MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING (MOU) IS MADE ON THIS.....DAY OF ....., 2024

BETWEEN

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

AND

TANZANIA COMMISSION FOR SCIENCE AND TECHNOLOGY (COSTECH)

CONSIDERING THAT TMDA is a body corporate established under the Tanzania Medicines and Medical Devices Act, Cap 219, a regulatory body responsible for regulating quality, safety and effectiveness of medicines, medical devices, diagnostics, biocidal and tobacco products in Tanzania of P.O. Box 1253, Dodoma or P.O. Box 77150, Dar es Salaam. (Herein referred to as "**TMDA**");

CONSIDERING THAT COSTECH was established under the Tanzania Commission for Science and Technology Act, No. 7 of 1986 responsible for coordination and promotion of research and technology development activities in the country of P. O. Box 4302, Ali Hassan Mwinyi Road, Kijitonyama, COSTECH Building (herein referred to as "COSTECH").

RECOGNIZING the global experience for massive development in science and technology with a number of innovative ideas developed among people especially youth;

RECOGNIZING the number of youths continue to increase in the country and opportunities for formal employment decrease, youths are utilizing the opportunities available on Innovative Medical Devices and In-vitro Diagnostic Devices and are engaging themselves in self-employment by establishing start-ups as a mean to earn their living;

RECOGNIZING that Tanzania has seen rising in number of innovators and start-ups with innovative ideas on health sector whereby, some ideas grow into consumable services or products while some do not;

RECOGNIZING that both parties are aware and do agree to contribute to the national vision as per Science and Technology policy of 1996 that aims to reduce dependence of imported technologies as well as attain a good balance between imports and exports of finished or semi-finished products.

RECOGNIZING that for any idea to mature into product or service, a number of tests are run on the product/service before the same is released to be utilized by the intended consumers;

RECOGNIZING for some innovative ideas to mature into product or services, they require piloting grounds or equipment and some of which may be too expensive to be afforded by innovators and start-ups or some piloting grounds may be restricted in gaining access;

APPRECIATING that **TMDA** and **COSTECH** have Identified the need to support innovators and start-ups by providing technical guidance and facilitation by making medical services and permissions available for them:

NOW THEREFORE, this MoU for collaboration between **TMDA** and **COSTECH** will help to facilitate the screening of the viable ideas and provide required resources and permissions under the terms and conditions of this MoU, the Annex to this MoU and further conditions that may be provided when issuing resources.

IN WITNESSETH WHEREOF the parties have agreed to engage in the following collaborations: -

i. Permission to pilot the prototypes or minimum viable products of medical devices in health centres or a place as identified.

ii. The use of TMDA experts and laboratory equipment for referencing of standards and perfection of prototypes or products.

iii. The use of TMDA accredited laboratories for certification of proven products at a subsidized rate as agreed by both parties.

1. OBJECTIVE

The Objectives of this MoU are:

i. To foster collaborations between TMDA and COSTECH in facilitating and supporting development of health innovations in the Country;

ii. To put a joint effort in Identifying Tanzanian innovators and start-ups that need support by facilitating and making medical services, permissions and devices available for them;

iii. To provides for roles and responsibilities of parties in supporting innovators and start-ups accessing required medical devices and permissions; and

iv. To provide clear guidelines and procedures to be followed by innovators and start-ups and to be adhered to by parties when providing support to the start-ups.

2. SCOPE

This MoU applies to the undertaking of supporting innovators and start-ups to freely access medical permissions under the mandate of TMDA for trial purposes only for a specific period of time to enable innovators and start-up to test their medical products or services before launching them for commercial purpose.

3. TMDA ROLES AND RESPONSIBILITIES

In order to attain the objectives of this MoU, TMDA undertakes to fulfil the following responsibilities:

i. To prepare and make available medical permissions and infrastructure for innovators and start-ups;

ii. Provide the required medical permissions and infrastructure for innovators and start-ups free of charge or at a subsidized rate for six months for each start-up at a time and extend such time when and where required;

iii. Provide platform where innovators and start-ups can make applications for the medical devices they require;

iv. Provide timely feedback on applications made by innovators and start-ups

v. Provide technical guidance when required to do so by COSTECH on utilization of medical infrastructure and permissions; and

vi. Regularly inform COSTECH of any available resources and their usage.

4. COSTECH ROLES AND RESPONSIBILITIES

In order to attain the objectives of this MoU, COSTECH undertakes to fulfil the following responsibilities:

i. To nurture innovators at their earliest research level before they engage into testing of their ideas;

ii. Analyse and ensure an innovative product is ready to be put into test and hence eligible for access to medical permission or infrastructure;

iii. Carry out due diligence to ensure that the person desires to be given access to medical permission and/or infrastructure meet all required qualifications including being an innovators and start-up owned and operated by Tanzanians and the persons are unable to pay for the resources;

iv. Indorse the innovators and start-ups applications before they are submitted to TMDA;

v. Follow up the innovators and start-ups after they are given access to medical permission or infrastructure resource to ensure they use for the purpose intended;

vi. Continue providing support and guidance to innovators and start-ups by ensuring take-off of their products or services after successful trials;

vii. Encourage innovators and start-ups whose trials fail to keep developing their innovative ideas and give them chances whenever they need;

viii. Give advice to innovators on progress of utilization of medical permission or infrastructure based on technical guidance from TMDA.

