MEMORANDUM OF UNDERSTANDING

BETWEEN

PHARMACY COUNCIL OF TANZANIA

AND

TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)

7/12/18

16/12/2018

MEMORANDUM OF UNDERSTANDING ON COOPERATION

BETWEEN

THE PHARMACY COUNCIL OF TANZANIA, WHOSE HEADQUARTERS ARE LOCATED AT MABIBO EXTERNAL, ALONG MANDELA ROAD, P.O. BOX 31818, DAR ES SALAAM
AS REPRESENTED BY THE REGISTRAR,

AND

THE TANZANIA FOOD AND DRUGS AUTHORITY, WHOSE HEADQUARTERS ARE LOCATED AT MABIBO EXTERNAL, ALONG MANDELA ROAD, P.O BOX 77150, DAR ES SALAAM

WHEREAS, Pharmacy Council of Tanzania, as a professional statutory body corporate under the Ministry of Health, Community Development, Gender, Elderly and Children(MoHCDGEC), established under the Pharmacy Act, Cap 311 (hereinafter referred to as the 'PC') for regulation and control pharmacy profession and practices including registration and licensing of warehouses, retail and wholesale pharmaceutical premises; and

WHEREAS, Tanzania Food and Drugs Authority as a statutory regulatory agency for food, medicines, cosmetics and medical devices (hereinafter referred to as 'TFDA') under MoHCDGEC is responsible for promoting and protecting public health by ensuring the safety, quality and effectiveness of food, medicines, medical devices and cosmetics including registration and licensing of importers of pharmaceuticals and medical devices as stipulated under the Tanzania Food, Drugs and Cosmetics Act, Cap 21; and

WHEREAS, PC and TFDA recognizes the significant contribution that can be made by both parties to their strategic objectives and therefore actively promote cooperation arrangements when enhancing the availability of safe and quality medicines and medical devices for the Tanzanian public and economic development as well as promoting and protecting public health; and

being among the functional units of the Ministry responsible for health and are responsible for the implementation of national planning frameworks that include the Vision 2025, National Strategy for Growth and Reduction of Poverty

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(NSGRP), Primary Health Services Development Programme (PHSDP), National Health Policy and Health Sector Strategic Plans.

WHEREAS, in order to achieve such cooperation and resolve overlaps and duplication of functions when carrying out duties and promoting good reputation and understanding of the roles of the two parties against consumers, PC and TFDA desire to operate within the framework of this Memorandum of Understanding (thereinafter referred to as the 'MoU').

THEREFORE,TFDA and PC (hereinafter referred to as collectively as 'the Parties') hereby declare as follows:

ARTICLE 1: PURPOSE

The purpose of this MOU is to establish the general working parameters under which PC shall collaborate with TFDA on activities that are of common interest to both parties and related to pharmaceutical services in the country.

Background

The Pharmaceuticals and Poisons Act No. 9 of 1978 was enacted in 1978 to establish the then Pharmacy Board and to regulate medicines and pharmacy profession. Due to a number of factors, which included among of others, trade liberalization, fast advances in science and technology, public sector reform policies; the government revised the Pharmaceuticals and Poisons Act of 1978 and the Food (Control of Quality) Act, 1978 and enacted the Pharmacy Act, No.7 of 2002 and Tanzania Food, Drugs and Cosmetics (TFDC) Act, Cap 219 in 2003.

However, for the same reasons and in order to streamline pharmacy profession activities, the Pharmacy Act was then repealed to introduce the Pharmacy Act, Cap 311 of 2011.

This Endeavour aimed at providing for a better legislation that regulates matters related to practice of pharmacy profession which were mandated to the Pharmacy Council and those related to quality, safety and efficacy of medicines and related products which were mandated to TFDA.

The TFDC Act, Cap 219, section 21 was amended through section 59 of the Pharmacy Act, Cap 311.

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Section 21 of the TFDC Act, Cap 219 was amended and gave mandate to PC to license and issue permits to non-importing wholesalers and retailers through section 59 of the Pharmacy Act, Cap 311.

Pharmacy Council is now responsible for controlling and regulating pharmacy profession, practice and licensing while quality, safety and efficacy of medicines and medical devices remain under the mandate of TFDA.

The changes have expanded regulatory mandate of PC significantly and brings a major challenge given the current limited institutional capacity of the Council.

On the other side powers which TFDA had in enforcing the law and regulating the quality, safety and efficacy of medicines were reduced because they can no longer revoke, suspend or cancel licenses and permits issued to those who commit malpractices and offences anymore.

Functions of these two parties are interrelated by law as follows; -

1. Functions and duties of both parties are crosscutting with mutual interest in improving pharmaceutical services in the country i.e. licensing and issuance of permits.

2. Majority of products that are regulated by TFDA are stocked in premises that are licensed and supervised by pharmaceutical personnel that are regulated by PC.

3. Inspections and supervisions involve the same premises, personnel and infrastructures;

If these two parties continue to work independently, it is a duplicate of resources and time.

Having realizing this, there is a need to establish common areas of interest and explore modalities of working together in a cost effective and under limited resources available.

