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| **BANGLADESH PHARMACY MODEL INITIATIVE (BPMI)** |
| **Bangladesh Pharmacy Model Initiative Incentive Strategy (BPMI Incentive Strategy)** |
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BPMI Incentive Strategy

Bangladesh Pharmacy Model Initiative (BPMI) Program

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Contents

[Abbreviations and Acronyms 3](#_Toc457648972)

[1.0 Introduction 4](#_Toc457648973)

[2.0 Scope of Work 4](#_Toc457648974)

[3.0 Methodology 4](#_Toc457648975)

[4.0 Health Sector in Bangladesh 4](#_Toc457648976)

[5.0 Role of Pharmacists in the Health System 5](#_Toc457648977)

[6.0 Pharmaceutical Market in Bangladesh 5](#_Toc457648978)

[7.0 Key Stakeholders in the Pharmaceutical Market 6](#_Toc457648979)

[8.0 Accredited Drug Shop Strategies in Tanzania and Uganda 6](#_Toc457648980)

[9.0 BPMI and proposed Standards 9](#_Toc457648981)

[10.0 Use of information technology to improve information access 9](#_Toc457648982)

[11.0 Key Findings 10](#_Toc457648983)

[12.0 Key Recommendations 13](#_Toc457648984)

[13.0 Conclusions 16](#_Toc457648985)

[14.0 Annex A: Action Plan 18](#_Toc457648986)

[15.0 Annex B: Scope of Work 22](#_Toc457648987)

[16.0 Annex C: Field Study Report on Retail Drug Shops in Bangladesh 24](#_Toc457648988)

[17.0 Annex D: Experiences of Accredited Drug Shop Strategies in Tanzania and Uganda 27](#_Toc457648989)

[18.0 Annex E: Recommendations – Immediate and Short-term Measures: 34](#_Toc457648990)

[19.0 Reference 38](#_Toc457648991)

# Abbreviations and Acronyms

|  |  |
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| ADDOADSAMSBAPIBBS  | Accredited Drug Dispensing OutletAccredited Drug ShopAccredited Medicine StoreBangladesh Association of Pharmaceutical IndustriesBangladesh Bureau of Statistics  |
| BCDS BPGABPMI | Bangladesh Chemist and Druggist *Samity* (Association)Bangladesh Pharmacy Graduates AssociationBangladesh Pharmacy Model Initiative  |
| BPS  | Bangladesh Pharmaceutical Society  |
| BDT  | Bangladeshi Taka  |
| CAB  | Consumer Association Bangladesh  |
| DARDFID  | Drug Administration Registration NumberDepartment for International Development  |
| DGDA  | Directorate General of Drug Administration  |
| DGHS  | Directorate General of Health Services  |
| DI  | Drug Inspector  |
| DOTS  | Directly Observed Treatment Short-course  |
| DS  | Drug Superintendent  |
| FGD  | Focus Group Discussion  |
| GMPHEPSHPNSDP  | Good Manufacturing PracticeCoalition for Health Promotion and Social DevelopmentHealth, Population and Nutrition Sector Development Program  |
| H.S.C.  | Higher School Certificate  |
| IECIMSITIDOJDTAF  | Information, Education and CommunicationIntercontinental Marketing ServicesInvention and Technological Ideas Development OrganizationJoint Donor Technical Assistance Fund  |
| KII  | Key Informant Interviews  |
| LMAFMNCMOHFW  | Local Medical Assistant and Family Welfare Multinational CorporationMinistry of Health and Family Welfare |
| MSHNDA  | Management Sciences for Health National Drug Authority |
| NGO  | Nongovernment Organization  |
| ORS  | Oral Rehydration Salts  |
| OTC  | Over The Counter  |
| PCBPHC  | Pharmacy Council of BangladeshPrimary Health Care  |
| SIAPS  | Systems for Improved Access to Pharmaceuticals and Services  |
| TBTFDATSH  | TuberculosisTanzania Food and Drugs AuthorityTanzania Shillings  |

# 1.0 Introduction

Management Sciences for Health (MSH) is implementing the project “Designing Implementation Strategy for Accredited Drug Seller Model” funded by Joint Donor Technical Assistance Fund (JDTAF) – a consortium of donors led by the Department for International Development (DFID) under the current health sector program “Health, Population and Nutrition Sector Development Program (HPNSDP)” of Ministry of Health and Family Welfare (MOHFW). The main purpose of this project is to design a Bangladesh Pharmacy Model Initiative (BPMI) program based on the MSH’s accreditation experiences in Tanzania, Uganda and Liberia. A dominant feature of the program is that private drug shop owners are granted certain incentives to induce them to become accredited to the program. For example, economic incentives are provided to the drug shop owners to assist them for making improvements of their shops through renovation and expanding stock levels and to help them improve their shops’ profitability and thus financial sustainability.

# 2.0 Scope of Work

A BPMI owner incentive strategy titled “Bangladesh Pharmacy Model Initiative Incentive Strategy” needs to be developed for implementation of the BPMI program in Bangladesh with a view to encouraging drug shop owners to become accredited to BPMI program, and to enhance the sustainability and quality of BPMI drugstores through (1) reviewing materials related to accredited drug shop incentives from Tanzania, Uganda and Liberia; (2) reviewing existing literature and incentive strategies implemented by other initiatives in Bangladesh; (3) working with BPMI incentive strategy technical working group to introduce the assignment and plans for developing the BPMI incentive strategy; (4) conducting key informant interviews and focus group discussions with stakeholders knowledgeable about retail pharmacy profitability and financing in Bangladesh. (Vide Annex B)

This report on the proposed BPMI incentive strategy is developed on the basis of evaluation of the incentive strategies of MSH’s retail drug shop accreditation experiences in Tanzania, Uganda, and Liberia, existing facilities available in Bangladesh, views and opinions of key stakeholders, and the information gathered during key informant interviews and focus group discussions as well as document review regarding policy and regulatory environments,.

# 3.0 Methodology

This study on BPMI incentive strategy is a retail drug shop based cross-sectional study to explore the perception of different stakeholders regarding the feasibility of providing certain incentives to the private drug shop owners to get their drug shops accredited to the BPMI program based on the MSH’s accredited drug shop in Tanzania, Uganda and Liberia. The study population of this paper includes (1) owners and dispensers of retail drug shops located in Dhaka city and its adjoining peri-urban and rural areas; (2) random samples of community members who usually purchase medicines from these shops [focus group discussions (FGDs)]; (3) key informant interviews (KII) with drug licensing and pharmacist registration certificate licensing authorities, regulators (MOHFW, DGDA, PCB); (4) members of professional associations (BPS, BCDS), and academics; and (5) document review for policy and regulatory environments. Annex C provides a narrative of field study on retail drug shops in Bangladesh.

# 4.0 Health Sector in Bangladesh

Private retail drug sellers are a major source of health care and medicines in Bangladesh, with more than 80% of the population seeking health care services from private health care providers. Retail drug shops are the preferred first point of contact for a majority of the people in Bangladesh, especially in the peri-urban and rural areas. In Bangladesh, currently 103,451 licensed retail drug shops and approximately equal number of unlicensed and unregulated retail drug shops are engaged in selling drugs and providing PHC treatments for fevers, headaches, coughs and colds, gastric problems, etc. Most of the drug shop owners/dispensers do not have required education and training in dispensing drugs, though they are offering diagnoses and PHC treatments. There is a huge gap between PCB’s total number of trained pharmacists (75,648) and DGDA’s total number of drug licenses issued (103,451). Majority customers come to drug shops to purchase medicines by self-referral without prescriptions. Besides selling medicines, owners/dispensers also provide clinical services such as pushing injections, providing first aid for burns, dressing and stitching cut wounds, giving vaccinations, measuring blood pressure and blood sugar, etc. which are not allowed under the current drug licenses issued by the DGDA office (SIAPS, 2015).

# 5.0 Role of Pharmacists in the Health System

All drug shop owners and dispensers working as pharmacists in the retail drug shops must have at least C-grade pharmacist registration certificates issued and renewed by Pharmacy Council of Bangladesh (PCB). A pharmacist’s prime concern is to ensure the health, safety, and well-being of the patients and the public. They should take all reasonable steps to ensure that the working conditions are so arranged that the safety of the patients and the public, and the people working in the drug shop premises is protected. They are required to sell quality medicines to the patients as per doctors’ prescriptions and counsel the patients/customers on how to take medicines properly to ensure rational use of medicines.

# 6.0 Pharmaceutical Market in Bangladesh

The demographic statistics of Bangladesh having approximately 161 million people growing annually at the rate of 1.6%, a consistent GDP growth rate above 6%, per capita health expenditure growing at an average rate of more than 3.41%, and continued pattern of increased life expectancy and poverty reduction clearly demonstrate the huge need for pharmaceutical products. These future health related needs will translate into demands in the market (SIAPS, 2015).

Prior to the implementation of The National Drug Policy and The Drugs (Control) Ordinance, 1982, the pharmaceutical market in Bangladesh was mainly controlled by MNCs, holding about 75% of the market share. Since 1985, the scenario has changed with local firms dominating the industry. At present, 97% of the local demand is met by local manufacturers with MNCs possessing only 9.05% of the market. Being a branded generic market, success in this market requires the competitive firms to strive for higher share in prescriptions as well as ensuring higher product availability in pharmacies. For this reason, firms’ marketing strategy is to undertake several product promotional activities including aggressive pricing, more relaxed credit policy and establishing relationships with doctors, hospitals and pharmacies. Now, their common business strategy is to employ more medical representatives to establish these relationships with a view to selling increased quantity of medicines in the market (Shawon, 2011).

IMS study indicates that pharmaceutical industry is more retail oriented in Bangladesh where mass distribution is done by companies themselves. Wholesalers usually have a limited role in marketing of such products. Due to higher direct sales and aggressive marketing strategy pursued by companies, wholesalers’ role is on the decline (Shawon, 2011).

# 7.0 Key Stakeholders in the Pharmaceutical Market

The key stakeholders in the pharmaceutical market of Bangladesh are the drug shop owners, dispensers, customers, pharmaceutical manufacturing companies, drug importers, wholesalers, politicians, health service professionals in hospitals and clinics, regulatory authorities at the district level, national-level regulatory authorities (MOHFW, DGHS, DGDA, PCB), members of professional associations (BPS, BAPI, BPGA, BCDS), and academics. Use of a participatory approach involving all stakeholders from the beginning of the program, and valuing and respecting community level inputs would be the BPMI program’s strengths in Bangladesh.

# 8.0 Accredited Drug Shop Strategies in Tanzania and Uganda

In 2003, the Government of Tanzania with technical support from MSH developed a new retail pharmaceutical regulatory regime through undertaking the Accredited Drug Dispensing Outlet (ADDO) program. In 2013, the program succeeded in achieving full national implementation. The program proved to be successful and self-sustainable. In 2009, the Government of Uganda with MSH’s technical support launched a pilot Accredited Drug Shop (ADS) program in Kibaale district based on the ADDO model but with some modifications. The ADDO model was also replicated in Liberia as Accredited Medicine Store (AMS). MSH worked with national and local stakeholders to develop accreditation models based on the Tanzanian experiences, but adapted to the two countries’ different needs and conditions. In both countries, evaluations showed that ADS and AMS increased the availability of quality pharmaceutical products, and improved dispensing and business skills (Rutta et al. 2015). (Vide Annex D)

The primary element that was essential for ADDO program’s success was stakeholder engagement at all levels. Stakeholders’ involvement ranged from publicly stating support for the concept to working closely on all aspects of the program design and implementation. Use of a participatory approach that involved all stakeholders, e.g. drug shop owners, dispensers, consumers, regulators and political leaders from the beginning; a fair and transparent process for drug license applications and approvals; respecting and valuing community level inputs were the ADDO program’s strengths in Tanzania. The ADDO program conducted an extensive information, education, and communication campaign to build awareness of the public and pharmacy stakeholders on the irrational use of drugs and their harmful effects, and importance of quality medicines, dispensing services and treatment compliance to increase customers’ trust and encourage them to buy affordable quality medicines from the reliable accredited drug shops (Rutta et al. 2015).

