

Memorandum of Understanding

Between

**Management Sciences for Health,
Center for Pharmaceutical Management (MSH/CPM)**

And

The Ministry of Health, Tanzania (MOH)

**on the Strategies for Enhancing Access to Medicines
Program (SEAM)**

This Memorandum of Understanding, hereinafter referred to as the MOU, is entered into by MSH/CPM and the MOH for the purpose of establishing the general working parameters under which these two organizations will collaborate on SEAM activities in Tanzania.

MSH/CPM and the MOH, hereinafter referred to as the Parties, collaborated in conducting an assessment of the pharmaceutical sector in Tanzania in 2001. On the basis of that assessment a proposal was developed to improve access to essential drugs and health supplies in Tanzania through developing public-private partnerships. The objectives of the proposal were to:

- (a) Improve the availability of cost-effective essential drugs and health supplies in public and mission hospitals;
- (b) Promote competitive pricing for selected essential drugs in the private sector in rural Tanzania;

- (c) Improve the quality of pharmaceutical services in the private sector in rural Tanzania;
- (d) Improve the quality of selected imported and locally manufactured essential drugs in the Tanzanian market.

The Parties agreed to accomplish these objectives through:

- (a) Designing, implementing and monitoring a network of Accredited Drug Dispensing Outlets (ADDO's), licensed and regulated by the Drug Regulatory Authority, with monitoring and enforcement carried out in collaboration with local government and community health structures;
- (b) Approving alternative suppliers to serve hospitals supported by public finances;
- (c) Implementing a system of screening, monitoring, and reporting on the quality of selected essential drugs under the Authority of the Drug Regulatory Authority.

The Parties to this Memorandum of Understanding and relevant contact information are as follows:

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Whereas MSH/CPM has received a grant of USD 29.9 million from the Bill & Melinda Gates Foundation to develop initiatives involving public-private partnerships that will contribute to enhancing public access to and appropriate use of essential medicines and has designated this activity the Strategies for Enhancing Access to Medicines (SEAM) Program;

Whereas MSH/CPM has identified Tanzania as a priority country and has approved an estimated budget ceiling of 4.6 million for establishing a program of activities under the SEAM Program that would be implemented over the next three years with an estimated completion date of not later than August 1, 2005;

And whereas, the parties understand that the intent of SEAM activities in Tanzania is to assist in the establishment of self-sustaining programs to be operated by Tanzanian organizations;

Now, **therefore,** in consideration of the premises and the mutual obligations of the Parties stated in this MOU, the parties hereby agree as follows:

1. To collaborate in the design, planning and implementation of the SEAM Tanzania program. Specific activities that will need to be completed collaboratively include:
 - (a) The establishment of Working Groups to provide regular and ongoing technical support and guidance to the SEAM Tanzania program.
 - (b) The development of specific program objectives, proposed interventions and budget to be implemented in Tanzania.

- (c) The selection of first phase districts and regions where program activities will take place.
 - (d) The implementation of the agreed upon interventions, including necessary training.
 - (e) The development of a program evaluation strategy and collection of the data necessary for completing the evaluation.
 - (f) The active participation in working groups, as they are required, to make technical preparations for SEAM activities related to the full range of program activities.
2. Where proposed interventions and/or activities require changes in or additions to MOH regulations or administrative procedures, to make good faith attempts to facilitate the making of such changes in a timely fashion. Examples of interventions or activities that may require such action include:
- (a) The development and approval of regulations for accredited drug dispensing outlets;
 - (b) The development and approval of quality assurance, product quality standards and regulatory remedies for selected imported and locally manufactured essential drugs;
 - (c) The development and approval of regulations and enforcement mechanisms for accredited drug dispensing outlets;
 - (d) The development, approval and implementation of appropriate public and professional advocacy initiatives in districts and regions that address drug, pharmaceutical service, and health education issues;

- (e) The selection and approval of additional distributor(s) to supply essential drugs to public and mission hospitals, and accredited drug dispensing outlets, in selected districts and regions;
 - (f) The development, approval and implementation of a Drug Product Problem reporting system;
 - (g) The further development and expansion of the existing Adverse Drug Reaction reporting system;
 - (h) The development and implementation of training and educational programmes relevant to the SEAM program;
 - (i) Any other activities that are jointly agreed as necessary for the success of the program.
3. Each Party shall be responsible for their own basic operating expenses incurred as a result of work performed under this MOU. This includes, but is not limited to communications and office supply expenses. Support for materials and personnel may be provided to a partner agency if needed to start work on a SEAM initiative, but such support would be limited.
- 3.1 MSH/CPM has approved an estimated ceiling of \$ 4.6 million for the SEAM Tanzania country program effective from January 2002 to August 2005. The value of the approved budget ceiling can be changed should the program be modified during the life of the project.
- 3.2 Funding of specific activities will be decided collaboratively by MSH/CPM and MOH.

