

Visit Summary Report

Visit to Accredited Drug Dispensing Outlets (ADDO) Program by
Representatives from Ministry of Health - Sierra Leone and
Ghana

25th – 30th June 2018



Prepared by Apotheker Consultancy (T) Ltd for LaunchDSI Program of MSH

20th April 2018

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2. Back Ground

Management Sciences for Health (MSH) with support from the Bill and Melinda Gates Foundation supported the Accredited Drug Dispensing Outlet (ADDO) program in Tanzania through 4 cycles of funding; The SEAM program supported the pilot phase, EADSI supported scale up in Tanzania and initiated similar program in another country (Uganda). The third grant was the Sustainable Drug Seller Initiatives (SDSI) which supported the maintenance and sustainability of ADDO program in Tanzania, Scale up in Uganda and initiated in another African Country (Liberia). The LaunchDSI program is the fourth grant with the aim of strengthening technical resource center for ADDO in Tanzania to support other countries intending to initiate ADDO like initiatives and support other interested African countries to initiate the ADDO like activities in their own settings.

Launch DSI provides technical assistance and small start-up grants to assist interested African countries to adopt the Accredited Drug Seller Initiatives (ADSI). For a successful startup in any country, a learning visit to Tanzania ADDO program has been identified as a critical initial step. Countries visiting Tanzania will have a firsthand experience on what Tanzania has done to achieve the ADDO program. Interested countries will also have the opportunity to compare and contrast the situation in Tanzania in reflection to their own country's pharmaceutical systems. They will ultimately identify what will work and what will need to be adapted based on their local context.

With support from LaunchDSI, Nigeria, DR-Congo and Burundi made a visit and are now in the process of organizing initial startup activities.

Sierra Leone and Ghana started expressing interest to visit ADDO since March 2018 and in June 2018, a joint visit was organized for the two countries to jointly visit Tanzania to start a five day tour of the pharmaceutical services in Tanzania.

3. Preparations for MOH- Sierra Leone and Ghana Delegates' Visit to Tanzania ADDO Program

With support from LaunchDSI, letters of interest were received at the Ministry of Health, Community Development, Gender Elderly and Children (MOHCDEGEC in Tanzania from Ministry of Health - Sierra Leone and Ghana. The MOH Tanzania through the Pharmacy Council accepted the request and worked with the two Countries to agree on the number of delegates and the dates. The Pharmacy Council Tanzania in collaboration with MSH/LaunchDSI facilitated communications with the two countries and visit dates were finally settled to be 25th to 30th June 2018. On Sunday 24th June 2018, a delegation from Ghana arrived followed by the Sierra Leone on 25th June 2018.

4. Composition of the delegation

4.1: Sierra Leone

A five member delegation from Sierra Leone pharmaceutical sector included the following;

| No | Name | Position |
|----|----------------------------------|--|
| 1. | Pharm. Michael Jack Lansana | Director of Drugs and Medical Supplies/Chief Pharmacist, Ministry of Health and Sanitation |
| 2. | Pharm. Dr. Wiltshire C.N Johnson | Registrar, Pharmacy Board of Sierra Leone |
| 3. | Pharm. Sitta Kamara | Head of Department, Policy, Standards and Practice - Pharmacy Board of Sierra Leone |

4.2: Ghana

Ghana MOH sent a five member delegation from Pharmacy Council, Pharmaceutical Society of Ghana and the Food and Drugs Administration.

| No | Name | Position |
|----|-----------------------------|---|
| 1. | Mr. Rauf Audu | Registrar, Pharmacy Council of Ghana |
| 2. | Mr Thomas Appiagyei | Past President and Head of Business Committee of PSGH |
| 3. | Mr. Kwame Peprah Boaitey | Deputy Executive Secretary PSGH |
| 4. | Mr. Vigil Edward Prah-Ashun | Head - Drug Market Surveillance FDA Ghana |
| 5. | Mrs. Jennifer Bonnah | Drug Evaluation And Registration FDA Ghana |

5. Objectives of the Visit:

The main objective for organizing this visit was to introduce the two countries on the ADDO program implementation in Tanzania for possible replication in their countries based on local needs and context. Specifically, the delegates are expected to accomplish the following specific objectives while in Tanzania.

