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| HEALTH SHOPS IMPLEMENTATION PLAN | October2016 |
| This document outlines the concept of Health Shop, highlighting the main activities to be undertaken in the implementation of the concept as a public health intervention. Summary budgets for a three-year period are included. The Summary budget excludes the first year.  | CONCEPT NOTE AND BUDGETS |



**ZAMBIA MEDICINES REGULATORY AUTHORITY**

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# BACKGROUND/INTRODUCTION

The Zambian Government takes health as a priority sector contributing to the well-being of its citizens. It is committed to providing quality health services to all. However, the country has continued to experience a high burden of diseases particularly Malaria, HIV and AIDS, STIs, NCDs and high maternal, neonatal and child mortalities and morbidities. To mitigate the challenges faced by the health sector, the National Health Strategic Plan (NHSP 2011-2015) supported by a national drug policy with a vision to provide equity of access for all Zambians to good quality, safe, and efficacious medicines which are affordable and rationally used as close to the family as possible was developed. In addition, the Zambian government enacted the Medicines and Allied Substances Act No. 3 of 2013, which provided for the Health Shop Concept. A health shop is a dispensing facility or premises permitted to sell a ZAMRA prescribed list of medicine under the control of an authorized person. This concept is a community-based private and public sector partnership platform to increase access to safe and quality assured medicines and public health services to the majority Zambians, especially those in low income and rural areas. As a result, the health shops is most accurately described as an essential medicines supplement to the existing public health sector architecture rather than as a separate approach

The implementation process is lead by Ministry of Health as the main stakeholder responsible for policy direction showing commitment to improving the supply of quality, safe and efficacious medicines to majority of the Zambian people. The legal authority is drawn from the Medicines and Allied Substances Act. Further commitment is shown through the continued support toward ZAMRA, the implementer and regulator of the pharmaceutical sector in Zambia.

To strengthen the good governance and leadership of the initiative a National Health Shop Steering Committee (NHSSC) composed of key stakeholders critical to the success and sustainability of the Health Shop Concept was established and is functional. The committee is providing strategic guidance to build a culture and a climate of consistency, responsibility, accountability, fairness, transparency and effectiveness of the implementation program. The professional body, Pharmaceutical Society of Zambia is bring in professional responsibility and ethical adherence as they strive to meet societal needs, particualry in the development and implementation of the training programs for dispensers and shop owners.. The Health Professions Council of Zambia is also a natural partner as the monitor the develop to protect the patient. The Pharmaceutical Business Forum, a consortium of the pharmaceutical wholesalers and manufacturers is a key player in the supply chain of medicines and allied substances.

Cooperating Partners are natural partners in development in assuring public health protection, especially in regards to diseases control and prevention of national importance, which include HIV/AIDS, Tuberculosis and Malaria. The kingpins of the health shop are the owners and dispensers whose role is critical to the success and sustainability of the health shops. They bring in their financial resources and human resources to bring in medicines and provide services to their communities.

**OBJECTIVE**

## The objective of the health shop concept is to improve access to affordable, quality medicines and pharmaceutical services in registered drug outlets in priority rural or peri-urban areas where private retail pharmacies are few and sparsely distributed or nonexistent.

# RATIONALE

It has been the intent of the Zambian government to avail quality medicines and pharmaceutical services through the conventional pharmacies. However, universal coverage would not be attained through this approach due to its high implementation costs and in particular reaching out to the rural and peri-urban areas. These areas are not economically viable to operate private retail pharmacies to complement public services. It is therefore logical to implement a relatively lower version private dispensing medicines outlet to provide the much needed quality essential medicines and services to the community.

# MISSION

The Health Shops Project is designed to improve access to medicines and services through a community-based private and public sector partnership platform for public health interventions. This project demonstrates Ministry of Health and ZAMRA’s commitment to working with the communities and private sector to effectively regulate and control Medicines and Allied Substances increasingly made available to the Zambian population, ensure their conformity to set standards of quality, safety and efficacy thereby safeguarding public health. The societal benefit is the capacity to improve the income, health status of communities and their health outcomes.

