Republic of Liberia Ministry of Health and Social Welfare

Liberia Medicines and Health Products Regulatory Authority

ACCREDITED MEDICINE STORES (AMS) INSPECTION STRATEGY: OPTIONS AND RECOMMENDATIONS

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A.T.C Building, Opposite J-mart Furniture & Showroom
Randall Street, Monrovia

Contents

Acronyms and Abbreviations

AMS	Accredited Medicine Stores
LMHRA	Liberia Medicines and Health Products Regulatory Authority
PAL	Pharmaceutical Association of Liberia
MSH	Management Sciences for Health
PBL	Pharmacy Board of Liberia
SDSI	Sustainable Drug Seller Initiatives
SWOC	strength, weakness, opportunities, and challenges
TOT	trainer of trainers

Executive Summary

Medicine regulation is needed to ensure that all pharmaceutical products on the market are safe, effective, and consistently meet approved quality standards. An effective inspection and enforcement system is an essential part of any medicine control program. This Accredited Medicine Stores (AMS) inspection strategy provides short- to long-term options and recommendation for development of the inspection and enforcement system in Liberia with a focus on the AMS.

The strength, weakness, opportunities, and challenges (SWOC) analysis has revealed the pharmaceutical regulatory SWOC that have faced the Pharmacy Board of Liberia (PBL) for decades in promoting and protecting public health against hazards which may have resulted from the use of medicines of unacceptable quality specifications.

The Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010 (LMHRA Act) established the Liberia Medicines and Health Products Regulatory Authority to provide comprehensive regulation of all matters related to safety and quality of medicines and health products. However, the control of medicines in retail businesses, such as AMS, remains under control of the PBL, which still has very weak regulatory and enforcement capacity.

This inspection strategy provides strategic options for the six key result areas, namely—

1. Strengthening the PBL
2. Widening the pharmaceutical cadre base
3. Building a strong AMS pharmaceutical inspection system
4. Fostering collaboration with the LMHRA
5. Improving public and provider awareness
6. Building a monitoring and evaluation (M&E) system

The options analysis also highlights participation from key stakeholders required for the effective implementation of the strategic options. This report documents the first step in developing a more comprehensive inspection strategy that would address PBL challenges. The identified key intervention areas and the strategic options to be used could facilitate achievement of the objectives set in the short and long terms.

Although a clear mandate divides responsibilities between the LMHRA and the PBL, because of the situation the PBL faces currently in terms of constrained human and financial resources and an outdated enabling act, the LMHRA will have to take a leading role in setting a strong legal framework—that may later benefit a restructured PBL.

Chapter 1: Background

The Liberian National Drug Policy calls for the establishment of an effective regulatory body for the pharmaceutical sector that includes building a strong inspectorate system. Until recently, the PBL was the sole body responsible for regulating products, services, and practices. The 2010 LMHRA Act, followed by establishment of the LMHRA in 2010, changed the situation. The LMHRA Act defines the mandate of the regulatory authority to regulate products, imports, and exports, including bulk distribution. The PBL, whose enabling act has not yet been reviewed, remains charged with the regulation of most services and professional practices within the pharmaceutical retail sector.

Nevertheless, a rapid situational analysis conducted as part of the Sustainable Drug Seller Initiatives (SDSI)/Liberia program found that within the current structure, the PBL has no capacity to effectively implement its mandate because of limited human and financial resources. Moreover, stakeholders including the LMHRA feel strongly that a poorly performing PBL will make the situation very difficult for any regulatory body to function effectively. For an effective regulatory system, both bodies should work collaboratively to attain the desired goals.

In the bid to rectify the regulatory system, the LMHRA, in collaboration with Management Sciences for Health (MSH) under the SDSI project, will initiate a new system for the operation of medicines stores in Liberia. The new system requires all medicine stores currently existing and those in the future to meet minimum operational requirements and standards before being registered and allowed to provide retail services at community level. The newly approved medicine store will be accredited by the responsible authority and will be known as an *Accredited Medicine Store* (AMS).

During the pharmaceutical assessment carried out by the government in collaboration with MSH, a very high level of violations was found by all those providing services through medicine stores. Inspections have never been effective and result oriented. Lack of an effective inspectorate system under the PBL was seen as the core reason for the observed high level of violations. Therefore, the government keenly recognizes that an effective regulatory system can be achieved only if a strong inspectorate system for the AMS is put in place and made functional.