1. Courtesy call to MOH and meeting with Chief Pharmacist MOH for an Overview of Pharmaceutical Sector in Tanzania.
2. Familiarize with Tanzania pharmaceutical sector supply and regulatory systems (Supply chain, regulation of food, medicines, cosmetics and medical devices and regulation of pharmacy practice, premises and personnel).
3. Learn the Tanzania ADDO Program implementation experiences (Pharmacy Council and MSH).
4. Conduct field visits to Pwani and Dar es salaam to learn about operations of pharmacies and ADDO.
5. Plan for country specific way forward and possibility for adaptation of ADDO model

6. Accomplished Activities Based on the Visit Schedule

6.1: Courtesy Call and Meeting at Ministry of Health Pharmaceutical Services Unit (PSU)

The delegation paid a courtesy call at the Ministry of Health on the afternoon of Monday 25th June 2018 and met with the Permanent Secretary Dr. Mpoki Ulusubisya. The meeting was also attended by the Chief Pharmacist Mr. Daudi Msasi and the Registrar Pharmacy Council Ms. Elizabeth Shekalaghe.

6.2: Meeting and Presentation by Chief Pharmacist:

The Chief Pharmacist who is also the Assistant Director- Pharmaceutical Services at the Ministry of Health agreed to meet with the delegates at MSH offices located adjacent to MOH for his presentation. The meeting was attended by Registrar of Pharmacy Council, and other PC and MSH staff. A presentation on pharmaceutical services under MoHCDGEC was made by PSU. Members of the delegation were able to understand how the Pharmaceutical Services Unit is structured at the Ministry of Health. They were also enlightened on the core functions of PSU and how the unit works with Medical Stores Department, Regional and Districts health services on supply of Pharmaceuticals and other health commodities.

6.3: Meeting with Pharmacy Council

On Tuesday 26th June, the Pharmacy Council staff met the delegation at MSH offices. The PC meeting was attended by the Registrar, Heads of Registration and Education departments and the ADDO Program coordinator. Presentations on overview of Pharmacy Council and ADDO program implementation were delivered by the Registrar in collaboration with ADDO coordinator.

6.3.1. Presentation on Pharmacy Council Overview

Delegates had an opportunity to learn on how the Pharmaceuticals and poison Act 1978 which established Pharmacy Board formed the Pharmacy Council under the Pharmacy Act 2002 and TFDA under the TFDA Act 2003. They were also highlighted on the core functions of the Council, members of the Council and the achievements made to date as well as challenges facing the Council. The registrar highlighted in her presentation that PC is responsible for registration and practice of pharmaceutical personnel of all levels (Pharmacists, Pharmaceutical Technicians, Pharmaceutical Assistants, Medicine Dispensers and ADDO dispensers). The institution is also mandated to oversee registration and licensing of pharmaceutical wholesalers, retail pharmacies and ADDOs. They are also responsible for registration and licensing of training institutions.



6.3.2. Presentation on ADDO Program Implementation, success and challenges

Delegates were taken through the ADDO model from its pilot implementation to scale up, sustainability and transfer to other countries. Some of the strategies highlighted included; stakeholders engagement, development of standards, capacity building to providers, marketing and awareness campaigns and monitoring and inspection systems. Pharmacy Council highlighted to the delegates on development of ADDO regulations, standards and inspection system. Delegates were also taken through the regulatory changes that mandated PC to take over ADDO activities from TFDA. They were highlighted on implementation status to date and the program activities are managed by District Pharmacists in collaboration with PC. The ADDO presentation was followed by key discussion areas on how stakeholders were engaged to support the program, political will and buy in from the government, role of pharmacists and their perception towards the program. Other areas of discussion included the resources mobilization to support program implementation and phasing out of illegally existing drug outlets in areas where ADDO program is implemented.