Customers’ empowerment through raising their awareness changed chaotic situation in Uganda’s pharmaceutical sector. The pressure of the drug shop owners for becoming accredited in the districts neighboring the pilot Kibaale district grew quickly when the drug shop owners saw their customers moving over the district border to access the accredited drug shops (ADS) available in the pilot Kibaale district. The cumulative effect of stakeholders’ pressure on the National Drug Authority (NDA), Uganda to scale up the program throughout the country grew quickly as the awareness of the benefits of the accreditation program became apparent to the general public and to the drug shop owners. This illustrative example of drug shop owners to become accredited to the program proves the accredited program’s proposition that “information is empowerment, and an informed population makes informed choices” (GIC Limited, 2011 and G1 Logistics Ltd., 2009).

Tanzania took a holistic approach for building the integrated capacity of the stakeholders, e.g. the customers, drug shop owners, dispensers and the regulators for changing the behavior and expectations of those who use, own, regulate or work in retail drug shops. Shop owners and dispensing staff were benefitted from the combined effects of skill development training and education, business incentives, supportive regulatory supervision and monitoring which increased customers’ demand for and expectations of affordable quality medicines and improved dispensing services from a reliable source. The behavioral change of owners and dispensers, and their improved dispensing and business skills, and good customer service increased customers’ trust in accredited drug shops. As a result, people’s demand for buying quality medicines at reasonable prices from reliable accredited shops increased significantly, thus enabling the ADDOs to maximize sales and take a larger share of the market (Rutta et al. 2015).

Both in Tanzania and Uganda, accredited drug shop owners were allowed to legally dispense certain prescription medicines from approved medicine lists not allowed before accreditations. They were also allowed to stock and sell some non-pharmaceutical products such as cosmetics, toiletries, food supplements, personal hygiene, etc. to their product range in order to reduce dependence on only one product type. In Tanzania, though the pilot program in Ruvuma had linked the majority drug shop owners with micro-finance institutions to help them in making improvements of their physical shop premises to become accredited, few shop owners in other regions used that option to finance their shop renovations or operations. 79% shop owners reportedly reinvested their business profits for this purpose. In Uganda, none of the ADS owners reportedly borrowed money to finance their shops’ renovations or operations (Rutta et al. 2015 and GIC Limited, 2011).

The program developed the accreditation standards, a critical part of the model design, to overhaul the existing regulations to suit the objectives of the ADDO program. The accreditation law required all accredited drug shop owners and dispensers to have a thorough understanding of accreditation regulations, standards and ethics. And accreditation standards in turn required them to receive skill development training on appropriate medicine use and patient referrals. One of the primary reasons that induced people to choose ADDOs over public health facilities was the consistent availability of popular quality medicines at affordable prices in ADDOs. In addition to appropriate dispensing, training also focused on the importance of record keeping. Owners and dispensers learnt how to monitor product sales, keep track of expiry dates, and what types of products to stock to improve businesses (Rutta et al. 2015).

Although the program design included owners’ incentives to become accredited in Tanzania, owners had repeatedly mentioned that dispensers’ training was the most highly valued program benefit. The training helped the owners and dispensers to acquire knowledge and expertise so that they could change their attitudes and have the practices needed to succeed in operating their businesses. Pharmacy Council, Tanzania was responsible for the institutions’ training standards and oversight with ADDO owners and dispensers covering all costs of the training. As owners and dispensers realized the benefits of accreditation, they became more willing to pay for accreditation costs such as branding, renovations, increasing inventories, and training that had been covered by donors in the program’s early years. In Uganda, the program offered a tapering charge scheme for providing training to dispensers with a number of the first drug shop owners applying for participation being offered free training and then a sliding scale being applied for later joiners (Rutta et al. 2015 and GIC Limited, 2011).

The Tanzanian experience showed that the effect of training of dispensers in the ADDOs increased their marketability with the result that some of these trained dispensers moved on to work outside the ADDOs or moved more frequently within the network. The loss of dispensers to the ADDO network resulted in demand for more dispensers to be trained. So, provisions for continued capacity building training should be considered in the scale up plan for replacements, if required (Rutta et al. 2015).

From the start of the program, accredited drug shops in Tanzania had been profitable. Majority owners (79%) reinvested their ADDO business profits. Evidence of profitability also came from the willingness of owners and dispensers to take over all costs associated with accreditation which had previously been donor funded. The program’s ADDOs not only increased access to essential medicines but also served as a platform for community-based public health interventions. Additionally, when National Health Insurance Fund incorporated ADDOs into its scheme, drug shop owners felt that the arrangement boosted their sales, ensuring more profitability and sustainability of the program. Most of the ADS owners in the pilot Kibaale district reportedly indicated that they all were making profits from their businesses (Rutta et al. 2015 and GIC Limited, 2011).

In addition to the government’s role in overseeing ADDO operations, Tanzania’s decision makers took initiatives to strengthen existing professional drug shop provider associations and facilitate the formation of new provider associations to serve as a governance resource and a professional “voice” for the owners and dispensers. In Uganda, NDA supported the development of trade association as an extension of the regulatory system which encouraged the association members to abide by the rules and regulations. Peer supervisions organized through provider associations were proved to be a sustainable way to complement local government supervision and inspection, ensuring ADS’s compliance with pharmaceutical sector’s regulations, standards and ethics (Rutta et al. 2015 and GIC Limited, 2011).

In Uganda, spray painting of building frontages with the ADS color and logo used to raise local people’s awareness in the pilot scheme seemed to have heightened the expectations of the general people for the painted drug shops before the drug shops had actually been accredited, and in several instances the buildings that received the painted frontages did not actually house any ADS which created confusions and misunderstanding among the local people. In some cases, actual accredited shops’ fronts were not painted and the signage for them to display their accreditation was small and unremarkable (GIC Limited, 2011).

Uganda’s HEPS (Coalition for Health Promotion and Social Development) created and implemented a consumer advocacy strategy related to consumers’ expectations about quality medicines and dispensing services, and their rights regarding healthcare services. Community cognizance about drug shops resulted in changes; for example, after receiving public pressure, an unqualified drug shop owner switched over from selling medicines to selling clothes in Balawoli sub-county in Uganda (Rutta et al. 2015).

In Uganda, district stakeholders from the community, government, businesses, and healthcare providers were targeted first to inform them of the impending change in pharmaceutical retail regulation, to explain the benefits of the new approach, and the steps to be needed to move to it. Districts were then encouraged to apply to the regional NDA offices to join the process (GIC Limited, 2011).

To help improve information access, Tanzania’s accreditation program engaged a local technology firm “Invention and Technological Ideas Development Organization (ITIDO)” to build a web-based regulatory database and website for Tanzania’s Pharmacy Council. The database used unique identification numbers for ADDOs and pharmacies as well as for all personnel. ITIDO trained Pharmacy Council staff on maintenance and use of the database and handed over to them the necessary equipment. They also trained the council staff on how to use GPS devices to geo-code premises and Google Earth maps to locate the geo-coded ADDOs and pharmacies. Incorporating information technology including mobile money and other applications had a potentially major impact on drug seller initiatives’ sustainability. Dispensers had no trouble reporting basic service statistics, and during the pilot, 129 people used mobile money to pay over 12 million TSH in fees. Shop personnel appreciated the ease of paying fees through M-Pesa. ADDO staff felt that it was much easier to get information through the new SMS-based helpline. Once the ADDO program was established, the primary financing issue shifted to shops’ profitability and sustainability, and program maintenance (Rutta et al. 2015).

# 9.0 BPMI and proposed Standards

A two-tier categorization of retail pharmaceutical service levels is proposed in BPMI program based on basic training qualifications, skills and competencies, and category of medicines/products to be handled by each cadre. Pharmaceutical providers are required to provide pharmaceutical services in a secure and safe environment in accordance with legal and professional requirements to set an example that will enhance the pharmacy profession’s image. Level I pharmacy will be managed or supervised by a grade-A or grade-B pharmacist who must be present on the premises. However, a grade-C pharmacist may assist him or her with dispensing as long as either grade-A or grade-B pharmacist is present. In level II drug shops, dispensing will be carried out at least by a person with grade-C level training. Level II drug shops can upgrade themselves to level I pharmacies if they could meet the appropriate standards required.

# 10.0 Use of information technology to improve information access

Like Tanzania’s ADDO program, Bangladesh can provide mandatory orientation training to owners and dispensers on how to manage and dispense the pharmaceutical products, and monitor the availability of medicines through mobile phone applications to keep records related to business and sales. They would be required to keep records of all prescription drugs sold and their selling prices, financial and sales information, customer complaints, expired and unregistered medicines, and suppliers’ invoices/receipts.

Like Tanzania’s accreditation program, Bangladesh could develop mobile applications for payment, indicator reporting, and information exchange through SMS-based helpline between accredited shops and DGDA and PCB. Bangladesh can also build a web-based regulatory database and website to use GPS devices to geo-code premises and Google Earth maps to locate the geo-coded accredited drug shops and pharmacies. Each accredited drug shop would be required to open a channel for registering customers’ complaints against drug shops and also for recording shop owners’ complaints about harassments by inspectors and other problems (Rutta et al. 2015).

In Bangladesh, drug shop owners/dispensers maybe allowed to use mobile money to pay issue/renewal fees for their pharmacist registration certificates to PCB. For drug license and renewal fees, shop owners will have to continue depositing their issue/renewal fees to the government treasury through treasury challans. Existing government treasury rules do not permit drug shop owners to pay drug license and renewal fees to DGDA office. DGDA office, being a pure government department, gets its budget allocations and other financial supports from the government.

DGDA, the regulatory and licensing authority, will be able to use mobile applications in more efficient ways to track activities related to BPMI drugstores and pharmacies, such as locations of drug shop premises, last inspection dates, compliant reports as follow up actions, track payments using database, license renewal dates, customers’ complaints, drug shops’ complaints against inspectors, and accreditation status.

Exchange of data through mobile platform between DGDA and the BPMI drugstores regarding sales and business records will not only help regulators quickly identify problems such as epidemics, but will also provide surveillance information on common conditions in the community. Accredited drug shops could provide useful insights for the regulators into new patterns of demand emerging in the market. A new relationship based on mutual respect and a two way flow of information can be established between the regulator and the accredited drug shop owners to the benefit of both sides.

Bangladesh should develop SMS-based helpline between accredited shops and DGDA and PCB, and a web-based regulatory database and website to use GPS devices to geo-code accredited drug shop premises and Google Earth maps to locate the geo-coded accredited drug shops. DGDA should introduce a fair and transparent online licensing process for drug license and renewal applications and approvals. It can use mobile platform for exchange of information between DGDA and the BPMI drug shop owners and dispensers. PCB should launch mobile money applications for drug shop owners and dispensers to pay pharmacist registration and renewal fees to PCB. It should also introduce an online process to apply for certified pharmacists’ training to ensure fair and transparent process.

# 11.0 Key Findings

The primary element that was essential for ADDO program’s success in Tanzania was its all vital stakeholders’ engagement at all levels ranging from publicly stating support for the program to working closely on all aspects of the program design and implementation. Decision makers realized the paramount importance of bringing the local interest groups on side so that their enthusiasm for the new regulation regime could become a powerful force in driving and enabling the changes to happen on the ground. So, they used a participatory approach involving all stakeholders from the beginning: owners, dispensers, consumers, political leaders, etc. In Uganda, district stakeholders from the community, government, businesses, and healthcare providers were targeted first to inform them of the impending change in pharmaceutical retail regulation, to explain the benefits of the new approach and the harmful effects of the existing system, and the steps that would be needed to move to it. Districts were then encouraged to apply to the regional National Drug Authority (NDA) to join the process. From Tanzania and Uganda’s accreditation experiences, it has become apparent that the primary element that would be essential for BPMI program’s success is stakeholders’ engagement at all levels ranging from publicly stating support for the program to working closely on all aspects of program design and implementation. BPMI program will also need to take a participatory approach involving all stakeholders, e.g. drug shop owners, dispensers, consumers, regulators, and political leaders from the beginning, and to ensure a fair and transparent online licensing process for drug license applications and approvals (Rutta et al. 2015).