With that objective in mind, in August 2012, MSH, through the SDSI project in Liberia, engaged Apotheker Consultancy (T) Ltd to develop a short-term strategy for an AMS inspectorate system. This strategy is embodied in a proposal to the LMHRA and the PBL upon which they will be able to construct and put in place an effective inspectorate system for this huge retail sector. A special inspectors' training manual has also been developed to facilitate training of local inspectors to support the inspection system for the AMS.

Chapter 2: Situational Analysis of the Regulatory System

The situational analysis previously carried out by various stakeholders identified key pertinent issues with respect to the status of Liberia's pharmaceutical regulatory system. The situational analysis identified various areas of strength, weakness, opportunities, and challenges for the regulatory system.

2.1 Strengths

As previously noted, the strength of the two bodies varies significantly. Whereas the PBL has little strength to effectively carry out inspectorate activity to control operations under the AMS in the whole of Liberia, the LMHRA, though newly established, has some strengths that would allow it to implement or fully support the PBL in implementing this strategy. Among the few strengths of the PBL identified are the following—

Presence of an Experienced Senior Pharmacist, the Registrar of the PBL

The current PBL Registrar is a government senior civil servant and a pharmacy graduate with many years of service within the pharmaceutical sector. He fully recognises the challenges and weaknesses facing the sector. If the capacity of the PBL could be improved, the experience of the registrar could be used to improve control of the AMS through an inspectorate team under the PBL.

Composition of PBL Membership

During the visit to Liberia, the consultants met with the chairman of the PBL and other members at a joint meeting with the newly formed LMHRA. The PBL has competent and experienced pharmacy professionals and other related professionals. Given the necessary resources to build capacity, the current PBL members can effectively manage and improve the performance of the PBL secretariat.

LMHRA Enactment and Its Subsequent Establishment

Enactment of the law that clearly spells out the division of the legal mandate between the LMHRA and the PBL, followed by establishment of the LMHRA within the government budget is a remarkable strength that any established inspectorate system can rely upon. With the new act in force, the LMHRA has a potential to attract more resources outside the government, especially from international bodies and development partners. The support could be both technical and financial and directed to regulatory strengthening.

Availability of LMHRA Organizational and Operational Structure

An effective regulatory system that will include the inspectorate system will depend on the organizational and operational status of the responsible body. Because the PBL currently lacks an effective inspectorate and regulatory system, one can reasonably assume that while things are being rectified at that level for the PBL to become fully functional, the LMHRA can

head and directly support the implementation of this strategy. However, because the law gives the mandate for inspection of retail services to the PBL, its full participation in setting up the inspectorate and in its joint implementation will be necessary.

2.2 Weaknesses

Lack of Effective Organizational and Operational Structure

The PBL has no effective organizational and operational structure. It has only one pharmacist, the Registrar of the PBL, and its few staff members are not trained in pharmacy. The consultancy team was not able to see an organizational chart, which means everything falls under a single person. Lack of organizational structure leads to the absence of operational structure; consequently no department or independent section deals with inspectorate. The Registrar engages and directly supervises all inspectors. Medicines, practices, and professional control are complex responsibilities needing a well-organized professional body. The current organizational and operational status of the PBL cannot perform this mandate effectively unless measures are taken to rectify the existing situation.

Inadequate Institutional Expertise Both in Terms of Sufficient Numbers and Appropriate Technical Skills

The PBL has only one technical person, the Registrar of the Board; the rest of the staff has no training in pharmacy. This situation makes the PBL unable to effectively carry out its legal mandate. The PBL has a vital responsibility to control the practice and services offered by the pharmaceutical retail sector. For an AMS inspectorate unit under this body to perform effectively, this area will have to be addressed quickly.

Weak and Outdated Pharmacy Board Act

The Liberian Pharmacy Board Act is old and has never been revised to address current pharmaceutical regulatory requirements, especially since the enactment of the LMHRA Act and subsequent establishment of the LMHRA. Establishment of the LMHRA removes some of the PBL's vital mandate. These changes are clear in the LMHRA Act but not in the corresponding unrevised Pharmacy Board Act. This situation creates confusion in the area of inspection because one body is responsible for products being distributed and another for seeing that services provided meet professional standards. For this reason, technical staff will have to meet in the same premises to carry out joint inspections. Absence of clear a mandate may bring unnecessary conflict and may cause public confusion on the roles of the two organizations. This weakness needs to be addressed as soon as possible.

