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POSTION PAPER: ILLEGAL DRUG STORES AND THE ADDO MODEL OF TANZANIA

Advocacy and Policy Committee Members

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1.0Background

For a number of years, *Duka la dawa baridi* (DLDB), or private drug shops, had been authorized by the Tanzania Food and Drugs Authority (TFDA) to provide nonprescription drugs in the private sector.

With an estimated 6000+ stores, DLDB constituted the largest licensed retail outlets for purchasing medicines in Tanzania.

However, DLDB are plagued with several problems such as a limited list of medicines that can be legally sold, not including basic essential prescription medicines, lack of adequate facilities for storing medicines properly, lack of basic qualifications and training for dispensing staff, lack of business skills for shop owners, and inadequate or non-existent regulation and supervision by inspectors.

A systematic and holistic approach to the problems of DLDBs was used to develop the Accredited Drug Dispensing Outlets (ADDO) program during the pilot program under the Strategies for Enhancing Access to Medicines (SEAM) Program funded by the Bill & Melinda Gates Foundation in 2000.

The goal of the ADDO program was to increase access to essential medicines through utilization of the private sector.

All aspects of the DLDB enterprise—including the physical premises, stock maintained by the owner, consumer choices, interactions with dispensers, and recommended treatments—had to be improved. In addition, the larger systems in which DLDBs are embedded, which include licensing, supply, training, and inspection, involving ward, district, regional, and national authorities, also had to be changed and strengthened.

After gaining support from key stakeholders, TFDA and the government of the region of Ruvuma, in collaboration with MSH, implemented the pilot ADDO initiative in 2003. Quality of both products and services was ensured through a combination of government accreditation and regulation mediated through routine monitoring by district/local government and community structures.

Accreditation as applied to the ADDO program aims to improve the availability of essential medicines and the quality of services by working with independent shop owners and dispensing staff via provision of education, training and supervision; commercial incentives combined with decentralized regulatory oversight. Accreditation is granted on achievement and maintenance of a set of pre-established standards.

Rolling out the ADDO Program

The SEAM Tanzania country program ended in 2005 but because of the success in Ruvuma and the Government of Tanzania's decision to adopt the ADDO model for the entire country (along with some budgetary allocation), the MoH, through the TFDA with support from MSH/RPM Plus and the Mennonite Economic Development Associates (MEDA) is expanding the ADDO model into other regions of Tanzania.

The TFDA, with technical assistance from MSH, is providing program planning and regulatory oversight; MEDA is directing business development and training and facilitating linkage of ADDOs with Micro financing institutions (MFI).

The ADDO program rollout is funded by USAID in the Morogoro region, the Government of Tanzania in Rukwa and Mtwara regions.Funding for integrating child health, malaria and HIV/AIDS components into already established ADDOs comes from USAID. Additional program support is also provided through the Danish International Development Agency (DANIDA).

In order for *Duka la dawa baridi* to be accredited as ADDO or *Duka la dawa muhimu (*DLDM), they must meet minimum required standards in the following areas—

- Shop location and building design/layout
- Personnel training and continuing education
- Drug availability—All medicines sold must be on the list of ADDO-authorized medicines, which includes a limited number of prescription-only medicines and selected lifesaving drugs such as certain intravenous (IV) fluids
- Drug quality—All medicines sold must be registered by TFDA and stored in an appropriate manner to lessen the likelihood of contamination or degradation
- Stock control, handling, and record-keeping—In particular, ADDOs are required to account for the purchase and sale of all prescription drugs
- Sanitation and hygiene of the premises and personnel