3.3 It is recognized that both MSH/CPM and MOH have budget limitations as well as restrictions relating to what can be funded. These limitations and restrictions will be taken into account as the program is designed. In this regard, it is recognized that MSH/CPM is constrained under the terms of the initial grant from the Bill and Melinda Gates Foundation to restrict expenditures largely to the following areas:

- Determine gaps in access to medicines, vaccines, and other health commodities;
- Provide technical assistance for the design and implementation of strategies that will improve both access to and use of essential medicines and other health commodities;
- Evaluate the impact of program designed to improve access;
- Improve access to and use of appropriate information.

4. The parties shall establish and maintain a Program Steering Committee to oversee and regulate implementation of the SEAM program.

4.1 The Ministry of Health shall appoint at least three representatives, from Pharmacy Board, Pharmaceutical and Supplies Unit (PSU) and Policy and Planning, one representative from Local Government and one representative from Christian Social Services Commission (CSSC) to serve as members of Program Steering Committee (PSC).

4.2 MSH shall appoint three of its representatives to serve as members of the PSC.

- 4.3 The PSC will meet twice in a year and will be chaired by the Chief Medical Officer.
 - 4.4 The PSC shall be responsible for assessing the proposals, workplans and progress of the program and provide guidance to the Working Groups on matters pertaining to program development.
5. In order to initiate the SEAM program activities; the parties agree to:
- 5.1 Facilitate the formation of Working Groups in each of the technical areas composed of staff of sufficient seniority and technical competence to participate authoritatively on behalf of their respective organizations in SEAM discussions and activities.
 - 5.2 The Working Groups shall:
 - (a) Prepare Workplans and budgets to implement the agreed strategies.
 - (b) Conduct regular supervision and monitoring of the programs;
 - (c) Provide quarterly progress report of the programs to the Program Steering Committee.
 - 5.3 Working with NGO's and faith based organisations
- The parties agree that it might facilitate achievement of programme objectives to collaborate with NGO or Faith Based organizations. Such collaboration could involve, for example, working with mission hospitals to establish a prime vendor programme for a group of hospitals. Each party agrees to cooperate with the other in exploring such collaborations.

6. The following terms also apply:

6.1. Proprietary information:

- (a) Both parties agree to share information related to pharmaceutical issues of relevance and within the limits of applicable laws and regulations so as to ensure the successful implementation of the SEAM program.
- (b) Both parties agree not to disclose proprietary information to any third party and not to use such information without the express written approval of the other party.
- (c) Each party further agrees to honour any copyrights, trademark rights and other proprietary rights of information shared in the process of carrying out joint activities.
- (d) 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.

6.2 Amendments: this MOU may be modified only by a written amendment hereto and executed by the duly authorized representatives of both parties.

6.3 Force majeure:

- (a) Failure on the part of a party to perform any of its obligations set forth in this Memorandum will not constitute a breach of this Memorandum to the extent such

failure arises from Force Majeure (as defined below), provided that if such failure persists for more than three months the other party may, at its option, terminate the Agreement and provided further that the party claiming Force Majeure shall give notice in writing of such Force Majeure as soon as possible to the other party.

- (b) “Force Majeure” shall mean circumstances beyond the reasonable control of the party affected which by the exercise of reasonable diligence the party is unable to prevent or provide against, and the effects of which cannot be overcome by reasonable expense, and may include, but not be limited to war or hostilities; riot or civil commotion; regulation, decree of action of any government, de jure or de facto, or any agency thereof, earthquakes, floods, fires or other natural physical disasters and strikes and industrial disputes by workers or employees.
 - (c) Any party failing to perform any of its obligations hereunder because of Force Majeure shall exercise all reasonable efforts within its power to terminate the effects of such Force Majeure, and upon the cessation of such Force Majeure, to take all reasonable steps to resume performance of its obligations with the least possible delay.
- 6.4 Termination: This MOU may be terminated by either Party, at any time, upon giving six months written notice of termination to the other Party.
- 6.5 Notifications: All notices pertaining to or required by the MOU shall be in writing, signed by an authorized representative, and delivered by hand or express certified mail to the Parties at the contact information listed above.

This MOU is made and signed in Dar es Salaam onday
of2002 with each party indicating their
acceptance by their signature herein below.

On behalf of MSH/CPM

On behalf of the MOH

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