HERA

HEALTH RESEARCH FOR ACTION

Development of the preferred PSM system for medical supply

Sierra Leone

Final Study Report

14/09/2010

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Consultant team

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The consultants would like to thank everyone we interviewed for the frank sharing of information as well as those that allowed us to search their document archives to access past and historical information.

During the June PSM options workshop the active participation of all stakeholders and individuals provided the additional insight and information that allowed us to develop this document.

List of abbreviations and acronyms

AfDB	African Development Bank
APPSA	Autonomous Pharmaceutical Procurement and Supply Agency
BOE	Bill of Entry
BPEHS	Basic Package of Essential Health Services
CHC	Community Health Center
CHO	Community Health Officer
CHP	Community Health Post
CMS	Central Medical Stores
CRS	Catholic Relief Services
DDMS	Department of Drugs and Medical Supplies
DMS	District Medical Stores
DHMT	District Health Management Team
DPI	Directorate of Planning and Information
EMLSL	Essential Medicines List of Sierra Leone
EU	European Union
EoS	Economies of Scale
FA	Fiduciary Agency
FHCI	Free Health Care Initiative
GFATM	Global Fund for the fight against Aids, Tuberculosis and Malaria
GoSL	Government of Sierra Leone
HPCC	Health Policy Coordination Committee
HR	Human Resources
INGO	International non-governmental organization
IO	International Organisation
LMIS	Logistics Management Information System
MOFED	Ministry of Finance and Economic Development
MOHS	Ministry of Health and Sanitation
NGO	Non-governmental organization
NMC	National Medicines Committee
NMP	National Medicines Policy
NPMP	National Pharmaceutical Master Plan
NPPA	National Public Procurement Authority
NPPU	National Pharmaceutical Procurement Unit
NRA	National Revenue Authority
PBSL	Pharmacy Board of Sierra Leone
PHC	Primary Health Care
PHU	Peripheral Health Unit
PMF	Pooled Medicines Fund
PPP	Public-private partnership
MRA	Medicines Registration Authority
SA	Statutory Authority
SL	Sierra Leone
TOR	Terms of Reference
QA/QC	Quality Assurance / Quality Control

UNICEF	United Nations Children‘s Fund
UNFPA	United Nations Family Planning Assocation
USD	United States Dollars
USP	United States Pharmacopeia
WHO	World Health Organization

Summary

This report is the final study report "Development of the preferred Procurement and Supply Management (PSM) system for essential medical supply" in Sierra Leone.

It describes the PSM system and its elements to some detail and it proposes a work plan with timelines and resources needed to develop the PSM system.

The corner stone of the PSM system is an autonomous pharmaceutical procurement and supply agency (which we have named APPSA for the purpose of this document). The creation of this agency depends on the government of Sierra Leone. It is essential to the development of the PSM system.

A firm will be contracted for a period of three years to support APPSA. The firm will also supply three technical assistants of which one will be the general manager and the other two will manage a department within APPSA.

The firm will also supply short-term technical assistance to APPSA, to the district medical stores and to the MOHS where and when necessary.

It is assumed however, that the currently active stakeholders in health (UNICEF, UNFPA, WHO and others) will continue and reinforce their technical assistance at district level and at national level with the MOHS and the health regulatory environment.

1 Introduction

The current document is the output of the Procurement and Supply Management (PSM) mission that started with a three-week visit in Sierra Leone in April 2010 and continued in June with a PSM options workshop in Freetown.

The aim of this document is to give a detailed description of the PSM system that has been agreed upon, a strategic approach to its implementation, a description of the various configurations and responsibilities of the stakeholders, outline a work plan with timelines and resources, present a realistic project budget and include outlines of a number of APPSA tools.[1,2] A projection of the APPSA accounts has also been included.

The objective is to have an operational PSM system which is able “To ensure that sufficient quantities of essential medicines and medical supplies of the required quality, safety and efficacy are available, accessible and affordable to the majority of the people” as described in the "The National Medicines Policy of Sierra Leone (NMP 2004)".

It is also paramount that the PSM system at national and district level are embedded in a sector wide National Essential Medicines Policy and Program (EMP). Although the development of an EMP is not part of the current terms of reference, many elements that are part of the EMP have been refered to, and described, in this document.

It is, however, recommended, that updating the EMP will be the next activity in the stakeholders' approach to reinforce the health sector.

[1] When the notion "stakeholders" is used, it refers to the MOHS and all development partners and often also including the districts. In fact, all organisations that have a "stake" in the particular issue addressed are referred to as "stakeholders".

[2] The PSM principles that were agreed upon in the June PSM workshop are presented in Annex 2 on page 84.

2 Strategic plan for the restructuring of the PSM system

2.1 Strategies

The strategies to restructure the Procurement and Supply Management (PSM) system focus around the creation of a statutory authority. The strategies are fivefold:

- To create of a statutory authority
- To ensure funding to support the statutory authority with sufficient financial and technical means to ensure proper procurement, storage and distribution up to local council level for an initial period of three years.
- To contract an external firm to supply the technical expertise necessary to develop and implement the tools and systems of the statutory authority through the use of long-term technical assistance with operational responsibility, targeted short-term technical assistance and various types of training.
- To develop a coordinated plan of action to reinforce local council level "ordering, storage and distribution" capacity:
    - Listing of priority actions and interventions per local council
    - Budgeting the priority interventions
    - Listing the stakeholders per local council and their interventions
    - Coordinating the interventions
    - Adding a formative auditor to each District Medical Stores (DMS) to ensure continuous support for the development and operation of the Logistical Management Information System (LMIS) and to ensure a continuous control of the documents that are produced by the DMS (ordering, receipt, storage, invoices, distribution and packing lists and aggregate reports).
- To reinforce the Pharmacy Board of Sierra Leone (PBSL) so that it can develop and maintain sufficient capacity and resources to effectively regulate and control the private and public pharmaceutical sector.

2.2 Policy and coordination: committees

The PSM policy has for a large part already been decided. The current document is a result of the policy to render the PSM independent from the Ministry of Health and Sanitation (MOHS). However, this process needs thorough and close coordination at

various levels. The main instrument for this coordination is a high-level committee. The following are committees that are recommended or exist already.

President's office: High-level steering committee

It is indispensable to have the support and if necessary, the intervention, of the highest level: the President's office. Currently, a High Level steering committee for the Free Health Care Initiative (FHCI) exists. This committee also covers the procurement and supply arrangements for the FHCI.

The state of affairs and the progress of the development of the APPSA and the implementation of the new PSM configuration and system should be a standard point on the agenda of the routine meetings of this committee. The main argument for this approach is that the supply of the FHCI products will eventually be the responsibility of APPSA and the DMS.

The managing director of APPSA can be asked to routinely report on the progress of the APPSA development and configuration. The proposed workplan can, in its final form, be the main instrument on the basis of which the APPSA managing director reports as it lists the main activities and gives clear time lines. A number of these activities can be defined as milestones.

In addition, the chair person of the Health Policy Coordination Committee (HPCC) will routinely report on the progress of the stakeholders to come to an integrated approach to district support. Once this approach has been agreed upon, the chair person will report on the progress of the agreed workplan which will include (i) the approach, (ii) which districts, (iii) which activities, (iv) who supports and/or funds, (v) progress on activities and other relevant information.

Alternative high-level steering committee

An alternative would be a Presidential Commission on Pharmaceutical Policy (PCPP), established by Law/Decree, coordinates the efforts for the development, monitoring and evaluation of the PSM development strategy and establishes action plans for all actors involved in the national pharmaceutical sector in order to ensure that the population have access to essential drugs of assured quality.

The PCPP is charged with advising the Minister of Health, developing guidelines for the National Essential Medicines Program and implementing the program.

The PCPP is chaired by the Director of the Ministry of Health and Sanitation (MOHS) and its members include representatives of the APPSA Board, the Pooled Medicines Fund, PBSL MOHS pharmaceutical department, hospitals, and the physician and pharmacist associations, development partners as UNICEF, WHO, UNFPA and others.

Ministry of Health and Sanitation: FHCI coordinating committee

Currently a FHCI coordinating committee exists at the MOHS. The consultants expect that this coordinating committee will eventually turn into an overall **Health policy coordination committee** (HPCC).

This committee has as main responsibilities the coordination of the core functions of the MOHS (policy formulation, standard setting, quality assurance, resource mobilisation, capacity development, technical support and others) with those of the different health interventions by the various stakeholders outside of the government. This intention has also been described in the National Health Sector Strategic Plan.

The HPCC should be an inclusive committee and open to all stakeholders that intervene formally in the health sector.

The HPCC will also routinely receive updates on the progress of the development of APPSA and the implementation of the district reinforcement plan. The managing director of APPSA and the chair of the PSM configuration coordination committee (as a HPCC sub-committee) will routinely report to the full committee during each of the regular meetings.

Logistics sub-committee

Currently, the logistics sub-committee discusses the logistical issues, including PSM, related to the FHCI. It reports to the FHCI coordination committee. Eventually, this committee may turn in to a **Pharmaceutical sector sub-committee**, which would cover all pharmaceutical related issues and would be a sub-committee to the Health policy coordinating or steering committee.

At the MOHS level, a representative committee will have to monitor the upcoming implementation of APPSA and the further development of the new PSM configuration. The question is whether the current FHCI committee should do this either in the plenary session or through the logistics sub-committee.

The consultants propose that for this purpose an ad hoc APPSA coordination committee is formed as soon as possible. This committee will report to the FHCI coordinating committee. Once APPSA has been formed, this committee will turn in the APPSA board.

Subsequently, the logistics sub-committee will assume the coordination of the development of APPSA and implementation of the district reinforcement plan and report to the overall coordinating committee. The general manager of APPSA will be a member of the logistics sub-committee. The director of the DDMS will chair the logistics sub-committee.

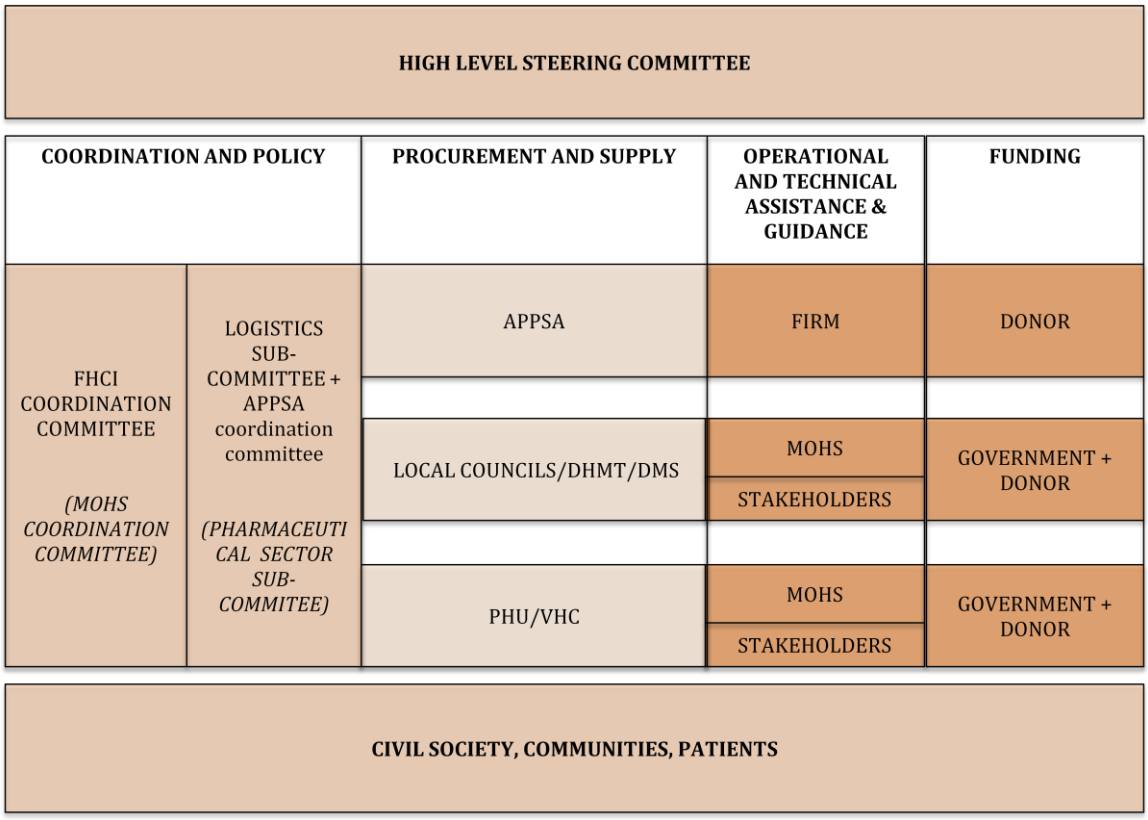
Once APPSA is operational and has started purchasing and distributing and a performance contract has been agreed upon between the MOHS and APPSA, the general manager will report on the progress of the operations in the logistics sub-committee using the indicators agreed in the contract. Eventually this may transform in the pharmaceutical sector sub-committee.

A "champion" should be appointed for the implementation or coordination of the district reinforcement plan. This champion reports on progress in the logistics sub-committee. The champion can be the newly configured DDMS.

A pharmaceutical sector sub-committee would not only be the appropriate forum to monitor APPSA operations. It would also be coordinating the execution of the National Medicines Policy (NMP) and it would be the policy coordinating contact for the PBSL. This committee could have an ad hoc Special Medicines Committee that evaluates requests for the funding of purchase of medicines that are not in the EML and the Treatment Guidelines.

In the next figure, the national level committees have been extended to cover the entire PSM chain up to and including the Peripheral Health Unit (PHU) level. This in no way implies that these committees take over any responsibility from local council or community level committees. It does imply that the national level MOHS core functions of policy formulation, standards setting and quality assurance do extend all way through the PSM chain without taking operational responsibility.

Figure 2-1: Policy, coordination, assistance, guidance and funding configuration



2.3 The development partners

The development partners will play an important role in the health sector development through their investments in inputs and technical assistants. In addition, it is important that they are active members of the HPCC and its sub-committees. The development partners are part and parcel of the coordinating and monitoring mechanisms.

In the past the European Union has invested heavily in an integrated development of the PSM system, in physical infrastructure as well as in systems at national level (construction of warehouse and PBSL office and laboratory, statutes NPPU for example) as at district level (construction of district medical stores).

Other organisations like the WFP and various NGOs have also invested in the development of the PSM system, since the end of the war, at national, district and PHU level, through capacity development and other investments. This wide development partners support is continuing at various levels by various organisations (for example GFATM through vertical programs, GAVI, Save the Children, MSF, Concern, CHSL and its members and others).

Currently, DFID funds the inputs for the FHCI that are procured through Unicef.

The Worldbank is making significant investments to reinforce district level capacity while the African Development Bank has invested significant funds to procure essential health inputs.

Unicef and UNFPA have worked together to reinforce the LMIS at district level and Unicef is supplying and distributing the FHCI inputs.

Although this short enumeration does not constitute an exhaustive mapping of all development partners it does indicate that the sum of existing funds and support is significant and that external support exists at national, district and PHU level.

What is of paramount importance now is that all development partners intensify the coordination of their efforts in collaboration with the MOHS. This should be done through the health policy coordinating committee.

By coordination we do not mean "informing the others of what we are doing" during the monthly meeting.

Although this it is not part of this consultancy we do assume that the inevitable short-medium term outcome of the development partners' interventions is to work through a SWAP agreement with a basket funding type of financing. Any such agreement is based on a joint (framework) plan for the development of the health sector (strategic plan, operational plan, annual plans etc.). This plan is developed, discussed, adapted and adopted through the health policy coordinating committee. The funding necessary will go as much as possible through a joint (actual or virtual) basket.

Through this inclusive and open process the interventions of the stakeholders (technical or operational assistance, funding or others) will be (re-)defined. The consultants advocate that this process is accelarated.

In regards to the PSM configuration and development we do assume that from the onset all the development partners will advocate for the new PSM system and will where and when possible transfer responsibility for procurement, storage and distribution of the health products that they currently manage, to APPSA. This will off course have to be managed and introduced progressively not to overburden the young organisation. The development partners will also give technical assistance when needed.

The following are the main stakeholders whose direct contributions to the re-organisation of the PSM system are indispensable in the short term from the point of view of technical, organisational and operational support. The contribution to the PSM system development of the other development partners will als be necessary but can, at this moment in time, not be defined to this level of detail.

UNICEF:

- will champion the change process and search for funding
- will manage the tender process to find a firm to manage the APPSA project
- will manage the TA contract and will establish an agreement between themselves, MOHS, APPSA and the TA firm
- will continue to supply FHCI supplies until APPSA is ready to take over
- will be one of the main partners to support the MOHS to establish functional coordination and planning of all health interventions
- will continue to give support to the strengthening of LMIS and other required capacity at district level

UNFPA

- will ensure continuous operational support to the DMSs specifically geared to the continuous operation of the adapted Channel software to ensure that it will remain functional and productive
- will employ and train the formative auditors (see section 10.8)

WHO:

- will continue to advise the MOHS in developing and executing its coordinating and planning role
- will support the PBSL and other pharmaceutical and health related organisations to reinforce the regulatory environment.

In addition, over the medium term the support and interventions of national and international NGOs will be indispensable to increase capacities at PHU level.

NGOs

- working at the PHU level to strengthen quantification, ordering and general stock management capacities

2.4 The firm and its role

The objective of this project is to have a functional nationwide PSM system. The system will be focussed around a national level institution, APPSA, the statutory authority, which is going to be built almost from scratch. This organisation has to become a professionally run, transparent and efficient, procurement and supply agency for the public, and possibly, private health sector.

The strategy that is chosen is to create this autonomous organisation within the legal Sierra Leonean framework which is government-owned. However, it will have its operations run by an external firm for the first 36 months while the responsibility for its overall functioning lies with the board of directors.

The firm will supply the technical expertise necessary to develop and implement the tools and systems of the statutory authority through the long-term technical assistance, targeted short-term technical assistance and various types of training.

This firm is going to be responsible for the operations of APPSA and, depending on the choices that are going to be made, also for the direct support to the DMSs by the formative auditors (see section 10.8 on page 64).

The firm has two main responsibilities:

Medium term: Ensuring that over a period of 36 months, APPSA will become a professional procurement and supply organisation with qualified staff and the tools and systems necessary to guarantee the procurement of quality health products for the best price, their storage under Good Storage Practices principles, timely distribution and a high level of customer service and satisfaction.

Short term: At the same time they have to ensure that APPSA becomes operational as quickly as possible and will be able to take over, wholly or partially, the PSM operations from the CMS and from UNICEF (for the FHCI), preferably within 6 months of installing the technical assistants.

This can only be done if and when the firm is given, through its technical assistants, direct responsibility for the APPSA operations.