1.0: Background of Illegal Drug Stores in Zambia

Zambia is a large country with a size of approximately 752,614 square kilometers and population of approximately 12 million. There are 80+? Registered pharmacies but unfortunately most of these are located mainly along the line of rail and major towns, leaving the vast majority of Rural areas serviced only by the DRUG STORES. The Drug Stores draw their permit to operate through different Act of Parliament than those regulating Pharmacies. The Drug Stores are outlets that are permitted to operate within a very restricted medicines range. Mostly General Sales medicines range. The Drug Stores become ILLEGAL DRUG STORES when indulging in the stocking and sell of Pharmacy and Prescription Only medicines range, for which they would require a license from PRA and operate under the supervision of a Pharmacist. Please take note that some of the medicines that an Illegal Drug store stock may have been obtained from legal Pharmaceutical Wholesalers. (Illegally) and some from brief case suppliers. This problem has contributed to the many illegal drugs stores that are currently operating all across the nation of Zambia. There are currently 251 registered pharmacists in Zambia. The Zambian government, along with the PRA and the National Drug Policy (NDP) are working hand in hand to strengthen the control of medicine in the country. The upgrade of the Zambian Drug Stores may require financial inputs. Will this be feasible in the Zambian context? The population of Tanzania is 41million and largely rural with a reasonable economic growth. Zambia`s population is only 12million. We have a school of Pharmacy graduating at least 35 Pharmacists every year. Would it be possible therefore to improve accessibility of medicines in the Rural areas through other means?? E.g. Motivation of Private Pharmacies into the Rural areas. Rural Areas tax free zones, Incentives schemes, Pharmacist Retention etc. However it's important to mention that there is already an initiative being piloted by the World Bank, Zambia Access to ACT Initiative (ZAAI) some member organizations of MeTA like MSH are involved in this initiative that seek to increase access ACT using the ADDO Model.

Operating a store that sells medical drugs without government and pharmaceutical approval is equally illegal. One of the major risks of illegal drug stores is that they carry medicines that have not been manufactured and monitored by the pharmaceutical or food and drug agencies within the country. According to studies done on illegal drug stores and illegal medicines, online or otherwise, the effect can be detrimental, such as:

- Most diagnosed diseases require the right medicines to cure the ailment. If illegal drugs are given to the patient(s), the effects maybe deadly due to the reaction of the toxins in the drugs and body respectively
- Some illegal drugs could cause brain damage, cancer, heart or liver problems, to mention but a few if taken on a consistent basis.

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2.0: A Sustainable Model of Combating the Problem

With the stock outs of essential medicines experienced in the public sector and subsequent rise in illegal drug stores and illegal medicines within Zambia, the need to address the problem cannot be ignored. With every problem, there needs to be a solution. Finding a sustainable way to a solution has to be the target of the Ministry of Health in particular the Pharmaceutical Regulatory Authority as well as other related stakeholders in the pharmaceutical industry. In trying to address this problem, a model has been looked at and recommended that could be contextualized for the Zambian nation. The ADDO Model or Program of Tanzania is one that, when studied, seems to be compatible with Zambia in more ways than one. First, the model has been tested on an African country and has proved successful. Second, the model not only addresses ways of combating illegal drug stores, but also addressing areas that deal with HIV/AIDS, Malaria and other diseases by providing manageable access of medications to these problems. This is advantageous because one is tackling two or problems with one solution which

In the proceeding sections, reasons will be given, recommending the need to seriously think about adopting the ADDO Model program and implementing it, helping the Health sector and its stakeholders in making Zambia a better country through providing the necessary healthcare and right pharmaceutical stores that will provide authentic medications to all patients.

3.0: Recommendations of adopting the ADDO MODEL of Tanzania

Tanzania, like many other African countries has faced its fair share of the quality of healthcare and illegal drug stores that has affected it citizens. The question has also been the use of illegal drug stores and illegal drugs that are sold to unsuspecting victims. In order to address this problem, the Tanzanian government, along with national health sectors within the country came up with a program that would hopefully change the landscape of healthcare and provide legal drug stores that would benefits its people. "The Program established a network of Accredited Drug Dispensing Outlets (ADDOs) also known in swahili as *"Duka la Dawa Muhimu* (DLDM)" to provide selected basic medicines and other medical supplies in rural and peri-urban areas." (*Tanzanian and Drug Authority: Protect and Promote Public Health: Addo Program at a glance. http://www.tfda.or.tz/Addopage1.html)* This pilot program was introduced in Tanzania from 2002 to 2005.