Participants were also oriented on different tools used on program implementation. These are; training manuals for dispensers, owners and inspectors, implementation guide, inspection checklist, drug register and referral forms.

They were also introduced to the ADDO video documentary prepared by MSH in collaboration with PC and TFDA and which gives a summary History of the program implementation from pilot phase to the current sustainability phase and introduction of the program to other countries.



6.4. Field Visit to Selected Pharmacies in Dar es Salaam and ADDOs in Mkuranga District

6.4.1. Visit to Retail Pharmacies in Dar es salaam:

Delegates had an opportunity to visit two retail Pharmacies, JD Pharmacy located at Mlimani City mall and Nakiete Pharmacy operating as wholesale and retail pharmacy. Delegates were exposed to set up of retail Pharmacy premises, registration and licensing process. They were also exposed on how the supply chain works in private sector, dispensing services and management of National Health Insurance Fund clients through private Pharmacies. Other areas exposed to the delegates were;

- The differences between premise set up in Pharmacies and ADDO where pharmacy premises are much larger in size than ADDO with sufficient storage and dispensing areas;
- Location- pharmacies are located more in urban settings, densely populated with more customers turn over than ADDOs;
- Registration and licensing – Certificates issued by PC for premise registration and business operations;
- A wider range of medicines for pharmacies (within registered products) than that of ADDOs

The visiting team commented on the separation of prescription medicines from other over the counter products, cosmetics and hygienic products. They also commended on the increased stock of non pharmaceutical products which are within the allowed products for sale and contribute to increased sales and overall business.

6.4.2. Visit to ADDOs in Mkuranga District

A field visit to Mkuranga District was collaboratively organized between MSH and PC. The visit was conducted on Thursday 28th June where delegates paid courtesy call to the District Executive Director and the District Medical Officer. The District Pharmacist with his team accompanied the visitors to selected ADDOs. Delegates were able to interact with ADDO owners and dispensers with the assistance

of PC and MSH staff. From the discussion with owners, dispensers, MSH and PC staff, delegates were able to learn the following;

- Branding and signage of ADDO using ADDO logo;
- Registration and licensing certificates for ADDOs issued by PC;
- Availability of trained dispensers with certificates displayed;
- Premise size and set up – two roomed premise, one for display/dispensing and customer service and one for storage of medicines and administration;
- Record keeping and documentation system placed in ADDOs
- Type of medicines sold in ADDO; selected prescription medicines and over the counter medicines. Availability of subsidized products for public health use such as anti-malarial, family planning pills and condoms and insecticide treated mosquito nets;

Delegates were impressed with the ADDO adherence to set standards and cooperation between inspectors/ supervisors and ADDOs. They commented on the transparency and collaboration shown by ADDOs and regulators as shown by dispensers availing filed inspection forms which showed inspection results and list of products seized by inspectors when inspecting the outlets. They were impressed on high level of health awareness in rural Tanzania where communities understand the role of drug shops and visit them when sick and in need of medicines. They were also impressed with the way ADDOs are branded and visible to everyone in the community. However, they were concerned with the limited stock that ADDOs had for sale which would limit the growth of their business. They were also concerned that the small township visited had many ADDOs, a situation which could cause business competition and hence a threat to business viability and also increase the risk of malpractices.

6.5. Visit to Tanzania Food & Drugs Authority (TFDA)

On Friday afternoon 29th June, the delegation visited TFDA and had an opportunity to meet with the Director General for courtesy call. TFDA meeting was attended by the Director for Business support and other staff from registration and inspection department. A presentation on overview of TFDA , product importation and registration was made. The delegates had an opportunity to learn about the structure of TFDA, functions of the organization and its set up across the country. They also had the opportunity to ask questions in relation to operations of TFDA. They finally had the opportunity to visit the Quality Control laboratory.