The firm will sign a contract that describes the relationship between the firm, APPSA and the donor or funding agency. The firm supplies the general manager and two directors who together form the core of the management team. They will function under the direction of the Board of Directors. The board of directors has to endorse their engagement. The contract covers the rights and duties of the firm during the contractual period. In addition to the contract, performance indicators will be agreed upon to be able to evaluate objectively the progress made and the services offered.

The general manager is responsible for the development of an annual business plan. This has to be endorsed by the board of directors and will determine part of the indicators that are part of the performance agreement.

It is important that the responsibilities between UNICEF, the MOHS, APPSA and the firm are clearly spelled out.

In the case of a conflict between the general manager and the board of directors, it has to be clear that the board of directors has the final say within APPSA. The contract that the firm signs, has to be clear on this point. It is also assumed that the donor or funding agency for this project will be a member of the board of directors.

This configuration has to be clearly spelled out and has to be transparent as well as acceptable to all parties involved.

2.5 Contracts and agreements

The following contracts and agreements will have to be developed:

1. Contract between the firm, the funding agency and the board of directors of APPSA. In case the board has not yet been founded, the MOHS will be the third signatory of the contract.
2. A general agreement between the MOHS and APPSA based on APPSA statutes but describes in more detail the tasks and responsibilities of these two main partners
3. Agreement between APPSA and the local councils (and MOFED maybe) in regards to the use of local councils' medicines budget
4. An annual performance agreement between MOHS and APPSA using quantitative and, especially during the first year, qualitative indicators that are based on APPSA's annual business plan and which are reviewed every year before APPSA's annual meeting. This can be a part or section of the general agreement described in point 2 although, in that case, the agreement will have to be updated annually.

   Nothing is written here about the possible place of a Fiduciary Agent (FA) in the overall configuration as we estimate that the creation of a Fiduciary Agent (FA) will not be realised within the first year of the APPSA operations as it will for a large part depend on the creation of a pooled medicines fund.

   However, as will also be emphasised later in the report, the creation of a FA as the manager of a pooled medicines fund is in line with the Government's wish to develop towards a SWAP like configuration.

3 Description of the Procurement and Supply system

3.1 PSM configuration

Central medical store
An autonomous pharmaceutical procurement and supply agency, which will be referred to as APPSA in this document, will be created and will be responsible for the procurement and supply of the essential medicines and medical supplies for primary and secondary health institutions in the health sector.

Legal status
APPSA will be created through an act of parliament as a statutory authority. A cabinet paper has been developed, submitted and approved by cabinet. At the time of writing the report the approved cabinet paper was at the legal office of cabinet for preparation for submission to parliament. The expected date of approval by parliament is not yet known. APPSA will have its statutes describing its objective. As a statutory authority, it will have full authority over its management and finances. It will have a board of directors which is representative of the health sector interests and inclusive. The chairman of the board will be appointed by the President. A statutory authority is government owned.

The currently existing statutes date from November 2004. They are well done and contain much of the essential elements needed to make APPSA an independently run and well monitored entity. However, there are a number of articles, specifically the premabule and the articles 1 and 2 that cover the transition between the current CMS and the newly created statutory authority. These have no place in the statutes but are part of a transition plan or a performance and transfer contract / memorandum of understanding between the MOHS and the statutory authority.

The statutes are added in Annex 1 on page 73 for information.

It is not clear whether it is still possible to adapt the statutes.

Founding principles
APPSA will be founded on the principles of transparency and inclusiveness. These principles have also been used to develop a code of conduct that is presented in Annex 10 on page 106.

Decentralised Configuration
APPSA will collaborate with the District Medical Stores based on a supplier-client relationship, the DMS being part of the local council. Both entities are and remain independent from each other. APPSA will not entrench on the DMS's authority. The principle of decentralisation will be respected.

3.2 Policy and management

APPSA Mandate
The procurement and distribution of **all essential medicines and medical supplies** (based on the EML, the BPEHS and any other products that are deemed essential by MOHS), for primary and secondary health institutions in the health sector.

Regular procurement and distribution
APPSA should be the monopolistic supplier of health commodities for the public health sector market for a period of five years. After a period of 5 years, under certain conditions (DMS capacity, regulatory environment and others), the local councils and hospitals should be allowed to procure also from the private pharmaceutical sector.

Private sector sales
APPSA is allowed to sell EML and non-EML health commodities to the private sector, including not-for-profit as well as for-profit organisations as long as it does not interfere with the public sector supply.

Framework contracts
APPSA will work with suppliers' framework contracts to allow for unanticipated changes in demand.

A framework contract is a contract, which defines fixed unit prices for certain supplies over a certain period of time, but without specifying the precise quantity of the supplies required or actually ordering any of the supplies.

Supplies are then ordered, as and when required, by individual call-off orders, which specify the required quantities of the supplies defined in the head contract. Deliveries and payments are made against each individual call-off order.

A more detailed description of framework contracts can be found in Annex 11 on page 110.

Private sector supplies to APPSA clients
If and when APPSA has stock-outs for certain products, its clients are allowed to purchase these from a list of suppliers that have been authorised by the Pharmacy Board: a so-called "green list". These purchases are only authorised in case an "out-of-stock" document has been received from APPSA. A supply document showing that not all products from an order have been supplied, is such an "out-of-stock" document.[3]

At the same time, APPSA can also purchase on the local market through direct contracting in case of stock-outs. It should in this way attempt to prevent the DMS to

[3] This document is indispensable for auditing and monitoring purposes

have to go to the green list suppliers. This would increase the DMS's transaction costs.

Private sector supplies to APPSA

Local suppliers will also have a role as they can participate in tenders issued by APPSA either on their own or as agents for overseas companies. They will also be used for "emergency supplies" if and when necessary as indicated in the previous paragraph.

Donations of medicines and medical supplies

Donations to the government of Sierra Leone can be treated in various ways.

1. They will be channeled through APPSA. APPSA will invoice the Government for the storage and distribution of these goods. Invoicing will be done on the basis of an activity based costing analysis. An initital contract will be drawn up to establish the conditions and terms of the handling of donations.
2. They will be channeled through APPSA. The donations will become part of the regular APPSA stock and will be sold as regular products. The proceeds from the sale (minus the APPSA costs) will be put in a MOHS account at APPSA. The MOHS can use the proceeds from that account to purchase and distribute in case of need.

Vertical programs and other central level procurement

Apart from the regular procurement and distribution, APPSA will offer its procurement, storage and distribution services to any vertical or national level program. APPSA will be able to offer prices for procurement activities (based on estimated time and resources spent by the procurement department), for storage activities (based on the storage costs per m^3 per defined time period) and for distribution activities (based on kilogramme/kilometre).

Contractual relationship

For purposes of monitoring and evaluation a performance contract between APPSA and the government of Sierra Leone (represented by the MOHS and the district councils) will be agreed upon. The performance contract will include a number of essential indicators and benchmarks which will be used to measure APPSA's peformance on an annual basis. The performance contract can be part of a memorandum of understanding describing the relationship between the government and APPSA.

It can be argued that because APPSA is a Statutory Authority this is not necessary as its statutes clearly describe its tasks and responsibilities. However, the statutes do not give APPSA's main clients a means to monitor its performance and to hold APPSA accountable. This can only be done by measering its operations. How that is done should be detailed in that performance agreement. As this can be a cause of conflict this has to be transparent and agreed to by all parties and not left to the general statutes.

Staffing

The General Manager will formally be appointed by the Board. Other management team members are also approved by the Board (as according to the Statutes). Other staff are confirmed by the APPSA General Manager. APPSA will have its own employment terms and conditions as approved by the Board. These will be competitive with the private sector.

The General Manager will be an expatriate expert who, with two other expatriate staff, will be supplied by the firm who wins the Phase 2 tender.

Other management staff and employees will be recruited through a competitive process published through advertisements. APPSA will have a recruitement committee. Appointments will be based on qualifications as required in the job descriptions. Remunerations for qualified technical staff (e.g. pharmacists) will be competitive with the private sector.

Three long term technical assistance positions with operational responsibility are required for the first three years. In addition a number of short term msisions will be organised depending on the specific expertise needed.

These three long term TA will will work with, and train on-the-job, local counterparts.

APPSA organisation

The senior management will consist of the following positions:

1. General manager (TA to be supplied by firm)
2. Quality assurance pharmacist
3. Internal auditor
4. Director procurement department (TA to be supplied by firm)
5. Director storage, sales & distribution (TA to be supplied by firm)
6. Director finance and administration (+ HR, security, maintenance, IT, etc.)

These six positions make up the management team.

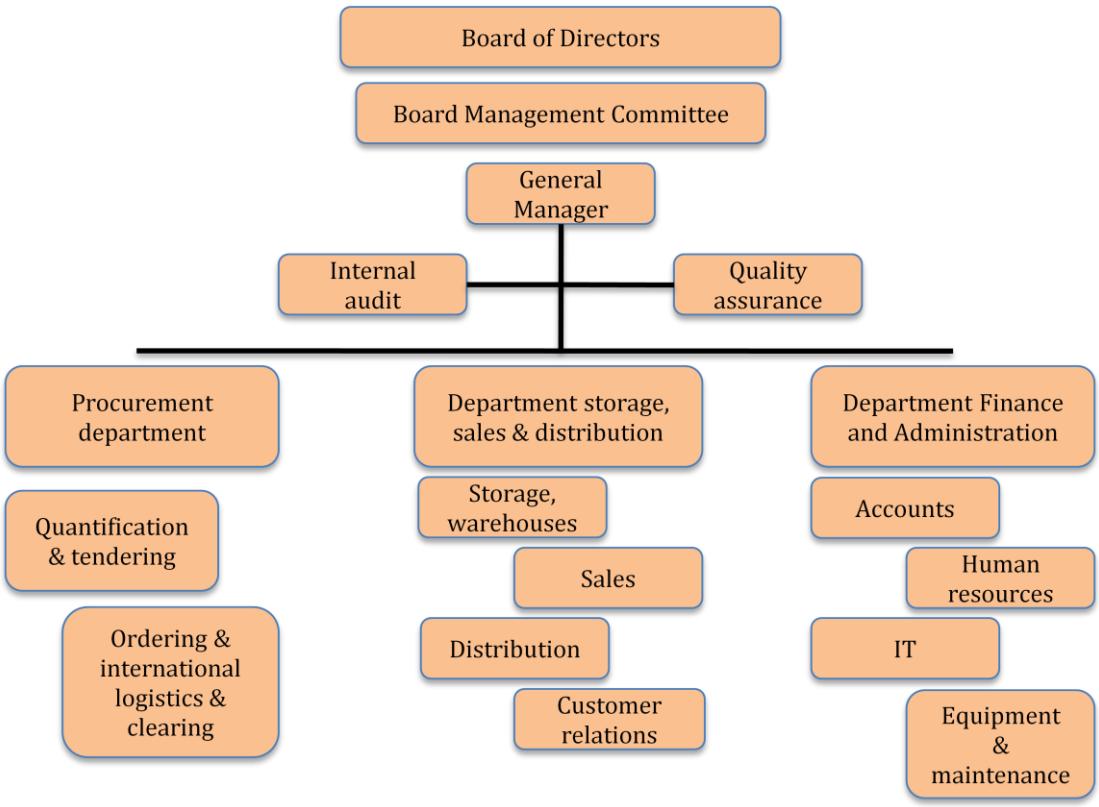
The positions of managing director, director procurement and director sales, distribution and marketing will be occupied by external technical assistants for a period of 36 months. From the second year onwards, they will work with adjuncts. The current idea is that the adjuncts will take over the TA positions after the project period of 36 months.

The managing director will have financial experience and will support the director finance and administration.

The director procurement will be a pharmacist and will support the quality assurance pharmacists.

The organisation will have the following organisational chart

Figure 3-1: Organisational chart APPSA



Quality assurance
APPSA will have its own Quality Assurance (QA) unit managed by a quality assurance pharmacist. This unit reports directly to the general manager.

Internal audit
The internal audit unit reports to the general manager. Their functions include a continuing audit of the standard operating procedures and the daily practices as well as regular controls of the financial and stock records.

Tender committee
This is not part of the organisational chart as it will be a standing committee which will be formed as the need arises. Same for a recruitement committee and an audit committee and whatever other committee may be found necessary by the board of directors or by the general manager.

A possible team of staff with kind and number of the positions that are part of the overall APPSA team are presented in the next table. However, this should not be taken as fixed. Once a first small team is on the ground (Phase 2) they should have the possibility to propose changes. Whether for example, a secretary to the general

manager should fall in the administration and finance department or be part of the general management unit is something that can differ according to personal preferences. Whether one needs 6 warehouse assistants (they do the picking of the orders, ensure that the warehouse are clean and any other manual labour in the warehouses) or 4 or 8 will depend on the final configuration of the warehouses and the volume of work. The list is for the first year, where there may not yet be any "adjuncts".

The list is a guideline even though it is the consultants' opinion that such a team is necessary to properly run a central medical store with a turnover of 9 million Usd.

Table 3-1: APPSA functions and number of employees

	Function	Number of employees
	Management team	
1	General manager	1
2	General manager adjunct	0
3	Director procurement	1
4	Director procurement adjunct	0
5	Director stores	1
6	Director stores adjunct	0
7	Director finance and administration	1
8	Quality assurance pharmacist	1
9	Internal Auditor	1
	Quality Assurance	
10	Assistant to quality assurance pharmacist	1
	Internal audit	
11	Assistant to internal auditor	1
	Procurement	
12	Quantification Officer	1
13	Purchasing Manager	1
14	Purchasing Officer	2
15	Clearing & handling Officer	1
	Sales, distribution and marketing	
16	Warehouse Manager	1
17	Assistant Warehouse Manager	2
18	Warehouse Assistants	6
19	Customer and sales manager	1
20	Customer Service Officer (sales)	3
21	Order Processing Clerk	1
22	Distribution manager	1
23	Packing and distribution assistant	2
22	Driver	3
	Finance and administration	
23	Cashier	1
24	Assistant Accountant	2
25	Human Resource Assistant	1
26	Administrative Assistant	1
27	Information Technology officer	2
28	Secretary	4
		44

3.3 Operational components

The operational components will all be described in standard operating procedures. These will be developed as soon as APPSA has been created and the firm has been contracted. The definition of the standard operating procedures is one of the reasons why it will take 4 to 6 months before APPSA can become fully operational.

Quantification
APPSA will initially manage quantification using inputs from the local councils, the hospitals and the DDMS. The quantification will be done in close collaboration with the main clients: MOHS and the local councils. Eventually, APPSA will quantify using their order and sales data.

The PHUs, local councils and hospitals will manage forecasting of their annual needs and quantification of their monthly or three-monthly orders. Support is given by the DDMS during regular supervisory visits. The DDMS also participates in the annual forecasting exercise at local council level. The main inputs in the forecasting exercise are the data that are produced by the LMIS system using Channel, which is expected to be fully operational.

Tendering
APPSA will use internationally recognised tendering procedures and standard documents. The tendering procedures and documents will be submitted to the NPPA for approbation.

The tendering procedures will be developed once the TA firm is in place.

The tender procedures will include articles on fraud and corruption as for example is the case in the Guidelines Procurement Under IBRD Loans And IDA Credits.[4]

Ordering
APPSA will place orders based on the outcome of the tenders. APPSA will use framework contracts to compensate for possible differences between the quantification and the actual demand.

Payment, letter of credit, Settlement invoices
APPSA will have its own bank accounts in Sierra Leone as well as abroad. Its financial management is subject only to the supervision and control of its board. APPSA procedures describe which levels of financial decisions

Box 1: PSM process steps options

APPSA:
1. Quantification
2. Tendering
3. Ordering
4. Payment, letter of credit
5. International logistics
6. Registration
7. Clearing
8. External quality control
9. Reception
10. Internal quality control
11. Settlement invoices
12. Storage
13. Sales order processing
14. Distribution planning
15. Packaging
16. Distribution

DMS and hospital level
17. Forecasting/quantification
18. Ordering
19. Reception
20. Registration
21. Storage
22. PHU order processing
23. Distribution planning
24. Distribution to PHU

PHU and hospital level
25. Rational prescription

[4] IBRD Loans and IDA Credits, May 2004 Revised October 1, 2006

head of departments and the management and board can make.

The MOHS will support APPSA in the negotiations with the Central Bank to have access to a foreign exchange facility. APPSA's foreign exchange needs will be forecasted on a regular basis (12-18 months).

International logistics
APPSA will have the communication means (telephone, high speed internet) to manage international logistics.

Registration
APPSA will ensure that for all pharmaceutical and other health products the Pharmacy Board regulations will be followed.

Clearing
APPSA will be responsible for clearing its own imports and all other imports for which they are the consignee (donations for example). They will do this in collaboration with a clearing agent. The clearing agent will have been selected using an open national tender. APPSA will negotiate long-term arrangements with Customs and the NRA.

Whether APPSA is exempt from import duties is yet to be determined. Two options were presented during the June workshop but no decision was made. The consultants' preference is Option 8a. The government can decide to reimburse the duties to APPSA as a way to decrease the price of the medicines.

Option 8a. APPSA will pay the 15% import duties on its imports. This will allow them to process importation documents quicker as it does not involve MOFED. It also promotes a clean competitive environment with the private suppliers. In other words APPSA is not exempt from import duties. APPSA will either include the import duties in the calculation of its sales prices or the MOHS through the MOFED will, once a year or once per trimester, reimburse the duties that APPSA has paid. This way the true costs of the medicines are known. There are here two different solutions:

1) Duties are paid by APPSA and included into sales price (population is financing duties)
2) Duties are paid by APPSA and reimbursed to APPSA through Government

Option 8b. APPSA is exempted from import duties

Quality assurance
The APPSA procedures will describe internal quality assurance measures covering the entire procurement and supply chain: from quantification up to delivery. Current thoughts on quality assurance will be taken into account.[5]

Receipt and Storage
The EU funded warehouses in Freetown will be the main APPSA site.

The government of Sierra Leone will lease the new EU funded warehouses to APPSA for a period of 15 years at no cost.

The government of Sierra Leone will donate all current DDMS logistical material to APPSA.

APPSA will invest in new logistical material as needed (computer hardware and software, mechanical and manual forklifts, pallets, pallet shelving, etc.).

APPSA will in principle follow the following stored quantities principle (AMC = average monthly consumption):

- Safety stock APPSA, stored centrally: 3 x AMC
- Regular stock, stored at APPSA: 3 x AMC
- Products in the pipeline: 3 x AMC

Sales order processing
Funding arrangements are described in detail in section 4 on page 31. The clients will have accounts at APPSA that are funded by the MOFED budget and possible other sources. In other words, all government clients start with a credit in their account. The regular orders are then initiated by the client (DMS, hospitals, PHUs,). Sales orders are compared to the credit (or budget) available to the client. When a client places an order, a pro-forma invoice is produced by customer service. The pro-forma shows the availability of the ordered goods, the prices, the remaining credit and the total costs. The customer service will also be able to show the client the credit remaining in their account. Based on the pro-forma, which is produced while the client is waiting, the client confirms the order.