Like Uganda’s ADS program, BPMI program’s communication focus should be on the rationale that “essential medicines save lives and improve health only when they are available, affordable, of assured quality and properly used”. The program should be positioned as an initiative that cares for people through providing quality and affordable drugs. The positioning would be communicated through mass media channels like TV, radio, signage along busy roads, billboards, branding of BPMI outlets, and community oriented channels like launch event, use of social networks, e.g. women’s groups, social clubs, and pressure groups like CAB (Consumers’ Association of Bangladesh). People’s adequate knowledge about the BPMI program and its objectives will increase consumers’ awareness of the importance of buying quality medicines from a reliable source. For this purpose, consumers must be assured that BPMI drugstores are such a reliable source for buying quality medicines (G1 Logistics Ltd., 2009).

Both in Tanzania and Uganda, majority drug shop owners did not borrow money to finance their investments in shop renovations, training, expanding stock levels, etc. They had financed the upgrading of their shop premises themselves from savings and business profits. In Bangladesh, when drug shop owners will realize the benefits of accreditation, they will themselves finance the extra expenses needed for accreditation. Access to trade credit already available in Bangladesh will improve significantly for BPMI drugstores because of expected increased sales in accredited drug shops. To increase sales and secure larger market share, manufacturing companies and wholesalers may start vying with each other to capture this lucrative market of accredited drug shops through offering more incentives to BPMI drug shops. The drug shop owners would be able to get more trade credit terms and discounts/commissions from their suppliers.

If required, drug shop owners would be able to obtain loans on the basis of their previous drug shop trading records or other businesses. Unemployed people with no business track records, no savings, and no assets to offer as collateral security could face problems in obtaining bank loans. As the purpose of the new regulatory regime is primarily to bring the existing 200,000 (approximately) drug shop owners within the new accreditation framework, a lack of access to finance will not appear to offer a material obstacle to a nationwide scale up of the program in Bangladesh. However, some of the drug shop owners were found interested in taking SME loans, if made easily available to them.

Most of the drug shop owners interviewed have identified stock out as a recurring problem which could lead to a loss of business and goodwill of their shops. In Bangladesh, owners/dispensers should be provided training on how to use stock cards to help control stock levels to avoid both over and under stocking. Like Uganda, BPMI owners may be allowed to offer some ancillary non-medical products such as cosmetics, toiletries, food supplements, personal hygiene, etc. to their product range in order to reduce dependence on only one product type. BPMI decision makers can take initiatives to get the regulators to accept this incentive. A well regulated BPMI network will be able to utilize government’s various social welfare projects such as health promotion projects, vaccination campaigns, disease reporting, etc. Government could employ interested dispensers to work as providers of TB DOTS by providing capacity building training and monetary incentives to them.

Majority of the drug shop owners illegally stock and sell non-pharmaceutical products such as nutritional supplements, baby food, cosmetics, medical supplies and devices which are not permitted in the existing drug license regime. Dispensers are also found providing clinical dispensing services such as checking or monitoring blood pressure, sugar level, body temperature, and providing primary health care (PHC) treatments for fevers, headaches, cough and colds, etc. which are also not permitted under the existing drug license issued by the DGDA office. So, specific regulations and guidelines should be made/ framed to permit accredited drug shops to legally stock and sell registered non-pharmaceutical products, and medical supplies and devices. Trained and qualified dispensers of the accredited drug shops can be permitted to perform clinical services in accordance with the rules and guidelines of the accreditation program. In most cases, untrained and unqualified dispensers are found providing these clinical services. These facilities must be restricted only to the accredited drug shops having trained and qualified dispensers who can maintain high standard of personal hygiene strictly following the guidelines on clinical dispensing, ethics, and other terms and conditions related to accreditation program and DGDA’s existing quality and standards. SIAPS program’s findings have revealed that the respondents from retail drug shops are willing to provide DOTS related services for TB. But to do so, drug dispensers need relevant training for diagnostic referrals and subsequent services for diagnosed cases. To increase their sources of income and enhance their image in the society, retail drug shop owners/dispensers will be ready to be a part of the public health program because the retail drug shops are the preferred first point of contact for majority of the people in the country. DGDA can take initiatives to send a proposal to the Ministry of Health and Family Welfare through DGHS to engage the trained and qualified dispensers who would be working in various accredited drug shops to increase more people’s access to such projects.

In Bangladesh, a person is exempted to pay income tax if his annual income does not exceed BDT 250,000; women’s ceiling is up to BDT 300,000. Manufacturing companies/wholesalers supplying medicines to the retail drug shops are reportedly required to pay VAT and advance income tax at source while supplying medicines to the retail drug shops. It may be possible for the government to consider and review the current drug license and renewal fees if the matter could convincingly be taken up with Finance Division.

A truly representative BCDS, if elected through free and fair elections, could play an important complementary role through working closely on all aspects of the program design and implementation by encouraging its members to abide by the rules and regulations for full compliance of the program’s standards and ethics. Like Uganda’s HEPS, Consumers’ Association of Bangladesh (CAB) and other similar associations as pressure groups can play a critical role in improving consumers’ levels of awareness for rational use of drugs by organizing awareness campaigns, and curbing corruptions and malpractices in the pharmaceutical sector through reporting the specific irregularities/illegalities to the regulators for taking actions and the electronic and print media for mass awareness. Uganda’s HEPS created and implemented a consumer advocacy strategy related to expectations about quality medicines and dispensing services and the consumers’ rights regarding healthcare services. HEPS implemented this strategy in Kamuli district by providing training to the community leaders and outreach volunteers to attend community events to talk about the people’s health rights, what services the public should expect from drug shops and rational medicine use. As a result, awareness of quality medicine uses in the community increased. The community members started asking drug sellers important questions about medicine packaging and handling which was not there before. Community cognizance about drug shops also resulted in changes: for example, after receiving public pressure, an unqualified drug shop owner switched over from selling medicines to selling clothes in Balawoli sub-county, and in Kitayunjwa, a general merchandise shop quit selling medicines.

In Bangladesh, 103,451 licensed retail drug shops and approximately 100,000 unlicensed unregulated retail drug shops are involved in selling drugs and providing PHC treatment for fevers, headaches, coughs and colds. Most of the drug shop owners/dispensers do not have training in dispensing drugs or offering diagnoses and PHC treatments. Reportedly, the lengthy, costly and cumbersome licensing processes discourage the drug shop owners from obtaining drug licenses. A fair and transparent online licensing process for drug license applications and approvals is needed. The huge informal hidden costs associated with getting licenses over and above the required nominal government fees (BDT 2,500 for urban areas and BDT 1,500 for rural areas) discourage the owners of unlicensed drug shops for obtaining license. Respondents unanimously complained about this hidden cost which could be up to BDT 20,000 and more. Most of the unlicensed drug shop owners and dispensers do not have pharmacist registration certificates required for drug license applications and approvals. This may be another important reason for not applying for drug license. From field study, it became clear that many drug shop owners/dispensers in the rural and peri-urban areas refrain from applying to obtain drug licenses because they do not possess pharmacist registration certificates required for drug license applications (Annex C). Rural drug shop owners/dispensers do not get chance for receiving training because they do not have easy access to BCDS leaders controlling the whole training process.

DGDA, the sole licensing and regulatory authority in the pharmaceutical sector, is authorized to properly regulate the supply chain of pharmaceutical products to the retail market. This responsibility extends from inspecting and monitoring the quality of the pharmaceutical products both manufactured at home and imported from abroad down through the supply chain to the retail outlets supplying the general public in the country.

In Tanzania, the model was revised to decentralize the implementation and oversight responsibility to the district level for rolling out in new regions with the central authority retaining the responsibility of overseeing the completed program in the pilot districts. Uganda adopted a devolved approach in accordance with their current government policy. If agreed, Bangladesh can decentralize the implementation and oversight responsibility to the district level for rolling out the program.