Inadequate Financial Resources

Currently, the PBL is working with very constrained financial resources. Lack of a proper system for collection of fees limits the PBL's ability to effectively collect revenue. It does not receive budgetary support from the government budget other than the salary of the registrar. Absence of reliable financial resources is one of the reasons for the PBL's low performance.

Wide Deficiency of Trained Pharmacists or Other Pharmaceutical Cadre

Liberia has only a single pharmacy professional school graduating a few pharmacists each year. Furthermore, the Liberian education system takes too long for a pharmacist to qualify because entry requires a pharmacy candidate to have pursued a full science degree before joining the pharmacy school. This makes studying pharmacy take longer than any other training in the country. Such time-consuming training does not motivate many to take this course, especially when no special remuneration attaches to it once one has fully qualified. A long training period with only one school available contributes to the low numbers of pharmacy professionals in the country. Deficiency in this cadre has a long-term impact on the performance of the two bodies, especially in areas of professional control of medicines and practices. This weakness needs to be addressed in both long-term and short-term strategies.

Inadequate Public Awareness on the Remaining Roles of the PBL

When the consultancy team visited Monrovia and made visits to the various types of outlets, providers complained about the lack of clarity on which body is responsible for which issue when all were formerly under the PBL. The public's absence of clarity may create difficulties for inspectors from the LMHRA or the PBL. This weakness will need to be addressed.

2.3 Opportunities

Enactment of the LMHRA Act

In 2010, the Liberian government enacted the LMHRA Act, followed by establishment of the LMHRA. Establishment of this new body will lead to an improved regulatory system. Because the new authority's key mandates include control of imports, regulation of manufacturing, registration of products in the Liberian market, and an overall mandate over importers and major distributors, the PBL is left with the mandate to control provision of services and professional practice in pharmaceutical retailing. The PBL is still weak and has limited resources, so reducing the range of its mandate in favor of the LMHRA could lead to the PBL being more efficient and effective in its limited new mandates. The new LMHRA brings a new direction in the medicines and health products regulatory system. The situation provides the PBL a close and reliable partner with similar end goals and objectives: provision of safe, high-quality medicines, health products, and services.

Capacity of Inspectorate Staff and Joint Inspections with LMHRA; Use of Minilab

An effective inspectorate system must be supported by an equally effective and competent inspectorate team and efficient laboratory services. The PBL currently has no capacity to carry out inspectorate activity effectively, and there is no laboratory facility to support the inspectorate system. The newly established LMHRA has started to build capacity in inspectorate and laboratory areas by providing specific training to its staff. The resulting

capacity within the authority can be used to support the PBL inspectorate team if the latter participates in joint inspections as an on-the-job training process to improve the performance of the PBL inspectorate teams.

Realizing the low capacity that the current PBL has in terms of skilled human resources, organization, and operations, the newly established LMHRA has initiated a program that allows inspectors from the authority to carry out joint inspectorate activity with PBL inspectors. Because the PBL uses non-pharmacists who are oriented to carry out only limited inspections, their participation in the LMHRA's inspection activities could improve skills within the PBL.

The LMHRA should plan to deploy the use of Minilab as the first-tier system for product quality testing and borrow from experiences of several African regulatory agencies.

Political Commitment to Support Medicine Regulation Demonstrated by LMHRA Act Enactment

The political stakeholders have realized the importance of dividing the mandate between the PBL, which had the entire mandate related to medicine control but no capacity, and the newly formed LMHRA, which takes over major mandate areas related to medicine control. This situation provides an opportunity for the PBL to concentrate its effort on control of the pharmaceutical retail sector. If fundamental restructuring and reorganizational changes are made in the PBL, followed by the establishment of a strong inspectorate team, the PBL should be in a position to control the retail sector effectively. However, because realization of this restructuring may take some time and the situation calls for an immediate intervention, the LMHRA should take the lead but closely collaborate with PBL to implement this inspection strategy.

The legislators will need to review the very old Pharmacy Board Act that is now totally out of date because of the new LMHRA Act. Revision of the Pharmacy Board Act will allow clear and transparent lines of responsibility and a joint and collaborative relationship between the two bodies.