# OPERATIONS

To attain the objective stated above, ZAMRA in collaboration with Ministry of Health and Management Sciences for Health designed the coordinated approach to smoothly roll out the strategy without compounding the already existing health service delivery challenges in the communities. The Health Shops program will be rolled-out countrywide starting with two selected districts per province. In the first year, the target provinces are Muchinga and Western Provinces. With additional funding, the roll out will be extended to an additional eight districts, two located in each of four provinces in the second year. Finally, the rollout program will be completed with an additional eight districts located in the remaining four Provinces in the third year. Through a ripple effect approach and additional final resources, other districts will concurrently enroll through expanded services in the primary districts in the provinces.

In the first year with the support of LaunchDSI, ZAMRA and its stakeholders has successfully carried out the following activities. Setup a leadership, management and governance structures to operationalize the program. A National Health Shop Steering Committee (NHSSC) was set up and meets quarterly to provide oversight and policy guidance. A management team lead by a Health Shops Coordinating Focal Person and support staff on short and long term has been recruited and are growing the project operations.

National and local stakeholder sensitization meeting (national information sharing and district sensitization meetings have been conducted);

* Concept branding and marketing activities are being provided in the focus districts and consumer awareness, will continue. The Health Shop Coordinator with the support of the short term consultants and key stakeholders coordinated the development of a curriculum and training materials; Ministry of Health programme managers actively participated in identifying and guiding the team on integrating public health services to complement the increased access to medicines. TEVETA and pharmacy training institutions, actively participated in directing the educational strategy of the training and recognition. The team also remained alert and intently incorporated business entrepreneurship to ensure an evolvement of sustainable health shops businesses for the communities.
* To make the medicines affordable the health shops team facilitate a supply chain coordination mechanism with the involvement of the Zambia Pharmaceutical Business forum and other suppliers. Competition is being encouraged with the intent of reducing the prices of the medicines to the end-patient. This is being supported by public awareness activities to help the clients make informed choices.

* Meanwhile, ZAMRA has maintained its responsibility to provide a regulatory and quality assurance oversight through training, licensing, inspection and enforcement of the regulations.

## EXPECTED RESULTS

It is anticipated that with the implementation of the health shops concept, the following will be achieved:

* Up to 95% of the Zambian population having access to quality medicines and pharmaceutical services by the end of the third year;
* Unregulated and illegal drug stores will be converted to health shops, resulting in improved quality of public health services;
* The provision of selected diagnostic services for diseases such as malaria, tuberculosis and HIV will result in increased success in detection and control of these communicable diseases, in priority rural and peri-urban areas; and
* Overall, this program will contribute significantly to the attainment of government’s goal of universal health coverage.

## PROGRAMME RESOURCES

The one year funding was secured from the Bill & Melinda Gates foundation through the Management Sciences for Health’s Drug Seller Initiative called LaunchDSI donated US$108,908 as startup package for operations. Building on the success of year one, the project need to speed up the geographical coverage and stabilization of the program additional funding is required. Project is in "replenishment phase", i.e. it needs additional stakeholders and funders to commit themselves to continued financing.

The Health Shops governance architecture mandates the Ministry of Health and its medicines regulatory agency, the Zambia Medicines Regulatory Authority to mobilize resources to build a sustainable and successful implementation of the provisions of the Act. This project, being a community-based private and public sector partnership platform to increase access to safe and quality assured medicines and public health services to the majority Zambians, especially those in low income and rural areas, seeks for public funds through the Global Fund mechanism. We call on the Ministry of Health through the Global Fund to join with their own contributions - financially, in kind and through shared expertise. A drastic scaling up of investments in health shops will not only save thousands of lives but also produce enormous economic gains. This particularly timely in reengaging journalists and refocusing the attention of policy makers on diseases of poverty. The health shops will also improve access to medicines and basic services to public health priority diseases such as to HIV/AIDS, Malaria and TB that have a social economic impacts.