The hospitals have the possibility to order directly from APPSA or to order from the DMS.

The pull system is respected. The hospitals and the local councils initiate an order for health commodities.

[5] See for example: United States Pharmacopeia Drug Quality and Information Program and collaborators. 2007. *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide.* Rockville, Md.: The United States Pharmacopeia Convention. Available online: www.usp.org/worldwide/dqi/resources/technicalReports. Or: Inter-Agency Guidelines A Model Quality Assurance System for Procurement Agencies. WHO/PSM/PAR/2007.3

Other types of clients (international or national NGOs, UN agencies, private sector) will either have to pay cash on delivery or will be allowed a 30-day credit period from the date of the invoice. A credit policy will have to be developed by the APPSA management. It is recommended that this will follow regular business practices.

Packaging

APPSA will package the orders according to the wishes of the client. In principle, supplies are in bulk to the DMS but supplies can be pre-packed by health facility if requested and the information is made available.

Packaging will be done using proper material. If necessary, APPSA will have cartons made according to its needs and specifications.

The boxes will be packed using straps and identifiable tape (with APPSA name and logo printed on it). Every box will have a label with order number, client number and name, weight, number of box and total number of boxes for that order.

Distribution

The distribution or supply of health commodities from the central level to the DMS and the hospitals is the responsibility of APPSA. The responsibility of the distribution from the DMS to the peripheral health units stays with the DMS and the PHUs. This will allow for pragmatic models depending on the particular circumstances of the district and the PHUs.

The active participation of the community members is required and should be encouraged by all stakeholders.

Whether the distribution to the PHUs will be done by the district or whether the PHUs will collect their orders is a question that will be resolved at the district level, between the PHUs and the DHMT, especially for areas with difficult terrain as in some of the eastern districts. Special arrangement may be called for, such as 6-9 months stock to overcome the rainy seasons.

The optimal solution will differ per district. APPSA may, for example, provide distribution services directly to the PHUs if requested by the local council. This will be factored in the price of the supplies.
The distribution will be documented in such a way that for every step and transfer in the process is documented and that for every batch the distribution chain can be traced and re-traced.

3.4 Local councils and hospitals

Forecasting, quantification, ordering at local council and hospital level

Accurate forecasting: the PSM system needs reliable forecasting of the needs of its clients to properly fulfil their needs and avoiding over stocked positions or regular stock-outs. This is linked to the establishment of the LMIS reporting system. The continuing support of UNICEF, UNFPA and other partners to the LMIS system that is being put in operation at local council levels is indispensable. This support should, amongst other things, consist of (i) help-desk like support for the operators of Channel, (ii) on site visits if necessary: if the software has crashed and has to be reinstalled, if the database has been corrupted and has to be restored etc., (iii) on site hardware repairs and maintenance. UNFPA indicated that they have committed themselves to this type of support for a period of five years.

LMIS support to PHU level is indispensible to improve the quality of reporting and ordering.

Logistical capacity at local council and hospital level
The key words are: training, follow up and supervision. The MOHS will, with the support of her partners, invest in raising the local council level logistical capacity.

Rational prescription
Forecasting can be done very accurately but if routine prescription is not rational, the PSM system may not be able to keep up with supplies. The National Medicines Policy of Sierra Leone (NMPSL 2004) contains a strategy for RDU for which implementation is the responsibility of the MOHS. The 1st edition of the **Essential Medicines List** (EMLSL) was prepared in 2004 by the National Medicines Committee (NMC). It contains 438 items and is the basis for procurement, prescribing and dispensing.

The **Standard Treatment Guidelines** for Sierra Leone were published in 2006 and are in line with the EMLSL. Both documents are not widespread in use in every facility and are in need of updating. Provisions have been made to make sure that updates in treatment guidelines and subsequent need for other essential medicines are being addressed (such as for HIV/AIDS).

Priority Actions
Reconvene the National Medicines Committee (NMC) in order to take charge of the coordination and implementation of these activities.

It also needs to revise the NMPSL to capture all the new strategies being developed and implemented.

The stakeholders together with the MOHS and the district health councils have to discuss in the HPCC how to reconvene the NMC and how to support the NMC in its work.

Even if the causes for the absence of rational prescription are found and the resources are available to address the root caues, it will depend on the regular supportive supervision of the district health team whether an improved rational prescription (which will have to be accomplished through training or an intensive period of monitoring) will last over the long term.

4 Funding needs

The reconfiguration of the PSM systme needs two types of funding:

1. Short term funds for the creation of APPSA and the reform of the PSM system at national and district level.
2. Long term funds to finance the medicines and medical supplies that the districts will purchase from APPSA.

Both are described in the following paragraphs.

4.1 Funds for the creation of APPSA and PSM system reform

The funds for the creation of APPSA are divided over four main categories:

1. Medicines and medical suppliers seed capital
2. Logistical and infrastructure investments
3. Technical assistance and training costs over the project period of three years
4. Miscellaneous costs

The funding needed for the main four categories are presented in Table 4-1. A detailed budget is given in Annex 2 on page 82.

Table 4-1: Budget categories with totals in Usd

Section	What	Amount	Nature
4.1.1	Investment in APPSA medicines and medical supplies seed capital	$9,000,000	1 time investment
4.1.2	Investment in logistical and infrastructural needs	$973,500	1 time investment
4.1.3	Investment in Technical Assistance and training (36 months)	$3,179,700	3-year project cost
4.1.4	Miscellaneous costs first 36 months (start up costs & subsidy)	$1,820,174	3-year project cost
	Total	**$14,973,374**	

The development of APPSA will be in three phases.

Phase 1: Month 0 through Month 6
During the first six months of the project APPSA is prepared for operationality. During that period it will be equiped with all the tools necessary to function (staff, procedures, systems, IT, equipment etc.).

Phase 2: Month 7 through Month 18
After six months APPSA will become operational and can start to receive, store and distribute medicines and medical supplies. It can however, not yet take over the

procurement function. More than 6 months are needed to develop, implement and activate an efficient procurement system within 6 months.

So from month 6 onwards through month 18, APPSA will receive, store and distribute medicines and medical supplies that have been procured by and through UNICEF (or another organisation whatever may be the case).

During month 7 through month 12, APPSA will finalise the procurement procedures and systems. It will start to apply these procedures from month 12 onwards and by month 18, APPSA will have finalised the pre-qualification of suppliers, it will have floated and evaluated the first international tender, the first orders will have been placed and it is expected that the first receipts of the medicines and medical supplies are arriving.

Phase 3: From Month 18 through Month 36
APPSA will 18 months after the start of the project be fully operational and will start start generating its own income.

This however, means that all operational costs for the first 18 months have to be funded by external sources.

4.1.1 Medicines and medical supplies seed capital

For APPSA to function efficiently it needs working capital. APPSA needs to have a working capital to purchase supplies and to finance its operations. The supplies are sold to its clients for a realistic sales price (see section 4.3 on APPSA pricing). This sales price will cover the replenishment of the stock and the operational costs.

However, an initial injection of funds is needed to jump-start this system. Without a substantial investment in the working capital of APPSA, the organisation will have nothing to work with.

The working capital is preferably provided as a donation. It can however also be provided as a long-term interest free loan. It should be given in funds rather than in medicines and medical supplies.

An investment in APPSA's working capital is not the same as funding medicines for the target population. APPSA will procure medicines and medical supplies for its clients and sell them. In other words, if the same donor funds the APPSA creation as well as the Free Health Care Initiative (FHCI), this donor may be paying twice for the same medicines and medical supplies.

4.1.2 Investment in APPSA logistical and infrastructural needs

APPSA needs substantial investments in logistical equipment and probably also in infrastructure. The current warehouse in Freetown will have to be adapted to cope efficiently with the flow of medicines and medical supplies over the years to come.

It will also need a proper information technology network with up to date and appropriate software programs at every level in the organisation.

At the storage level it needs a cold room, pallet racks and shelves. It needs trucks to distribute the supplies to the districts and it needs regular cars to maintain national and district level contacts with stakeholders, policy makers and, most importantly maybe, its clients.

4.1.3 Technical assistants and training

Three long-term technical assistants are proposed as senior management as described above. However, as these have operational responsibility they will have to be assisted by short term technical expertise to develop all the APPSA internal tools (standard operating procedures mainly).

A number of short term visits by technical experts is foreseen. In addition a large number of training days has been budgeted for to make sure that the board of directors, the APPSA staff but also district level staff and the formative auditors will be covered by the training.

An annual training plan will be developed for the staff. This is not dependent on the project but will be part of the APPSA human resources development plan.

Technical assistance for the reform of the DDMS and the development of a long term support and investment program for the PBSL is also budgeted under this heading. It has not been detailed as it is the content or nature of the technical assistance necessary is not yet known. This will have to be discussed with the two organisations in more detail.

4.1.4 Other cost and activities

The batch tracking exercises, two per year, are budgeted here. These will be conducted by the MOHS and the stakeholders.

The district level formative auditors (see section 10.8 on page 64 for details) who will be based at district level are funded under this heading.

The operational costs are funded for 100% during the first 18 months as described above. It is expected that it will take 18 months before APPSA will start generating its

own funds. The costs to run APPSA the first 18 months are budgeted under this heading. The details of these costs are presented in the APPSA accounts in Annex 5.

4.2 Funds for APPSA operations

Once APPSA is up and running, there will no longer be any direct financial support to the organisation. APPSA will use its working capital to procure, store, sell and distribute medicines and medical supplies. It is expected that it will take 18 months before APPSA is fully up and running.

The pharmaceutical and health products will be sold for a price that will cover the APPSA operations, including depreciation, capital investments, increase in security stock and inflation.

4.3 Pricing levels

The APPSA sales prices will include the following elements:

1. Cost price: This includes the purchase price (FOB), quality control pre-shipment if necessary, international transport, insurance, clearing and associated costs where appropriate up to the APPSA doorstep. This can also be called the landed costs
2. Mark-up: This will be established on an annual basis and will most probably be within the 15-20% range. The mark-up is expressed as a percentage of the landed costs. It covers (i) the APPSA running costs (including distribution and depreciation), (ii) future capital investments, (iii) reserves to cope with future price fluctuations and (iv) increase in working capital.

The distribution costs from the national level APPSA warehouse to the district medical stores are part of the mark-up. The APPSA sales prices include delivery to the doorstep of the DMS or the hospital.

This has been decided to ensure that the sales prices of the APPSA products are the same wherever the public sector client may be located in the country and that at that level there is equitable access.

APPSA management will develop a pricing policy, which will be approved by the board.

In case of sales to the private sector, the sales prices for private sector institutions will be the same as for public sector institutions to ensure that all Sierra Leoneans have access to quality assured medicines regardless of the type or kind of health institutions they visit.

4.4 APPSA projected turnover and different costs 2011 - 2015

Assuming the APPSA will have an annual turnover of approximately 8,500,000 USD during the first full year of its operations (month 24 - 36), an estimation has been made of the accompanying costs and the final financial result.

The salary scales have not been related to real existing private sector remunerations. This can be adapted if more information on the salary scales is available. When the salary levels in the "APPSA accounts and project budget" spreadsheet are changed it will not only have an effect on the accounts as presented but also on the overall project budget as the different sheets in the spreadsheet are linked.

It is assumed that the costs of the technical assistance as well as the initial investments, the training programs and the short-term technical assistance are funded outside of the APPSA budget.

The detailed accounts are presented in Annex 5 on page 86.

4.5 Local councils' budgets and cost recovery

APPSA's clients buy medicines using the medicines budget that is allocated by the MOFED. These budgets used to be transferred to the local councils. However, it has now been proposed that the local councils' budgets for medicines and medical supplies will no longer be transferred to local council level. They will be kept at central level.

There are two main options for the payment of the medicines. Option 2 is the preferred option.

1) the local council orders, APPSA supplies and sends the invoice to MOFED for payment
2) the local council orders and APPSA supplies. MOFED has already transferred the local council's budget to APPSA. Each local council has a credit in its account.

Which option is retained depends on the negotiations with MOFED and with the local councils.

In case of option 2, the local councils are kept informed of their budget, the credit in their APPSA account. APPSA will supply the local councils with an 3-monthly overview of the budget, expenditure and balance at each order or delivery.

The cost recovery accounts are kept at local councils' level. The local councils will use them to purchase medicines from APPSA.

4.6 Pooled medicines fund

In the long term it is beneficial to have a pooled medicines fund (PMF). This fund will be kept at national level and all the funding sources for the purchase of medicines and medical supplis will be paid into this fund. One advantage is that it becomes transparent what all stakeholders (including the government) contribute to the medicines budget. Another advantage is that it makes it easier to implement pharmaceutical policy when it is clear from the onset what the available funds are.

A **phased implementation** with organic growth from a limited pooled medicines fund to a full PMF is proposed.

The creation of a PMF can take place over a period of 18 months. The PMF will only become operational once APPSA starts its own procurement. As a reminder: for the first 18 months APPSA is clearing, storing and distributing medicines and medical supplies that are procured by Unicef. There is therefore no need yet to pay APPSA for supplies it has supplied.

The PMF is initially created as one foreign currency account that is managed by an entity that is chosen amongst, or by, the development partners and the MOHS.[6] That entity, the PMF manager, has signature power for the account. The PMF manager will eventually pay APPSA, once a week or once a month for supplied medicines and medical supplies.

The stakeholders have to agree on a set of operating procedures for the PMF. These can be developed by a consultant over a relatively brief period of time (a 4 to 6 week consultancy) and adopted by the health policy coordinating committee.

APPSA prepares weekly a file containing for each supply that they have made copies of: (i) the order from the district, (ii) delivery note signed by the district and (iii) the invoice. The file also contains a document with aggregated figures for supplies over an agreed period. The PMF manager will pay APPSA on the basis of the supplied files. The PMF manager can either pay and verify ex post or agree with APPSA to verify ex ante and pay after verification. The verification can be done either on the basis of a sample of invoices (the concerned districts are contacted by the PMF manager) or on the basis of reports that have been sent by the formative auditors.

The PMF is initially seeded by development agencies that are willing to fund the medicines and medical supplies for the districts. During the creation phase, continuing negotiations with the Ministry of Finance and the districts have to make sure that eventually also the districts medicines and medical supplies budgets are paid in to the PMF. The Ministry of Finance has to transfer the budget directly to the PMF without passing by the districts.

[6] For example: In Bangladesh, which has the largest SWAP program in the world in terms of USD, the SWAP funds, including the medicines funds, are pooled and managed by the World Bank.

Eventually, the PMF can be managed by a fiduciary agent (FA) overseen by a PMF board or committee in which the districts and other stakeholders have a seat. The PMF will eventually also take over the verification services from the formative auditors and/or from the initial PMF manager.

The FA ensures transparent and reliable management of the funds. The FA can be a private auditing or consulting firm. This is a decision that has to be made at the HPCC level.

The advantages for the funders are that a FA will be able to objectively monitor the activities in the fund and routinely report on them using agreed objectively verifiable indicators as well as absolute figures. At any point in time the FA should be able to produce a report that shows (i) the level of funding available, (ii) the expenses made, per local council and per period, (iii) the commodities supplies per local council and per period.

It is expected that at the level of the MOHS, the HPCC will advocate that donors pool their resources and not manage separately specific medicines, disease programmes or projects.

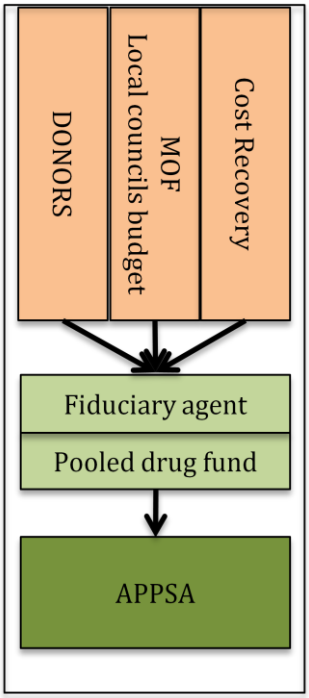
A pooled medicine fund financing medicines and medical supplies procurement by APPSA is only possible if and when the APPSA procurement system and its tools and procedures have been verified by the main donor agencies and have been accepted as sufficient to replace the agencies' specific procurement guidelines.

It is expected that the technical expertise provided by the firm will ensure that the design of APPSA's procurement system will comply with the highest technical and ethical standards.

The advantage of a pooled medicine fund managed by the FA for APPSA is that APPSA can invoice one particular organisation and concentrate on the logistical issues, without having to worry about the financial issues. In addition, a guaranteed source of funds is important as cash flow and treasury management is often an issue in central medical stores. There are a number of examples world-wide where central medical stores were not able to perform as intended because the government did not honour its financial commitments.

The FA can also be mandated with monitoring, supervision and auditing tasks at central and district level.

Figure 4-1: Fiduciary agent and Pooled Medicines Fund



5 Work plan

5.1 Activities

The work plan with a detailed list of activities is presented in a spreadsheet in the Annex 4 on page 85. It includes the activities, the (proposed) responsible organisation, resources needed and time lines. The work plan is organised around the following different phases:

1. Formal creation of the statutory authority
2. Intermediate activities (before funding is assured)
3. Preparatory activities (once funding is assured)
4. Support activities national level
5. Start up statutory authority national level
6. Start up district level activities

No priority interventions have been defined as the success of the reconfiguration of the PSM system depends on many factors. One of them being a consistent and continuous approach by all stakeholders towards supporting technical capacity building at all levels.

However, this is not one activity but is a result of many activities.

The key words are: long term commitment, sufficient financial resources, political support, independent operation, strengthening of regulatory environment, building of technical capacity and the sharing of PSM information.

For the first three phases (1 to 3 of above list) a PSM systems development "champion" is needed. This champion (one organisation, not a committee) will support, promote, coordinate and develop the activities that are needed to arrive at the operational phases. The champion will do this in close collaboration with the MOHS and the FHCI steering committee in the President's office. Taking the current situation in to account it is most logical that this champion is UNICEF: they have the trust of all other stakeholders, they have the technical expertise or are able to hire this, they have the financial resources and they have already started the process.

Once these phases have passed and the operational phases have started, there is no more need for a PSM systems development "champion". Different institutions will promote and defend their needs and interests: the APPSA board of directors supported by its senior management, the MOHS supported by the DDMS, the DMS supported by the individual agencies, the PSM stakeholders in general. The role of the stakeholders will also change and will become a role, which includes monitoring and supervision, consumer of APPSA services and possibly that of donor agency.