7.0. Debriefing Session and Presentation by Sierra Leone and Ghana

On Friday morning 29th June, both Sierra Leone and Ghana made a presentation on Pharmaceutical services in their countries. The session was attended by MSH and PC staff and was held at MSH offices. The first presentation was done by the Sierra Leone -Registrar of Pharmacy Board followed by the Ghana presentation made by the Deputy Executive Secretary of Ghana Pharmaceutical Society. The two presentations highlighted on the structure of Pharmaceutical services in the two countries, lesson learnt from the Tanzania visit as well as possible way forward upon return to their respective countries.

7.1. Pharmaceutical Sector challenges in Sierra Leone, lessons learned from Tanzania and way forward

7.1.1. Some of the challenges related to medicine access in Sierra Leone

- Current legislation is weak and inadequate to meet current regulatory requirements.
- 53% of the geographical chiefdoms do not have any private pharmaceutical premises
- Inadequate numbers of appropriately qualified health personnel within Sierra Leone making regulation of health services a challenge
- Poor / low health literacy, and knowledge attitude and practices of the communities being served
- Sale of medicines to and by unauthorized personnel
- Presence of dispensing Doctors who are not licensed to do so and are not effectively regulated by their professional body.
- Drug peddling by street vendors and market traders

7.1.2. Lessons Learnt by Sierra Leone team on Tanzania visit

- Despite working in different environments, the three countries have similar regulatory challenges
 - Political will to support regulation and control.
 - Poverty

- Inadequate funding
- Weak Regulatory Infrastructure and enforcement Capacity
- Inadequate Human resource for health care services
- The threat of smuggling illegal and sub-standard products from neighboring countries
- Regulatory System- The system of separating regulatory functions (practice and products) has proven benefits in terms of efficiency of work.
- Engagement of the community in the management of pharmaceutical services i.e. CTFDC through out the country provides the opportunity to manage the pharmaceutical services at the community more effectively.
- Establishing a different cadre of pharmacy personnel with the permission to dispense an appropriate approved list of medicines has promoted access to pharmaceutical services at the community level. There is therefore need for a paradigm shift in the training of pharmacy personnel in West Africa and in Sierra Leone in particular.
- Evidently ADDOS have contributed to improving access to essential medicines by the community, the program is similar to that in sierra Leone i.e. the patent medicine seller program.
- The engagement of all stakeholders(national, regional and community) is key to implementing access to medicines programs such as the ADDO initiative
- There is need for a country wide gap analysis and mapping to identify the needs of communities in order to plan the access to medicines scheme.
- However the ADDO'S provides an expanded range of products including certain prescription products based the training that is provided. There is however need to build the capacity for services providers in terms of accurate diagnosis possibly supported by the use of RDTS and the implementation of a surveillance programs to monitor AMR .
- There is need to ensure a secure supply system at regional and community levels from where ADDO'S license holders can access their supplies.
- The ADDO's program is a means to an end but not an end in its self. Countries should aspire to upgrade the level of pharmaceutical services providers serving the community so that lower cadres are not needed. Serious consideration should there be given to develop strategic plans to develop a robust and effective pharmaceutical sector in its entirety.