## ACTIVITY BUDGETS

**Year 1**

| **Activity No.** | **Description** | **No. of Persons** | **No of Days** | **Timelines** | **Cost****(USD)** |
| --- | --- | --- | --- | --- | --- |
| ***National Health Shop Steering Committee(NHSSC)Meetings*** |  |  |  |  |
|  | NHSSC meeting to present the ToRs and clearly define its mode of operation | 10 | 1 | Q1 | 700 |
|  | Quarterly NHSSC meetings | 10 | 4 | Q1-Q4 | 2,800 |
| **Subtotal** |  | **3,500** |
| ***Stakeholder Sensitization and meetings (National and local implementation area)*** |  |  |  |  |
|  | Hold National Key Stakeholders (from all 10 provinces) information sharing meeting with potentialfacilitators,financiersandimplementers | 9 from out of Lusaka  | 1 | Q1 | 3,645 |
| 45 Lusaka | 1 | Q1 | 3,150 |
|  | Hold District Stakeholders(potential shop owners, training institutions, local government, professional associations) sensitization, mapping and recruitment meeting (Muchinga Province: Chinsali District meeting and Nakonde District meeting;Western Province: Mongu District meeting ad Sesheke District meeting) | 25 | 4 | Q2 |  11,040 |
| **Subtotal** |  | **17,835** |
| ***Health Shop Focal Person/Coordinator*** |  |  |  |  |
|  | Contract Salary for Focal Person on a 1 year renewable performance contract  | 1 | 280 (1 year) | Q1-Q4 | 30,000 |
| **Subtotal** |  | **30,000** |
| ***Health Shop Guidelines*** |  |  |  |  |
|  | Draft guideline based on HS regulations and the Medicines and Allied Substances Act*(ZAMRA is already undertaking this activity at an estimated cost of USD20,000. The costs are being covered by ZAMRA)* | - | - | Q1 | - |
|  | Publication (including printing) and dissemination of HS guidelines | 650 copies | 1 | Q1-Q2 | 3,250 |
| **Subtotal** |  | **3,250** |
|  ***Curriculum Development and Implementation (Training Curricula)– Participants’ guide and Teachers’ guide*** |  |  |  |  |
|  | Engage curriculum development consultant to facilitate the drafting and adaption of the curriculum for the training of HS. This involves information gathering, identification and facilitating key contributors to the curriculum, consolidation of materials in a draft a draft curriculum. | 1 | 24 | Q1 | 5,800 |
|  | Hold consultative meetings with key stakeholders to consolidate the curriculum (PSZ, HPCZ, ZDA, MoH, Program Managers – HIV, TB, Malaria, Maternal/Child health, etc.). to provide guidance on the content, educational strategies, educational ethos, assessment methods, trainers, trainees, length of program, develop Trainers’ Manual and Students’ Manual | 10 | 4 | Q1 | 3,000 |
|  | Conduct Training of Trainers for Implementation of Training Program (Training Institutions, District/Provincial focal persons) | 20 | 4 | Q1-Q2 | 5,200 |
|  | Training of Health Shop owners and Dispensers (To be provided by accredited training institutions and cost of training to be borne by trainees/end users) | - | - | Q2-Q4 | - |
| **Subtotal** |  | **14,000** |
| ***Training coordination in the first 2 districts*** |  |  |  |  |
|  | Coordinate the implementation of training of trainers and Health Shop owners/Dispensers to ensure adherence to Curriculum | 3 | 5 | Q1-Q4 | 8,160 |
| **Subtotal** |  | **8,160** |
| ***Supply Chain Coordination and Management*** |  |  |  |  |
|  | Advocacy/communication strategy (inform communities of the opportunity available for them to open/run health shops; and public awareness on availability of services to be accessed from the health shops : Radio, drama, face to face, social media, etc. | 3 | 8 | Q1-Q2 | 8,640 |
|  | Develop/publish guidance documents for facilities to access micro-financing, and products sourcing | 1000 | 1 | Q2 | 1,000 |
|  | Supply Chain Mechanisms | 20 | 4 | Q1-Q4 | 2,000 |
| **Subtotal** |  | **11,640** |
| ***Regulatory and Quality Assurance Framework*** |  |  |  |  |
|  | Develop regulatory framework implementation plan for monitoring/providing QA for the supply chain of HS-specific commodities (develop procedural manual(s) and SOPs/WIs for all HS-related regulatory activities (issuance of permits, inspections, PMS and product sampling etc.))*(ZAMRA is already undertaking this activity as part of the development of an institution-wide QMS system. The cost of developing and implementing the Total QMS system is budgeted at USD64,613. The costs are being covered by ZAMRA)* | - | - | Q1-Q2 | - |
|  | Identify and train stakeholders(MoH provincial and district, Local Government) to support/collaborate with ZAMRA in undertaking HS-related QA activities (provide training to inspectors (part-time) and collaborating agencies (for processing applications and issuance of permits) | 20 | 4 | Q1-Q2 | 8,400 |
|  | Implementation/Conduct of Regulatory Activities (Administrative, Inspection, Sampling, Reporting, Enforcement activity costs) | 15 | 4 | Q2-Q4 | 3,960 |
| **Subtotal** |  | **12,360** |
| ***Monitoring and Supervision*** |  |  |  |  |
|  | Conduct quarterly visits to monitor the implementation of activities | 3 | 4 | Q1-Q4 | 8,160 |
| **Subtotal** |  | **8,160** |
| **GRAND TOTAL** | **USD108,908** |