# 12.0 Key Recommendations

* Introduce a fair and transparent online process for drug license applications and approvals to ensure efficiency and transparency. It is unlawful to run a retail drug shop business without obtaining valid drug license from DGDA. To obtain drug license, the owners/dispensers must have at least grade-C pharmacist registration certificates issued from PCB. In the rural areas, many drug shop owners are doing this business without obtaining drug licenses. Those who have already obtained drug licenses do not renew them. When asked, they reported that the existing licensing and renewal processes are too complicated, lengthy, very costly and cumbersome which discouraged them from obtaining drug licenses and getting their expired licenses renewed.
* Undertake a large-scale crash program to train the huge number of dispensers within a short period of time through franchising an upgraded curriculum to PCB’s accredited training institutes in the public and private sectors including NGOs to enable the interested dispensers to avail the commercial benefits of the program. As mentioned earlier, many drug shop owners/dispensers especially in the rural areas do not have grade-C pharmacist registration certificates, a minimum requirement for doing drug shop business and providing clinical dispensing services. They are doing this illegal business and clinical services. For which, they are to frequently face various legal and administrative problems. To obtain drug license and get the expired license renewed they need to possess at least grade-C pharmacist registration certificates issued from PCB. Many shop owners/dispensers do not get chance to receive training needed for legally doing this business. So, a huge number of untrained dispensers need to be trained.
* Incorporate mobile money applications and SMS-based reporting system to facilitate payments of registration and license issue/renewal fees, and communication between the accredited drug shops and the regulatory authorities to ensure easy and transparent payment process. Existing payment system cannot check corruption and irregularities going on at the grassroots level. Incorporating mobile money applications to facilitate payments for registrations, license issue/renewal can ensure easy and transparent payment process.
* BCDS and project implementation officers can jointly take initiatives to facilitate accredited drug shop owners’ easy access to SME loans and microfinance opportunities.
* Conduct a nationwide extensive information, education and communication (IEC) campaign to enhance knowledge and awareness of the public and the drug shop owners/dispensers on the irrational use of drugs and their harmful effects, and the importance of quality medicines, dispensing services and treatment compliance to encourage consumers to buy medicines from a reliable source like accredited drug shops. Project implementation officials can launch a marketing campaign encouraging consumers to buy quality medicines from reliable source like accredited drug shops. For this purpose, consumers must be assured that accredited drug shops are such a reliable source for buying quality medicines.
* Increase BPMI drugstores’ sales volume through product range diversifications by allowing BPMI drug shops to stock and sell some ancillary non-pharmaceutical products such as cosmetics, toiletries, food supplements, personal hygiene, etc. Most of the retail drug shops are illegally doing this business because existing drug license does not permit them to do so. Specific regulations and guidelines can be framed to allow accredited drug shops for stocking and selling non-pharmaceutical products.
* Allow BPMI drug shops to stock and sell medical supplies and devices other than medicines as long as they meet DGDA’s established quality standards, and are kept separated from medicines. Most of the retail drug shops are illegally doing this business because existing drug license does not permit them to do so. Specific regulations and guidelines can be framed to allow accredited drug shops for stocking and selling medical supplies and devices.
* Make provisions for allowing drug shop dispensers to check or monitor blood pressure, sugar level, and body temperature and administer rapid diagnostic tests but they should not be allowed to conduct any medical clinical services including pushing injections. In most cases, untrained and unqualified dispensers are found illegally providing such clinical dispensing services because existing drug license does not permit them to do so. Trained dispensers working in the accredited drug shops could be permitted to perform such clinical services in accordance with the rules and guidelines to be framed in this connection.
* Provide orientation training to owners and dispensers on how to manage and dispense the pharmaceutical products, and monitor the availability of medicines through computerized inventory management system and use of cash register to print cash memos. This will strengthen their shops’ profitability and thus financial stability.
* Provide capacity building training to the drug shop owners/dispensers on financial management for development of their business skills on how to monitor product sales, use stock cards to avoid both over and under stocking, keep track of expiry dates, and what types of products to stock to improve businesses. This will help them to avoid stock outs which results in losing sales. They should know how to keep financial records, monitor daily sales, track monthly profits, and use stock cards to control stock level.
* Open a channel for registering customers’ complaints against drug shops and drug shop owners’ complaints about harassments by inspectors and other problems through DGDA website. This will ensure accountability of the inspectors as well as the drug shop owners and dispensers.
* Offer a tapering charge scheme for providing training to drug shop owners/dispensers with a number of the first drug shop owners applying for participation being offered free training and then a sliding scale being applied for later joiners. But if the training arrangements are such that training would be provided free of cost, then this recommendation may not hold true.
* Upgrade the training curriculum for capacity development of C-grade pharmacists to help them become first-line PHC dispensers at level II drug shops by incorporating topics such as health education, first aid, and referral guides to higher levels of treatments in the revised curriculum. Since retail drug shops are the preferred first point of contact for majority of the people in the country, dispensers’ skill development training will benefit the people especially in the rural areas who usually come to them for PHC treatments.
* Engage BPMI drug shops in government’s various health promotion projects such as vaccination campaigns, disease reporting, etc. to serve as a platform for community-based public health interventions. To increase their sources of income and enhance their image in the society, retail drug shop owners/dispensers will be ready to serve as a platform for community-based public health interventions.
* Employ BPMI drug shops’ owners/dispensers interested to work as providers of TB DOTS by providing capacity building training and monetary incentives to them. SIAPS program’s findings have revealed that the respondents from retail drug shops are willing to provide DOTS related services for TB. But to do so, drug dispensers need relevant training for diagnostic referrals and subsequent services for diagnosed cases.
* Create an opportunity for BPMI drug shop owners to engage them with health insurance facilities or any other providers of medical cover to provide pharmaceuticals to their members, if introduced in future.
* Ensure shop branding to increase visibility and customers’ trust in accredited drug shops and ensure that only actual accredited drug shops’ building frontages are painted with BPMI color and logo to help raise their profiles by improving visibility needed to increase customers’ trust in BPMI drug shops. Displaying BPMI logo and painting of the exterior of the accredited drug shops in the approved color scheme will raise accredited drug shops’ profile by improving relevance and visibility and thus customers’ trust in their drug shops as a genuine and reliable source of quality medicine and appropriate dispensing services. But there is a chance that some drug shop owners without obtaining accreditation under the new scheme may paint the exterior of their buildings with the new color scheme and logo of the BPMI project to increase their shops’ visibility and thus customer trust in their drug shops. This may create confusion in the mind s of the customers. In Uganda, some drug shop owners tried to cheat the general customers in this way. To avoid confusion and misuse of signage, it must be ensured that only actual accredited drug shops’ building frontages are painted with BPMI approved color scheme and logo to conspicuously display their accreditations needed to increase customer trust in their accredited drug shops.
* Ensure that building specification is clear, simple and unambiguous so that business owners ahead of time could know exactly the minimum standards that they would be required to provide for accreditation purpose. This will help in quick implementation of the program by reducing delay in designing model drug shop plans needed for accreditation program, ensuring hassle-free arrangements.
* Allow some existing drug shop owners a grace period of one year to renovate their drug shops’ premises to meet the specific standards for accreditation. This facility may only be given to the deserving drug shop owners as and when required.
* Regulate stringently the supply chain of the pharmaceutical products from the wholesale market down to the retail market by inspecting and monitoring the quality of the pharmaceutical products both manufactured at home and imported from abroad down through the supply chain to the retail outlets supplying the general public in the country to increase more reliable sources of affordable, quality wholesale products for enhancing their competing business interests. If some unscrupulous manufacturers, importers, and wholesalers who are actively engaged/involved in manufacturing and marketing/supplying of fake, counterfeit, poor quality and unregistered drugs try to supply them to the retail drug shops especially in the rural areas through providing unusual higher commissions/discounts and allowing longer/ extended trade credit terms, some greedy shop owners even with full knowledge about the poor quality of the medicine may get induced to buy such poor quality medicines from them to avail these facilities. However, some ignorant drug shop owners may get induced to buy these medicines due to attractive huge commissions/discounts and trade credit terms offered by the suppliers. Regulators will need to keep the accredited drug shops under constant surveillance to ensure that essential medicines of assured quality are available at reasonable prices in such shops. That is, consumers must be assured that BPMI drug shops are such a reliable source for buying quality medicines. Accredited drug shops may face difficulty in competing with the shops buying these poor quality medicines at much cheaper rates. If the main source of supply chain remains adulterated, only keeping constant vigilance at the retail outlets might not help in achieving the desired goal of the program quickly. So, a comprehensive two way drive, simultaneously targeting both the upper and lower levels of supply chain needs to be undertaken for early success of the program. DGDA is authorized to take necessary legal and administrative actions against such illegal activities.
* Develop the administrative and regulatory capacity of DGDA through increasing its manpower strength up to upazila level, and amending The Drugs (Control) Ordinance, 1982, and The Bengal Drugs Rules, 1946 (as amended up to December 1952) to meet the current requirements of the accreditation standards. DGDA and project implementation officers will need to launch a marketing campaign encouraging consumers to buy quality medicines from such reliable accredited drug shops. For this, customers must be assured that BPMI drug shops are such a reliable source for buying quality medicines. DGDA will need to keep the accredited drug shops under constant surveillance to ensure that essential medicines of assured quality are available at reasonable prices in such accredited shops. In this connection, DGDA’s another key responsibility is to ensure more reliable sources of affordable, **quality wholesale medicines and pharmaceutical products** to the accredited drug shops so that they can maintain the required quality and standards as per rules and guidelines of the accreditation program. DGDA, the sole licensing and regulatory authority in the pharmaceutical sector, is solely authorized to properly regulate the supply chain of pharmaceutical products from the source to the retail market. So, DGDA’s both administrative and technical capacity must be enhanced to address these problems.
* Undertake measures to provide pooled procurement opportunities to the accredited drug shop owners. Members of a truly representative Bangladesh Chemist & Druggist Somity (BCDS) elected through free and fair, especially owners of the accredited drug shops can organize themselves to form cooperative societies to enable them to have joint procurement of drugs, other pharmaceutical products, and non-pharmaceutical products to enjoy the economies of scale resulting from bulk purchases. DGDA and BPMI project implementation officials need to extend full cooperation and administrative support for its success.

# 13.0 Conclusions

The accreditation process under the new regulation requires the drug shop owners to improve their retail drug shop premises, and for them and their dispensers to attend and pass a training program. The training will help drug shop owners/dispensers to acquire improved dispensing and business skills so that they can change their attitudes and have the practices needed to succeed in operating their businesses. When the awareness of the benefits of the accreditation program in contrast to the current irrational use of drugs and their harmful effects will become apparent to the general public and the drug shop owners, people’s demand for buying quality medicines at reasonable prices from the reliable accredited drug shops will increase significantly and the pressure of the drug shop owners to become accredited will grow quickly to retain their customers who could otherwise move on to other areas to access BPMI drug shops. For achieving quick progress, drug shop owners need to be convinced that implementing a higher level of standard will give them an advantage over the others implementing much lower standards.

An acute shortage of trained pharmacists, especially in the rural areas could be a significant obstacle to the success of the program. So, a crash training program should urgently be undertaken to train the huge number of untrained owners/dispensers working in the drug shops. Providing regular supportive supervision to dispensers could be a challenge for the success of the program in Bangladesh because DGDA’s current limited number of staff with inadequate logistic support would not be able to inspect drug shops frequently to ensure compliance with accreditation regulations and standards. Development of association-based peer-peer supportive supervisions could be a sustainable way to complement the government’s supervision and inspection. It should be mentioned that local interest groups’ enthusiasm for the accreditation program could be a powerful force for quick implementation of the program. It should also be mentioned that once the BPMI program gets established throughout the country, the primary financing issue of the program will shift to shops’ profitability and sustainability, and program maintenance.

# 14.0 Annex A: Action Plan

Action Plan (Based on Key Recommendations):

| **Sl.** | **Item** | **Initiated by** | **Endorsed by** | **Implemented by** | **Timeframe\*** |
| --- | --- | --- | --- | --- | --- |
| 1 | BCDS and project implementation officers can jointly take initiatives to facilitate accredited drug shop owners’ easy access to SME loans and microfinance opportunities. | DGDA | DGDA | DGDA | Short-term |
| 2 | Engage BPMI drug shops in government’s various health promotion projects such as vaccination campaigns, disease reporting, etc. to serve as a platform for community-based public health interventions  | DGDA | DGHS | MOHFW,DGHS | Short-term |
| 3 | Undertake a large-scale crash program to train the huge number of dispensers to avail themselves the opportunities of BPMI program | DGDA | MOHFW,PCB | MOHFW,PCB | Short-term |
| 4 | Introduce a fair and transparent online process for drug license applications and approvals to ensure efficiency and transparency | DGDA | MOHFW | MOHFW,DGDA | Short-term |
| 5 | Conduct a nationwide extensive IEC campaign to create knowledge and awareness of the public to encourage consumers to buy quality medicines from reliable accredited drug shops | DGDA | MOHFW | MOHFW,Ministry of Information | Short-term |
| 6 | Employ BPMI drug shops’ owners/dispensers interested to work as providers of TB DOTS by providing capacity building training and monetary incentives to them | DGDA | DGHS | MOHFW,DGHS | Short-term |
| 7 | Increase BPMI drugstores’ sales volume by allowing them to stock and sell some ancillary non-pharmaceutical products such as cosmetics, toiletries, food supplements, personal hygiene, etc. | DGDA | MOHFW,DGHS | MOHFW,DGHS | Short-term |
| 8 | Allow BPMI drug shops to stock and sell medical supplies and devices as long as they meet DGDA’s established quality standards, and are kept separated from medicines | DGDA | MOHFW,DGHS | MOHFW,DGHS | Short-term |
| 9 | Allow drug shop dispensers to check or monitor blood pressure, sugar level, and body temperature and administer rapid diagnostic tests but not allowing to conduct any medical clinical services including pushing injections | DGDA | MOHFW,DGHS | MOHFW,DGHS | Short-term |
| 10 | Provide training on how to monitor product sales, use stock cards to avoid both over and under stocking, keep track of expiry dates, and what types of products to stock to improve shops’ profitability | DGDA | MOHFW,PCB | MOHFW,PCB | Short-term |
| 11 | Allow some existing drug shop owners a grace period of one year to renovate their drug shops’ premises to meet the specific standards for accreditation. This facility may only be given to the deserving drug shop owners as and when required. | DGDA | DGDA | DGDA | Short-term |
| 12 | Upgrade the training curriculum for capacity development of C-grade pharmacists to help them become first-line PHC dispensers by incorporating health education, first aid, and referral guides in the revised curriculum | DGDA | MOHFW,PCB | MOHFW,PCB | Medium-term |
| 13 | Regulate stringently the supply chain of the pharmaceutical products to the retail market to increase more reliable sources of affordable, quality wholesale products for enhancing BPMI drug shops’ competing business interests | DGDA | MOHFW,DGDA | MOHFW,DGDA | Medium-term |
| 14 | Ensure that only actual accredited drug shops’ building frontages are painted with BPMI color and logo to help raise their profiles by improving visibility needed to increase customers’ trust in BPMI drug shops | DGDA | DGDA | DGDA | Short-term |
| 15 | Open a channel for registering customers’ complaints against drug shops, and drug shop owners’ complaints about harassments by inspectors | DGDA | DGDA | DGDA | Medium-term |
| 16 | Offer a tapering charge scheme for providing training to drug shop owners/dispensers with a number of the first drug shop owners applying for participation being offered free training and then a sliding scale being applied for later joiners | DGDA | MOHFW,PCB | MOHFW,PCB | Short-term |
| 17 | Develop the administrative and regulatory capacity of DGDA through increasing its manpower strength, and amending the existing rules and regulations to meet the current requirements of the accreditation standards to ensure full compliance with regulations and standards to safeguard accredited drug shops’ competing interests | DGDA | MOHFW | Ministry of Public Administration,Finance Division,Ministry of Law and Parliamentary Affairs,MOHFW | Medium-term |
| 18 | Incorporate mobile money applications and SMS-based reporting system to facilitate payments, and communication between the accredited drug shops and the regulatory authorities to ensure easy and transparent payment process | DGDA | MOHFW,National Board of Revenue (NBR) | MOHFW,Internal Resources Division (IRD) | Medium-term |
| 19 | Provide orientation training on how to manage and dispense the pharmaceutical products, and monitor the availability of medicines through computerized inventory management system and use of cash register to print cash memos | DGDA | MOHFW,PCB | MOHFW,PCB | Medium-term |
| 20 | Create an opportunity for BPMI drug shop owners to engage them with health insurance facilities, if introduced in future | DGDA | MOHFW | Ministry of Public Administration,Finance Division,Banking and Financial Institutions Division,MOHFW | Long-term |
| 21 | Undertake measures to provide pooled procurement opportunities to the accredited drug shop owners. Members of a truly representative Bangladesh Chemist & Druggist Somity (BCDS) elected through free and fair, especially owners of the accredited drug shops can organize themselves to form cooperative societies to enable them to have joint procurement of drugs, other pharmaceutical products, and non-pharmaceutical products to enjoy the economies of scale resulting from bulk purchases. DGDA and BPMI project implementation officials need to extend full cooperation and administrative support for its success. | DGDA | DGDA | DGDA | Medium-term |

