Memorandum of Understanding:

Participation in the African Vaccine Regulatory Forum (AVAREF) facilitated product authorization procedure by National Regulatory Authorities – Commitment of Undertaking (document code: MOU-NRA-FPA)

Agreement to participate in the AVAREF facilitated product authorization (FPA) procedure between the World Health Organization (WHO) AFRO and National Regulatory Authorities (NRAs) in the evaluation of a technical dossier (or assessment reports) for marketing authorization/emergency authorization of vaccines and medicinal products and national decision (approval or otherwise) within AVAREF defined timelines.

Details of NRA

Name of NRA	Tanzania Medicines and Medical Devices Authority
Postal address	Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P.O. Box 1253, Dodoma
Country	United Republic of Tanzania
Telephone number (please include codes)	+255 22 2450512/ 2450671/ 2452108
Email (please indicate contact details as appropriate for inclusion in the list of participating NRAs maintained on the WHO website)	info@tmda.go.tz

Details of WHO AFRO Contact Person

Name	Dr. Yonah Hebron Mwalwisi
Postal address	Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P.O. Box 1253, Dodoma
Country	United Republic of Tanzania
Telephone number (please include codes)	+255 620 602 653
Email	Yonah.hebron@tmda.go.tz

Scope of Agreement

Applicants for a joint review of a technical dossier for facilitated product authorization (FPA), hereafter referred to as "Applicant" may express their interest to AVAREF Secretariat to convene a joint review. AVAREF will convene a technical workshop for the facilitated authorization of the product or candidate product as the case may be, in which the National Regulatory Authority (NRA) will participate provided the designated focal point (head of agency

in copy) receives an invitation via email 5 working days prior to the technical workshop start date.

Subject to the NRA agreeing to participate in a FPA, the NRA confirms for each such FPA, that it will adhere to agreed timelines for issuance of a national decision on the product/candidate product and collaborate with the WHO/AVAREF Secretariat and the Applicant during the procedure.

Confidentiality of Information

WHO/AVAREF agrees to make the following information available to the NRA through a restricted-access SharePoint platform exclusively for the purpose of the facilitated product authorization procedure, henceforth referred to as The Purpose:

- Assessment reports (WHO / EMA / Other)
- all such data, reports, information and documentation being hereinafter referred to as "the Information".

The NRA agrees to treat any Information provided by WHO/AVAREF as aforesaid as strictly confidential and proprietary to the applicant and/or parties collaborating with WHO/AVAREF. In this regard, the NRA agrees to use such information only for the purpose of the facilitated product authorization process and to make no other use thereof. Thus, the NRA undertakes to maintain the information received from WHO/AVAREF in strict confidence, and to take all reasonable measures to ensure that the Information received from WHO/AVAREF shall not be used for any purpose other than the facilitated product authorization process and the national decisions accompanying the review (The Purpose).

- the Information shall only be disclosed to persons who have a need to know for the aforesaid Purpose and are bound by confidentiality undertakings in respect of such information and documentation which are no less stringent than those contained herein.

- The NRA warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations. The obligations of confidentiality and restrictions on use contained herein shall not cease on completion of the Purpose.
- The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the Information which the NRA is clearly able to demonstrate:
    - was in the public domain or the subject of public knowledge at the time of disclosure by WHO/AVAREF to the NRA under the Procedure; or
    - becomes part of the public domain or the subject of public knowledge through no fault of the NRA; or
    - is required to be disclosed by law, provided that the NRA shall in such event immediately notify WHO/AVAREF and the Applicant in writing of such obligation and shall provide adequate opportunity to WHO/AVAREF and/or the Applicant to object to such disclosure or request confidential treatment thereof (provided always, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO/AVAREF and/or as submitting WHO/AVAREF to any national court jurisdiction).
- Upon completion of the Purpose, the NRA shall cease all use and make no further use of the Information disclosed to it under the Procedure and shall promptly destroy all of the Information received from WHO/AVAREF which is in tangible or other form, except that the NRA may retain copies of the Information in accordance with its established archival procedures, subject always, however, to the above-mentioned obligations of confidentiality and restrictions on use.
- The Purpose for each product shall be deemed completed as soon as:
    - the Applicant discontinues participation in the Procedure for the particular FPA;
    - the CTA authorization is cancelled or nullified by the NRA;
- The access right of the NRA's focal point(s) to the restricted-access website will cease automatically upon the NRA ceasing to participate in the Procedure.
- If and as soon as an NRA focal point is replaced by a new focal point or ceases to be an employee of the NRA, such focal point's access to the restricted-access website shall automatically terminate.