### Annual Activity Budget: Year 2

| **Activity No.** | **Description** | **No. of Persons** | **No of Days** | **Timelines** | **Cost****(USD)** |
| --- | --- | --- | --- | --- | --- |
| ***National Health Shop Steering Committee(NHSSC)Meetings*** |  |  |  |  |
|  | Quarterly NHSSC meetings | 10 | 4 | Q1-Q4 | 2,800 |
| **Subtotal** |  | **2,800** |
| ***Stakeholder Sensitization meetings& mapping (National and local implementation area)*** |  |  |  |  |
|  | Hold National Stakeholders information sharing meeting with potential contributors and players (half day) | 9 (outside Lusaka) | 1 | Q1 | 4,059 |
| 45(Lusaka) | 1 | Q1 | 5,197 |
|  | Hold Regional Stakeholders sensitization meeting (North Western Province: 2 District meetingEastern Province: 2 District meetingLuapula Province: 2 District MeetingsCentral Province: 2 District Meetings) | 25 | 16 | Q1 | 46,200 |
| **Subtotal** |  | **55,458** |
| ***Health Shop Focal Person/Coordinator’s office expansion*** |  |  |  |  |
|  | Contract Salary for Focal Person on a 1 year renewable performance contract  | 1 | 280 (1 year) | Q1-Q4 | 45,000 |
|  | Contract Salary for assistant coordinator | 1 | 280(1 year) | Q1-Q4 | 25,000 |
|  | Motor Vehicle to facilitate for the undertaking the coordinating activities | 1 | 1 | Q1 | 30,000 |
| **Subtotal** |  | **100,000** |
| ***Health Shop Guidelines*** |  |  |  |  |
|  | Guideline review based on HS regulations and the Medicines and Allied Substances Act | - | - | Q1 | - |
|  | Publication (including printing) and dissemination of the revised HS guidelines | 650 copies | 1 | Q1-Q2 | 3,250 |
| **Subtotal** |  | **3,250** |
|  ***Curriculum Development and Implementation (Training Curricula)– Participants’ guide and Teachers’ guide*** |  |  |  |  |
|  | Conduct Training of Trainers for Implementation of Training Program (Training Institutions, District/Provincial focal persons) | 20 | 4 | Q1-Q2 | 5,200 |
|  | Training of Health Shop owners and Dispensers (To be provided by accredited training institutions and cost of training to be borne by trainees/end users) | - | - | Q2-Q4 | - |
| **Subtotal** |  | **5,200** |
| ***Training coordination in the districts*** |  |  |  |  |
|  | Coordinate the implementation of training of trainers and Health Shop owners/Dispensers to ensure adherence to Curriculum | 3 | 5 | Q1-Q4 | 8,160 |
| **Subtotal** |  | **8,160** |
| ***Supply Chain Coordination and Management*** |  |  |  |  |
| **30.** | Quarterly meetings with Suppliers and Manufacturers | 20 | 4 | Q1-Q4 | 2,000 |
| **Consumer awareness and advocacy** |
|  | Advocacy/communication strategy (inform communities of the opportunity available for them to open/run health shops; and public awareness on availability of services to be accessed from the health shops : Radio, drama, face to face, social media, etc. | 3 | 8 | Q1-Q2 | 8,640 |
| **Subtotal** |  | **10,640** |
| ***Regulatory and Quality Assurance Framework*** |  |  |  |  |
|  | Identify and train stakeholders(MoH provincial and district, Local Government) to support/collaborate with ZAMRA in undertaking HS-related QA activities (provide training to inspectors (part-time) and collaborating agencies (for processing applications and issuance of permits) | 20 | 4 | Q1-Q2 | 8,400 |
|  | Implementation/Conduct of Regulatory Activities (Administrative, Inspection, Sampling, Reporting, Enforcement activity costs) | 15 | 4 | Q1-Q4 | 3,960 |
| **Subtotal** |  | **12,360** |
| ***Monitoring and Supervision*** |  |  |  |  |
|  | Conduct quarterly visits to monitor the implementation of activities | 3 | 4 | Q1-Q4 | 8,160 |
| **Subtotal** |  | **8,160** |
| **GRAND TOTAL** | **USD214,188** |