Ad.1: Formal creation of the statutory authority

As of the date of this document the statutory authority had not yet been created. The final content of the statutes is therefore not yet known. One of the main issues that have to be determined through the statutes is the composition of the board of directors. Once this is known, the APPSA "pre-board" committee can be formed to accompany the subsequent phases.

Ad.2: Intermediate activities

These activities are mainly targeting funding and the keeping up to date of the implementation plan to incorporate new developments. These activities are managed by the above-mentioned "champion".

Ad.3: Preparatory activities

Once the funding is assured, the PSM reinforcement project can begin with the contracting of a supporting firm through the development and launch of a tender.

The following phases are for a large part the responsibility of APPSA and its technical assistants. For district level and non-APPSA activities, the responsibility is born by a MOHS steering committee, individual agencies, UNICEF and others working in the PSM system.

Ad.4: Supporting activities national level

This is mainly targeting the Pharmacy Board of Sierra Leone (PBSL). From the start of the program the PBSL will be supported. The PBSL and the APPSA share the same compound in Freetown and they should also share the same development. As has been argued before, the lack of sufficient regulatory inspection in the private and public pharmaceutical sector will hurt the APPSA operations in the long term.

Ad.5: Start up statutory authority

The exact starting date of the start up activities depends on the installation of the technical assistants by the firm that has been selected to manage and coordinate the PSM systems development project. It is expected that within 1 month after the signing of the contract all three technical assistants will be in place.

The technical assistants with a core team of recruited staff (the complete senior management team and other positions) will take six months to develop the essential tools to set-up and manage APPSA.

The six months are essential for the development of internal systems and procedures for the statutory authority. A number of short-term experts will assist the regular APPSA team to make sure that the main processes and are properly described in the procedures.

For the main processes: (i) general logistics, (ii) procurement, (iii) storage, (iv) sales and distribution, (v) administration, (vi) finance and (vii) information technology, the priority activities needed to start operations after six months are described in the workplan.

One of the first activities will be the recruitment of essential staff and the hand-over of the MOHS CMS goods.

The organisation will also need an accounting system that includes a chart of accounts. This chart of accounts will have to be designed during this six months period.

APPSA will need an enterprise resource planning software. The exact needs for this ERP have to be established and then the software will have to be tendered for. Once a software package has been purchaed, it has to be installed and all staff will have to be trained in its use. The ERP software is modular so not everyone has to be trained in all modules (finance, procurement, storage, sales, human resources etc.).

It is also advised to create a website during the first phase through which the clients and stakeholders can be kept informed of the project progress. The construction of a website will be outsourced.

At the end of the six months, the senior management team will have finalised a business plan for 2011 that will include plan of activities, budget, balance sheet and profit and loss account. They will also have started work on a strategic plan 2011-2015 but this will probably take longer as more stakeholders will be involved in its development.

During the same period, a training session will be organised for the board of directors. This training session will focus on the roles and responsibilities of a board of directors and its relationship with the operational management. It will also include a session on the management information system, its role in monitoring the operational activities and the priority indicators to be monitored.

After 6 months, APPSA can start taking operational responsibility for storage and distribution. As described above, the systems and procedures to be able to implement procurement will take another 12 months.

Ad.6: Start-up district level activities

The formative auditors (whose role in the PSM system is described in detail in section 10.8 on page 64) will have to be recruited, trained and installed. It is not yet clearly defined by which organisation they will be contracted so little can be said about them at this stage. In any case, they have to be trained and installed before the start of the APPSA operations.

6 District level support

It has to be ensured that the District Health Management Teams (DHMT), and specifically the staff that is responsible for the District Medical Stores, receive the support that they need. Specifically, the consultants identify as priorities:

General support at district level:

1. Strengthening integrated supportive supervision by the DHMT of the PHUs.
2. Specifically reinforcing rational prescription supervision.
3. Organising regular district level rational prescription sessions. Short and to the point rational prescription modules will be presented and discussed during the monthly joint PHU/DHMT meetings. Every month two protocols could be presented in a 30-minute session.

In general, awareness building interventions on rational prescription and rational medicines use should be considered. This can be in the form of training but also through radio messages, community meetings, posters, supervision and other, more innovative, ways that suit the purpose and the audience. Important is that these approaches are agreed upon by all stakeholders and implemented nation wide to ensure a common and unambivalent message.

This will have to be followed up by conducting surveys on the systems of prescribing, dispensing and patient compliance over a period of a number of years to document changes.

Specific DMS support:

4. LMIS support to the DMS.
5. Overall management support to the DMS.
6. Reporting support to the DMS

It should be emphasised that the kind of support needed differs from district to district. The exact type of intervention per district will have to be determined through a consultative process with the districts and the stakeholders.

Both sets of priorities can be taken up by the HPCC. This committee can, if needed, strengthen the district level standard supervisory tools and methods. These tools and methods will have to be adopted by all development partners and by the districts. All development partners working at district level will have to commit to supporting the integrated supervision with a special emphasis (for a certain period of time) on rational prescription.

The HPCC can also make rational prescription tools available to the districts and the development partners. The development partners working at district level commit to support the monthly "continuing medical education" with an emphasis on rational prescription. The consultants expect that over a period of two years, these two specific interventions will significantly improve rational prescription.

The HPCC will designate a "lead agency" or "champion" for these interventions.

To make certain that the progress can be measured, the HPCC should commission a rational prescription base line study. A sample of x PHUs in all districts will be part of the study. The same study will be done 12 months and 24 months after the initial study.

Unicef and UNFPA have already invested significantly in the second set of priorities. The LMIS investments done so far (development, training, hardware) have to be continued and followed up with regular supervision and support missions in all districts. Both organisation commit to this LMIS support for a period of 3 years for all districts. Other development partners can join where and when possible but only in a HPCC coordinated manner.

The formative auditors (which are described in more detail in section 10.8 on page 64) are a main element in the strengthening of the overall management of the DMS. The consultants do not have a preference who employs the formative auditors as long as it is not the MOHS. The reason is the formative auditors have to be independent from the MOHS and the DMS staff. Their contracts can go through APPSA, UNFPA or Unicef or another development partner.

The HPCC will make sure that all development partners support the DMS using the same set of documents and procedures. The development partners will also commit to that approach in the HPCC.

7 Risks

A long list of issues that can put the development of the PSM system at risk can be identified: a) risks at the national, APPSA, district, PHU/community, firm level; and b) risks that are related to policy, funding, coordination or operations.

Government commitment, leadership and political momentum. The current policy environment is conducive to risk management. The government fully supports rendering autonomous the PSM functions while APPSA is initially managed by expatriate experts with no immediate link to past practices. This greatly reduces the possiblity for large scale leakages at national level. Once autonomous, there are still possibilities for government interference but less so as procudures and reports will be transparent and all APPSA operations will be available on the APPSA website (see below).

Payroll integrity. Within APPSA, salaries and other costs will be under the responsibility of the general manager who will be an expatriate. That plus the procedures that will be developed and an increasing involvement of modern banking (APPSA will open bank accounts for staff and pay them by cheque) makes internal fraud less likely. The imposition of inappropriate staff on the payrol will also be limited by the presence of the expatriates in the management team and the, initially, monthly reporting to the board of directors.

A major element of risk management is the transparancy. Through the APPSA website, all international orders, district orders and supplies, prices and invoices are accessible to all clients and all PSM members. This will include information on type and volumes purchased as well as prices and expenditurs. In addition, indicator based reporting on a monthly basis will keep all stakeholders up to date.

Another element that is part of risk management is a joint position by the development partnes vis-à-vis the health sector development through the IHP+ compact, to be signed by government and main / all development partners. Guided by the various principles defined in the Paris Declaration and the Accra Agenda a common position of the development partners in case there are problems, reported by the expatriate APPSA team, can constitute a major factor in risk management.

The following lists are not exhaustive but do represent some of the main risks as identified by the consultants. Some are very obvious other less so. In any case, the proposed configuration of policy and coordination committees, the funding arrangements, the APPSA organisation, the district level support, the monitoring and evaluation configuration and other elements that are directly or indirectly part of the PSM configuration have all been described while taken these risks in to account.

National level

1. No funding for the creation of APPSA
2. Lack of support for an independent APPSA: start of political interference from presidential or ministerial level

3. MOFED medicines budgets not available for APPSA or not earmarked for APPSA
4. Not involving the local councils from the beginning of the process
5. No reinforcement of the regulatory authorities (leading to uncontrolled smuggling of poor quality, harmful medicines onto the market)
6. No "champion for change" or a "champion" with little influence or resources
7. No coordination of supportive district level activities or no supportive district level activities continued or initiated by stakeholders

APPSA

1. Insufficient technical and management expertise provided by firm
2. Weak human resource capacity at staff and board of directors level
3. Too little training possibilities or training budget for staff and board of directors
4. Board of directors interferes with day-to-day operations
5. Storage capacity insufficient
6. Too little funding for the operations of APPSA
7. Operational responsibility APPSA is not given to external technical assistants

District level

1. Collaboration of district councils is below expectations
2. Insufficient, or even lack of, DMS human resource capacity: technical and in numbers
3. No outside checks and controls
4. Lack of coordination of stakeholders' interventions
5. Formative auditors not accepted by the local councils
6. Hardware and software support to ensure the operationality of Channel is continuous. In general, absence of continuous support for tools and reports
7. Lack of logistical capacity (transport, storage equipment, storage)
8. No routine, regular supervision of PHUs or no budget for this routine activity

PHU level

1. Lack of information, education and communication with the communities concerning PHU management
2. Lack of community commitment
3. Long term continuation of irrational prescription
4. Lack of supervision or support from the district health team
5. Creation and or reinforcement of the village or community health committees not possible or not tried
6. No distribution arrangements are found

Firm

1. Not sufficient technical expertise
2. The general manager does not have the necessary communication and diplomatic skills to liaise with the board, MOHS and funding agency
3. Personalities not accepted by the board of directors and stakeholders

Although not much has been said about the creation of a Fiduciary Agent, the consultants are of the opinion that a FA can reduce certain risks. While the creation of a FA is not necessarily essential for the success of the PSM configuration development, it can contribute to the success. It is rather an instrument that can facilitate pooled medicine funding, payments and financial reporting and thus indirectly contribute to a more efficient and transparent configuration. Transparancy is an essential factor to reduce risks.

If a FA is created, there is however also the risk that the organisation managing the FA will not have the necessary capacities. The FA may then become a risk factor itself.

8 Redefining and reorganisation the role of the DDMS

The fact that APPSA will take over the procurement and supply functions for the health products from the MOHS will result in a changed role for the Director Drugs and Medical Supplies (DDMS). It is proposed that the DDMS will become the co-coordinating/focal point for pharmaceutical PSM issues. The DDMS will also be the coordinating deparment, the champion, for the reinforcement of district level PSM capacities. The DDMS will have the following responsibilities:

- Supporting local council and hospital level in developing and maintaining logistical management capacity through training and formative supervision
- Pro-actively function as a logistical management "help desk" for the local councils, hospitals and any other health service delivery organisation
- Coordinating and monitoring the implementation of the district PSM reinforcement plan
- Identifying funding sources
- Identifying, quantifying and costing the needs at the different levels, making sure that procurement plans are aligned to the regular planning and budgeting process; donor coordination, enforcing donations guidelines
- Selecting the products to be procured (together with the NMC maintaining the EDL and other lists of essential medical products, BPEHS)
- Monitoring the budgets of the local councils and the hospitals (with the MOF)
- Monitoring and evaluating APPSA on behalf of the government
- Supporting efforts to increase rational use of medicines at PHU and hospital level

The above mentioned functions are within the core functions tasks defined in the NHSSP :[7]

- Policy formulation
- Standards setting and quality assurance
- Resource mobilization
- Capacity development and technical support
- Provision of nationally coordinated services, e.g. epidemic control
- Co-ordination of health services
- Monitoring and evaluation of the overall sector performance
- Training

How exactly the DDMS's role is going to be redefined is beyond the scope of this document. This will however have to be researched further.

In the project budget, a line has been reserved to engage appropriate expertise to assist the MOHS in redefining the DDMS's role.

[7] National Health Sector Strategic Plan 2010-2015

9 Reinforcing the Pharmacy Board of Sierra Leone

There is evidence that illegal handling of medicines in Sierra Leone is quite substantial. Apart from an increasing number of ineffective, poor quality and counterfeit medicines, smuggled from neighbouring countries, it is being suspected that medicines distributed trhough the MOH systems leak to drug peddlers. This forms a big risk for the regular supply system and therefore puts the development of APPSA at risk and needs to be addressed.

Availability of quality medicines can only be ensured if a medicines regulatory system is in place, which ensures that only good quality medicines are on the market and handled according to up to date standards and norms.

The Pharmacy Board of Sierra Leone (PBSL) will be in the centre of the development of a comprehensive and integrated Quality Assurance (QA) system, which includes the following functions:

1. Determining and issuing standards, norms and rules;
2. Registration of medicines;
3. Market surveillance;
4. Inspection, licensing and enforcement;
5. Quality control (QC);
6. Pharmaco-vigilance; and
7. Medicines Information services.

These functions are to be supported by adequate legislation[8]. The steps to be taken should start with an assessment of the current system and legislation using a standard WHO tool[9]. Based on the assessment, a strategic plan needs to be developed that covers all the technical and organisational aspects of the new PBSL and other parties involved.

Annual PBSL business plans may be derived with clearly defined costed actions and targeted objectives. One of the aims is to create a PBSL that has professional autonomy and adequate financing and is able to attract and retain professional staff.

In the light of the development of APPSA and the overall PSM systems at national and district levels, the following issues need to be addressed over the coming two years:

- Analyse and evaluate the PBSL registration function needs. Subsequently develop a list of needs to prepare for the choice of a registration need tools,

[8] For this purpose, the current Drugs and Pharmaceutical Act of 2001 may need to be reviewed.
[9] WHO 2008, WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014; can be downloaded from http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/

including human resources, information technology hardware and software tools, training, reporting formats, follow-up activities, standard operation procedures and others.

> The only of the shelf software tools for MRAs are SIAMED (WHO developed) and PharmaDex (MSH developed). It is possible to develop a custom software tool based on the evaluated needs of the PBSL. The choice has to be made on the basis of an evaluation and analysis of PBSL's needs and preferences.
>
> The experiences with SIAMED vary. In Tanzania they have abandoned SIAMED for a custom developed tool. In Mali, SIAMED was installed in 2006 but is no longer functional. In the Dominican Republic 3 years were spend customizing SIAMED and their needs are still not fully addressed. PharmaDex was developed by the MSH for the Namibia RMA.

- Develop a QA Policy and to adopt as an integrated part of the SL NMP
- Ensure that the QC Laboratory is able to test most essential medicines from the EMLSL
- Create a sustainable financing system by a combination of licensing fees, QA-tax on medicines' imports and government subsidies.
- Actively involve the important stakeholders (pharmacists, insurers, hospitals and professional associations) in the development of norms and standards for pharmaceutical care.
- Strengthen regional and international collaboration, in particular with stringent Medicines Regulatory Authorities and QC labs regarding information and/or work sharing, such as quality of procured medicines, procedures used and development of norms and standards.
- Adapt the current legislation to the new requirements.

Similar to other countries in the regio, Sierra Leone is relatively small with limited resources. It is not realistic to expect that it will be able to set up and maintain its own a fully fledged regulatory system as is the case in countries with a so-called 'stringent' regulatory authority.

Without giving up its own mandate, it is recommended that the PBSL make use of 'stringent' MRAs work in other countries and of the WHO prequalified medicines lists.[10] However, there are no written guidelines for this strategy, although for example, the GFATM is making use of this strategy since at least 2004.[11] The PBSL needs to develop specific guidelines, especially in order to establish that the medicines registered and brough onto the market are indeed the same medicines that are WHO prequalified or registered by 'stringent' MRAs.

A innovative approach to fight the illegal trade in medicines (including counterfeit) is to strengthen the existing system to record and test each batch of legally imported

[10] The PBSL did inform us that they do already accept medicines that are duly registered with the Ghanaian RMA.

[11] See: http://www.theglobalfund.org/documents/psm/Annex1-%20FullTextRevisedQualityAssurancePolicy_en.pdf. Accessed on 12/09/2010

medicines. When the basic characteristics of medicines as finished products (i.e. the product description, name and address of manufacturer, product number and batch number) of each and every medicine found anywhere in the country can be matched against the same data of all legally imported medicinesit it is quite simple indeed to establish whether the medicines are legal or not.

When the APPSA and the other medicines distributors will introduce batch tracking in their PSM system, it will also be possible to establish if medicines have leaked or not.

A generic approach for MIS System development[1]

There are four components to address:

- the actors who take decisions (managers, procurement officers, warehouse staff, Advisory Board, MoH);
- the data and information that is useful for decision-making;
- the procedures that determine how the actors relate to the data;
- the tools that facilitate the collection, analysis, storage and dissemination of the data.

All four components are important and necessary to address in the **design phase of a MIS**. Without a **needs analysis** that includes all actors, an **operational manual** that explains who does what and when (not just how to use the software) and a **database structure**, hardware and software programs are likely to be almost useless.

The first step is to describe the business operations. It is important to gain an intimate knowledge of the major current (As-Is) operations. This process involves a thorough analysis of what is currently in place, where there are problems or shortcomings, why they exist and where improvements are required. Also future (To-Be) business operations and the business' policies should be identified to achieve the strategy of the business. Subsequently, the gap between As-Is and To-Be should be made understood.

The next step is to develop an Information Technology (IT) strategy, It will guide in defining what kind of IT infrastructure is required to be in place (or replaced) to support the business in general terms. It is important to define the boundaries of the system, on which areas the system should focus. The boundaries depend not only on the required infrastructure but also on the skills and the level of ability of staff to work with the system.

After developing an IT strategy the functional and technical requirements of the system should be identified, resulting in a List of Requirements[1]. Functional requirements may be those that will resolve or reduce the problems in the existing system (As-Is operations), and those that are new functional abilities which the current system cannot provide (To-Be operations). It is usual that a lot of functional requirements of the old system are kept and integrated in the new MIS.

Technical requirements involve: IT infrastructure (hardware, LAN), OS system Server / Workstations, software (back-up, anti-virus, etc.), general system requirements like data security, integrity, compatibility with other (office) software and migration of existing data in the new system and data transfer.

Adapted by Rob Verhage (HERA) from a report by Mr. Gert Kaasschieter, MedICT, The Netherlands 2008

With the support of the stakeholders, the PBSL may be able to find a long-term partner who is able and willing to support the PBSL with the assessment and subsequent strenthening of the QA system and legislation.

The consultants had a meeting with a representative of the United States Pharmacopeia (USP). He confirmed that the USP is in principle interested to work in

Sierra Leone through its "Promoting the Quality of Medicines" program. This is a $35 million, five–year program that is already active in a number of African countries.[12]

The WHO also has a pool of excellent experts in the area of regulatory functions. They can be asked to support the initial assessment of the PBSL needs.