Strong Support from the MoHSW Chief Pharmacist Who Recognizes That a Weak PBL Will Affect the Performance of the Newly Established LMHRA

The Chief Pharmacist of Liberia well understands that without strong support to the PBL, the efforts made to establish the LMHRA will not bring significant improvement in regulating the pharmaceutical sector. He realizes that an effective and functional PBL is equally important for a fully effective and performing new LMHRA. He has shown high interest and continuously lobbies with the Ministry of Health and Social Welfare (MoHSW) to increase support to the PBL in terms of finances and human resources. If the ministry fully supports the PBL, its performance will be improved and it will be able to effectively carry out its mandate of control of the pharmaceutical retail sector. The Chief Pharmacist also sees the need to revise the old Pharmacy Board Act to be in line with the changes caused by the newly established LMHRA. "Review of the PB Act will make division of mandate between the

two bodies very clear, bringing efficiency and identifying areas of joint performance," he emphasized.

Potential for Collaboration with the LMHRA to Enhance Medicine Control Activities

The new management of the LMHRA sees the PBL as a close collaborative partner that if left to become ineffective will result in a failure to perform for both entities. The LMHRA therefore is determined to work closely with the PBL and support it technically. The fact that the authority holds joint meetings with the two boards and joint inspectorate activities is a clear indication of support to the PBL. If the PBL seizes this opportunity, it will improve its performance in controlling the sector under its mandate.

Key Stakeholder Recognition of the Importance of Having a Functional PBL to Control Pharmacy Practice and Services

A functional pharmacy board is a symbol of the presence of the pharmacy profession in any country; it is therefore very likely that the first group of stakeholders that will support the PBL is the pharmacy profession, represented by the pharmacists. Therefore, the PBL is expected to receive support from this group that would like to see that the PBL effectively performs to preserve the profession's values. Other key supporters are similar bodies and associations within and outside the region that would like to see the PBL performing to preserve the traditional professional competence of the pharmacy profession in providing retail services to the community. With clear development goals set, the PBL is likely to get needed support to strengthen its control mandate over the retail sector.

2.4 Challenges

The Potential for the PBL to Lose Its Significance in the Presence of an Increasingly Well-Organized and Functional LMHRA

Establishment of the LMHRA takes over a number of vital legal mandates that may prompt the government to decide to do away with the PBL since the presence of two bodies in the same functional area could create confusion to the public and between the bodies' technical staff. Furthermore, the PBL has been very ineffective for a long time, leading to the current difficult situation. Why should the MoHSW continue to let the PBL exist, especially if the new LMHRA shows excellent performance in contrast to the PBL? In terms of financial support, from this perspective the government may think financing the PBL could be seen as a waste of its meagre financial and technical resources. Perhaps the government would rather strengthen one authority to do all that is needed.

Wide and Open Sale of Pharmaceuticals at Unregulated Premises and Places (Open-Market Sale)

During the consultancy visit in Monrovia, the team was able to make short visits to different categories of premises providing pharmaceutical services. The impression was that although several premises provide legally sanctioned services, huge numbers of outlets provide

services in violation of the law. Lack of adherence to legal requirements and practice standards in the sector has proliferated into openly selling prescription medicines in open marketplaces. Because this has been happening for a long time, the public and those providing such services take this situation as normal and a right, which would lead to high resistance if they are obliged to abandon these types of practices.

Thus, when this strategy is implemented, the LMHRA and the PBL will sometimes need to use police force and take legal actions against serious violators. Such action in an environment where the community does not see the difference between good and bad may lead the community to join forces with the violators and create political turbulence, thus making implementation of the inspection strategy very difficult.

High resistance should be anticipated from the violating providers because their business environment is going to be highly controlled by law enforcers, followed by frequent punitive legal actions. The ignorant community that is not aware of rational and correct medicine use and the importance of effective legal control of pharmaceutical services may support the violators. If these two groups are not correctly prepared for the proposed changes, they form a very strong negative force against implementation of this strategy.

Tendency of Some Stakeholders or Business Interests to View the Parallel Existence of the PBL and a Strong LMHRA as Additional Bureaucratic Bottlenecks Affecting Their Way of Doing Business

Most of those doing business in the pharmaceutical sector were used to working with the PBL, which was weak in terms of enforcement. The situation benefited this group. Moreover, they had one stop to finalize their business-related issues, contrary to the current situation where two bodies share legal authority. Finally, because a weak regulatory system has existed for a long time, some officials may have been benefiting taking advantage to secure personal gains but to the detriment of the legal system. They all form a force against making any significant changes that they know would take away previous advantages they were enjoying under the poorly controlled system.

