**Bangladesh Pharmacy Model Initiative (BPMI)**

**Improving Inspection and Monitoring for Private Retail Pharmaceutical Services in Bangladesh**

**Recommendations for Addressing Inspection Resource Needs**

**November 2016**

**Background:**

During implementation of the Bangladesh Pharmacy Model initiative (BPMI), Management Sciences for Health (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. One of the major components of the BPMI is to support DGDA and PCB to strengthen regulatory oversight and operations of retail drug outlets in Bangladesh.

The regulatory component consists of other sub components such as development of regulations and standards for Pharmacies and Medicine Shops. Another sub component is the review and revision of the inspection and monitoring system of drug shops, which includes levels of inspection and related human resources, inspection tools and reporting. Effective implementation of these components will require sufficient resources.

Currently, inspection activities are not adequately carried out because DGDA does not have sufficient financial resources to effectively carry out routine inspection and monitoring of premises providing retail pharmaceutical services. Discussions with different stakeholders at central and district/upazila level have assisted in identifying areas which could potentially assist in resource mobilizations. The following recommendation aims at guiding DGDA on how it can improve in mobilizing resources to support its regulatory activities especially routine inspections and monitoring of drug outlets operations

**RECOMEDATIONS FOR RESOURCE MOBILIZATION TO SUPPORT INSPECTION ACTIVITIES UNDER THE BPMI PROJECT**

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| No. | Area | Current Situation | Recommendations For Improvement |
|  | Advocating for improving the Central Government budget for DGDA to support regulation and operations of retail drug outlets | DGDA is a central government regulatory directorate that falls directly under the Ministry of Health and Family Welfare. The regulatory body therefore receives annual budgetary allocations from the Ministry of Finance (treasury) to support its regulatory, administrative activities and human resource. Although DGDA prepares budget based on the needs of the organization, it is often not possible for the government to provide sufficient financial resources due to other equally important commitments. In this case, DGDA has to do with a limited budget and therefore cannot cover all activities that are needed for an effective regulation. In such situation routine inspection and monitoring activities are likely to be the ones more affected. | 1. The proposed new DGDA Pharmacy/Medicine Shops wing to start developing a comprehensive annual budget for management of private retail pharmaceutical services which includes inspection and monitoring and licensing of Pharmacies, AMS and other drug outlets. 2. Use this budget to lobby for increased central government annual financial allocation to support inspection/monitoring activities. |
|  | Advocating for inclusion of inspection and monitoring of AMS/Pharmacies to Upazila and District health budgets | Although the 1989 memo from MOHFW provided for responsibilities of District Drug Licensing Committee and Task forces at District and Upazila, the committees and task forces did not seem to be functional in almost all districts. The proposed BPMI review and strengthening of district and upazila committees will require additional budget to allow for functioning of the committees | 1. Closely work with the MOHFW through DGHS to accept integration of inspection/monitoring activities within the District/Upazila health budgets. This approach would reduce DGDA central budget to include only audit and special inspections by superintendents and central inspectors. 2. It is proposed that the DGDA and District budgets could come from different sources of funds such as:    1. GOB revenue budget    2. City Corporation budget    3. DGDA budget support    4. Annual operation plans    5. Donors support |
|  | Review of Pharmacies and Medicine shops fees for possible adjustment | The fees charged for registration and licensing of retail drug outlets are still seen by experts to be very low compared to what is charged in other developing countries with even less developed pharmaceutical sector and general economy of the country. The fees although seen to be low, they are also paid in every two years making the payment period too long for the owners not give it priority and sometimes they end up forgetting to make the payments. | It is suggested that registration and license renewal fees rates should be reviewed in order to increase them to a reasonable level that goes in line with the efforts to ensure that the fees collected can substantially contribute to costs associated with inspections and monitoring activities |
|  | Improve fees collection from Pharmacies, AMS and other licensed retail outlets | Bangladesh has a relatively large number of registered and unregistered drug outlets that provide pharmaceutical retail services at community level. Even among those registered by the authority not all drug outlets pay the annual fees as required by law.  If collection of fees is carefully planned and strictly monitored, it can be a huge financial resource to support regulatory activities. | 1. Set up an inspection plan to ensure that every drug outlet that operates is registered by DGDA and registration and license renewal fees are paid. Options to enforce this include;    1. Prepare a comprehensive routine inspection plan under the newly proposed pharmacy/AMS wing at DGDA    2. Collaborate with BCDS to encourage its members on payment of license renewal fees.    3. Increase inspection visits through district and upazila committees    4. Explore on other fees payment methods such as use of mobile money payments mechanisms 2. Contrary to the current practice where permit fees are paid biannually, it is proposed that all drug outlets should pay their fees annually in order to improve the collection and make owners feel responsible for fees payment. |
|  | DGDA to impose direct fines and penalties and utilize the funds to support inspection and monitoring activities | Regulatory bodies in other countries have developed their own fines and penalties’ rates for different offences or violations that are directly collected by the authorities themselves and returned for use within the organization. Besides what is in the law, rules or Orders in terms of fines and penalties, DGDA does not have a guideline that clearly regulates rates of fines and or penalties, but depends fully on the outcome of proceedings conducted by mobile courts and other court case. | 1. DGDA should first develop or regulate fines and penalties and then look for possibilities of being permitted by the Government to retain and use the collections. |