\*Short-term indicates an implementation period of 2 years; medium-term 3 to 5 years; and long-term more than 5 years.

# 15.0 Annex B: Scope of Work

**Background**

MSH has been awarded a project titled Designing Implementation Strategy for Accredited Drug Seller model in Bangladesh, which is funded by Joint Donor Technical Assistance Fund (JDTAF)—a consortium of donors led by the Department for International Development (DFID).The project’s primary objective is to design a Bangladesh pharmacy model to be introduced to Bangladesh as the Bangladesh Pharmacy Model Initiative (BPMI) program. In developing the BPMI program, MSH aims to strengthen the capacity of the Directorate General of Drug Administration (DGDA) and the Pharmacy Council of Bangladesh (PCB) to ensure improved access to and appropriate use of quality medicines and pharmaceutical services in Bangladesh through accreditation and monitoring of private sector drug shops and pharmacies. This project encompasses the first eight-month phase of work, which includes preliminary model development, planning for targeted district implementation and evaluation, and capacity building of national institutions to move the BPMI implementation phase forward.

A key component of the BPMI program is that BPMI accredited pharmacies are granted certain incentives to encourage pharmacy owners to become accredited. These are often economic incentives, which help owners improve their shop’s profitability and thus financial sustainability, and assist the owner in making improvements to the shop, such as shop renovations or expanding stock levels. Examples of economic incentives from MSH’s experience implementing similar private-sector drug shop initiatives in Tanzania, Uganda, and Liberia include micro-financing opportunities, access to interest free loans, capacity building in relation to financial management, shop branding to increase visibility and customer trust and business, and pooled procurement opportunities. Another incentive in these countries has been to allow accredited drug shops to legally dispense certain prescription medicines from an approved medicines list, which improved shops’ profitability while improving access to these medicines at the community level.

As Bangladesh prepares to introduce at BPMI program, MSH is seeking a consultant to develop a BPMI owner incentive strategy, which can be implemented during the BPMI implementation phase to encourage pharmacy owners to become part of the program. The incentive examples from MSH’s previous experience may be relevant in the Bangladesh context, but the consultant should also consider whether there are additional incentives that may be appropriate and effective. An incentive example in the Bangladesh context includes reduced registration or renewal fees for becoming BPMI accredited.

**Objective**

To develop an incentive strategy that encourages pharmacy owners to become accredited under the BPMI program and enhances the sustainability and quality of BPMI pharmacies.

**Activities**

1. Review materials related to accredited drug shop incentives from Tanzania, Uganda, and Liberia.
2. Review existing literature and incentive strategies implemented by other initiatives in Bangladesh (if available). If possible, visit the project sites or implementing organizations to talk to relevant stakeholders to learn about the incentive mechanism.
3. Work with the BPMI incentive strategy technical working group to introduce the assignment and plans for developing the BPMI incentive strategy.
4. Conduct key informant interviews and/or focus group discussions with stakeholders knowledgeable about retail pharmacy profitability and financing in Bangladesh at the central and district level to learn of challenges that pharmacies encounter when engaging with financial institutions and estimate need and types of support required to develop a sustainable initiative.
	1. Central level interviewees should include MOHFW, DGDA, PCB, BAPI, Bangladesh Chemist and Druggist Samity (BCDS), and select microfinance institutions, banks, and large NGOs engaging in microfinance work.
	2. District level interviewees should include pharmacy owners, district health officials, select microfinance institutions and banks at district level, and BCDS representatives including local government at the district and upazila level.
5. Based on the experiences in Tanzania, Uganda, and Liberia, and other initiatives in Bangladesh the information gathered from stakeholders, develop a concept note describing a proposed BPMI incentive strategy, which details the following:
	1. Incentives to be included in the BPMI program and justification for each incentive
	2. Strategy for introducing the incentive strategy to pharmacies and measuring incentives’ effectiveness
	3. Strategy for maintaining the incentives (if applicable)
	4. Resources and expertise required to introduce and maintain the incentives
6. Hold a BPMI incentive strategy technical working group meeting to solicit stakeholder feedback on the concept note.
7. Based on stakeholder feedback, revise the concept note for the BPMI incentive strategy.
8. Present proposed BPMI incentive strategy to a broader group of key stakeholders at a workshop for final approval of the strategy.

**Deliverables**

1. Tentative schedule and list of key informant interviews and focus group discussions due March 28, 2016.
2. Brief report on technical working group meetings and information gathered during key informant interviews and focus group discussions due by April 8, 2016.
3. Concept note on the proposed BPMI incentive strategy due by April 22, 2016.
4. Revised BPMI incentive strategy to be submitted for finalization during workshop due by May 6, 2016.
5. Final BPMI incentive strategy due by May 27, 2016.

**Timeframe**

March-May 2016

# 16.0 Annex C: Field Study Report on Retail Drug Shops in Bangladesh

This field study report on BPMI incentive strategy is a retail drug shop-based cross-sectional study carried out to explore the perceptions of different stakeholders regarding the feasibility of providing certain incentives to the private drug shop and pharmacy owners to get their drug shops accredited to the Bangladesh Pharmacy Model Initiative (BPMI) program based on the MSH’s accreditation experiences in Tanzania, Uganda and Liberia.

The study population of this paper includes (1) owners and dispensers of retail drug shops located in Dhaka city and its adjoining peri-urban and rural areas; (2) samples of community members who usually purchase medicines from these shops [focus group discussions (FGDS)]; and (3) key informant interviews (KII) with drug licensing officers, regulators, members of professional associations and academics.

Ten drug shops were randomly selected from the rural and peri-urban areas, and ten were from Dhaka city area. The salespersons/dispensers, drug shop owners, and owner-cum-dispensers of each of the drug shops who were present at the time of the survey was included as the respondents for this study. Only owners of the shops, if found present among others, were interviewed for the study.

In addition, a sample of community members who generally purchase medicines from such drug shops was interviewed for this study. FGDs were conducted to elicit the participants’ perceptions of services received and their expectations from these retail drug shops. They were explained the issues of the failure of the current regulations regime and how would those failures be addressed in the new regulations. When asked they all supported the idea of introducing new regulations for the benefit of the people seeking quality medicines and dispensing services at affordable prices. This question was asked to ascertain customers’ satisfaction, i.e. the value difference of the services a customer expected and those that he/she actually received. Key informant interviews (KII) were also conducted with relevant stakeholders including key personnel from DGDA, PCB, BCDS, SME Foundation, Dhaka University, and MOHFW. While conducting the study, structured observations of the drug shop owners/dispensers, customers, and community members were carried out simultaneously.

All the sampled drug shops visited both in the urban and rural areas had been in operation for more than 10 years. Floor space of the rural drug shops was found larger in size than those in the urban and peri-urban areas. All the shops surveyed had business licenses issued by respective local union councils for rural areas and city corporations for the urban areas. But only 80% of the shop owners could show their drug licenses issued by DGDA. Most of them were not renewed, which was a violation of the mandatory provision for renewal within two years from the dates of issue/renewal. When asked, most of the drug shop owners/dispensers could not show their pharmacist registration certificates. Some said that they had LMF degree certificates obtained from somewhere in Gazipur or Jamalpur district. But they managed to obtain drug license from DGDA without submitting mandatory pharmacist registration certificates. When Secretary, PCB was contacted, he said that only LMF degree certificate could not entitle a person to get drug license. Any person applying for C-grade drug license must submit his/her pharmacist registration certificate to DGDA office for license. So, it became clear that majority of the drug shop owners/dispensers in the rural and peri-urban areas refrained from applying to obtain drug licenses because they did not possess pharmacist registration certificates required for application.

Around 40% of the respondents in the rural areas when asked said that they received dispensing training from pharmaceutical companies. Some reported that they learned dispensing working with MBBS doctors as apprentices. When asked how they could face the awkward situations when DGDA’s inspectors came to visit their drug shops and asked for showing relevant documents especially drug license – new or renewed, pharmacist registration certificate – new or renewed, etc. they made oblique comments saying that somehow or other they could manage such embarrassing situations. But when asked why they did not obtain drug licenses required for drug shop business, majority of the respondents mentioned that the licensing process was too complicated, lengthy and costly. Some respondents perceived the process of getting a drug license to be too lengthy, spanning from a few weeks to a few months. Though official licensing fee (new) is fixed at BDT 2,500 for urban areas and BDT 1,500 for rural areas throughout the country, majority of respondents (60%) perceived that the cost of license fee might be BDT 20,000 to BDT 30,000. They also believed that license renewal fee might be more than BDT 10,000. But official license renewal fee is fixed at BDT 1,800 for urban areas and BDT 700 for rural areas across the country. Getting drug licenses renewed was also a lengthy, cumbersome and difficult process requiring at least one week’s efforts for lobbying in DGDA offices.

Majority respondents in the rural area reported that their drug shops were not inspected by any DS or DI of DGDA office during the last two years, but respondents in the urban area when asked reported that their drug shops were occasionally inspected by the officers working in the DGDA offices. When asked, majority shop owners/dispensers could not show Bound Inspection Books usually maintained for writing the observations and irregularities/illegalities (if any) detected and remedial measures suggested by the inspecting officers.

Majority of the customers came to purchase drugs by self-referral without prescriptions. Besides selling medicines, owners/dispensers also provided clinical services such as pushing injections, providing first aid for burns, dressing and stitching cut wounds, giving vaccinations, measuring blood pressure and blood sugar, etc. which were not allowed under the current drug license issued by the DGDA offices. Primary health care (PHC) treatments for fevers, headaches, coughs and colds, gastric problems, etc. were also available from these shops. These practices were found both in rural and urban areas. Majority drug shop owners when asked said that they procured medicines through medical representatives of pharmaceutical companies and wholesalers located near Mitford Hospital in old Dhaka city area. Most of the shop owners were able to obtain trade credit terms from their wholesale suppliers once they had established a good trading record with them; the credit period varied extending up to 30 days in some cases. When asked, some respondents reported that expired drugs were either dumped or returned to the suppliers.