Some of the ways the ADDO MODEL has tried to address this problem includes:

- Improve the *quality of medicines* that people buy from drug sellers.
- Increase the *availability* of essential medicines throughout the country.
- Improve the *quality of dispensing services* from both technical and consumer perspectives.

Upon its completion as a pilot program, the ADDO program had yielded success in combating their programs in the following ways:

- Increased community access to quality, safe and effective drugs: There were less than 2% unregistered drugs in the market at end line evaluation as compared to 26% at baseline survey in the pilot region.
- Improvement in rational drug use through adherence to requirements for dispensing prescription drugs. This was evidenced by the finding that only 14% could dispense antibiotics for treating Upper Respiratory Tract Infection as compared to 39% at baseline survey.
- All 210 ADDOs in Ruvuma are manned by certified dispensers trained in basic drug dispensing.
- A change in medicines-taking behavior through good dispensing practices and patient counseling.
- ADDO contributed to malaria and HIV/AIDS prevention and treatment through improving access to insecticide treated nets (ITNs), condoms, antimalarials, and drugs for opportunistic infections. Furthermore, they were found to be important centers for provision of health education
- Improvement in inspection of drug outlets by ward and district inspectors
- Improvement in documentation and record-keeping
- Improvement in compliance to laws regulating pharmaceutical businesses

It should be noted that this success was a joint effort of all health sectors, government agencies, private and public stakeholders in Tanzania. One of the reasons this program has been successful is because each agency took personal responsibility in seeing to it that what the program offered would be the solution for each respective community. In addressing this situation, the ADDO Model had key elements of the program to work from:

- Sensitization and mobilization of stakeholders on ADDO Program
- Mapping and preliminary pre-accreditation inspections
- Training of ADDO drug dispensers, owners and inspectors
- Accreditation of drug outlets
- Supervision and inspection
- Monitoring and evaluation

Having a strategy in place helped the ADDO model find footing to be implemented and yield the results it has since obtained. “There are 210 ADDOs in five districts of Ruvuma region and in Morogoro region there are 67 ADDOs in Ulanga and 140 in Kilombero, with additional ADDOs established in Morogoro region by July 2007. In addition to replicating the basic ADDO system, the program will further develop ADDOs to support other public health interventions such HIV/AIDS, child health and ACT-based malaria treatment.”

It is with this background that the recommendation to use the ADDO Model is being submitted to the Ministry of Health and government at large in Zambia for consideration.

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4.0: Why Implement the ADDO MODEL in Zambia?

In looking at the work of the ADDO program, one cannot underestimate its success in the nation of Tanzania. Even though no other country in the African region has yet to adopt the ADDO Model, the success it has garnered allows other countries to take note and consider implementing such a program. Below are some of the reasons this model is being recommended. All recommendations are based on the work from the ADDO Program:

4.1: Statistical Proof

One of the key elements in determining the success of a program is by reviewing the pretest results and post test results. If the post tests are favorable, then one must conclude that what was implemented worked. Such is the case when it comes to the ADDO program.

- When the pilot program begun, there were 26% unregistered drug stores in all respective regions to 2% unregistered drug stores upon completion of the program.
- The survey had registered up to 39% of administered drug treatment of Tuberculosis, compared to only 14% when the program was completed, demonstrating an "Improvement in rational drug use through adherence to requirements for dispensing prescription drugs."

4.2: Objectives of the Program

The objectives of the ADDO Program are consistent with providing the right medication for any citizen regardless of which country or region they are from. Here again are the objectives of the ADDO Program

- Improve the *quality of medicines* that people buy from drug sellers.
- Increase the *availability* of essential medicines throughout the country.
- Improve the *quality of dispensing services* from both technical and consumer perspectives.

The ADDO program has been able to set small shops across Tanzania that dispenses the right medications-non prescription medicines to the private sector, in line with their objectives.