- The NRA agrees that it has no right in or to the Information and that nothing contained herein shall be construed, by implication or otherwise, as the grant of a license to the NRA to use the Information other than for the Purpose.

Timelines

In respect of each FPA that the NRA agrees to participate in under the Procedure, the NRA undertakes to abide by the terms of the Procedure, including but not limited to the timeline agreed for issuance of a national decision on the product/candidate product following the completion of the technical workshop, and meeting of all requirements by the Applicant.
If the NRA finds a situation when they cannot meet the agreed timelines, the NRA should inform AVAREF as soon as the potential causes of delays are identified.

Focal Points

The NRA has designated the person(s) listed below to act as focal point(s) for access to WHO/AVAREF's restricted-access SharePoint and to represent the NRA in the technical workshop. The undertaking(s) completed and signed by the focal point(s) is (are) attached hereto as an Appendix to this agreement.
Any change in designated focal points must be communicated to WHO/AVAREF without delay in writing and will be subject to the new focal point having signed and submitted to WHO/AVAREF the undertaking in the attached Appendix. The NRA also undertakes to inform WHO/AVAREF if and as soon as a designated focal point ceases to be an employee of the NRA.

1. Primary Focal Point
Mr/Ms/Dr
First name (and initials): RUKIA
Surname/family name: SAIDI MNG'OMBE
Title in NRA: SENIOR DRUG REGISTRATION OFFICER
Email: rukia.mngombe@tmda.go.tz or saidir@nm-aist.ac.tz
Telephone: +255 717210782 or 785 611098
A signed Undertaking is attached.

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2. Alternate Focal Point
Mr/~~Ms/Dr~~
First name (and initials): TRYPHONE
Surname/family name: OCTAVIAN GUJEMA
Title in NRA: DRUG REGISTRATION OFFICER
Email: tryphone-octavian@tmda.go.tz / gujematryphone@gmail.com
Telephone: +255 656 361415
A signed Undertaking is attached.

Miscellaneous

- The NRA agrees that WHO/AVAREF may list its name on the WHO/AVAREF website as a participant in the Procedure. Except as provided hereinbefore, neither party shall, without the prior written consent of the other party, refer to the relationship of the parties under this Agreement and/or to the relationship of the other party to the FPA the Information and/or the Purpose, in any statement or material of an advertising or promotional nature.
- This Agreement shall not be modified except by mutual agreement of WHO and the NRA in writing. The NRA furthermore undertakes to promptly inform WHO/AVAREF of any circumstances or change in circumstances that may affect the implementation of this Agreement.
- The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Agreement. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or in the absence of agreement, with the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules in effect on the date of this Agreement. The parties shall accept the arbitral award as final.

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It is agreed furthermore that nothing contained in this Agreement shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Head of NRA

Signature:

Name: ADAM M. FIMBO

Title: DIRECTOR GENERAL

Place and date: DAR-ES-SALAAM, 23/6/2023

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Appendix: Signed Undertaking(s) of NRA focal point(s)

I have read and understood my role and responsibilities as described in the content of this document. I accept the responsibility of focal point for the AVAREF facilitated product authorization procedure for the duration of this nomination until such a time that another focal point is nominated in my stead.
I agree to proactively consult AVAREF Secretariat where any detail of the role or responsibility is unclear.
I agree to proactively inform AVAREF Secretariat if a delay in any of the steps of the agreed timeline for issuance of a national decision may occur.

Primary Focal Point

Signature:
Name: RUKIA SAIDI MNGOMBE
Title: SENIOR DRUG REGISTRATION OFFICER
Place and date: DODOMA, TANZANIA
11/07/2023

Alternate Focal Point

Signature:
Name: TRYPHONE OCTAVIAN GUJEMA
Title: DRUG REGISTRATION OFFICER
Place and date: DODOMA, TANZANIA
11/07/2023