Most of the owners said that they started their drug shop business from their own funds and by taking loans from friends and relatives; they did not approach for bank loans provided at higher interest rates. They alleged that obtaining loans from banks was very lengthy and cumbersome process. A few owners took bank loans at higher interest rates by mortgaging their landed properties as collateral security going through a lengthy and difficult process. When asked whether they would take bank loans for improvements of their shop premises, renovations and operations, training, and expanding stock levels required for accreditation, they said that if hassle-free soft loans could be made available at lower interest rates, they would consider taking bank loans. However, most of them replied that they would not require taking any bank loans for accreditation; they would reinvest their business profits/savings for this purpose. When asked, some respondents reported that pharmaceutical companies paid VATs and advance income tax at source when selling the medicines.

Some participants in the FGDs mentioned that they had known the drug shop owners/dispensers for more than 10 years. Some respondents perceived that all drug sellers in their areas had dispensing training required for obtaining drug license and selling medicines and dispensing services. Some respondents, when asked, could not tell whether their dispensers had pharmacist registration certificates issued by Pharmacy Council of Bangladesh (PCB) required for retail drug shop business. They could not even know about their educational qualifications. Most respondents said that prescription was not necessary for common health problems such as coughs and colds, fevers, headaches, gastric problems, etc. Some FGD participants mentioned that they could not check the expiration dates of the medicines they bought because they did not have sufficient knowledge required for checking expiry dates. They had put their trust on the drug shop owners and dispensers and knew that sellers would not betray their trust.

One respondent said that if a prescribed drug was not available, the dispensers would go to the neighboring shops to collect it and sometimes they would substitute another brand of the prescribed medicine. Most of the respondents stated that drug sellers did not explain the side effects of the drugs but some of them informed the side effects and gave advice accordingly. Another respondent said that dispensers did not provide receipts for payments, and the customers were also not interested to ask for receipts after buying drugs because sellers were known to them. Some respondents, when asked, said that drug shops provided some clinical services such as first aid for burns, dressing and stitching cut wounds, measuring blood pressure and blood sugar, pushing injections, etc. when local people went to them for such treatments.

When asked, some FGD participants said that sometimes mobile courts led by executive magistrates were held both in urban and rural areas to detect the expired, unregistered and damaged medicines. Some drug shop owners and dispensers were punished with fines or imprisonments or both for keeping illegal drugs in their shops; illegal medicines were seized and then destroyed in presence of the magistrates holding the mobile courts. When asked, some respondents said that they never asked the dispensers whether they had drug license required for selling medicines and dispensing service. They perceived that drug shop owners must have drug license because without it they could not legally operate this business.

All the regulators interviewed unanimously supported the need for developing Bangladesh Pharmacy Model named Bangladesh Pharmacy Model Initiative (BPMI) to ensure improved access to and appropriate use of quality medicines and dispensing services in Bangladesh. Some regulatory participants said that a drug shop owner must obtain a drug license for opening and operating a drug shop because without possessing license the storage, display and sale of drugs are punishable offense in Bangladesh. DGDA, the sole licensing authority in the country, has so far issued 115,439 drug licenses to drug shops. A drug shop owner must have at least SSC certificate to obtain drug license for operation of a drug shop. And a drug dispenser must be a registered pharmacist possessing a professional certificate (grade A to grade C) issued by the Pharmacy Council of Bangladesh (PCB). A drug license issued for a period of two years must be renewed and the licensee must apply for a fresh license before the expiry of the license in force.

PCB reported that particulars of 62,473 C-grade certified pharmacists working in retail drug shops and community pharmacies, 10, 239 B-grade diploma pharmacists working in government and private hospitals and clinics, and 2,936 A-grade graduate pharmacists mainly working in the pharmaceutical companies have been kept separately and registered in Registers of pharmacists and apprentices maintained u/s 23(1) of the Pharmacy Ordinance, 1976. The C-grade certificate course is conducted by the PCB with the help of the BCDS and the BPS; PCB prepares the curriculum of the training program, organizes the class routines and conducts the pharmacist registration certificate examinations. Section 25 of the said ordinance prescribes the procedure for registration of pharmacists and section 26 makes provisions for issue and renewal of certificates of registration. A certificate of registration issued/renewed u/s 26 remains valid for five years which must be renewed after the expiry dates of issue/renewal.

Bangladesh Chemist and Druggist Samity (BCDS), a registered association of the drug shop owners approved by the Social Welfare Ministry, has its network spreading throughout the country, extending from the central to the upazila levels in the rural area. BCDS members reported that only 120,000 drug shops obtained drug licenses out of the existing 300,000 drug shops operating throughout the country. They emphasized that all drug shop owners must possess drug licenses – new or renewed – to open and operate drug shops. Most of the drug shops do not have any registered pharmacists. These illegalities/irregularities persist because of inadequate regulatory enforcements. To address the acute shortage of trained pharmacists, a crash program should be undertaken to train the huge number of untrained and unqualified dispensers working in the drug shops within a short span of time. When asked whether BCDS would give full cooperation for implementation of the BPMI program if launched throughout the country, they said that they would whole-heartedly extend their support for success of the program. They suggested that DGDA and PCB should upgrade their respective administrative and regulatory capacities to ensure training of the huge untrained dispensers and issue/renew of numerous unlicensed drug shops within a reasonable period of time. They also suggested strengthening the regulatory enforcement capacity of the inspectors by ensuring regular supervision of drug shops for compliance. They said that government’s commitment and whole-hearted support are needed for successful implementation of the program.

# 17.0 Annex D: Experiences of Accredited Drug Shop Strategies in Tanzania and Uganda

The main purpose of MSH’s project titled “Designing Implementation Strategy for Accredited Drug Seller Model” funded by Joint Donor Technical Assistance Fund (JDTAF) – a consortium of donors led by DFID is to design a Bangladesh Pharmacy Model Initiative (BPMI) program based on the MSH’s accreditation experiences in Tanzania, Uganda and Liberia with a view to ensuring improved public access to and appropriate use of affordable, quality medicines and pharmaceutical services in Bangladesh through accreditation, regular supportive supervision and close monitoring of private sector retail drug shops and pharmacies in Bangladesh.

A dominant feature of the program is that private drug shop and pharmacy owners are granted certain incentives to induce them to become accredited to the program. For example, economic incentives are provided to the drug shop owners to help them improve their shops’ profitability and thus financial sustainability and to assist them for making improvements of their shops through renovation and expanding stock levels. Examples of some economic incentives provided to the private retail drug shop owners of Tanzania, Uganda and Liberia for implementation of drug shop accreditation program included micro-financing opportunities, access to interest-free loans, capacity building of drug shop owners regarding financial and inventory management, shop branding to increase visibility and customer trust in business, and pooled procurement opportunities. Another incentive given to the accredited drug shop owners was to allow them to legally dispense certain prescription medicines from an approved medicine list which improved their shops’ profitability while improving access to these medicines at the community level. It may be mentioned here that previously drug shops of these countries were allowed to sell only over-the-counter (OTC) medicines, although sellers who were untrained and unqualified often illegally sold prescription drugs of questionable quality (Rutta et al. 2015). So, a BPMI owners’ incentive strategy titled “Bangladesh Pharmacy Model Initiative Incentive Strategy” needs to be developed to encourage drug shop and pharmacy owners to become accredited to the BPMI program and to enhance the sustainability and quality of BPMI pharmacies.

Tanzania’s accredited drug dispensing outlet (ADDO) model was based on the assumption that to address the problem of getting access to affordable, quality medicines and pharmaceutical services effectively and sustainably in a resource-limited setting, all aspects of the drug shop enterprise – the physical premises, medicine inventory management, providers’ capacity and interactions with consumers, and appropriateness of recommended treatments according to national guidelines must be addressed comprehensively and systematically. Moreover, product licensing and supply, training, record-keeping, reporting and inspection system must be strengthened in the pharmaceutical sector.

To make good progress in achieving the project’s objectives, Tanzania took a holistic approach that had a combined effect of changing the behavior and expectations of the customers, drug shop owners, dispensing staff, and the regulators engaged in regulatory enforcement of rules and regulations. This holistic approach built the capacity of shop owners, dispensers, and the regulatory institutions. Shop owners and dispensers got benefitted from the combined effects of training, business incentives, supervision and regulatory enforcement which increased customer demand for and expectations of available, affordable, quality medicines, and improved dispensing services. The program developed accreditation standards and code of ethics based on government instituted standards and regulations for regulatory enforcement and supervision of drug shops. For this purpose, they created a public sector-based regulatory and inspection system and strengthened the local regulatory processes and capacity of the regulators. They also took supportive measures to develop drug shop owners’ business skills, to provide them with business incentives such as access to micro-financing and legal authorization to sell a limited list of essential prescription medicines not allowed before accreditation and to facilitate access to convenient and reliable sources of quality medicines. The accreditation program changed the behavior of dispensing staff working in retail drug shops through providing training and supervision. This changed behavior of owners/dispensers helped the ADDOs to maximize sales and to take a larger share of the market in the pharmaceutical sector (Rutta et al. 2015).

The program launched an all-out nationwide campaign to raise general awareness of consumers regarding quality of medicines and dispensing services and the importance of treatment compliance through public education and marketing campaigns to encourage consumers to buy affordable, quality medicines from accredited drug shops. The ADDO program showed an interesting and educative example of how the use of regulation “control knobs” could influence and structure the performance of the retail private pharmaceutical sector. The law required that all ADDO owners and dispensers must have a thorough understanding of accreditation regulations, standards and ethics. Accreditation standards required the dispensers to receive training on appropriate medicine use and patient referral. In addition, consumers buying medicines from ADDOs could be assured of better quality because standards had improved drug storage and management practices. No unregistered products were found in ADDOs. In a survey, it was found that 93% of 243 drug samples had passed quality tests. ADDO dispensers also received training on importance of not selling expired drugs. Research indicated that expiry of medicines was no longer a major problem in the accredited drug shops. One of the primary reasons that induced people to choose ADDOs over public health facilities was the more consistent availability of popular quality medicines at affordable prices.

The program had oriented owners and dispensers on how to manage and dispense the products and monitor the availability of medicines through mobile phone applications. ADDO owners and dispensers were trained to keep records related to business and sales. Dispensers would track who bought medicines (in addition to select demographic information) and for what conditions. The availability of such records at ADDOs had allowed supervision and inspection teams to review and assess ADDO dispensers’ performance and the shops’ compliance with standards and regulations. ADDOs were required to keep records of all prescription drugs sold and their selling prices, financial and sales information, customer complaints, and expired medicines. These records were used for supervision purposes which must be made available for review by inspectors. A channel existed for registering customers’ complaints against ADDOs and also for recording shop owners’ complaints about harassment by inspectors or other problems. ADDO program not only increased access to essential medicines but also served as a platform for community-based public health interventions. Under the Integrated Management of Childhood Illness Initiative program, dispensers were given training on child health care. Other integrated programs were tuberculosis case identification and patient referrals, distribution of subsidized artemisinin-based combination therapies, and knowledge and control of antimicrobial resistance. Such engagements of ADDOs with community-based public health programs increased owners’/dispensers’ incomes and improved their social images in the community (Rutta et al. 2015).

In addition to appropriate dispensing, training also focused on the importance of record-keeping. Owners and dispensers learned how to monitor product sales, keep track of expiry dates, and what types of products to stock to improve business. In a survey of owners and dispensers after accreditation, almost all reported keeping financial records (94%) and monitoring daily sales (98%); in addition, 69% tracked monthly profits. Although the program design included owners’ incentives to become accredited, such as expanded list of allowable drugs to stock, owners had repeatedly mentioned that dispenser training was the most highly valued program benefit (Rutta et al. 2015).