7.1.3. Way Forward for Sierra Leone

- The engagement of all stakeholder(national, regional and community) is key to implementing access to medicines programs such as the ADDO initiative
- There is need for a country wide gap analysis and mapping to identify the needs of communities in order to plan the access to medicines scheme
- Establishing pharmacy training institutions in other parts of the country will greatly improve on the manpower gap in the pharmaceutical sector and contribute to improving access.
- There is also need to propose the training of other cadre of pharmacy personnel which will be used to serve the community drug distribution facilities.
- Consideration should be given to establishing public dispensaries.(ADDOS)

- Establishment of special access to medicines schemes in the private sector for deprived areas of our communities. This includes the role out of the Board's access to medicines project that will see the establishment of community medicines points or accredited drug sellers in every community where in any community with less than 500 population will be entitled to have an entrepreneur trained and given a free patent license to sell over the counter medicines

7.2. Pharmaceutical Sector Challenges in Ghana, lessons learned from Tanzania and way forward

7.2.1. Some of the Challenges of Pharmaceutical sector in Ghana in relation to medicine access

- Inadequate geographical coverage of pharmaceutical facilities i.e. Pharmacies and OTCMS outlets
- Inadequate trained personnel to stock and dispense medicines in defined levels and conditions.
- PC deployed the distance criteria in 1995 to influence equitable distribution of pharmaceutical facilities
- 80-85% of pharmacies are located in Greater Accra and Ashanti Regions.
- 15-20% in remaining 8 regions .
- Most of these pharmacies are located in the regional capitals, Implications for pharmacy practice?
- PC is to transform pharmaceutical service delivery in Ghana.

7.2.2. Lesson Learnt on Tanzania visit

- Stock levels in ADDOs appeared to be low, need to research on this
- Community engagement on ADDO services in Tanzania is high - (weeding out peddlers),
- High level of health literacy and Self-regulation was seen
- Good and up to date record keeping at the ADDO's
- Access to simple technology in ADDO to send and receive information on services
- Supervision of ADDO was excellent as a result of the good decentralization model
- Availability of the list of POM's medicines in ADDO's and display of the medicines that could be stocked in the ADDO's

7.2.3. Concerns on ADDO model as observed by Ghana delegation

- ADDO's are congested within the small township of Mkuranga -key to sustaining the business
- Non-availability of herbal medicines within ADDO facilities,

7.2.4. Way forward by the Ghana delegation

- Facilitate the Introduction of the model pharmacy which will consider the ADDO model in rural settings
- Improve Community engagement and ownership of the facilities,
- Need for an improvement of record keeping of the OTCMS.

- Coordinated training program for OTCM's

8.0. Observations, Remarks/Conclusion

The Apotheker team formed part of the Tanzania MSH team in organizing and hosting the delegation. Based on our experience on similar visits to ADDO program in Tanzania, we have made the following observations/remarks to this visit

- Although it was a two country joint delegation, the visit was successfully coordinated from arrival in Tanzania, hotel services, logistics to visit different locations and meetings held in different places.
- The Pharmacy Council this time played a very active roll to fully own the delegation from participated in the events. correspondences prior to visit, coordinating all activities in the planned visit schedule, and delivering the necessary presentations. Many of the PC staff including the Registrar fully
- Delegates were able to meet the Permanent Secretary MOH who happened to be in Dar es salaam at the time of their visit. In the past, such situation was difficult because the PS is mostly settled in Dodoma where recently the Government offices have moved to.
- Type of delegates from each country formed a good combination of experts from Pharmacy Council/Board, Pharmaceutical Society, Food and Drugs Administration and office of Chief Pharmacist – MOH. Recommendations to be made to the Ministry based on lesson learnt from Tanzania will likely be easily accepted and moved forward for implementation
- Presentations on the Pharmaceutical sector from the two countries were very comprehensive and they all highlighted on the rural challenges, lack of adequate pharmaceutical human resource and the need to set up ADDO like initiatives.
- The LaunchDSI project has made a significant step to engage three more West African Countries (Nigeria, Sierra Leone and Ghana) to introduce the ADDO initiative after Liberia which is now implementing the AMS project since 2012.

Follow ups after visit will be important to ensure that immediate steps are taken by each country to debrief their MOH leadership and define initial ADSI activities for possible financial support by LaunchDSI.