Failure to Revise the Pharmacy Board Act to Address the Current Situation on the Ground and to Delineate PBL and LMHRA Responsibilities

One should see that failure to revise the Pharmacy Board Act to be in line with the LMHRA Act may lead to difficulties in implementing the roles of the two bodies. Currently the danger is not very obvious because the Acting Managing Director and Chair of the LMHRA is a very influential person widely respected in Liberia by all in the administrative and political level. This situation is unlikely to continue when the two acts do not strictly delineate the roles and responsibilities for each of the two bodies. It is therefore very important that this happen as soon as possible so the large influence of the current LMHRA chair can be exploited to build a system that is clear in mandate. If this action is delayed, implementation of this strategy may be seriously affected.

Chapter 3: Strategies for the Future: Emerging Themes and Options

The following important six themes emerge from the environmental SWOC analysis carried out in the previous chapter. This chapter discusses various strategic options in the context of these emerging themes and provides some insights on the way forward to successful establishment and effective operationalization of the AMS inspection strategy. The six key themes are as follows—

1. Strengthening the organizational and operational capacity of the Pharmacy Board
2. Broadening the base of the pharmaceutical cadre to carry out professional responsibilities
3. Building a stronger pharmaceutical inspectorate system
4. Fostering stronger collaboration between the LMHRA and the PBL
5. Improving public awareness on correct medicine use and control of medicines for the public benefit
6. Building a strong M&E system

3.1 Strategic Options

KEY RESULT AREA 1: Strengthening the PBL

1.1 Revision or enactment of a new Pharmacy Board Act

The enactment of the LMHRA Act has made the existing Pharmacy Board Act largely redundant and brings confusion to all administrators, to technical staff, and worst of all to the public. Carrying out this activity as soon as possible is therefore important.

1.2 Provision of direct government financial and technical support to the PBL

Besides the salary of the Pharmacy Board Registrar, the PBL is not currently receiving any other financial or technical support from the central government. This situation has left the PBL dependent on fee collections from registered premises, which is not enough to warrant employment of professional pharmacists to work at the PBL. In turn, the PBL has resorted to using non-pharmaceutical cadres to carry out vital inspectorate functions, which results in poor performance of the whole inspection system and high violation of pharmaceutical law. Government resource support is key to the future strengthening of the PBL's functionality.

1.3 Reorganization and operationalization of the PBL

Currently the PBL has no clear organizational and operational structure. This situation makes a single person responsible for everything, lacks transparency, and creates mistrust in the system. A functional PBL and subsequently an inspectorate system will mainly depend on the existence of a clear management structure and transparent and clear division of labour and responsibilities. Working staff need to know their terms of reference, employment, and benefits within the organizational structure but not depending on a single individual's likes or dislikes. With the implementation of item 1.2 key result area, this key result area should be able to be implemented as well.

KEY RESULT AREA 2: Broadening the pharmaceutical cadre base

2.1 Strengthening the current PAL short course

Currently the Pharmaceutical Association of Liberia (PAL) provides a short training course for lower pharmaceutical cadres—the dispensers. This course has one major objective: to create a cadre that will eventually work in the pharmaceutical retail system to reduce the acute shortage of professional pharmacists in the market. Nevertheless, the expansion of this course to take more candidates per year with a higher yield every year has been slow and has not happened at the rate that it should have. The authorities should attach special interest to the development and recognition of this course and its cadres because they will be key players for a long time to come for improving the functionality and control of services of the pharmaceutical sector. Therefore strengthening this course and other related courses is important for achieving this strategy's objectives.

2.2 Introducing an integrated course for primary AMS inspectors within the PAL dispensers' course

An acute shortage exists in the market of pharmaceutical professional graduates who could be employed as full-time AMS inspectors. But a substantial number of professional pharmacists need to be employed as on-the-job inspectors' trainers or trainers of trainers (TOTs) for the same and to head various inspectorate units at various county levels. The well-oriented and trained trainees from the University of Liberia School of Pharmacy would form the core of inspectorate teams to be established under the headship of trained pharmacists in different counties.