To help improve information access, the project engaged a local technology firm, Invention and Technological Ideas Development Organization (ITIDO), to build a web-based regulatory database and website for the Pharmacy Council. Council staff was trained on how to use GPS devices to geo-code premises and Google Earth maps to locate the geo-coded ADDOs and pharmacies. ITIDO developed mobile applications for payment, indicator reporting, and information exchange through SMS-based helpline between ADDOs and Pharmacy Council (Rutta et al. 2015).

Incorporating information technology including mobile money and other applications had a potentially major impact on drug seller initiatives’ sustainability. Dispensers had no trouble reporting basic service statistics, and during the pilot, 129 people used mobile money to pay over 12 million TSH in fees. Shop personnel appreciated the ease of paying fees through M-Pesa. In the past they had to close their shops and go all the way to the Council, and there they might find a long queue and sometimes they had to spend the whole day there. ADDO staff felt that it was much easier to get information through the new SMS-based helpline. The launch of the mobile money application made it easier for pharmacy and ADDO staff to pay fees to the Pharmacy Council (Rutta et al. 2015).

In line with a number of relevant global initiatives, the program began partnering with UNICEF to improve community access to new products to treat childhood pneumonia and diarrhea – amoxicillin dispersible tablets and oral rehydration solution (ORS)/zinc co-packs. Program’s activities included orienting owners and dispensers on how to manage and dispense the products and monitoring the ability through a mobile phone application. This meaningful partnership with UNICEF had widened the ADDOs’ scope of social welfare activities in the communities (Rutta et al. 2015).

From the start of the program, accredited shops had been profitable; although the pilot program in Ruvuma linked the majority of owners with microfinance institutions to help them make the improvements to become accredited, few owners in other regions used that option to finance their shop renovations or operations. The majority of owners (79%) reinvested their ADDO business profits; 11% tapped personal savings for business financial needs; and 8% used a combination of financing options. Evidence of profitability also came from the willingness of owners and dispensers to take over all costs associated with accreditation which had previously been donor funded. Additionally, when the National Health Insurance Fund incorporated ADDOs into its scheme, owners felt that the arrangement boosted their sales, ensuring more profitability and sustainability of the program (Rutta et al. 2015).

Tanzania’s Pharmacy Council was responsible for the institutions’ training standards and oversight with ADDO owners and dispensers covering all costs of training. As owners and dispensers realized the benefits of accreditation, they became more willing to pay for accreditation costs, such as branding, renovations, increased inventories, and training that had been covered by donors in the program’s early years (Rutta et al. 2015).

In addition to the government’s role in overseeing ADDO operations, decision makers worked to strengthen existing professional drug shop provider associations and facilitate the formation of new provider associations to serve as a governance resource and a professional “voice” for the owners and dispensers. Some ADDO owners said that they would expect the association to give them a strong unified voice on matters relating to their businesses; provide them with a platform to engage with various regulatory authorities; provide them with a mechanism for self-regulation to minimize non-compliance with pharmaceutical sector regulations and standards. On the other hand, some dispensers mentioned that the association would provide them with a platform to deliberate on issues of interest; give them a common voice to air grievances to owners; help them demand better salaries and work conditions, including standard working hours, overtime payment, and annual leave; provide them with a forum to exchange ideas and experiences in line with their training and enable them to improve their skills and promote self-compliance to standards and regulations (Rutta et al. 2015).

Providing regular supportive supervision to dispensers was a challenge to the accreditation model. While local officials could periodically inspect shops to ensure compliance with accreditation regulations and standards, they did not have the time or resources to make more frequent supervisory visits. Development of association-based peer-peer supervision in Accredited Drug Shops (ADS) in Uganda’s Mityana district was a notable activity for playing effective supervisory roles. Peer supervisions organized through provider associations were proved to be a sustainable way to complement local government supervision and inspection, enhancing ADS’s compliance with pharmaceutical sector’s regulations, standards and ethics (GIC Limited, 2011).

In Uganda, a local organization namely “Coalition for Health Promotion and Social Development (HEPS)” was engaged to create and implement a consumer advocacy strategy related to expectations about pharmaceutical services and rights regarding health care. HEPS implemented the strategy in Kamuli district by providing training to the community leaders and outreach volunteers to attend community events to talk about the public’s health rights, what services the public should expect from drug shops, and rational medicine use. As a result, awareness of medicine issues in the community increased. The community members started asking the drug sellers important questions about medicine packaging and handling which was not there before. Community cognizance about drug shops also resulted in changes; for example, after receiving public pressure, an unqualified drug shop owner switched over from selling medicines to selling clothes in Balawoli sub-county in Uganda (Rutta et al. 2015).

The primary element that was essential to the ADDO program’s success was stakeholder engagement – the successful buy-in and sustained commitment came directly from the effort, time, and resources spent to fully connect with all vital stakeholders at all levels. Involvement ranged from publicly stating support for the concept to working closely on all aspects of the program design and implementation. At the end of the pilot in Ruvuma, regional and district stakeholders reported the following as program strengths: use of a participatory approach that involved all stakeholders from the beginning: owners, dispensers, consumers, political leaders; a fair and transparent process for permit application and approvals; the dispenser training component; and respecting and valuing community level opinions. Decision makers should realize the paramount importance of bringing the local interest groups on side so that their enthusiasm for the new regulation regime could become a powerful force in driving and enabling the changes to happen on the ground (Rutta et al. 2015).

During the program’s critical early period, a study visit of Parliament’s Social Welfare Committee was organized to observe the ADDO program in Ruvuma. Their enthusiastic reaction regarding the program paved the way for the allocation of additional funding for rollout from the government. Such a high-level commitment of the government’s own budget provided an incentive for continued donor interest and support which was considered as one of the milestones of the program. Another sign of government ownership was the various strategic documents that started addressing the ADDO program as a “key MOHSW program” and not a “donor-funded project”.

As the program expanded, it quickly became clear that a centralized Tanzania Food and Drug Authority (TFDA) did not have the capacity to continue implementing the rollout in new regions while overseeing the existing program. So, the model was revised to decentralize the implementation and oversight responsibility to the district level. Although the national-level champion was the key to a successful model launch, a mature program could rely on the commitment of local officials to support inspection and program maintenance (Rutta et al. 2015).

Once the ADDO program was established, the primary financing issue shifted to shop profitability and program maintenance – private sector shops needed to stay in business and cover their costs and the public sector could not rely on ongoing donor contributions to fund program maintenance costs. To increase efficiency and thereby contributing to program sustainability, some steps were taken. Mobile money applications and SMS-based reporting were incorporated to facilitate payments and communication between the shops and the regulatory body. Shop owner/dispenser associations were strengthened to empower providers to govern themselves through peer-supervision and create mechanisms to boost members’ financial sustainability. Awareness of the community was improved to increase demand for quality pharmaceutical services and products. Training was institutionalized by shifting the responsibility and costs from the public to the private sector (Rutta et al. 2015).

Tanzania’s ADDO model was transferred and replicated in Uganda’s and Liberia’s settings through establishment of Accredited Drug Shops (ADS) in Uganda and Accredited Medicine Stores (AMS) in Liberia. In both countries, evaluations showed that ADS and AMS increased the availability of quality pharmaceutical products and improved dispensing and business skills (Rutta et al. 2015).

In Uganda, access to loan finance was not perceived as a problem by the ADS owners and access to trade credit terms had been improved significantly in the pilot Kibaale district by inclusion of the drugs previously supplied illicitly. The ADS model in Kibaale district showed that owners were able to operate a mark-up multiplier of around 2.4 times wholesale prices with a gross margin of around 50%, indicating that the business model was capable of generating sustainable profits through a range of operating costs. Various steps were undertaken to improve ADS profitability and sustainability through broadening the product range to reduce over-reliance on pharmaceutical sales; participating in social welfare programs; responding to developments that might occur in health insurance. ADS owners were encouraged to add permitted non-pharmaceutical products to their range in order to reduce dependence on only one product type; to receive support to implement the good management practices such as stock management practice to avoid stock outs; to work together through the establishment of trade associations; to participate in social welfare campaigns (GIC Limited, 2011).

The additional costs of complying with the new regulation piloted in Kibaale reportedly did not seem to present any fundamental difficulty for drug shop owners. District stakeholders from the community, government, business and healthcare providers were targeted first to inform them of the impending change in pharmaceutical retail regulation by explaining the benefits of the new approach and the steps that would be needed to move to it. Districts were then encouraged to apply to the regional National Drug Authority (NDA), Uganda to join the process (GIC Limited, 2011).

ADS owners reportedly said that they were pleased with the level of profits that they were making from their businesses. However, none of these owners relied solely on the ADS for their income; they all had at least one, and in some cases, two or more alternative sources of income. It was reported that no owners had borrowed money to finance their investment in the accredited shops. All the owners had financed the upgrading of their premises themselves from their business profits/savings. Some had reached agreements with their landlords for rent-free periods to offset partially or fully the investment in improving the premises. Some had agreements with landlords that they would renovate the interior whilst the landlords should renovate the exterior. However, most owners appeared to have shouldered the cost of the premises improvements themselves without any offset arrangements or borrowing. All the owners said that they would be able to obtain loan as and when required. They thought it would be possible for them to obtain loans on the basis of the previous trading record of their drug shops or other businesses. So, access to finance was not an issue among the drug shop owners. Unemployed people with no business track record, no savings and no assets to offer as collateral security could face problems in obtaining bank loans. As the purpose of the new regulatory regime was primarily to bring existing 21,000 drug shop owners within the new accreditation framework, a lack of access to finance did not appear to offer a material obstacle to a nationwide scale up of the program (GIC Limited, 2011).

Most of the ADS owners said that they were able to obtain trade credit terms from their wholesale suppliers once they had established a good trading record with them. Typically, the credit period would extend to 30 days. The value of trade credit had been extended considerably for the ADS because a significant element of their purchases became legitimate, whereas before they were illicit and had to be paid for in cash. The new regulatory model supporting ADS had improved the availability of finance for the business through getting credit period facilities extended which in turn increased its sustainability.

Before accreditation, some drug shop owners revealed their concerns regarding stock out problems which resulted in lost sales. After accreditation, none of the ADS owners identified expired stock as a problem because they could select long expiry date stock and manage their purchasing to ensure quick rotation of stock. Owners/dispensers were trained on how to use stock cards to help control stock levels to avoid both over and under stocking (GIC Limited, 2011).

NDA supported the development of trade associations as an extension of the regulatory system which encouraged the association members to abide by the rules and regulations through sending favorable reports for the compliant drug shops and adverse reports for non-compliant shops to the NDA. Owners viewed the association as a source of guidance, training and support as well as a forum through which they could make suggestions for regulatory change. Owners also said that the association had an important role to play in ensuring that members maintained standards and in developing the ADS reputation and standing in the community (GIC Limited, 2011).

As stated earlier, local interest groups’ enthusiasm for the accreditation program could be a powerful force for quick implementation of the program. The pressure of the drug shop owners for becoming accredited in districts neighboring Kibaale grew as they saw their customers moving over the district border to access the ADS. The cumulative pressure on the NDA to scale up across the country grew quickly as awareness of the benefits of the new regulation regime became apparent to the public and to the drug shop owners (GIC Limited, 2011).