9. 0. Attachment: Visit Schedule

SIERRA LEONE and GHANA Delegation Visit to Tanzania Visit Schedule 25TH -30TH June, 2018

Objectives:

1. Courtesy call to MOH and meeting with Chief Pharmacist MOH for an Overview of Pharmaceutical Sector in Tanzania.
2. Familiarize with Tanzania pharmaceutical sector supply and regulatory systems (Supply chain, regulation of food, medicines, cosmetics and medical devices and regulation of pharmacy practice, premises and personnel).
3. Learn the Tanzania ADDO Program implementation experiences (Pharmacy Council and MSH).
4. Conduct field visits to Pwani and Dar es salaam to learn about operations of pharmacies and ADDO.
5. Plan for country specific way forward and possibility for adaptation of ADDO model

| Date | Time | Activity | Responsible |
|-------------------------------------|------------------|---|---|
| Sunday 24 th June, 2018 | | <ul style="list-style-type: none"> • Arrival in Dar es Salaam airport pick up to Hotel | Pamela Lema-MSH |
| Monday 25 th June, 2018 | 8.00am-10.00am | <ul style="list-style-type: none"> • Courtesy call to MSH office and familiarization to agenda • Briefing on MSH Tanzania | Dr. Kimatta and Dr. Lema -MSH |
| | 10.30am -12.00pm | <ul style="list-style-type: none"> • Courtesy Call to PS-MoHCDGEC: | Director – Pharmaceutical Services - MoHCDGEC Registrar – Pharmacy Council |
| | 12.30pm -1.00pm | Lunch Hour | All |
| | 1.00pm – 04.00pm | <ul style="list-style-type: none"> • Discussion with Pharmaceutical Services Unit of MOH-- for briefing on the Pharmaceutical Sector in Tanzania. | Director – Pharmaceutical Services - MoHCDGEC Registrar – Pharmacy Council |
| Tuesday 26 th June, 2018 | 8.30am--01.00pm | Presentation on Pharmacy Council <ul style="list-style-type: none"> • Overview of Pharmacy Council • Regulation of personnel, premises and practice • ADDO Program Implementation [success and challenges] | Pharm. Elizabeth Shekalaghe (Registrar) |
| | 01.00 – 02.00pm | Lunch Hour | |
| | 02.00 – 04.00pm | Visit Pharmacies in Dar es Salaam | PC, MSH |

| | | | |
|---|----------------------|--|--------------------------------|
| Wednesday 27 th June 2018 | 08.00am- 04.00pm | <ul style="list-style-type: none"> Field visit to Accredited Drug Dispensing Outlets(ADDO) in Mkuranga District | PC, MSH |
| Thursday 28 th June, 2018 | 08.00 - 12.00am | Preparation of presentation by Sierra Leone and Ghana | Sierra Leone & Ghana Delegates |
| | 12:00am- 01:00pm | <ul style="list-style-type: none"> Lunch hour | |
| | 01.00pm – 04.00pm | <ul style="list-style-type: none"> Free afternoon to visit Dar es salaam | |
| Friday , 29 th June 2018 | 08.30am – 12.00am | <ul style="list-style-type: none"> Presentation on the Pharmaceutical Sector in Sierra Leone and Ghana, lesson learned from Tanzania visit and way forward Discussion and closure | Sierra Leone & Ghana Delegates |
| | 12.30- 03.00pm | Visit to Tanzania Food and Drugs Authority (TFDA) premises <ul style="list-style-type: none"> Overview of TFDA and regulation of food, medicines, cosmetics and medical devices Drug registration and importation Tour to TFDA QC Lab | TFDA DG-Agnes Sitta |
| | 03.00- 04.00pm | <ul style="list-style-type: none"> Lunch hour | |
| | 07.00 – 09.00pm | <ul style="list-style-type: none"> Farewell cocktail (Serena Hotel) | Pamela Lema |
| Saturday, 30 th June 2018 | | <ul style="list-style-type: none"> Departure: Hotel to JN International Airport | Pamela Lema |