5. TERMINATION CLAUSE

This MoU may be terminated by either party by giving a 30 day notice indicating party's intention to terminate provided that, such termination shall not affect any ongoing undertaking at the time of the said notice.

6. DISPUTE RESOLUTION

In the event a dispute or differences arise out of or in relation to the implementation of the roles and responsibilities in this MoU, parties shall endeavour to settle the dispute or difference amicably.

7. EFFECTIVE DATE AND AMMENDMENT

This MoU will enter into force upon signature by the parties and may be updated or amended any time in writing as parties may mutually agree to modify the terms or otherwise adjust provisions of this MOU to address their interests.

8. CONFIDENTIALITY

Parties agree that, any classified information shared to each other that is indicated so, apart from the information that is to be shared to public for the purpose of informing Tanzanian start-ups of the existing opportunities, shall remain confident and where a party provide information to the other party that is otherwise intended to be confidential must indicate with the words "confidential" so as to allow the party receiving the information to treat as such.

IN WITNESS WHEREOF, the parties hereto, by their duly authorised representatives, have executed this Memorandum on the day and year first herein above written.

SIGNED for and on behalf of **TMDA** by:
Name: Dr. Adam M. Fimbo
Designation: Director General
Signature: .....
Date: 6/8/2024

In the presence of:-
Name: Martha S. Malle
Designation: Acting Manager Legal Serv
Signature: .....
Date: 6/8/2024

SIGNED for and on behalf of **COSTECH** by:
Name: DR. AMOS NUNGU
Designation: DIRECTOR GENERAL
Signature: .....
Date: 04th July, 2024

In the presence of: -
Name: PHILEMON MUEGU
Designation: LEGAL SERVICES MANAGER
Signature: .....
Date: 04th July, 2024

Annex 1

Conditions for Assignment of Communication Resources for Start-Ups

i. Any start-up wishing to get access to medical permission or infrastructure set aside by TMDA for trial purpose shall make application for the same

ii. The applicant can be an individual, the company and/or organization.

iii. The applicant should submit an application letter to TMDA requesting for the need of access, specifying intended use, location where it will be used, the start date for the trial and attached with endorsement from COSTECH.

iv. TMDA remains with the right to assign required resources basing on availability and usage

v. Under no circumstances will assignee claim right of ownership of the resource assigned, every assignment is meant for trial purposes and for specific period of time only

vi. The assigned resource should be used only for the service assigned to

vii. Assignment of any resource, unless expressed otherwise during assignment, shall last for six **(6) months** only from the date of the assignment.

viii. The assignee must discontinue the use of assigned resource after the six months.

ix. Where assignee discontinues using the resource before the lapse of six (6) months, should inform TMDA and COSTECH by letter.

x. Should the applicant require to continue using the assigned resource beyond six (6) months should make an application to TMDA, through COSTECH, for extension of time.

xi. Applications for extension of time shall be submitted one month before the expiry period.

xii. The resources assigned should in no way be used for business purposes and no promotion of whatever kind will be allowed.

xiii. The assignee shall be responsible for the resource assigned and should use for resource provided for trial purposes only.

xiv. Any assignee who breaches the condition of usage of resources assigned, may have his right to use resources revoked by TMDA through consultation with COSTECH.

xv. Every application for medical permission and/or infrastructure must be evaluated and endorsed by COSTECH before the same is submitted to TMDA

Regulatory Framework for Medical Devices and In-vitro Diagnostic Devices

Table of Abbreviations

TMDA =

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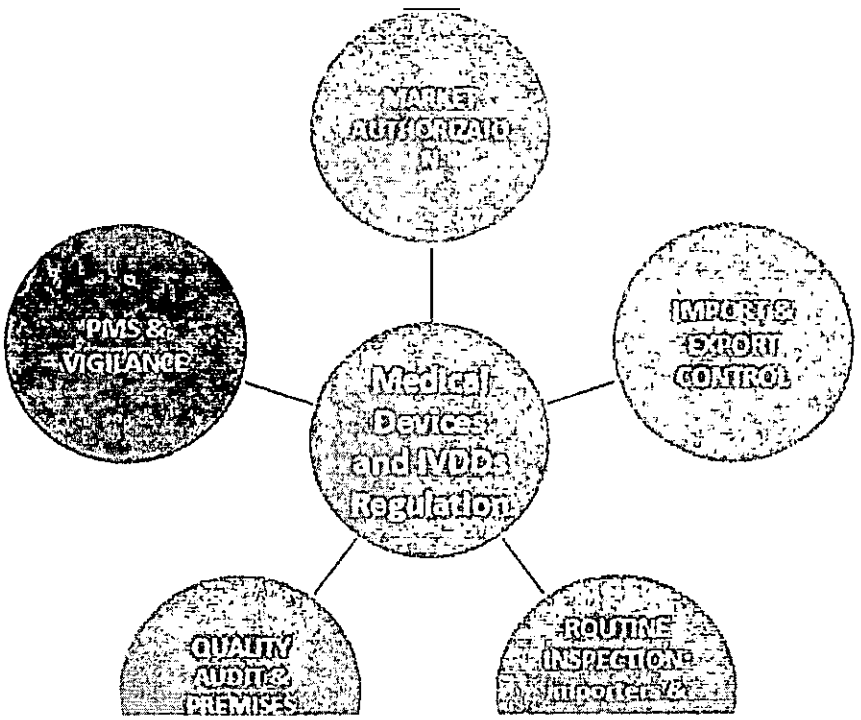
Regulatory Framework for Medical Devices & In-vitro Diagnostic Devices