[12] For more information see: http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=3vfHBQURlPR5gn7FVQ5XzQB3sPSss9Z%2BLh1Y%2BHMENPA%3D . Accessed 12/09/2010.

10 Monitoring and evaluation of the PSM reform project

10.1 Ethical principles in supply chain management

Ethical principles are introduced at various levels in the supply chain. The main objective of these principles is to reduce fraud and corruption.

The basic principles of the Codes of Ethics published by international organisations such as the one of the *Chartered Institute of Purchasing and Supply* (CIPS) or of IFPMM (*International Federation of Purchasing and Materials Management*) are usually similar and focus on the following principles:

Purchasers have to:

A. be loyal to the organisations in which they are employed,
B. treat suppliers in fair way,
C. support fair competition, and
D. defend the profession's reputation.

Some substantial rules have been developed from these principles:[13]

- Personal interests, that possibly have a conflict of interest with the organisation, have to be reported to the management.
- Requesting or accepting cash, loans or credit from (potential) suppliers is prohibited. Receiving presents from the supplier, even in the form of recreation possibilities, favours or services should be avoided.
- All information and information sources on the purchasing process need to be handled in a way that is exclusively in the interest of the organisation.
- Purchaser can only accept a discount on goods for personal use after written approval from the management of the organisation.
- All potential suppliers will get the same, correct information.
- Suppliers will not be requested to give information regarding competitors.
- All information in the supplier's offers for goods, works and services will be handled confidentially.
- Personal reasons will not effect the selection of suppliers.
- Purchasers will pursue the highest level of expertise.
- All agreements and appointments will be kept.
- Purchasers need to contribute to the advancement of the quality and the status of the procurement.

[13] Freely translated from a publication of NEVI, the Dutch branch of IFPMM with input from the consultant

The ethical principles are the basis of a code of conduct for the APPSA employees. The enforcement of the principles will be supported by a number of institutions and activities:

At the level of APPSA

1. A code of conduct/ethics will be attached to each employment contract and will be signed by each employee. This is done to have an active commitment of every individual involved in the supply chain and to make him or her aware of the boundaries
2. The code of conduct will also be signed by the members of the Board of Directors
3. APPSA will have a zero tolerance towards fraud and corruption at any level in its organisation
4. Specific and explicit articles on fraud and corruption will be part of the standard bidding documents

Compliance with ethical principles will be monitored on a regular basis by the Board of Directors for the senior management and by the senior management for the other staff.

The monitoring and evaluation plan of the PSM reform project

The organisation of this component depends on the requirements of the funder of the project. An external mid-term review is proposed to validate the progress of the project.

Addressing the three fold impact of potential corruption and fraud:

(i) Poor government capacity to provide access to good-quality medicines,
(ii) Economic, as pharmaceutical expenditure presents a large part of the public health budget and
(iii) The credibility of public institutions is reduced by abuse and lack of transparency.

Source: Adapted from "Good Governance for Medicines", WHO, 2010

10.2 Oversight, regulation, audit and monitoring

Good governance is "the process of decision making and the process by which decisions are implemented (or not implemented)".[14] To ensure that this is done one needs oversight bodies, a well-defined regulatory environment, systematic monitoring and routine audits.

In this paragraph, three figures present institutional relationships of bodies involved in some form of oversight: (i) routine oversight bodies, (ii) internal PSM system checks and (iii) temporary monitoring initiatives. For each body possible role and functions in the oversight are described.

[14] UN ESCAP: http://www.unescap.org/pdd/prs/ProjectActivities/Ongoing/gg/governance.asp. May 2010

10.3 Routine oversight bodies

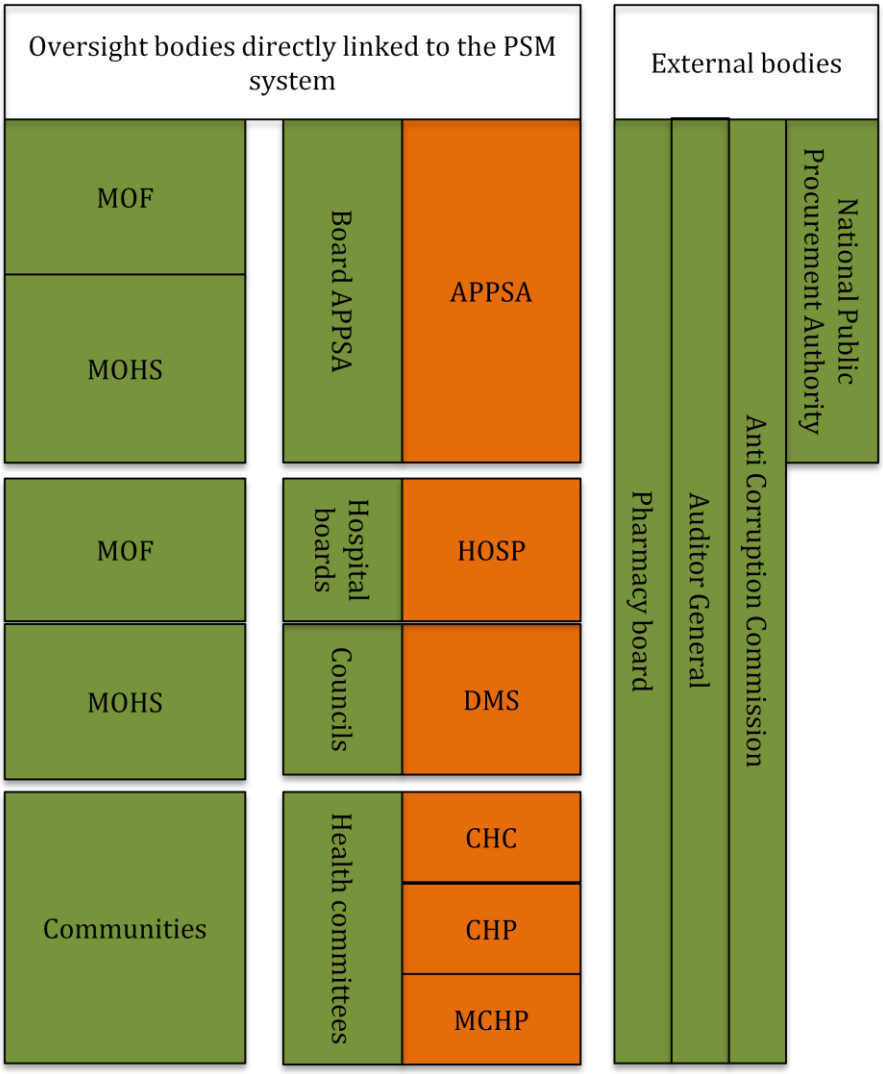
The system already includes a number of routine oversight bodies.

In the long term, these are the main bodies that ensure that the PSM system is governed well.

A general PSM monitoring strategy is to put procurement and supply information as much as possible in the public domain.

For this purpose an investment will be made, from the beginning, in an APPSA website. Information on the website will include distribution lists with quality, quantities and dates per district, APPSA prices, local council and hospital budgets and donor funded budgets per local council and hospital.

Figure 10-1: Routine oversight bodies



10.3.1 APPSA Board

The board is the first line of supervision.

A Board of Directors of which the Chair is appointed by the President. The membership is described in the statutes. The members are selected from different major stakeholders such as the MOHS, MOF, local councils, tertiary hospitals, development partners, NGOs, special health programs, business community, civil society and others.

All members will have appropriate qualifications needed for the fullfillment of the Board tasks, which are either, pharmaceutical, public health, logistics, financial, administrative management, business or legal expertise. The number of members should be sufficiently large to allow for a divers representation as indicated above. If the number of statutory board members does not allow for a representation of all groups or capacities, the board has the authority to coopt members for specific purposes.

It is highly recommended that the president of the board and the general manager of APPSA are both routinely invited, or members of, the High Level Steering Committee. This will ensure that all stakeholders will be informed of any opportunities and issues as soon as they arise.

To ensure that the board and the senior management work closely together, especially during the first 2 years, it is strongly advised that the board selects a **board management committee** that meets with senior management once a month and whenever deemed necessary. The board management committee will have 3 to 5 members who can easily come together on short notice to deal with daily issues and give quick solutions. The members have to have the confidence of the other board members. This committee also functions as the board's eyes and ears.

Responsiblities of the board management committee:

- Monthly supervision based on the data produced by the management information system: management information dashboard
- Assisting the senior management with policy matters
- Assisting the senior management in its relationship with the main stakeholders

The board management committee will refrain from interference with the actual management tasks of the APPSA and avoid conflicts of interest by managing themselves.

A special training session will be organised for the board of directors on their role and responsibilities and how to exercise these in the best way possible.

10.3.2 APPSA internal audit unit

One of the main instruments of the APPSA board is the APPSA internal audit unit. The information produced by the internal audit unit is for direct use by the general manager and the board of directors.

Some of the internal audit unit's tasks are:

1. Monitor the compliance with the standard operating procedures.
2. Regularly take random sample of batches and follow their document trail from order to expedition
3. Organise, weekly, "rolling inventory" exercises whereby for 3 to 5 products which are part of the top 50 selling articles an inventory is done

10.3.3 APPSA external audit

The board and the government will commission an annual external audit to be conducted by an independent private audit firm. They will conduct annual financial and procurement audits as per internationally accepted standards. Part of their mandate is to certify the accounts but also to validate a sample of the concluded tenders and to conduct an inventory sample. The external auditors will present their findings and recommendations to the board of directors.

More details on the role and functions of the internal and external audit functions in Annex 12 on page 112.

10.3.4 Hospital boards, local councils and community health committees

In the same way that the APPSA board supervises the operations of the APPSA, the hospital committees supervise the operations of the hospitals, DMS' and PHUs respectively. Although this may not be done on a regular basis, nor do all PHUs have community health committees yet, these are routine oversight bodies that are part and parcel of the system. In the medium term they will play an important "first line" role.

APPSA will provide the hospital boards and local councils with supply information on request. APPSA will also put supply information on its website where it can be accessed by hospital boards and local councils.

The role of the communities in supervising the health facilities is through the village or community health committees. They are the most sustainable and long-term viable option to ensure regular supervision (of governance issues, not including technical issues) of PHUs.

10.3.5 Communities

In any case the active participation of the community members is required. To achieve this, the village health committees will be revived, or established where they no longer exist, with the village headman or chief as chairperson and the in-charge of the health facility as secretary to the committee. Other members can include representatives of youth groups, women groups, traditional healers, head teacher of the school and, where present, extension workers present in the village.

Receipt of drugs and supplies (whether supplied by the DMS or collected by the PHU) are witnessed by at least two committee members including the chief/headman or his/her representative. They will sign or thumb point the delivery notes after comparing the quantities of drugs and supplies received with the quantities mentioned on the packing list. These supplies are then taken over by the in-charge and properly recorded and stored.

Visiting members of the District Health Management Team are to use their monitoring and supervision visits also to sensitize the community about fake drugs on the market, the FHCI and the regular cost recovery program.

The community will ensure adequate security for the drugs and supplies and its correct use for the various groups. Supplies will be requested by the in-charge based on utilisation. Any PHU order will be co-signed by the president of the village health committee.

10.3.6 Ministry of Health and Sanitation

The relationship between the MOHS and APPSA will be governed by a general agreement and a performance agreement (which may be part of the general agreement). In the contract, the institutional, operational and reporting details and obligations will be described in more detail than this is done in the statutes. The performance agreement will include indicators and benchmarks. The DDMS will monitor the implementation of the contract and the APPSA performance (i.e. have they achieved the agreed benchmarks of the peformance indicators) which will be discussed annually or more often as the case may be.

The Department of Drugs and Medical Supplies (DDMS) will monitor APPSA as well as the DMS operations and report to the logistics sub-committee (or the pharmaceutical sector committee as the case may be).

The same department will receive information produced by the APPSA MIS. The MIS is able to produce verifiable information about all their operations. The MIS will also include a "dashboard" for the APPSA management and for the APPSA board.

The DDMS will also receive information directly from the DMS through the logistical management information system being put in place currently.

The DDMS:

1. will, together with the APPSA board be able to initiate an external audit of the APPSA operations.

2. will manage the batch tracking exercise every 6 months or however often is deemed necessary.

3. will receive routine reports from the APPSA on the quantities and values purchased and distributed.

4. will receive the order and distribution information per client when it concerns a government institution like the DMS or a public hospital.

5. will manage bi-annual system audits. These will be batch-tracking exercises. The batch numbers appear on each and every document in the entire supply chain. Batch tracking exercises are based on a sample of batches taken at national level. The batches are chosen through a qualified random procedure. For each of the batches a sample of the clients (local councils and hospitals) will be taken. At the DMS level another sample of the clients (PHUs) will be taken from the distribution list of the batches in the sample. This exercise follows thus a batch throughout the supply chain, from APPSA to PHU. This exercise has various advantages: it evaluates the quality of the administration and documents at all levels while at the same time it audits the supply chain.

6. will also be able to follow-up on private sector orders made by a DMS. As indicated above, a DMS is allowed to procure from the private sector in case APPSA does not have the particular product in stock. The DMS should keep a document in their administration that shows that APPSA could not fulfil their order. This document justifies the private sector order. This is relatively easy for the DDMS to check: comparing the DMS document with the APPSA documents.

7. will work with the formative auditors to set up a SMS based inventory audit system of 5 to 10 key indicator medicines on a weekly basis (see for more information section 10.8).

10.3.7 Ministry of Finance and Economic Development

The Ministry of Finance and Economic Development (MOFED) is responsible for the funding of the medicines budgets of the local councils. Through the government's auditor general they audit the local councils.

10.3.8 Pharmacy board

The role of the Pharmacy Board within the health and pharmaceutical sector is well defined.

APPSA is subject to all rules and regulations of the Pharmacy Board in the same way as all other pharmaceutical importers, wholesalers and distributors.

It should be clear that APPSA should comply with the valid laws and regulations.

10.3.9 APPSA non-routine but expected regular monitoring

APPSA will receive regular auditing and monitoring visits from those donors that partake in its financing either directly or by using APPSA as a service delivery organisation. These specific visits also constitute a check on the APPSA operations.

10.4 Additional project related monitoring

For the first years into the new PSM system, investments in additional non-permanent, non-routine oversights will be made specifically at district level. At national level the above-described oversight configuration is regarded as sufficient.

At district level "formative auditors" positions will be created. These individuals will report to the Fiduciary Agent (FA) or, in case there is no FA, to APPSA or to an oversight committee (in fact they report to the organisation that employs them). They are responsible for day-to-day supervision of the DMS operations. Their main tasks are:

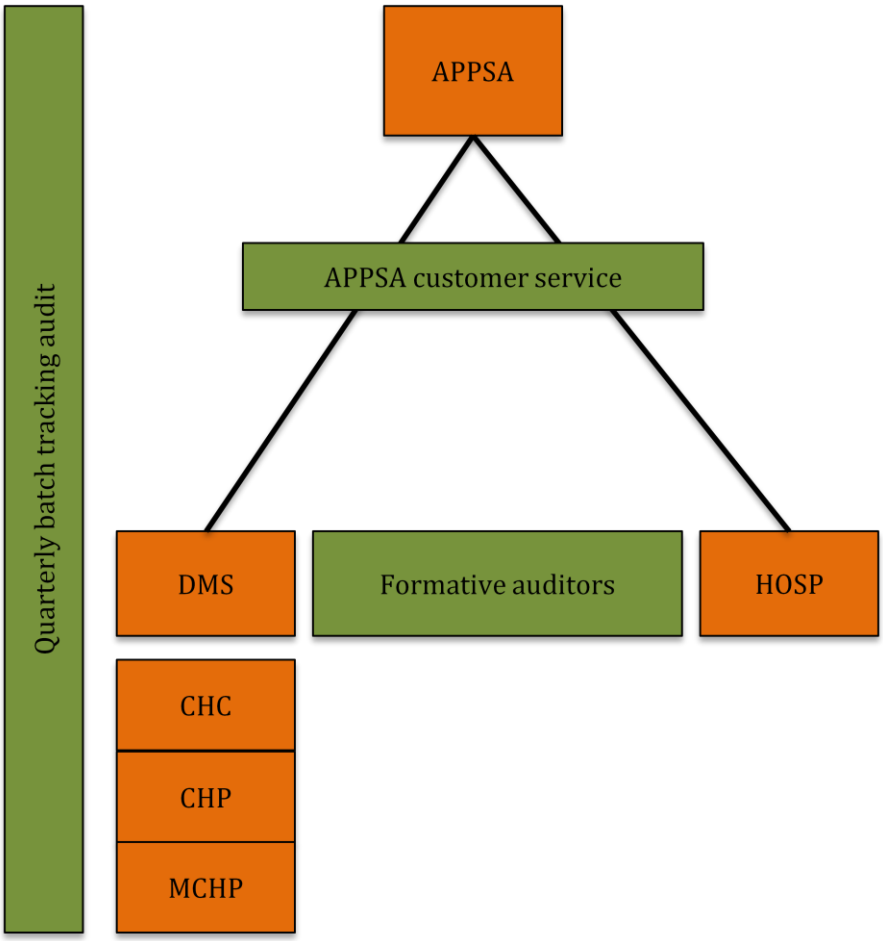
1. They will play a role in supporting the DMS in managing their logistical management (information) software.
2. They will also validate all receipt, supply and stock inventory documents and assist the DMS management in the filling out of the documents if and when necessary or requested.
3. They will have access to all information also from central level.
4. They will assist with the management of all PSM documents in the DMS: filing and archiving.

When this is done over a period of two years, one can expect that the DMS have been sufficiently supported to be able to use the LM(I) software. It can also be expected that good practices in regards to document maintenance and management have been installed.

The position of the formative auditors should be negotiated and approved by the local councils. Without their support, this additional position will not have the added value that can be expected.

APPSA has a customer services (or marketing department or unit) that assists the clients in preparing their orders. The local councils together with the main hospitals represent a relatively small number. Each of these main APPSA clients can be visited on a regular basis. How often these visits would take place depends on the ordering frequency. It is assumed that every regular order would be preceded by a visit from a customer representative.

Figure 10-2: Additional monitoring



10.5 Internal checks and balances

Internal to the organisations that make up the PSM system there are a number of checks and balances.

Three members of the senior management team are externally funded technical assistants. They do report to the APPSA board and they are subject to the APPSA internal rules and regulations. They have a contract with the TA firm and are expected to function exemplary and set the highest moral standard in conducing the APPSA business. The TA firm will be supervised by (i) the MOHS, (ii) the APPSA board and (iii) the organisation that has contracted them.

There is the proposed APPSA internal audit unit.[15] This unit reports directly to the general director. This unit monitors the compliance of the organisations with its own procedures.