2.3 Training professional pharmacists as inspection experts

Each year the University of Liberia School of Pharmacy produces a few pharmacy graduates that feed into the market but not enough to meet the market needs. These pharmacists are needed in the public sector as well as in the private. The government with limited financial resources and many obligations to cover is not competitive enough compared with the private sector. With better remuneration offered, more pharmacists are likely to join the private sector, leaving very few available for the public. With such limited numbers and the need to provide attractive

remuneration, the best approach is to employ a few in key positions to support those with lesser skills and knowledge working under them. Therefore, these few pharmacists need to be competent in areas of inspection systems so they can continuously provide on-the-job training to their subordinates. A special training course is therefore needed for inspectors who could then be used to form a core team of TOTs for the country on inspectorate issues and systems. This may be a long-term approach, but it could also be taken as a short-term approach because in any case the LMHRA will employ qualified pharmacists and with support from development partners a few of them can be trained to form core TOTs for other inspectors with less professional training.

KEY RESULT AREA 3: Building a strong AMS pharmaceutical inspectorate system

3.1 Employing core professional pharmacists

Currently the market availability of professional pharmacists is experiencing a very acute shortage; nevertheless, a strong inspectorate system cannot be built without full involvement of pharmaceutical professionals. Employing professional pharmacists widely as routine inspectors is not currently possible. Nevertheless, pharmacists can be employed as key technical staff to head inspectorate systems and units established. The units can then be filled with pharmaceutical trainees of lower cadres. Core professional pharmacists will act as supervisors of several such units in their counties and continuously carry out on-the-job training to sharpen subordinates' skills and knowledge in inspection issues.

3.2 Employing pharmaceutical cadres of lower level

The consultants recommend using the graduates from the Liberia Dispensers School with additional basic training in pharmaceutical inspection. A short training curriculum could be added to the current dispensers' course so some of them can be engaged to take up inspection activities as employees of the PBL and maybe the LMHRA. The basic knowledge received during the course can be expanded and strengthened through on-job-training provided by their competent supervisors who should be professional pharmacists.

3.3 Establishing an inspection and supervision system beyond Montserrado County

One of the weakest structures that the consultancy team noted is the non-existence of a reliable system to support inspection activities or system in the counties other than Montserrado County in which Monrovia is located. Unavailability of an inspectorate system at each county level is the great weakness of the regulatory system. Liberia has about 15 counties all providing private retail services, but no effective inspection system exists. The strategy needs to address this gap as a priority undertaking.

KEY RESULT AREA 4: Fostering closer collaboration with LMHRA

4.1 Planning for joint inspection

It is encouraging that even before the development of this strategy, the LMHRA and the PBL have already on their own initiative started to carry out joint inspections and progress review meetings. The joint inspection collaboration is key for two main reasons: First, the PBL is weak and uses only nonpharmaceutical staff who have with very little inspection knowledge and skills to carry out inspections. Thus, for years PBL inspection activities have been ineffective. Second, the LMHRA believes that it cannot perform to its expectations if the PBL is weak because the two regulatory bodies interact at some vital points, including the inspectorate system. The proposed strategy sees this collaboration as an important undertaking that should be strengthened.

4.2 **Planning for joint performance review and joint actions**

Carrying out joint inspections is one thing, but reviewing jointly the performance of each authority on issues agreed to be addressed by each authority or jointly is very important to make the joint operations meaningful. Reviews like this will provide indications of the need to take actions to improve identified weakness in performance. Making joint decisions on how and what action to take is a vital indication to the public and providers that the regulatory system acts as one strong team with joint objectives.

4.3 Conducting joint inspectors' training courses

The LMHRA has a stronger organizational and operational structure with an established department responsible for inspectorate system. All the inspectors in the department have substantial experience and are pharmacy graduates. If the PBL is going to jointly carry out training with the inspectors of the LMHRA, the non-pharmacy-trained inspectors of the PBL would benefit more and attain necessary skills and knowledge resulting into better performance.

KEY RESULT AREA 5: Improving public and providers' awareness

5.1 Setting sensitization and advocacy strategy to improve awareness

Liberia is currently experiencing great problem in terms of very little or no public and provider awareness about rational medicine use and a regulatory system that controls provision of medicines and pharmaceutical services as a whole. If the PBL or the LMHRA institutes a strict regulatory system without improving public and provider awareness, that action is likely to face stiff resistance from the ignorant public and providers. The two groups could form a strong opposition to any justifiable legal action taken by both authorities. Therefore addressing the issue of public and provider awareness of issues related to correct medicine use and reasons for the actions about to be taken is important for the strategy to properly regulate the pharmaceutical system. A strong public campaign and providers' involvement in key steps being taken need to be included as part of a strategy for an effective result-oriented inspectorate system.