4.3: Benefits of the Program

Benefits of programs to an organization or country are critical for success. Without a good benefit plan in place, there can be no progress of implementation. Some of the benefits of the ADDO Program in Tanzania can benefit the nation of Zambia as a whole. For a complete list of benefits from the ADDO Program, the ADDO homepage can be accessed at: http://www.tfda.or.tz/Addopage1.html

- Improved access to quality, safe, effective and affordable medicines to a larger population.
- Creation of income generation activities for ADDO owners;
- Creation of a skilled pool of trainers, dispensers, and inspectors..
- Improved referral system for patients who first consult drug outlets

- Creation of a system for application and repayment of loans by ADDO owners through micro financing institutions

4.4: The Potential in improving public health

Besides coming along government to help in the area of distributing medicines, some of the ways the ADDO Program can help improve public health is through:

- Improving access of essential medicines to rural and peri-urban areas
- Scale up of IMCI through involvement of private sector
- Distribution of subsidized ACTs
- Health education and distribution of IEC materials on HIV/AIDS, malaria and other common diseases
- Potential source of medicines for opportunistic infections
- Distribution of Condoms, contraceptives and ITNs

Granted, some the recommendations may need to be contextualized to the Zambian nation, the evidence provided gives stakeholders something to consider and possibly implement.

SOME ADVANTAGES OF THE ADDO SYSTEM IN ZAMBIA

This could improve accessibility of good quality medicines in the Rural areas through the specialized Drug Stores.

- This will legalize the supplies from legal Wholesalers of restricted medicines range to Drug Stores

SOME DISADVATAGES OF THE ADDO SYSTEM

The freedom to stock restricted medicines in a Drug Store could lead to over treatment of patients with antibiotics or ant malaria which could lead to Drug resistance. This would therefore require close monitoring

- Referrals to hospitals may be limited because of monetary gains

5.0: Recommendations

As for every project that needs implementation, the starting point is critical to the success or failure thereof. What is hoped for in the recommendations made in this paper is that the program is successful enough to change the landscape of illegal drug stores, illegal medicines and their impact on the Zambian people. The following are the recommendation given in the implementing process.

- Give an opportunity to the stakeholders (in this case, the Ministry of Health and its subsidiaries, the pharmaceutical companies, distributors of medicines, etc,) an opportunity to research on the ADDO Program and see how best it can fit into the Zambian context.
- Be fully engaged in the project if adopted with all stakeholders. There will need to be pretests and posttests of the project to determine the effectiveness of the ADDO Model within the context of the Zambian community. An extensive survey should be done, more so in problem spot areas where the number of illegal drug stores are operating from.
- The healthcare stakeholders, in collaboration with the Ministry of Health, should also be intentional in training private retail outlet pharmaceutical store owners on how to prescribe the right medication etc. At the end of the day, those trained should be qualified and have the knowledge of how to prescribed medicine properly.
- All illegal drug stores that are found operating after initial warnings to be shut down should be fined accordingly and shut down by the proper governing body so as to send a strong message across the nation about the seriousness of providing the right medications to people in need.

6.0: Conclusions

Adopting an effective program as the ADDO Model will be beneficial to the Zambian nations. Providing the right medicines to people in need is a human rights issue and it needs to be adhered to immediately. The health of people is at stake the longer illegal drug stores and illegal medicines are prescribed to sometimes unsuspecting clients. "The lesson learnt is that pharmaceutical services in developing countries can be substantially improved through technical support: i.e. training, accreditation, and regulation of private-sector drug sellers. Even prescription medicines can be rationally dispensed through local outlets, but monitoring is necessary to support improvements in rational use. (http://www.gtz.de/de/dokumente/en-backup-guide-examples-08.pdf)." The stakeholders, in this case, the Ministry of Health, should be able to take a proactive role in insuring that all drug stores operating in Zambia are licensed and providing the right medicines authorized by the pharmaceutical industry.