Within APPSA there are two moments where responsibility for stock products is transferred from one department/unit to another. Within APPSA, the procurement, storage and distribution functions will be separated. Transfers between these functions are documented.

Between APPSA and its clients (in the figure below, the DMS and the hospitals) there is a distinct and documented transfer of responsibility.

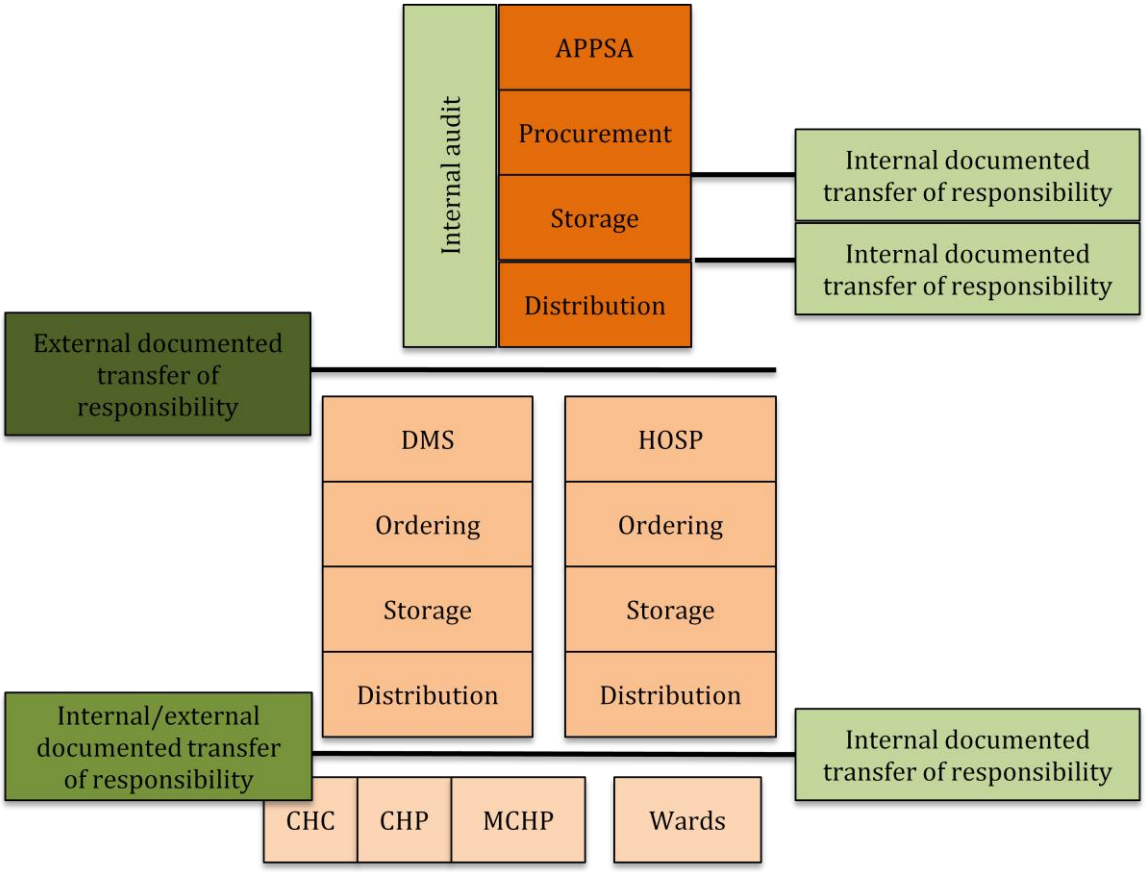
Between the DMS and the PHUs there is another documented transfer of responsibility. It is partly internal and partly external. Internal as the PHUs are part of the district health system but external as the community is involved in the receipt of the orders.

Within the hospitals, there is also supposed to be a documented transfer of responsibility.

These documented transfers allow internal and external auditors and monitors to track a document trail through the PSM system. Any product, identified by description and batch number, can be traced from the moment it is imported to the moment that it is entered on the PHUs' stock card. Any order, either by order number or through the batch number of a product on the invoice or supply form can be traced from the moment it enters APPSA until it is entered on the PHUs' stock card.

[15] Internal Audit is based on the existence of internal controls, measuring compliance with these policies and procedures and recommending improvement actions to management. Internal Audit 'advises' management on issues that arise and whether follow-up action has been taken. It is an ongoing process.

Table 10-1: Internal checks and balances



10.6 Follow-up

If and when improprieties are found in the PSM system, these have to be followed up. Without an immediate and consistent follow-up supported by all stakeholders and implemented by the regulatory authorities nothing will change.[16] At APPSA level, changes can be introduced relatively quickly as it is an independent organisation with limited time staff contracts (people can be let go or suspended, procedures can be adapted etc.). However, at local council and hospital level, it is more complicated. Staff at those levels is government employed, procedures have been developed and implemented following government practices. Change at that level does not come easy. The local councils in close collaboration with the MOHS should find appropriate solutions.

APPSA can suspend supply to a client if and when audit or monitoring reports have found improprieties or where there is no timely payment.

[16] Examples were given to the consultants of improprieties which had been discovered but had not been followed up because of either political pressure or lack of police investigative capacity. This is not something that can be addressed by reconfiguring the PSM system only.

10.7 Sharing of documents

The MOHS and her partners have to lead by example: fair and transparent regulations, proper recording and sharing of information.

The following table presents a list of documents that will be available in the PSM system and which will be taken into account during monitoring, supervision and audit visits.

Many of these documents will be available on the APPSA website and will be open to public scrutiny.

Table 10-2: Documents used in oversight systems.

Type of document and information	Owner	For whom	Public domain
Annual report APPSA	APPSA Board	Board and stakeholders	Yes: APPSA website
Annual plan APPSA	APPSA board	MOHS and stakeholders	Yes: APPSA website
Annual budget APPSA	APPSA board	MOHS and stakeholders	Yes: APPSA website
Tender prices	APPSA	APPSA, local councils, hospitals and others	Yes: APPSA website
Awards to suppliers	APPSA	APPSA, local councils, hospitals and others	Yes: APPSA website
Internal receipt and transfer documents	APPSA	APPSA internal audit, external auditors, MOHS	No
Distribution lists	APPSA	local councils, hospitals, others	Yes: APPSA website
Invoices clients	APPSA	local councils, hospitals, others	Yes: APPSA website
Internal audit reports APPSA	APPSA management	Board and management APPSA	No
External audit APPSA	APPSA Board	Board and stakeholders	No
Certification of APPSA accounts	APPSA Board	Board and stakeholders	Yes
Memoranda of understanding (between MOH and APPSA, between APPSA and donors or clients)	MOHS & APPSA	Board and MOHS	Yes
Contracts between APPSA and external clients	APPSA	Board and management APPSA	No
Annual medicines budget local councils	Local councils	General public	Yes: APPSA website
Annual medicines budget hospitals	MOFED	General public	Yes: APPSA website
Cost recovery budgets	Local councils/MOFED	General public	Yes: APPSA website
Donor budgets	Donors	MOHS, local councils, hospitals, APPSA, General public	Yes: APPSA website
MOHS supervision reports	MOHS	local councils, hospitals	No
APPSA supervision reports	APPSA	local councils, hospitals, others	Yes

Type of document and information	Owner	For whom	Public domain
MOHS LMIS reports and indicators	MOHS	local councils, hospitals, others	Yes: APPSA website
Reports NPPA	NPPA	NPPA	Yes
Reports PBSL	PBSL	PBSL	Yes

10.8 Formative auditors

The creation of one externally funded PSM position at each local council level was agreed upon. This position is called "formative auditor". The title tries to capture two of the main functions of this position: (i) training and support and (ii) checks and controls.

The three main reasons to have this district level position:

1. It emerged during the interviews and visits to the local councils that the introduction of the new standard operating procedures, the LMIS and the Channel software will, as is the case with all introductions of new or renewed elements in a system, create "teething" problems.

2. The creation of a new central medical store with its own procedures and documents will also cause changes at local council level as they will have to use different order forms or different payment, ordering or distribution conditions. APPSA can work through the formative auditors to ensure that these changes are well understood and integrated

3. Finally, all stakeholders agreed that an additional PSM system check and control at local council level is necessary.

The position will be funded for a period of two years. It is assumed that this period will suffice to ensure that all "teething problems" are out of the system and that the standard operating procedures are fully understood and applied in every DMS without a need for continuous external verification.

The positions are local technical assistants' positions. The formative auditor is not part of the MOHS structure. Either APPSA or the funder of these positions contracts the position, whatever is the most practical.

The reports and verification certificates produced by the formative auditor will be available for the DMS, the DMHT, APPSA, the funder, the MOHS and other stakeholders that work in that particular local council.

The objectives of this position are three-fold and related to (i) audit (supervision, control, final check), to (ii) support ("helpdesk" for Channel and SOPs) and the (iii) dissemination of information (reports, orders and others). Specifically the terms of reference can be build around the following activities:

1. to ensure that all receipt, storage and distribution related documents as well as all reports produced by the local council's storage facility (either the DMS or the storage facility at city level) are accurate and timely
2. to supply the stakeholders every month with a signed declaration that the documents have been verified and have been found in order
3. to assist the DMS management with the preparation of the APPSA orders and liaise with APPSA for order, supply, invoicing and budget issues
4. to assist and support the DMS management with the full application of the LMIS manual
5. to assist and support the DMS management with the manipulation of the Channel software (on-the-job training and assistance) and the production of the Channel reports
6. to ensure that at least two DMS employees know how to operate Channel
7. to ensure that the hardware and software necessary to operate Channel is up to date and functional

8. they will be asked to collaborate with the DDMS on a continous inventory exercise. It is proposed that the stakeholders with the DDMS design a simple weekly stock auditing system whereby the DDMS sends a list of 10 products to all the formative auditors by SMS. A slightly different list every week. The formative auditor do an inventory of the products and compare stock cards with physical quantity on the shelf. The formative auditors report back to the DDMS within 24 hours with the results. To facilitate this system a SMS reporting software (frontline SMS for example) can be installed at the DDMS. The inventory results will be expressed "0" and "1". When for a product the inventory is correct, it is a "1", otherwise a "0". The SMS send from the formative auditors to the DDMS will be a chain like "0001010011". The SMS software can automatically convert this to a list of products and the results. The results can be put on the APPSA website every week for every DMS.

The formative auditors will be trained on the relevant issues by APPSA and other relevant stakeholders before they will be send to the local councils. The training will revolve around the issues described above and will include all the LMIS training that DMS managers have had since the development of the new LIMS manual and the application of the Channel software. They will be in regular contact with APPSA and Channel technical assistants.

A specific training module will be compiled from the existing training modules with in addition a section on their contractual and reporting structure, a section on their role and responsibilities vis-à-vis the local councils and a section on the APPSA systems and procedures.

10.9 Risk mitigation measures

To sum up the risk mitigation measures for medicines availability and quality monitoring at all levels that have been described above:

- by making most PSM information (quantities, prices, order and delivery dates, order fulfilment rate and others) available on the APPSA website
- through the DDMS agents: batch tracking exercises through the PSM system from APPSA to the PHU
- through the MOH regular monitoring systems at central and district level
- through the FA (if one is going to be created and installed): regular auditing of orders, inventory, supplies, invoices and payments
- through DMS formative auditors that are based at the district level: DSM and Hospital pharmacies. Contract with fiduciary agent and reporting to FA and the MOHS.
- through regular visits of DHMT and DMS monitors at PHU level
- Community involvement at PHU level

10.10 Monitoring and evaluation schedule 36 months

PSM implementation phase is 36 months. We have drafted an M&E calendar with all activities that are part of the M&E with frequency, report and subject. There are two main types of M&E over the first 36 months of the project (i) PSM project M&E and (ii) PSM routine M&E.

	Routine PSM system M&E							Project related PSM M&E		
Month	**APPSA M&E**			**Health Policy Coordinating Committee (HPCC)**	**Pooled Medicines Fund**	**PBSL**		**Formative auditors**	**Batch tracking exercise (BTE)**	**Project M&E**
Month 1		Board of Directors meeting (BOD)	Monthly dashboard indicator (MDI) reporting: website and HPCC			Inspection premises		Monthly reporting to HPCC		
Month 2		BOD management supervision committee (MSC)	MDI					MR		

	Routine PSM system M&E							Project related PSM M&E		
Month	**APPSA M&E**			**Health Policy Coordinating Committee (HPCC)**	**Pooled Medicines Fund**	**PBSL**		**Formative audit ors**	**Batch tracking exercise (BTE)**	**Project M&E**
Month 3		BOD	MDI	Progress report firm to PHCC on APPSA development (PR) based on the work plan and project contract				MR		
Month 4		MSC	MDI					MR		
Month 5		MSC	MDI					MR		
Month 6	Tender committee	BOD	MDI	PR				MR	BTE	
Month 7		MSC	MDI					MR	BTE	
Month 8		MSC	MDI					MR		
Month 9	Tender committee	BOD	MDI	PR				MR		
Month 10		MSC	MDI					MR		
Month 11		MSC	MDI					MR		
Month 12		BOD	MDI	PR		Inspection premises		MR	BTE	

	Routine PSM system M&E							Project related PSM M&E		
Month	**APPSA M&E**			**Health Policy Coordinating Committee (HPCC)**	**Pooled Medicines Fund**	**PBSL**		**Formative audit ors**	**Batch tracking exercise (BTE)**	**Project M&E**
Month 13		MSC	MDI					MR	BTE	
Month 14	Annual financial audit	MSC	MDI					MR		
Month 15		MSC	MDI	PR				MR		
Month 16		MSC	MDI					MR		
Month 17		MSC	MDI					MR		
Month 18	Quality control first arrivals + reception committee	BOD	MDI	PR		Quality control		MR	BTE	Mid term review
Month 19		MSC	MDI		Verification invoices M1			MR	BTE	
Month 20		MSC	MDI		VF M2			MR		
Month		MSC	MDI	PR	VI M3			MR		

	Routine PSM system M&E							Project related PSM M&E		
Month	**APPSA M&E**			**Health Policy Coordinating Committee (HPCC)**	**Pooled Medicines Fund**	**PBSL**		**Formative audit ors**	**Batch tracking exercise (BTE)**	**Project M&E**
21										
Month 22	?	MSC	MDI	?	VI M4			MR		
Month 23	?	MSC	MDI	?	VI M5			MR		
Month 24	?	BOD	MDI	PR	VI M6	Annual inspection premises		MR	BTE	
Month 25	?	MSC	MDI	?	VI M7			MR	BTE	
Month 26	Annual financial audit	MSC	MDI		VI M8			MR		
Month 27	?	MSC	MDI	PR	VI M9			MR		
Month 28		MSC	MDI		VI M10			MR		
Month 29		MSC	MDI		VI M11			MR		
Month 30	?	BOD	MDI	PR	VI M12			MR	BTE	
Month 31	?	MSC	MDI	?	VI M13			MR	BTE	
Month 32	?	MSC	MDI	?	VI M14			MR		
Month 33		MSC	MDI	PR	VI M15			MR		

	Routine PSM system M&E							Project related PSM M&E		
Month	**APPSA M&E**			**Health Policy Coordinating Committee (HPCC)**	**Pooled Medicines Fund**	**PBSL**		**Formative audit ors**	**Batch tracking exercise (BTE)**	**Project M&E**
Month 34		MSC	MDI		VI M16			MR		End of project evaluation
Month 35		MSC	MDI		VI M17			MR		
Month 36		BOD	MDI	PR	VI M18	Annual inspection premises		MR	BTE	
Month 37	Annual financial audit	MSC	MDI		VI M19			MR	BTE	

ANNEXES

Annex 1 November 2004 NPPU Statutes

Creation of a new Statutory Authority for the procurement, storage, supply and distribution of essential drugs and medical consumables for the public sector in Sierra Leone.

Draft Statutes (5)
November, 2004

1. Preamble

1.1 Under the financing agreement signed between the Government of Sierra Leone and the European Union in 2002, provision was made for the establishment of a new, autonomous entity to replace the existing Central Medical Stores (CMS that would provide the population of Sierra Leone with a regular supply of affordable essential drugs and medical consumables on a self-financing and sustained basis.

1.2 The GOSL/ADB/HSRP Pharmaceutical component in collaboration with HSSP is currently revising the National Medicines Policy which reflects this development of creating an autonomous CMS to address essential medicines supply system.

1.3 The concept of an autonomous central drugs procurement and supply unit is not new, and has been practiced for 10-15 years in several neighboring countries, in particular Benin, Cameroon, Burkina Faso, Zambia, Uganda etc.

1.4 In order to study more closely the feasibility and opportunities for the creation of a similar unit in Sierra Leone, the Health Sector Support Programme (HSSP), an EU-funded programme, sponsored among other interventions 1) a study tour to the above countries by key CMS and Ministry of Health and Sanitation (MOHS) officials in April 2004 and 2) a consultancy by a pharmaceuticals legal expert in May and in October 2004.

1.5 Contact was also established with the Attorney-General's office in Freetown and with local legal experts. A task force was formed comprised of officials from the CMS, A G's office, MOHS and HSSP (Health Sector Support Programme) and Consultants which prepared the first draft of legal considerations for the new purchasing and supply unit

In addition the HSSP international legal consultant developed a paper for the MOHS outlining the advantages and disadvantages of several options for the creation of the unit (Ref. report Gerald Moore, May 2004 with Addendum and Update August/September).

1.6 The report concluded that there were major advantages to be gained by the formation of an autonomous Statutory Authority to take the place of, and take over the functions of the present CMS.

1.7 Through letter of September 6, 2004, the Minister of Health indicated here concurrence with the conclusions of the report and directed for further action and to proceed with the drawing up of the necessary legal framework and statutes for the new Statutory Authority.

1.8 1.8. The following are proposed draft Statues for the new Authority which would be presented by the MOHS through the Attorney General office to the Cabinet Office and then to Parliament for legislative action. These Statutes were and discussed at a workshop convened by the Hon Minister for Health on October 7th 2004. Agreed revisions by the stakeholders have been included in the draft Statues.

DRAFT 5

2. Establishment of a Statutory Authority (SA) for the National Pharmaceutical Procurement Unit (NPPU) for Sierra Leone.

Draft Statutes (revised 19th November, 2004)

Article 1

There shall be formed a Statutory Authority (SA) to be known as the National Pharmaceutical Procurement Unit (NPPU) which shall be responsible for the procurement, storage, supply and distribution of essential drugs and medical consumables to the people of Sierra Leone. This new entity shall take some of the responsibilities of the existing Central Medical Stores (CMS) however with expanded functions and responsibilities.

2.1. The NPPU shall be an auto0nomous body corporate having perpetual succession and capable of acquiring, holding and disposing of any property and assets, whether movable or immovable, and of suing and being sued, and of performing all such acts as bodies corporate may be law perform.