### Annual Activity Budget: Year 3

| **Activity No.** | **Description** | **No. of Persons** | **No of Days** | **Timelines** | **Cost****(USD)** |
| --- | --- | --- | --- | --- | --- |
| ***National Health Shop Steering Committee (NHSSC) Meetings*** |  |  |  |  |
|  | Quarterly NHSSC meetings | 10 | 4 | Q1-Q4 | 4,620 |
| **Subtotal** |  | **4,620** |
| ***Stakeholder Sensitization meetings and Mapping*** |  |  |  |  |
|  | Hold National Stakeholders information sharing meeting with potential contributors and players (half day) | 9 (outside Lusaka) | 1 | Q1 | 4,059 |
| 45(Lusaka) | 1 | Q1 | 5,197 |
|  | Hold Regional Stakeholders sensitization meeting and mapping.(Southern Province: 2 District meetingsNorthern Province: 2 District meetingsCopperbelt Province: 2 District MeetingsLusaka Province: 2 District Meetings) | 25 | 16 | Q1 | 46,200 |
| **Subtotal** |  | **55,456** |
| ***Health Shop Focal Person/Coordinator*** |  |  |  |  |
|  | Contract Salary for Focal Person on a 1 year renewable performance contract  | 1 | 1 year | Q1 | 58,500 |
|  | Contract salary for assistant Coordinator on a 1 year renewable performance contract | 1 | 1 year | Q1 | 32,500 |
|  | Contract salary for a second assistant Coordinator on a 1 year renewable contact | 1 | 1 year | Q1 | 25,000 |
| **Subtotal** |  | **116,000** |
| ***Training Curricula (Curriculum Implementation) – Participants’ guide and Teachers’ guide*** |  |  |  |  |
|  | Provide Training of Trainers for Implementation of Training Program (Training Institutions, District/Provincial focal persons) | 14 | 8 | Q1 | 18,480 |
|  | Training of Health Shop owners and Dispensers (To be provided by accredited training institutions and cost of training to be borne by trainees/end users) |  |  | Q1-Q4 | - |
| **Subtotal** |  | **18,480** |
| ***Training coordination in the first 2 districts*** |  |  |  |  |
|  | Coordinate the implementation of training of trainers and Health Shop owners/Dispensers to ensure adherence to Curriculum | 4 | 5 | Q1-Q4 | 6,468 |
| **Subtotal** |  | **6,468** |
| ***Supply Chain Coordination and Management*** |  |  |  |  |
| **8** | Quarterly meetings with suppliers and wholesalers  | 4 | 1 | Q1-Q4 |  |
| ***Customer awareness & advocacy*** |  |  |  |  |
|  | Advocacy/communication strategy (inform communities of the opportunity available for them to open/run health shops; and public awareness on availability of services to be accessed from the health shops  | 10 | 4 | Q1 | 9,240 |
| **Subtotal** |  | **9,240** |
| ***Regulatory and Quality Assurance Framework*** |  |  |  |  |
|  | Identify and engage stakeholders to support/collaborate with ZAMRA in undertaking HS-related QA activities (provide training to inspectors (part-time) and collaborating agencies (for processing applications and issuance of permits) | 15 | 4 | Q1 | 13,860 |
|  | Implementation/Conduct of Regulatory Activities (Administrative, Inspection, Sampling, Reporting, Enforcement activity costs) | 15 | 4 | Q1-Q4 | 13,860 |
| **Subtotal** |  | **27,720** |
| ***Monitoring and supervision*** |  |  |  |  |
|  | Conduct quarterly visits to monitor the implementation of activities | 3 | 8 | Q1-Q4 | 18,720 |
| **Subtotal** |  | **18,720** |
| **GRAND TOTAL** | **USD256,624** |