ARTICLE 2: RESPONSIBILITIES OF THE PARTIES

Subject to their respective laws, rules, regulations, practices, procedures, and the availability of funds and other resources,

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2.1 PC agrees to:

i) Recognize inspectors from TFDA who can perform their duties as inspectors of PC when directed by Registrar after communication with Director General, TFDA.
ii) Allow PC inspectors to be recognized by TFDA.
iii) Recruit more inspectors to fulfill the common goal under this MOU.
iv) Provide and share necessary information needed to attain the common goal under this MOU.
v) Facilitate communications and cooperation between PC and TFDA.
vi) Provide technical and financial assistance related to this MOU.
vii) Provide necessary, allowable and allocable material, equipment, transport and human resources support to implement work plan to be agreed between the parties.
viii) Appoint a coordinator for the collaboration and follow up of agreed activities.
ix) Ensure availability of key staff and other personnel to provide guidance and facilitate implementation of activities.
x) Develop common tools for the inspection/supervision activities.
xi) To register and issue permits to non-importing wholesalers and retailers of human medicines

2.2 TFDA agrees to:

i) Recognize inspectors from PC who can perform their duties as inspectors of TFDA when directed by Director General after communication with Registrar, PC.
ii) Allow TFDA inspectors to be recognized by PC.
iii) Provide and share necessary information needed to attain the common goal under this MOU.
iv) Facilitate communications and cooperation between TFDA and PC.
v) Provide technical and financial assistance related to this MOU.
vi) Build the capacity of the PC staff and systems.
vii) Provide necessary, allowable and allocable material, equipment's, transport and human resource support to implement work plan agreed by both parties.
viii) Appoint a coordinator for the collaboration and follow up of agreed activities.
ix) Ensure availability of key staff and other personnel to provide guidance and facilitate implementation of activities.
x) Develop common tools for the inspection/supervision activities.
xi) Register and license retail and wholesale medical devices outlets.

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xii) To register and issue permits to importing wholesalers.

2.3 Both PC and TFDA jointly agree to:

i) Collaborate in the design, planning and implementation of agreed activities such as inspections, operations and licensing of crosscutting premises.
ii) Jointly develop annual work plans of activities to be completed including training of Inspectors.
iii) Oversee the implementation of agreed activities including supervision, monitoring, and evaluation.
iv) Provide necessary and appropriate resources needed for the tracking of activity progress and performance reviews.

ARTICLE 3: COMMUNICATIONS AND DECISION MAKING

The relationship between PC and TFDA should be mutually respectful with clearly established channels of communication and involvement in decision making that affect the other Party.

a) Requests for official support from both parties should be directed to the Registrar and Director General respectively from the responsible persons for PC and TFDA.
b) The Registrar and Director General will communicate in writing on activities to be collaborated between PC and TFDA.

The responsible persons for PC and TFDA shall jointly discuss activities proposed in the annual work plan. They shall work collaboratively to ensure mutual consent and agreement upon designated activities in the work plan and an overall estimated level of funding and resources needed.

ARTICLE 4: PERIOD OF AGREEMENT

The present Memorandum of Understanding is valid for the period of three (3) years (from July, 2018 to June, 2020). Should additional time be available to undertake the above-mentioned activities as outlined in this MOU, the responsible persons from PC and TFDA shall modify the end date of this MOU through a letter of modification to the MOU that does not require counter signature.

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ARTICLE 5: COST

Transfer of funds associated with this agreement will depend on activities agreed to in the jointly developed work plan. Both Parties shall be responsible for basic operating expenses incurred as a result of work performed under this MOU. This includes, but not limited to communications and office supply expenses.

ARTICLE 6: CONFIDENTIALITY

In the process of collaborating with each other, each party may become privy to certain confidential information including that relating to the business practices of the other Party. Each Party agrees that it will clearly designate proprietary and confidential information where possible and not divulge or transmit such information to any other person or organizations without the expressed written permission of the owner of the information. Each Party agrees that information need not be marked as confidential to be considered and treated as such under the terms of this clause. All such confidential information shall be considered proprietary unless it is provided specifically for disclosure to the public or other entity.

All Parties agree to share information related to agreed activities and issues of relevance and within the limits of applicable laws and regulations so as to ensure the successful implementation of the agreed activities. All Parties agree not to disclose proprietary information to any third party and not to use such information without the express written approval from the other Party.

Each Party further agrees to honor any copyright, trademark rights and other proprietary rights of information shared in the process of carrying out joint activities. Both Parties also agree not to quote any portion of reports or documentation out of context, misrepresent the findings of either Party, or otherwise use the information inappropriately.

This confidentiality obligation survives the termination of this MOU.

ARTICLE 7: AMENDMENT AND TERMINATION

This MOU shall be amended in writing by mutual consent of each Party's duly authorized representative.

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This MOU may be terminated for convenience by mutual agreement of the two Parties. It is understood that in the case of termination, the Parties shall complete the remaining obligations in effect at the time of termination subject to availability of funds and other resources.

ARTICLE 8: RESOLUTION OF DISAGREEMENTS

The Parties shall use their best efforts to settle amicably any disagreement or controversy arising out of, or relating to this MOU. Since this is a Memorandum of Understanding, any disagreement or any such dispute, controversy or claim between the Parties arising out of and not mutually resolved by the Parties shall result in termination of this memorandum without further notice.

The parties by signing this MOU understand that since there is transfer of funds between the parties, there can be claims made on a party by the other party.

ARTICLE 9: ENTIRETY OF AGREEMENT

This MOU contains the entire agreement of the mutual collaboration and understanding between the Parties. All future projects shall be accommodated in this MOU between the two Parties.

In **WITNESS WHEREOF**, the duly authorized representatives of the Parties sign this Memorandum of Understanding in two (2) originals in the places indicated below and for each Party to retain an original each for their files.

For PHARMACY COUNCIL:

Registrar, Pharmacy Council,

Registrar
Pharmacy Council
P. O. Box 31616
Dar-es-Salaam

Date: 10/12/2018

For TFDA:

Acting Director General, TFDA

Date: 07/12/18