathways in its regulatory decisions to accelerate the approval of various activities, such as clinical trials, GMP/GCP compliance, quality control

procedures, medical product marketing authorization, and vigilance decisions. The reliance aims to reduce timelines compared to standard regulatory practices, but the authority shall remain responsible and accountable for the decisions taken.

This risk-based approach considers various factors, such as the type of products, public health needs and priorities, level of resources and expertise available, and opportunities for reliance.

For instance, in the case of marketing authorization, the assessment process may involve additional tasks when using the following four (4) reliance pathways:

i. **Verification of the sameness** of the product is necessary to ensure that the medical product is the same as the one assessed by the reference regulatory authority.

ii. **Confirmation of the applicability of the assessment outcomes** of another authority is essential for regulatory decision-making in the national context. This includes assessing legal and regulatory settings, benefit-risk assessment, co-morbidities, unmet medical needs, risk management plans, and quality-related specificities such as climatic zones for product stability. In case of any differences, such as in the target population, epidemiology, and other disease-related features, concomitantly used medicines, and other factors that can substantially affect the benefit-risk profile of the medicine, as well as quality parameters, particularly related to the stability under different climatic conditions, appropriate action needs to be taken.

iii. **An abridged review** of the quality, safety, and efficacy data should be conducted, taking into account the information provided in the assessment reports of the reference regulatory authority.

iv. **Joint assessment or work-sharing** between two or more regulatory authorities is recommended. This can involve a primary review by one authority, followed by a second review by another authority, and a joint assessment session to finalize the assessment report and comments.

v. **Recognition procedures** involve a model in which authorities/organizations review medicinal products intended to be marketed in countries or regions other than their own. Examples of such review procedures include EMA's Article 58 procedure, Swissmedic's Marketing Authorization for Global Health products, and medicines reviewed through the WHO collaborative prequalification program. With such review procedures, the authority can directly recognize the outcome of this review.

6. Areas of Reliance

Areas of reliance are: registration and marketing authorization, GMP/GCP inspections, clinical trials, vigilance, and quality control testing-related decisions to ensure full implementation and compliance with the reliance route.

6.1 Marketing Authorization of medical products

The authority may apply reliance procedures for granting marketing authorization in the following situations:

i. The product should have been evaluated and listed as a WHO-prequalified product through the WHO PQ collaborative registration procedure.

ii. The product should have been evaluated and listed as a product authorized through stringent procedures, including through the European Union (EU) Article 58 procedure, the Swissmedic Marketing Authorization for Global Health Products, or the International Generic Drug Regulatory Programme.

iii. The product should have been registered and/or granted marketing authorization in either an ICH founding regulatory member state/region, or ICH standing regulatory member state/region, or ICH regulatory member: European Union member states (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, and The Netherlands), United Kingdom, Japan, United States, Swiss Medic of Switzerland, Health Canada, Australia, Norway, Iceland, and Liechtenstein.

iv. The product should have been jointly evaluated and listed as an output of the East African Community (EAC).

v. Furthermore, products registered by WHO-listed agencies may be considered through the reliance pathways on a case-by-case basis.

vi. Where a Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP) or Confirmation of API Prequalification (CPQ) is issued, it may be considered through the reliance pathway by only focusing on specific sections not covered under CEP or CPQ.

6.2 Post-approval changes

Following the same principles as for initial marketing authorization, reliance can also be applied broadly for assessing post-approval changes already approved by NRAs considered as reference authorities.

6.3 GMP/GCP Inspections

The authority may apply reliance procedures for GMP/GCP inspections through desk assessment when pharmaceutical manufacturing facilities meet any or all of the following criteria in the following situations:

a. Located in countries with Stringent Regulatory Authority (SRA) or should have been inspected and approved by WHO-Listed Authorities (WLA) as follows:

    i. Founding regulatory members of the International Conference on Harmonization (ICH), namely the European Commission (EC)/European Medicines Agency (EMA), Japan, and the United States of America; Standing regulatory members, namely Health Canada and Swiss Medic (or as may be updated from time to time and approved by TMDA); and

    ii. Regulatory members, namely the Health Science Authority (HSA) Singapore, the Therapeutic Goods Administration (TGA) Australia, and Agencia Nacional De Vigilancia Sanitaria (ANVISA) Brazil.

b. Inspected and approved by World Health Organization (WHO) under Medicines Prequalification Program.

c. Inspected and approved by Regional Harmonization Initiatives, namely the East African Community (EAC) and the Southern African Development Community (SADC).