### Annual Activity Budget: Year 4

| **Activity No.** | **Description** | **No. of Persons** | **No of Days** | **Timelines** | **Cost****(USD)** |
| --- | --- | --- | --- | --- | --- |
| ***National Health Shop Steering Committee (NHSSC)*** |  |  |  |  |
|  | Quarterly NHSSC meetings | 10 | 4 | Q1-Q4 | 5,082 |
| **Subtotal** |  | **5,082** |
| ***Stakeholder Engagement*** |  |  |  |  |
|  | Hold National Stakeholders information sharing meeting with potential contributors and players (half day) | 9 | 1 | Q1 | 4,465 |
| 45 | 1 | Q1 | 5,717 |
|  | Hold Regional Stakeholders sensitization meeting (Muchinga Province: 2 District meetingWestern Province: 2 District meetingNorth Western Province: 2 District MeetingsEastern Province: 2 District Meetings) | 25 | 16 | Q1 | 46,200 |
| **Subtotal** |  | **61,002** |
| ***Health Shop Focal Person/Coordinator*** |  |  |  |  |
|  | Contract Focal Person on a 1 year renewable performance contract  | 1 | 1 year | Q1 | 75,400 |
|  | Contract salary for assistant Coordinator on a 1 year renewable performance contract | 1 | 1 year | Q1 | 42,250 |
|  | Contract salary for second assistant Coordinator on a 1 year renewable contract | 1 | 1 Year | Q1 | 32,500 |
| **Subtotal** |  | **150,150** |
| ***Training Curricula (Curriculum Development and Implementation) – Participants’ guide and Teachers’ guide*** |  |  |  |  |
|  | Provide Training of Trainers for Implementation of Training Program (Training Institutions, District/Provincial focal persons) | 20 | 8 | Q1 | 20,328 |
|  | Training of Health Shop owners and Dispensers (To be provided by accredited training institutions and cost of training to be borne by trainees/end users) |  |  | Q1-Q4 | - |
| **Subtotal** |  | **20,328** |
| ***Training coordination in the first 2 districts*** |  |  |  |  |
|  | Coordinate the implementation of training of trainers and Health Shop owners/Dispensers to ensure adherence to Curriculum | 4 |  8 | Q1-Q4 | 7,115 |
| **Subtotal** |  | **7,115** |
| ***Consumer awareness and advocacy*** |  |  |  |  |
|  | Advocacy/communication strategy (inform communities of the opportunity available for them to open/run health shops; and public awareness on availability of services to be accessed from the health shops  | 10 | 4 | Q1 | 10,164 |
| **Subtotal** |  | **10,164** |
| ***Regulatory and Quality Assurance Framework*** |  |  |  |  |
|  | Identify and engage stakeholders to support/collaborate with ZAMRA in undertaking HS-related QA activities (provide training to inspectors (part-time) and collaborating agencies (for processing applications and issuance of permits) | 15 | 4 | Q1 | 15,246 |
|  | Implementation/Conduct of Regulatory Activities (Administrative, Inspection, Sampling, Reporting, Enforcement activity costs) | 15 | 4 | Q1-Q4 | 15,246 |
| **Subtotal** |  | **30,492** |
| **Regulatory Impact Assessment** |  |  |  |  |
|  | Carry out Impact Assessment of Implementation The Health Shop concept | 10 | 50 | Q4 | 63,525 |
| **Subtotal** |  | **63,525** |
| **GRAND TOTAL** | **USD347,858** |