- Executive Agency under Ministry of Health
- Established under the Tanzania Medicines and Medical Devices Act, Cap 219.
- The Act;
  - Provides for regulation of quality, safety and efficacy of medicines and medical devices
  - Section 5(1) of the Act mandates TMDA to regulate all matters relating to safety and performance of medical devices

Regulatory Framework for Medical Devices & In-vitro Diagnostic Devices



Procedure for Applications for Authorization of Innovative Medical Devices and In-vitro Diagnostic Devices

Step 1: [illegible] notification or registration

- ☐ Consult TMDA during the research phase to determine the class i.e. before the prototype or pilot device has been manufactured
- ☐ Apply for registration of premises, business permit & Quality Audit inspection of the site as per ISO 13485
- ☐ Once production has been greenlighted, consult TMDA during the development phases and testing (validation & verification of the device)
- ☐ Start clinical performance evaluation process (Clinical trials)

Step 2: Compile the technical requirements

- ☐ Quality requirements are as per respective guidelines
  - ☐ Class A non-registrable (Notification guidelines)
  - ☐ Class A (registrable), Class B, Class C and D (Guidelines for medical devices or IVDDs)
- ☐ Reports of clinical trials conducted to confirm safety and clinical performance
- ☐ Include a plan for PMS and vigilance of the product

Step 3: Submit an application

- Create a Traders account
- Lodge the application through the online system

Process outcomes: At the end the applicant shall attain proof of quality, safety and performance of their product

- Premise license and business permit
- Quality audit certificate
- Certificate of product registration

Available guidance documents

a. TMDA Act, Cap 219
b. The TMDA (Control of Medical Devices) Regulations, GN 315, 2015
c. Guidelines for Importation and Exportation of Medical Devices Including In Vitro Diagnostics and Laboratory Equipment (*in case of raw materials*)
d. Draft TMDA (Good Storage and Distribution Practises) Regulations, 2021
e. Guidelines on Submission of Documentation for Registration of Medical Devices, 3rd Edition, April 2022
f. Guidelines on Submission of Documentation for Registration of In vitro Diagnostic Devices, 3rd Edition, April 2022
g. Draft Guidelines for Notification of Products Exempted from Registration, 2022
h. Applicable ISO standards
    i. ISO 1348:2016
    ii. ISO 14971 Risk Management
    iii. ISO 15223-1 Symbols
    iv. Applicable ISO Standards for specific devices

Note: all guidance documents can be accessed through TMDA website, www.tmda.go.tz

Overview of the critical parts of Control of Medical Devices Regulations, GN 315, 2015

Regulation 5: Sets the provision for classifying devices according to risk
- Class A is lowest risk
- Class D is highest risk
- Groups, Family or kits are grouped into the class that presents the highest risks

Regulation 6, 7, 10, 11: State that devices need to register prior to distribution:
- Outline the technical requirements details are provided in respective guidelines
- Requirements for fees details are provided in Fees & Charges Regulations

Regulation 26: States the obligation of the permit holder of ensuring safety and performance of device and to keep evidence of such

Regulation 27 & 29: Outlines the measures that need to be taken by the manufacturer to ensure safety and performance of their device and the responsibility of the manufacturer to ensure
a. Compatibility of the device with other devices that it may be used together with (or interact) with (this also includes compatibility of the materials).
b. Risks are minimized
c. Proper sterilization of devices using a validated sterilization method,
d. Devices with measuring function comply with appropriate tolerance limits and optimal performance of the software system

Regulation 39 & 40: Explains how the owner of the product needs to ensure that they have distribution records in order to ensure traceability and follow up of their product

Regulation 41 – 44: Defines the incidences that require reporting (failure of device, reduced performance, inadequate labelling, death or serious adverse event) stipulates that any incident needs to be reported to the Authority in a timely manner along with the details that need to be submitted

Regulation 59 – 64: Handling of unfit medical devices
Regulation 65 – 67: Recall of medical devices
Regulation 68 – 73: Promotional materials and advertisement