6.4 Reliance in Vigilance related decisions

The Authority shall continue to ensure the safety of marketed products through its established vigilance systems. To ensure that safety issues are promptly identified and the necessary interventions implemented, the Authority considers decisions from competent authorities on the safety of medical products that impact negatively on the health of patients.

i. Regulatory decisions of the Authority by leveraging safety decisions from reference regulatory authority (ies), regional or international bodies are geared towards ensuring appropriate and safe use of registered medical products.

ii. The medical product of concern should have been registered and/or granted marketing authorization in either an ICH founding regulatory member state or region such as European Commission (EMA), United States (United States Food and Drug Administration), Japan (MHLW/PMDA) or an ICH standing regulatory member state or region such as Canada (Health Canada), Switzerland (Swissmedic).

iii. Further, Vigilance decisions on products registered by WHO-listed agencies may be considered through the reliance pathways on a case-by-case basis.

iv. Vigilance regulatory decisions taken, reports, or safety information published on medical product reports by the National Regulatory Authority, regional, and international bodies that have signed treaties with TMDA.

6.5 Clinical Trials Authorization

The authority may apply reliance procedures for clinical trial authorization if:

i. The product under investigation has already been evaluated and listed as a WHO Prequalified Product through the WHO PQ collaborative registration procedure between WHO and the Authority.

ii. The product under investigation has already been evaluated and listed as a product of the WHO collaborative registration pilot for stringently assessed products, including through the European Union Article 58 Procedure or the Swissmedic Marketing Authorization for Global Health Products or the International Generic Drug Regulatory Programme.

iii. A trial has been authorized or the investigational product has been granted marketing authorization in an ICH founding regulatory member state or region, such as the European Commission (EMA), the United States (FDA), Japan (MHLW/PMDA), or an ICH standing regulatory members state or region, such as Canada (Health Canada) or Switzerland (Swissmedic).

iv. Products registered by WHO-listed agencies under (SRA) investigation may be considered through the reliance pathways on a case-by-case basis.

v. The trial or investigational product has been evaluated and judged satisfactory at a joint review meeting facilitated by the World Health Organization under the African Vaccine Regulatory Forum (AVAREF).

vi. The clinical trial has been authorized or the investigational product has been evaluated and judged satisfactory by the National Regulatory Authority that has signed a treaty or agreement with TMDA.

6.6 Quality Control (QC) Testing-related decisions

The Quality Control Laboratory (QCL) of the Authority leverages a provision that allows the Authority to rely on or recognize analytical reports from laboratories that are WHO Pre-qualified or ISO/IEC 17025:2017 accredited for recognition by an International Laboratory Accreditation Cooperation (ILAC) member on a case-by-case basis.

7. Reliance Procedures

7.1 Verification of Documentations

The Authority shall 'verify' that the product intended to be imported and distributed in Tanzania or the clinical trial to be conducted in TMDA has been duly registered or authorized respectively by a stringent regulatory authority.

In the case of marketing authorization, the product characteristics (use, dosage, precautions) for local registration should conform to those agreed upon in the authorization by the stringent regulatory authority. In addition, there should be an assurance that the product is either identical or similar to that approved by the stringent regulatory authority in terms of quality, safety, and efficacy.

In case the reliance is for clinical trial submissions, the application (protocol, Investigational brochure, nonclinical reports, previous study reports, and other relevant documents) should be identical to that submitted, evaluated, and approved by the stringent regulatory authority.

The authority reserves the right to subject all submissions for approval to an 'abridged' evaluation of a certain part of the application (e.g., relevant to use under local conditions) such as product quality data about climatic conditions and distribution infrastructure and a benefit-risk assessment about use in the local ethnic population, medical practice/culture, and patterns of disease.

7.2 Reliance Documentations

In addition to the full assessment report from the stringent regulatory authority, the applicant must also submit a complete Clinical Trial Application, Application for Marketing Authorization, and Application for GMP inspection, as required by the Authority's guidelines for authorization via the reliance pathway.

7.3 Assessment based on reliance procedures

The assessment or evaluation of the imported assessment report(s) shall be conducted according to the established procedures to ensure the relevance and comprehensiveness of the assessment findings and conclusions.

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