KEY RESULT AREA 6: Building a monitoring and evaluation system

6.1 Developing M&E indicators

To measure the success of this strategy, a comprehensive M&E system should be established. For monitoring to be effective, indicators to monitor should be identified beforehand. These indicators will be built into the M&E system to measure performance of the inspectorate system. The intervention then can be evaluated periodically to allow the authorities to take necessary action if rectifications are necessary.

6.2 Instituting and managing an M&E system

Based on the current status, it should be jointly agreed that LMHRA should house the system while each participating body such as the PBL can establish indicators that it would like to follow and evaluate from time to time. The LMHRA should also set up a system whereby periodic joint system review meetings are held to discuss findings and observations and to plan relevant actions to be executed by each responsible body.

3.2 Stakeholder Participation

The nature of the strategic option is diverse and therefore broad-based stakeholder participation will be necessary for effective implementation of the strategies. The following table highlights potential responsible stakeholders for implementation of different strategic options.

Stakeholder Participation Analysis

Strategic option	Responsible stakeholder
KEY RESULT AREA 1: Strengthening the PBL	
1.1 Revision or enactment of a new Pharmacy Board Act	PBL; LMHRA; Office of the Chief Pharmacist; PAL; development partners
1.2 Provision of direct government financial and technical support to PBL	MoHSW; LMHRA; PBL; PAL; development artners
1.3 Re-organization and operationalization of the PBL	MoHSW; task force (LMHRA; Ministry of Finance; ministry responsible for public services, PAL, and technical adviser)
KEY RESULT AREA 2: Broadening the pharmaceutical cadre base	
2.1 Strengthening the current PAL short course	Liberia Dispensers School; PBL; MoHSW; LMHRA; development partners
2.2 Introducing integrated course for primary AMS inspectors within the PAL dispensers' course	PBL; PAL school; LMHRA; MoHSW; development partners
2.3 Training professional pharmacists as inspection experts	LMHRA; PBL; development partners
KEY RESULT AREA 3: Building a strong AMS inspectorate system	
3.1 Employing core professional pharmacists	LMHRA; PBL; development partners
3.2 Employing lower-level pharmaceutical cadres	LMHRA; PBL; PAL school; development partners
3.3 Establishing a strong supervision system	LMHRA; PBL; development partners
KEY RESULT AREA 4: Fostering closer collaboration	
4.1 Planning for joint inspection	LMHRA; PBL; development partners
4.2 Planning for joint performance review	LMHRA; PBL; development partners
4.3 Conducting joint inspectors' training courses	LMHRA; PBL; development partners

Strategic option	Responsible stakeholder
KEY RESULT AREA 5: Improving public and providers' awareness	
5.1 Setting sensitization and advocacy strategy to improve awareness	LMHRA; PBL; consumers' associations; community activists; public and private media; development partners
KEY RESULT AREA 6: Building a monitoring and evaluation system	
6.1 Developing M&E indicators	LMHRA; PBL; stakeholders
6.2 Instituting and managing the M&E system	LMHRA; PBL; stakeholders

Conclusion

The trip to Liberia was a very useful undertaking as it gave the consultants the opportunity to understand the situation on the ground, got the feelings of different stakeholders and their desires towards improving the regulatory system of the pharmaceutical sector. This short situation analysis, options and recommendations done in this document has identified strengths, weaknesses, challenges and opportunities that the pharmaceutical sector and system in Liberia has. It provides a guide on the possible direction that the LMHRA and the PBL may take as interventions towards improved regulatory system especially for the AMS in Liberia.

Furthermore, the document points out available opportunities such as readiness of the government and political will to support and build a strong and effective LMHRA, strong support from international development partners that are ready to work with the new LMHRA to strengthen its regulatory capability by building necessary regulatory systems and a strong and influential chair that is determined to build a strong regulatory authority. Other opportunities that the LMHRA may at once grasp to address inspection challenges are the strong legal mandate given by the new LMHRA legal framework and the ongoing accreditation process of drug outlets which seems to be widely accepted by the service providers. Accreditation is a key strategy towards controlling and regulating the pharmaceutical retail services in the country which are currently poorly managed and controlled.

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