2.2. The resources of the NPPU shall comprise, but not be limited to:

- Funds or other monetary contributions provided by the Government of Sierra Leone.
- An initial endowment in cash and medicines put at the disposal of the NPPU by projects financed by sponsors, donors and aid agencies operating in and supporting the Health sector in Sierra Leone.
- The value of the buildings, fixtures and fittings and all equipments at the site of the present Central Medical Stores in Freetown and elsewhere put at the disposal of the NPPU by the State of Sierra Leone.

- Revenue collected from the transfer or sale of pharmaceutical and other types of medical products.
- Income from investments.
- Subvention and donations
- All other resources attributed or attributable to the NPPU by legal document or legislation or held by other agencies eg Ministry of Health and Sanitation

Article 2

2.2. The National Pharmaceutical Procurement Unit (NPPU) is to be a national institution with financial and operational independence, though with reporting responsibility to a Board of Directors and ultimately to the Hon Minister for Health and Sanitation.

2.3. The registered office of the NPPU is to be in Freetown at the site of the present Central Medical Stores (CMS) complex, but it may be transferred anywhere in the country.

2.4. At the commencement of the implementation of the proposed legislation, the Ministry of Health shall allocate to the NPPU buildings, fixtures and fittings and all current stocks of essential drugs and medical consumables either in storage or in transit to the present CMS. At this date, the Minister of Health shall allocate adequate land space, offices, equipments and vehicles currently available at the present CMS complex excluding land space, building, offices equipment and vehicles belonging to other units within th4e complex.

2.5. All credits, accounts and moneys standing in any account belonging to the Central Medical Stores, a department of the Ministry of Health and Sanitation (MOHS)m shall be transferred to and become the property of the new NPPU.

Personnel

2.6. The new NPPU shall not take over the current staff of the CMS per se but shall open up all key positions to new employment procedures according to qualifications and experience. The NPPU staff would be recruited on a competitive basis and managed according to procedures to be determined by the Board in a comprehensive Staff Manual.

2.7. At the formation of the new NPPU the current employees at the CMS may with the requisite formal qualifications, working experience, skills and aptitude for the vacancies concerned will be considered for employment (See joh Descriptions attached). Those not recruited in the NPPU shall be re-deployed in other government departments of need in consultation with the Establishment Secretary.

Article 3

3. The NPPU has the following objectives and responsibilities

Reporting to a Board of Directors, the NPPY will:

3.1. The NPPU will be charged with the responsibility for procuring in the most cost/efficient means, essential medicines and medical consumable items in accordance with the National Medicines List(NML) and outside this list when necessary, for both public and private sectors in Sierra Leone; and to distribute and sell same at socially air prices to those institutions, but at price level which will enable the NPPU to cover operational costs, establish reserves, and confront the future expected rise in price of pharmaceuticals and consumables.

Supplies of essential medicines may be sold to the private sector in Sierra Leone if two conditions are strictly satisfied.

1. Supplies to the public sector remain the first priority of the NPPU and that stocks for supply to public health and non-profit health institutions are not compromised by such actions.

2. Prices for the private sector are determined by the Board

3.2 Take responsibility for the good quality for all goods procured it is mandatory for the NPPU and other drug suppliers to ensure that good quality controls are always carried out before final purchase contracts are signed, either in-country or in local, regional (e.g. WHO) or international laboratories. Wherever possible, use shall be made of the WHO certification Scheme of pharmaceutical products moving in international commerce and in accordance to the provision of the Pharmacy and Drug Act of Sierra Leone.

(Essential medicines are those that appear on the national essential medicines list of Sierra Leone. However in certain cases with respect to need and with the exercise of due diligence regarding quality, the NPPU may import, purchase or otherwise supply (e.g. through donation) drugs or consumables which may not (yet) appear on the national list of essential medicines or which may not (yet) be registered with the Pharmacy Board).

3.3 Provide suitable storage, protection and packaging for supplies procured that will ensure that those supplies are secure in storage, stored in the right conditions of temperature and humidity and otherwise that their quality, safety and efficiency will be maintained through to delivery to the end user with the maximum of shelf-life and to monitor and inspect such items down the supply chain to ensure that they are delivered in safe and good condition.

3.4. Receive, manage and otherwise coordinate donations whether in cash or kind and ensure that the supplies are procured stored and delivered for the purpose for which the donations are intended.

3.5 Do all such things as are necessary, expedient or conducive to the attainment of the general objectives stated above, i.e. the provision of essential medicines to satisfy the health care needs of the population of Sierra Leone on a financially sustainable basis.

(Medical consumables are understood to be those items of rapid turnover in a health facility, such as dressing, syringes, needles etc as well as small diagnostic instruments such as stethoscopes and laboratory consumables. It should be the NPPU's responsibility under the new Statutory Authority framework to procure, store and supply large equipment items such as refrigerators, hospital beds, X-Ray machines and other such large capital items which should remain the responsibility of the Ministry of Health and Sanitation). Vaccines will also be excluded from the NPPU's operations for the foreseeable future.

3.6. The NPPU shall procure supplies as much as possible through international tender and for reasons of autonomy and the special considerations relating to pharmaceuticals shall be subject to the scope or provisions of laws wither present or future governing public sector procurement generally for the supplies of good quality essential medicines.

Article 4

Regulatory

4.1 Once established the NPPU shall be subjected to the provisions of the Pharmacy and Drugs Act of Sierra Leone as a body corporate.

Article 5

Financing

5.1 The new NPPU shall be allowed to maintain foreign accounts at Commercial Banks in order to procure pharmaceuticals on the international market, either through the Bank of Sierra Leone, the commercial banking system or through the use of donations, donor funds, loans or grants.

The NPPU shall provide the Board of Directors and through it, the Ministry of Health, the Ministry of Finance and Bank of Sierra Leone with annual forecasts of sales and expenditures, financing requirements including foreign exchange components, at least 12months in advance.

The NPPU shall also prepare annual budget and shall seek approval from the Board of Directors.

5.2 Any surpluses or resources accumulated at the end of the fiscal year shall be utilized to maintain or reduce price levels of the most essential medicines, or to

build up stocks of the same, or both, and improvement on storage, transportation etc.

5.3 However, subject to the approval of the Board of Directors, the NPPU may be authorized to invest surpluses in fixed deposits or other such financial instruments to raise additional income which should be put back into stocks, reductions in prices, improvements to storage and transportation facilities etc.

5.4 The NPPU shall be exempted from taxation for essential medicines and medical consumables in stock or procured by the NPPU.

Article 6

Accountability/Audit

6.1 The NPPU shall prepare an annual financial statement in accordance to international standard.
6.2 The new NPPU will be required by law to keep proper books of account and other records in relation to its activities, property and finances, in a form to be approved by the Auditor-General or an auditor appointed by the Board.

6.3. For the purposes of any external audit, the Board shall recruit an auditor who shall be entitled to have access to all books of accounts, vouchers, bank statements and other financial records and to require the NPPU –to give any such information and reporting thereon as may be considered necessary.

6.4. To ensure proper accountability the NPPU shall establish and maintain an internal Audit Services which shall report directly to the Managing Director of the NPPU.

6.5. The Internal Auditor shall using generally accepted auditing standards, initiate, control and direct the Internal Audit functions in the manner if considers suitable.

Article 7

Reporting

The Governing Body – Board of Directors.

7.1 The Governing Body of the new Statutory Authority, the NPPU, shall be the Board of Directors who shall have control and supervision of the NPPU. The Chairman of the Board will be a Presidential appointee and shall report to the Hon. Minister for Health and Sanitation. The Board shall compose of thirteen members.

7.2 The Board shall be composed of a Chairman, appointed by the President for his/her proven ability and experience in business management or public administration, without any undertaking, either direct or indirect, in any business related to the activities of the NPPU.

7.3. Other members of Board should be senior level representative(s) of the following bodies, institutions and organizations:

The Ministry of Health and Sanitation (2)
The Ministry of Finance (1)
The Ministry of Justice (1)
The Procurement reform unit (1)
The Bank of Sierra Lone (1)
The Regions of Sierra Leone, one from each regions (4)
Multilateral Cooperation Institutions (1)
Non-Governmental Organizations active in the health sector (1)

The Managing Director (MD) of the NPPU shall attend as Secretary to the Board meetings.

The Board shall have the following but not limiting powers.

7.4. It shall approve and where necessary review or develop the policies, strategies and operational procedures of the NPPU.

Personnel

7.5.1 The Board shall have the authority to recruit, appoint and dismiss the Managing Director (MD) of the NPPU, and the Managers/Department Heads Recruitment shall be through open competition. Dismissals of the MD and Department Managers should be justified though performance appraisals and other means of verification. Proposals for dismissal of Department Manager will require appropriate request by the MD backed up by solid evidence.

7.5.2 Other staff will be recruited by the MD supported by the respective Department Heads according to qualifications and expertise relating to the position to be filled. The Board shall review and adopt the staff manual which details staff issues with regard to employment, including termination, remuneration, grievance procedures, among others. The board shall adopt procedures for their meetings.

Organogram

7.6 The Board shall review and approve the organ gram of the NPPU periodically as and when necessary.

Program of Activities and Budget

7.7 It shall receive and deliberate on quarterly, biannual and annual reports to be sent to it by the NPPU's Managing Director, as well as other reports emanating from the Directors office.

7.8 It shall review and approve the programs of activities and budgets prepared and submitted by the MD for the incoming fiscal year.

7.9 It shall be empowered to propose any changes or amendments to the NPPU's statues for the effective running of the NPPU.

Audits

7.10. It shall recruit external auditors and examine reports submitted by these auditors arrange for control, audits and other appropriate inspections in any way or manner it considers suitable.

Board Meeting

7.11 The Board shall meet at least 4 times a year, and at other times it deems appropriate, notwithstanding other meetings, it shall meet.

- Once during the last quarter preceding the end of the fiscal year, to assess, among other business, the programme and budget proposed by the Managing Director for the next fiscal year.
- Once during the quarter following the close of the fiscal year to assess the results, operational and financial, of the NPPU in the form of an annual report, decide on the use of its surplus – if any – arrange for audits and other control p[procedures and decide on any management or procedural changes or adjustments in the NPPU. The annual report of the NPPU shall include the accounts and financial statement in the form approved by the Auditor General.

7.12 The Board shall sit legitimately representing a quorum if there are seven (7) members present. The Chairman of the Board shall call for Board meetings at least two weeks in advance. Minutes shall be taken and circulated to all members within two weeks after the meeting.

7.13 The absence of the Chairman shall not impede the holding of Board meetings. If there is a quorum, the members of the Board shall appoint a Chairman for the session from among its members. Decisions shall be taken by majority vote. Any member of the Board may request the calling of a meeting, based upon a defined agenda, and the Chairman of the Board shall decide whether to call an extraordinary meeting to consider the agenda or whether to include such requests in the regular quarterly meetings.

7.14 The Board may at any time co-opt any person or persons to advice or other wise assist the Board at any of its meetings but the person(s) co-opted shall not vote on any matter before the Board.

7.15 All minutes of Board meetings as well as other decisions or reports emanating from the Board shall be sent without delay, inter alia, to the Minister for Health and Sanitation.

7.16 The Minister may in writing comment on any aspect concerning the Boards deliberations and decisions relating to the conduct of the NPPU business, with any recommendations deemed appropriate by the Minister, and the Board shall, upon receipt of such comments and/or recommendations consider the same and report back to the Minister without undue delay.

7.17 The Board shall have the power to request clarification of any comments and/or recommendations made by the Minister, in whole or in part, and shall notify the Minister accordingly, setting out the reasons for its request.

Article 8: Management of NPPU

Managing Director

8.1. The NPPU shall be managed by a Managing Director (MD) in his/her absence, the MD shall appoint one of the Department Managers ad MD ad interim. The MD will be recruited by the Board on an open and competitive basis for four years of services and subject to renewal based on performance.,

The duties and responsibilities of the MD shall include the following:

8.2 Technical administrative a\nd financial responsibility for the NPPU's operations to the Board of Directors including achievement of objectives as set out in approved annual programs and budgets.

8.3 The MD shall attend Board meetings and organize the Secretariat at such meetings he/she shall ensure the implementation of all decisions taken by the Board.

Freetown November 19th 2004.

Annex 2 Principles decided in June PSM workshop

Outcome of the PSM discussion paper meeting June 14 & 15 2010
Hill Valley Hotel
Freetown

Introduction

The stakeholder meeting that has taken place on June 14 and 15 has agreed on a number of general principles and issues for the construction and implementation of APPSA and a reformed PSM system.

A PSM position paper will be developed based on the presented PSM discussion paper. It will include the results of the cited meeting.

To make sure that all participants are fully aware of the results of the meeting and to maintain a consensus as not to hamper future steps, the main general principles and issues on which the APPSA PSM system is going to be founded are briefly presented here.

All participants are requested to go through this document and send any comments to the facilitator of the workshop to Ed Vreeke (ed@hera.eu) so that these can be incorporated in the final PSM position paper.

The points below are presented in the same order as they have been presented.

Any other comments relating to issues addressed in the discussion paper that have not been addressed during the workshop should also be sent to the same address.

For the comments to be included in the first version of the position paper, the participants are kindly requested to send their comments by the 28th of June.

Ed Vreeke
Freetown
June 16, 2010

Agreed general principles and issues

APPSA will distribute to district level to ensure equal pricing

APPSA will collaborate with the DMS to increase management and logistical capacity to improve district to PHU distribution

Current DDMS stock and logistical material will preferably be transferred to APPSA following an audited and signed inventory

APPSA has the right to refuse to supply if a client is not in good financial standing (unpaid invoices)

APPSA will establish sales prices based on its cost price + mark-up.

The APPSA board will approve the APPSA sales prices without external interference. APPSA will respect national pharmaceutical pricing policies if and when established.

APPSA invoices the full sales price to its clients. This means that the day-to-day APPSA operations are funded from its turn over and that no direct subsidy of operational costs (salaries, fuel, maintenance, office sundries etc.) will be provided.

The establishment of APPSA will be externally financed: stakeholders will finance seed capital, logistical means necessary and technical assistance and staff training.

The APPSA board will be inclusive and diverse. It will include civil society representation along professionally appropriate lines (business and health experience) as well as local council level representation.

APPSA will have a strong customer service and marketing department that will reinforce the technical support to increased managerial and logistical capacity at local council level

The hospital boards are indispensable monitoring tools and have to be supported

Existing PSM oversight and monitoring bodies have to be recognised and reinforced where necessary

Community level involvement is key to long term sustainable monitoring at community level

Information is the key tool and input to oversight bodies: in principle all APPSA and DMS PSM information is routinely shared through accessible means of communication (website, MIS etc.).

For a period of up to 24 months, formative auditors will be based at the local councils to technically support the DMS and to ensure full disclosure of quality

ordering, stock and supply information on a routine basis based on LMIS and Channel produced reports. These auditors will not be part of the MOHS but rather contracted by APPSA or other non-governmental organisation.

APPSA + the formative auditors will ensure a continuing routine documenting of the procurement and supply lines.

The formative auditors will be contracted by a non-ministerial organisation (UNICEF, UNFPA, APPSA....).

Batch tracking exercises will be done every 4 months over a 36-month period to identify system issues and leakages (by the DDMS with external collaborators).

Pharmaceutical policy documents have to be reviewed and updated where necessary

Tax and duty policy of essential medicines has to be looked at.

There are a few issues for which no agreement could yet be found:

The final board composition was not discussed

The need for a Memorandum of Understanding between APPSA and the government was not immediately seen, as the statutes would cover most issues. However, to supervise APPSA's performance the government, the local councils and APPSA will have to agree on performance-based indicators that are routinely monitored.

Annex 3 APPSA budget

See separate Excel spreadsheet: "2010 09 14 APPSA accounts + project budget"

Annex 4 APPSA workplan

See separate Excel spreadsheet: "2010 09 14 APPSA workplan"

Annex 5 APPSA accounts

	PROJECTED ACCOUNTS APPSA									
			Expected Yearly Growth of :			***10%***	***10%***	***10%***	***10%***
Currency :		**USD**	***Expected Average Monthly Turn Over***		***0***	*801,938*	*842,034*	*922,296*	*1,005,855*
			Budget for drug purchase 2012 (USD) :		**2011**	**2012**	**2013**	**2014**	**2015**
Red fields are modifiable, others are protected			**3,500,000**		**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**YEAR 5**
				Value EXW Total	**0**	**3,561,997**	**7,480,193**	**8,228,213**	**9,051,034**
		From EXW to CIF (sea) :	15%	***Value EXW (see):***	***0***	***3,043,478***	***6,391,304***	***7,030,435***	***7,733,478***
		From EXW to CIP (air) :	35%	***Value EXW (air):***	***0***	***518,519***	***1,088,889***	***1,197,778***	***1,317,556***
1	**Medicines and medical supplies purchases**			-	**0**	**3,500,000**	**7,350,000**	**8,085,000**	**8,893,500**
	Drug purchase value CIF Port of Freetown (sea)			*80.00%*	*0*	*2,800,000*	*5,880,000*	*6,468,000*	*7,114,800*
	Drug purchase value CIP Airport of Freetown (air)			*20.00%*	*0*	*700,000*	*1,470,000*	*1,617,000*	*1,778,700*
1.1	**Custom duties and taxes on CIF-CIP**			-	**0**	**525,000**	**1,102,500**	**1,212,750**	**1,334,025**
1.11		Customs duties and taxes	% purchase	Rate	*0*	*525,000*	*1,102,500*	*1,212,750*	*1,334,025*
		Drugs	80%	15.0%	*0*	*420,000*	*882,000*	*970,200*	*1,067,220*
		Medical supplies	20%	15.0%	*0*	*105,000*	*220,500*	*242,550*	*266,805*
1.2	**Additional costs up to warehouse**				**0**	**70,000**	**147,000**	**161,700**	**177,870**
1.21		transport CIF Port of Freetown - Warehouse		0.50%	0	14,000	29,400	32,340	35,574
1.22		Transport CIP Airport of		0.50%	0	3,500	7,350	8,085	8,894