The need and the techniques that were appropriately used for sensitization of the general public in the pilot scheme were unlikely to be the same for a national roll out. For example, the techniques of spray painting of building frontages with the ADS color and logo used to raise local people’s awareness in the pilot scheme seemed to have heightened the expectations of the general people before the drug shops had been accredited, and in several instances the buildings that received the painted frontages did not actually house any ADS, which was confusing and misleading. The properly accredited shops’ fronts were not painted and the signage for them to display their accreditation was small and unremarkable. So it was suggested that the use of electronic and print media advertising should continue to be the main communication channel whilst the use of painting the exterior of buildings in the color scheme and logo of the ADS should be confined to the building of genuine ADS owners who could successfully obtain accreditation under the new scheme, helping to raise their profile by improving relevance and visibility (GIC Limited, 2011).

To increase sales volume through product range diversifications, ADS owners were allowed to offer other non-pharmaceutical products such as cosmetics, personal hygiene or food supplements, etc. for sale apart from pharmaceuticals as long as the products did not compromise the standards required for the sale of pharmaceuticals and were stored and displayed separately from the pharmaceuticals (GIC Limited, 2011).

Provisions were made for keeping a permanent training centre after full national implementation to cater for replacements and additions as and when required. Tanzanian owners were willing to spend more money than they were currently being asked to contribute towards the training cost of their dispensing staff. Most of the ADS owners were quite willing to make a contribution to the training costs. It might be possible to offer a tapering charge scheme with a number of the first drug shop owners applying for participation being offered free training and then a sliding scale being applied for later joiners (GIC Limited, 2011).

ADS network could offer opportunities for government community healthcare initiatives to begin engaging the ADS with service or equipment distribution like Tanzania where a trend of engagement with ADDOs as a natural distribution channel for healthcare campaign information or product was becoming established, with ADDO owners being paid a small fee or allowance for their services. Like Tanzania’s ADDOs, opportunities should be made for ADS owners to engage with insurers or other providers of medical coverage to provide pharmaceuticals to their members (GIC Limited, 2011).

A change in regulation regime could often result in additional expense for business owners which might be acceptable as business risk provided that the changes were not too frequent, were consistent and were well thought out. So, regulatory requirement should be reviewed to ensure that it was robust, sensible and was unlikely to need change during the lifetime of the scale up. During the sensitization process, it should be made quite clear to all concerned that access to loans from a bank or micro-financing organization would depend solely upon the collateral security that a person could offer or his businesses’ established trading history. During inspection of premises, building specification of the retail facility for selling pharmaceuticals should be reviewed in the light of the Kibaale pilot. The specification should be clear, simple and unambiguous for the building so that business owners could know exactly the minimum standards that they would be required to provide, not allowing any scope for a wide degree of interpretation (GIC Limited, 2011).

The Tanzanian experience showed that the effect of training of dispensers in the ADDOs increased their marketability with the result that some of these trained dispensers moved on to work outside the ADDOs or moved more frequently within the network. The loss of dispensers to the ADDO network resulted in demand for more to be trained. So, continued provisions for capacity building training should be considered into the scale up plan for certain percentage of replacements (Rutta et al. 2015).

# 18.0 Annex E: Recommendations – Immediate and Short-term Measures:

1. Transparent licensing and renewal process

**Existing problem:** The existing process is lengthy, costly and cumbersome and thus discourages the drug shop owners from obtaining drug licenses and renewal copies.

**Probable Solution:** Introduce a fair and transparent online process for drug license applications and approvals to ensure efficiency and transparency.

**Strategic Approach to solve the problem:** Build a web-based regulatory database and website for DGDA and PCB; develop mobile applications for payment, information exchange through an SMS-based helpline between drug shop owners and DGDA & PCB; make provisions for online submission of drug license and renewal applications along with other requisite documents, a copy of the treasury challan and pharmacist registration certificates to DGDA office. DGDA office will then get the treasury challans and pharmacist registration certificates verified online from Bangladesh Bank/Sonali Bank’s treasury branch and the PCB before according approval for drug license/renewals.

1. Training of dispensers and owners

**Existing problem:** Majority drug shop owners and dispensers especially in the rural and peri-urban areas do not possess pharmacist registration certificates required for drug license applications and for working as dispensing staff in drug shops.

**Probable Solution:** Undertake a large scale crash program to train the huge number of dispensers working in various drug shops.

**Strategic Approach to solve the problem:** The training curriculum of grade C pharmacist should be standardized and then franchised to various accredited health institutes in the public and private sectors including NGOs for training the vast number of untrained dispensers in a reasonable span of time.

1. Mobile money application for payment

**Existing problem:** Existing payment system cannot check corruption and irregularities reportedly going on at the grassroots level

**Probable Solution:** Incorporate mobile money applications and SMS-based reporting system to facilitate payments for registration, license issue/renewal fees, and the communication between the drug shops and the regulatory authorities to ensure easy and transparent payment process.

**Strategic Approach to solve the problem:** Launch mobile money applications and SMS-based reporting system to make it easier for retail drug shop owners to pay fees to DGDA and PCB.

1. Provision of selling non-pharmaceutical products

**Existing problem:** Most of the drug shops illegally sell non-pharmaceutical products which are not permitted in the existing drug license regime.

**Probable Solution:** Create specific regulations and guidelines for stocking and selling food supplements, Vitamins and Minerals, Baby food, Toiletries, Cosmetics and other hygienic health promotional products to be identified with signage (an officially approved accredited logo).

**Strategic Approach to solve the problem:** Permit accredited drug shops to legally stock and sell registered non-pharmaceutical products as per provisions of the rules and guidelines to be framed in this connection. Non-pharmaceutical products must be stocked and displayed separately from medicines and pharmaceutical products.

1. Provision for other health services

**Existing problem:** In most cases, untrained and unqualified dispensers are found checking or monitoring blood pressure, sugar level, body temperature, pushing injections and dressing & stitching cut wounds, giving vaccination and providing primary health care (PHC) treatments for fevers, headaches, cough and colds, gastric problem etc. which are not allowed under the current drug license issued by the DGDA office.

**Probable Solution:** Permit accredited drug shops’ trained dispensers to check or monitor blood pressure, sugar level, body temperature and administer rapid diagnostic tests for conditions such as malaria and pregnancy. Drug shop dispensers must not be allowed to conduct any medical clinical services other than those mentioned above including pushing injections.

**Strategic Approach to solve the problem:** These facilities will be restricted only to the accredited drug shop owners having trained and qualified dispensers; maintaining high standard of personal hygiene following the guidelines on dispensing, ethics and other terms and conditions related to accreditation.

1. Provision for medical supplies and devices

**Existing problem:** Many drug shops are found illegally stocking and selling medical supplies and devices in the absence of regulatory control over these products.

**Probable Solution:** Create specific rules and guidelines for allowing accredited drug shops to legally stock and sell such products.

**Strategic Approach to solve the problem:** Permit the accredited drug shops to legally stock and sell medical supplies and devices as per rules and guidelines to be framed and also in accordance with DGDA’s existing established quality standard. All medical supplies and devices must be stocked and displayed separately from medicine and pharmaceutical products.

1. Empowering dispensers to be part of public health program

**Existing problem:** In Bangladesh, retail drug shops are not engaged in govt.’s various health promotion projects such as vaccination campaigns, disease reporting etc. to serve as a platform for community-based public health interventions, though retail drug shops are the preferred first point of contact for majority of the people in the country.

**Probable Solution:** DGDA may send a proposal to the Ministry of Health & Family Welfare (MoHFW) through Directorate General of Health Services (DGHS) for engaging accredited drug shops’ trained dispensers in various public health promotional projects by providing capacity building training on relevant medical clinical services and monetary incentives to them.

**Strategic Approach to solve the problem:** DGDA can take initiatives to send a proposal to the Ministry of Health & Family Welfare (MoHFW) through Directorate General of Health Services (DGHS) to engage the trained and qualified dispensers working in various accredited drug shops to increase more people’s access to such projects.

1. Providing pooled procurement opportunities

**Existing problem:** Many retail drug shops procure their medicines and other pharmaceutical products direct from the pharmaceutical industries that are more retail oriented and where mass distribution is done by companies themselves. Due to higher percentage of direct sales and aggressive marketing strategy pursued by companies, scope of pooled procurement opportunities is somewhat limited.

**Probable Solution:** A truly representative Bangladesh Chemist & Druggist Samity (BCDS) elected through free and fair elections may organize the accredited drug shop owners to engage them to have joint procurement of drugs, other pharmaceutical products, and non-pharmaceutical products through providing full cooperation and support for this purpose.

**Strategic Approach to solve the problem:** BCDS members especially owners of the accredited drug shops can organize themselves to form cooperative societies to enable them to have joint procurement of drugs, other pharmaceutical products, and non-pharmaceutical products to enjoy the economies of scale resulting from bulk purchases. DGDA and BPMI project implementation officials need to extend full cooperation and administrative support for its success.

1. Shop branding to increase visibility and customers’ trust in accredited drug shops

**Probable Problem:** Displaying the approved logo and painting of the exterior of the accredited drug shops in the approved color scheme will raise accredited drug shops’ profile by improving relevance and visibility, and customer trust in their drug shops as reliable source of quality medicines and appropriate pharmaceutical services.

But there is a chance that some drug shop owners without obtaining accreditation under the new scheme may paint the exterior of their buildings with the new color scheme and logo of the BPMI project to increase their shops’ visibility and thus customer trust in their drug shops. This may create confusion in the mind s of the customers. In Uganda, some drug shop owners tried to cheat the general customers in this way.

**Probable Solution:** Use of painting of the exterior of the buildings in the color scheme and logo of the BPMI project should be confined only to the buildings of genuine accredited drug shop owners who can successfully obtain accreditation under the new scheme to increase visibility and customer trust in their businesses.

**Strategic Approach to solve the problem:** To avoid confusion and misuse of signage, it must be ensured that only actual accredited drug shops’ building frontages are painted with BPMI approved color scheme and logo to conspicuously display their accreditations needed to increase customer trust in their accredited drug shops.

1. Financial management capacity building

**Existing problem:** Most of the drug shop owners do not know how to keep business records needed to strengthen their shops’ profitability and sustainability. In most cases they cannot even avoid stock outs which results in loosing sales.

**Probable Solution:** Drug owners/dispensers’ skill development training should focus on the importance of record-keeping in addition to appropriate dispensing practices. They should learn how to monitor product sales, keep track of expiry dates, and what types of products to stock to improve business. They should also know how to keep financial records, monitor daily sales, track monthly profits and use stock cards to control stock level to avoid both over and under stocking.

**Strategic Approach to solve the problem:** Drug shop owners/dispensers’ capacity building training should focus on appropriate dispensing practices and rational medicine use as well as development of their business skills. In some cases, providing refresher training may play an important role to ensure that all the lessons given are eventually applied rather than forgotten.

1. Providing model (interior) design of a drug shop

**Probable problem:** Many drug shop owners especially in the peri-urban and rural areas may not know how to design a model drug shop plan needed for accreditation.

**Probable Solution:** Project implementation officers can design a model drug shop’s type plan and provide this type plan free of cost to the drug shop owners interested to get their shops accredited in the new scheme.

**Strategic Approach to solve the problem:** A model drug shop’s type plan should be designed in such a way that majority drug shop owners especially in the peri-urban and rural areas can implement this plan with some minor modifications as and when required.

1. Providing support from Bazar (Market) Committee

**Existing problem:** In many cases, especially in the peri-urban and rural areas, drug shop premises cannot be expanded/relocated due to non-cooperation/resistance from the land owners of the vacant space adjoining the drug shops or non-availability of lands for relocations. Sometimes, drug shop owners want to have their inaccessible approach roads expanded for customers’ easy access to their shops but they cannot get the land owners to agree to their proposals, causing inconveniences for them.

**Probable Solution:** Influential members of the local Bazar Committees can help them by taking the matter with the concern land owners to help negotiate/settle the issue through arbitration to the benefits of both the parties.

**Strategic Approach to solve the problem:** District level leaders of the BCDS can seek help from the influential members of the relevant Bazar Committees to negotiate/settle the issues through arbitrations.

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