		Freetown - Warehouse								
	1.23	Other costs (including clearing & demurrage)			1.5%	0	52,500	110,250	121,275	133,403
2	**COSTED PRICE**				-	**0**	**4,095,000**	**8,599,500**	**9,459,450**	**10,405,395**
	Mark up on costed price (in %)					17.5%	17.5%	17.5%	17.0%	16.0%
3	**TURN OVER**				-	**0**	**4,811,625**	**10,104,413**	**11,067,557**	**12,070,258**
= > >	**EXPECTED MARGIN = (3) - (2) =**					**0**	**716,625**	**1,504,913**	**1,608,107**	**1,664,863**
4	**OTHER VARIABLE COSTS**				-	**0**	**208,163**	**437,141**	**480,855**	**528,941**
4.1	**miscellaneous costs and consumables**				Basis	**0**	**54,600**	**114,660**	**126,126**	**138,739**
4.11		Financial costs		0.25%	Costed price	0	10,238	21,499	23,649	26,013
4.12		Quality control cost		0.50%	Costed price	0	20,475	42,998	47,297	52,027
4.13		Stock insurance		0.25%	Average stock (4 Mo)	0	3,413	7,166	7,883	8,671
4.14		Consumables (packaging for sales, etc..)		0.50%	Costed price	0	20,475	42,998	47,297	52,027
4.2	**Transport of sales to customers**					**0**	**153,563**	**322,481**	**354,729**	**390,202**
4.21		Transport of sales from warehouse to clients		3.50%	Costed price	0	143,325	300,983	331,081	364,189
4.22		Transport insurance		0.25%	Costed price	0	10,238	21,499	23,649	26,013

5	**FIXED RUNNING COSTS**				Basis	**312,797**	**312,797**	**312,797**	**312,797**	**312,797**
5.0		Unexpected costs		1%	Total fixed running costs	**3,097**	**3,097**	**3,097**	**3,097**	**3,097**
5.1	**Supply and services**			-	-	**13,200**	**13,200**	**13,200**	**13,200**	**13,200**
5.10		Water		12	250	3,000	3,000	3,000	3,000	3,000
5.11		Rent		12	0	0	0	0	0	0
5.12		Bank charges		12	500	6,000	6,000	6,000	6,000	6,000
5.13		Uniforms and Protective Clothing		12	350	4,200	4,200	4,200	4,200	4,200
5.16				12		0	0	0	0	0
5.2	**Other costs and miscellaneous**			-		**244,500**	**244,500**	**244,500**	**244,500**	**244,500**
5,200		Office stationary & computer maintenance		12	1,000	12,000	12,000	12,000	12,000	12,000
5,201		Generator fuel & maintenance		12	2,500	30,000	30,000	30,000	30,000	30,000
5,202		Telephone		12	1,500	18,000	18,000	18,000	18,000	18,000
5,203		Postal Services		12	250	3,000	3,000	3,000	3,000	3,000
5,204		Office insurance		1	2,500	2,500	2,500	2,500	2,500	2,500
5,205		Internet		12	500	6,000	6,000	6,000	6,000	6,000
5,206		Maintenance fees ERP		1	10,000	10,000	10,000	10,000	10,000	10,000
5,207		Maintenance (warehouse, office, outside)		12	250	3,000	3,000	3,000	3,000	3,000
5,208		Regular staff training sessions		1	25,000	25,000	25,000	25,000	25,000	25,000
5,209		Client's meetings, marketing, after sales service, outreach		12	4,500	54,000	54,000	54,000	54,000	54,000
5,210		Fuel and Lubricants		12	750	9,000	9,000	9,000	9,000	9,000
5,211		Motor Vehicle Maintenance Costs		12	500	6,000	6,000	6,000	6,000	6,000
5,212		Motor Vehicle Insurance		12	250	3,000	3,000	3,000	3,000	3,000
5,213		Transport and Travelling		12	1,500	18,000	18,000	18,000	18,000	18,000
5,214		Subsistence & Meal Allowances		12	1,500	18,000	18,000	18,000	18,000	18,000
5,215		Hotel Accommodation Charges		12	1,500	18,000	18,000	18,000	18,000	18,000

	5,216	External Travel		2	4,500	9,000	9,000	9,000	9,000	9,000
	5,216					0	0	0	0	0
5.3	**Fixed costs linked to administration and management**					**52,000**	**52,000**	**52,000**	**52,000**	**52,000**
	5.30	Board meetings & catering (DSA + travel)		12	750	9,000	9,000	9,000	9,000	9,000
	5.31	Quarterly meetings with local councils		4	4,500	18,000	18,000	18,000	18,000	18,000
	5.32	Financial audit		1	25,000	25,000	25,000	25,000	25,000	25,000
	5.33					0	0	0	0	0
=>	**Added Value (= EXPECTED MARGIN -4 -5)**					**(312,797)**	**195,666**	**754,974**	**814,454**	**823,125**
6	**HUMAN RESOURCES COSTS**				Basis	**372,120**	**325,800**	**456,120**	**456,120**	**456,120**
	6.1	Salaries			Salaries	265,800	265,800	325,800	325,800	325,800
	6.2	Charges to be paid by employees			0.00%	0	0	0	0	0
	6.3	Charges to be paid by APPSA			40.00%	106,320	106,320	130,320	130,320	130,320
=>	**GROSS OPERATING SURPLUS (GOS =Added value +6-7)**					**(684,917)**	**(130,135)**	**298,854**	**358,334**	**367,005**
7	**Depreciation**		# Year	% Dep.	Appraisal	**83,735**	**83,735**	**83,735**	**68,735**	**68,735**
	7.1	Offices and warehouse	40	2.5%	750,000	18,750	18,750	18,750	18,750	18,750
	7.2	Vehicles and other rolling material	5	20%	175,000	35,000	35,000	35,000	35,000	35,000
	7.3	IT equipment	8	33%	45,000	14,985	14,985	14,985	14,985	14,985
	7.4	Other equipment	3	20%	75,000	15,000	15,000	15,000	0	0

8	**Compulsory Endowment**			%	Basis	**0**	**61,425**	**128,993**	**141,892**	**156,081**
	8.1	For stock depreciation (average stock in months)		1.00%	Costed price	0	40,950	85,995	94,595	104,054
	8.2	For financial risks (dubious debtors)		0.50%	Costed price	0	20,475	42,998	47,297	52,027
> = >	**NET OPERATING SURPLUS (NOP = GOS -8 -9)**					**-768,652**	**-275,295**	**86,127**	**147,707**	**142,189**
	SUBSIDY FOR RUNNING COSTS				-	**768,652**	**275,295**	**0**	**0**	**0**
		Running costs + depreciation subsidy				**768,652**	**275,295**	**0**	**0**	**0**
		APPSA RESULT BEFORE EXCEPTIONAL CHARGES AND TAXES				**0**	**0**	**86,127**	**147,707**	**142,189**

Annex 6 Outline APPSA standard operating procedures

Department	Functionality	Number	Title
Introduction			
	Explanation of terms	INTRO 01	Glossary
	Structure of the manual	INTRO 02	Structure of the manual Objective of the manual
	Description of how to introduce changes in the manual	INTRO 03	Changes in the procedures Change register
Board of Directors			
	Internal	BOD INT 01	Signed statutes
		BOD INT 02	Copy of non-signed statutes
		BOD INT 03	Positions and affiliations of board of directors
		BOD INT 04	Code of conduct
		BOD INT 05	Anti-fraud policy and statements of no Conflic-of Interest
		BOD INT 06	Responsibilities of the Board of Directors
		BOD INT 07	"Remuneration" Board of Directors
		BOD INT 08	Statutory organizational chart
		BOD INT 09	Functional organizational chart
	Audits	BOD AUD 01	Audit principles
		BOD AUD 02	Internal financial and procurement audit
		BOD AUD 03	External financial and procurement audit
		BOD AUD 04	Internal pharmaceutical quality control audit
		BOD AUD 05	External pharmaceutical quality control audit
	Legal matters	BOD LEG 01	Original and copy authorization pharmaceutical wholesaler
		BOD LEG 02	Original and copy contract/agreement with the MOHS
		BOD LEG 03	Original and copy other legal documents 1
		BOD LEG 04	Original and copy other legal documents 2
		BOD LEG 05	Original and copy other legal documents 3
		BOD LEG 06	Original and copy other legal documents 4
General manager	General	GEM GEN 01	Planning cycle, policy and communication
		GEM GEN 02	Applicable norms and standards
		GEM GEN 03	Risk management
		GEM GEN 04	Emergency and catastrophy planning and prevention
		GEM POL 01	Mark-up policy
		GEM POL 02	Sales price calculation
		GEM POL 03	Supply and payment conditions
		GEM POL 04	Budget management

Department	Functionality	Number	Title
		GEM POL 05	Cash flow management
	MIS reporting	GEM RAP 01	Introduction MIS dash board
		GEM RAP 02	General dash board indicators
		GEM RAP 03	Calculation of the dash board indicators
		GEM RAP 04	Financial ratios dash board
		GEM RAP 05	Human resources dash board
		GEM RAP 06	Pharmaceutical (procurement and supply) dash board
		GEM RAP 07	MOHS and other stakeholders dash board
		GEM RAP 08	Quarterly report
		GEM RAP 09	Annual report
Finance & admin	Administration	FINAD ADM 01	Contracts
		FINAD ADM 02	Client codification
		FINAD ADM 03	Client agreements
		FINAD ADM 04	Client performance
		FINAD ADM 05	Keys and access management
		FINAD ADM 06	Security and guarding of premises
		FINAD ADM 07	Management of rolling material
		FINAD ADM 08	Management of assets
		FINAD ADM 09	Supplier codification
	Human resources	FINAD HR 01	General
		FINAD HR 02	Staff contracts and job descriptions
		FINAD HR 03	Recruitment and engagement
		FINAD HR 04	Orientation of new staff
		FINAD HR 05	Working conditions
		FINAD HR 06	Career management
		FINAD HR 07	Professional travel and missions
		FINAD HR 08	Holidays
		FINAD HR 09	Staff evaluations
		FINAD HR 10	Staff evaluation criteria
		FINAD HR 11	Disciplinary measures
		FINAD HR 12	End of contract
		FINAD HR 13	Hygiene and security
		FINAD HR 14	Daily laborers
		FINAD HR 15	Consultants
		FINAD HR 16	Health care
		FINAD HR 17	Staff obligations
		FINAD HR 18	Employer obligations (marriage, funeral etc.)
		FINAD HR 19	Temporary staff
		FINAD HR 20	Pay scales and salaries
		FINAD HR 21	Staff categories
		FINAD HR 22	Labor code Sierra Leone
	Information technology	FINAD IT 01	Users and support staff IT responsibilities
		FINAD IT 02	IT installation and hardware maintenance
		FINAD IT 03	Installation, updates and daily maintenance
		FINAD IT 04	IT security
		FINAD IT 05	Anti-virus program and maintenance
		FINAD IT 06	Back-up individual work stations

Department	Functionality	Number	Title
		FINAD IT 07	Back-up main server
		FINAD IT 08	Internet access
		FINAD IT 09	Copyright
		FINAD IT 10	Enterprise resource planning software ERP
		FINAD IT 11	Maintenance telephone PBX system
		FINAD IT 12	Management of APPSA website
	Logistics	FINAD LOG 01	Types of transport
		FINAD LOG 02	Buildings
		FINAD LOG 03	Material
		FINAD LOG 04	Maintenance
	Archiving		
		FINAD ARC 01	Paper archiving
		FINAD ARC 02	Electronic archiving
	Accounting	FINAD STRU ACC 00	Plan of accounts
		FINAD STRU ACC 01	Main accounts
		FINAD STRU ACC 02	Subdivision of accounts
		FINAD STRU ACC 03	Changing the chart of accounts
		FINAD STRU ACC 04	Journals
		FINAD STRU ACC 05	Automatic movements in and between accounts
		FINAD STRU ACC 06	Depreciation principles
		FINAD STRU ACC 07	Depreciation tables
		FINAD STRU ACC 08	Foreign exchange
		FINAD STRU ACC 09	Corrections
		FINAD STRU ACC 10	Specific accounting issues
		FINAD STRU ACC 11	Regular routine operations
		FINAD STRU ACC 12	Bank operations
		FINAD STRU ACC 13	Cash operations
		FINAD STRU ACC 14	Cheque operations
		FINAD STRU ACC 15	Payment authorizations international accounts
		FINAD STRU ACC 16	Payment authorizations local accounts
		FINAD STRU ACC 17	Client advances
		FINAD STRU ACC 18	Supplier advances
		FINAD STRU ACC 19	Depreciations + physical checks

Department	Functionality	Number	Title
		FINAD STRU ACC 20	Standard description account movements
		GEM GEN 02	Applied norms and standards
	Invoicing	FINAD INV 01	Invoicing
		FINAD INV 03	Dubious debtors and payment recovery
	Purchasing non-pharma	FINAD QAS 01	Purchasing methods
		FINAD QAS 02	Purchasing investments goods
		FINAD QAS 03	Purchasing services
		FINAD QAS 04	Purchasing goods for internal use
		FINAD QAS 05	INCOTERMS
Procurement			
	Purchasing pharma	PROC PUR 01	Purchasing methods pharmaceuticals
		PROC PUR 02	Choice of products
		PROC PUR 03	Planning
		PROC PUR 04	Pre-qualification suppliers
		PROC PUR 05	Open international tenders
		PROC PUR 06	Open national tenders
		PROC PUR 07	Direct purchasing
		PROC PUR 08	Management of tender files
		PROC PUR 09	Quality evaluation
		PROC PUR 10	Evaluation medical supplies
		PROC PUR 11	Evaluation medicines
		PROC PUR 12	Technical information sheet supplier
		PROC PUR 13	Product codification
		PROC PUR 14	Opening and analysis of tenders
		PROC PUR 15	Evaluation criteria manufactures
		PROC PUR 16	Evaluation criteria wholesaler
		PROC PUR 17	Suppliers Performance Monitoring
		PROC PUR 18	Tender opening protocol
		PROC PUR 19	Terms of reference tender committee
		PROC PUR 20	Ordering & international logistics
		PROC PUR 21	Clearing
		DIR GEN 02	Applicable norms and standards
Stores	Storage	STORE STO 01	Good distribution practices WHO
		STORE STO 02	GDP APPSA: check list
		STORE STO 03	Receipt merchandise
		STORE STO 04	Quantitative check receipt merchandise
		STORE STO 05	Complaints process (quantitative issues)
		STORE STO 06	Receipt of merchandise from a partner organization
		STORE STO 07	Management of donations
		STORE STO 08	Rolling inventory
		STORE STO 09	Annual inventory
	Sales	FINAD INV 01	Invoicing
		STORE BAO 01	Back-orders
		SAL CSE 01	Customer service

Department	Functionality	Number	Title
	Delivery	DIR POL 03	Supply and payment conditions
		STORE LIVR	Different ways of supply and delivery
	Quality assurance	QAS ASQ 01	Quality assurance
		QAS ASQ 02	Suppliers' qualification
		QAS ASQ 03	Analysis certificate
		QAS ASQ 04	Quality control laboratory tests
		QAS ASQ 05	Release of batches
		QAS ASQ 06	Management of expired products
		QAS ASQ 07	Complaints process (qualitative issues)
		QAS ASQ 08	Recalling a product or a batch

Annex 7 Outline APPSA procurement rules and regulations

This annex presents a more detailed proposal for the APPSA Procurement Standard Operating Procedures. This section can replace the section on pharmaceutical procurement in the previous annex (PROC PUR01 through PROC PUR19).

1	Introduction
1.1	Basic principles
1.2	Organization of the procurement manual
2	Organization of APPSA Procurement Department
3	Terms of reference tender committee
4	Terms of reference Procurement Department positions
5	APPSA Business Manual ("how to do business with APPSA")
6	Pre-qualification of suppliers and products
6.1	Introduction
6.2	Steps in the pre-qualification process
6.3	Standard documents available for pre-qualification process
7	Standard documents for pre-qualification of suppliers and products (models)
8	Procurement methods
8.1	Introduction
8.2	SBD International Competitive Bidding
8.3	SBD National Competitive Bidding
8.4	Standard Documents Direct Purchase
8.5	Standard Documents Pro Forma Based Procurement
9	Standard Operating Procedures regular procurement process
9.1	Introduction
9.2	Quantification and tender planning APPSA
9.3	Annual Procurement Plan.
9.4	Purchase method chosen
9.5	Tender procedure chosen
9.6	Tender documents prepared
9.7	Finalized tender documents approved
9.8	Tender launched
9.9	Offers received
9.1	Opening of offers and administrative evaluation by bid committee
10	Technical evaluation of offers by bid committee
11	Financial evaluation of offers by bid committee
12	Adjudication of tender
13	Closing and filing of tender file
14	Contracting

15	Preparing an order calendar
16	Preparing of orders
17	Finalized orders approved
17	Insurance
18	Orders sent
19	Order monitoring
20	Preparation of clearing documents
21	Clearing of orders
22	Preparation of receipt receipt documents
23	Receipt documents are sent to receipt section (to inventory manager)
24	Receipt of orders
25	Inspection of receipt using the receipt documents (by inventory manager) and the release of batches documents (by QA manager)
26	Receipt report is send back to procurement unit
27	Procurement unit to follow up on any discrepancies
28	Maintaining suppliers' performance module
29	Evaluating suppliers' performance on a 6 monthly basis
30	Moving a supplier to the APPSA black list
31 32 33	Closing and filing of order file. Monitoring & Evaluation Ethics

Annex 8 Outline APPSA recruitment procedures

Principle

APPSA is an organisation that promotes gender equality and does not take into account tribal origin, affiliation, or not, with trade unions, political parties, religion or other legal civil or other-natured organisations, when considering a person for recruitment.

Recruitment is only justified by the need to fill a position that is or will become vacant or when the decision has been taken to create a position.

The recruitment policy will be different depending on whether it is an internal or an external recruitment. However, no appointment can be made without that the selecting officials have received all the necessary and available information to guide their choice.

This information is:

- The job description or terms of reference;
- The Curriculum vitae of all potential candidates;
- The application letter;
- Candidate profile both in terms of training and experience and in terms of ability and character.

Criteria

All recruitment within APPSA must be judged using the following criteria:

- skills and qualifications
- experience
- ability and willingness to work in the different departments of APPSA if required
- the ability and willingness to work outside normal hours as required by the position
- moral standing of the candidate
- be at least 18 years of age

Procedure

The various stages of the recruitment process are as follows:

1. Expressed need for recruitement
2. Job description
3. The scheduling process
4. Announcement and publication of vacancy in appropriate newspapers, APPSA website, recruitment website and bulletin boards
5. Screening / selection of candidates
6. Written tests
7. Interview
8. Checking references
9. Decision
10. Paperwork
11. Orientation

The need for recruitment

The recruitment can be for a new position when a new project is implemented or after a review of the organizational structure or because the volume of work has increased. It can be because of the departure of a staff member following a resignation, dismissal, transfer, retirement, death. The line manager concerned will submit the request for recruitment to the hierarchy who will, after review and approval, transmit the request to the director finance and administration.

The creation of a new position is always preceded by the confirmation of the availability of funds by the director finance and administration.

The definition of the position

There can be no recruitment without job description. If a position becomes vacant following the departure of a staff member, the existing job description may be updated at the time of recruitment.

Job responsibilities could be modified to reflect changes in the post or on the job market.

The job description is prepared by the direct supervisor of the position and the head of department concerned. The director finance and administration will ensure that the responsibilities that are part of the job description are consistent with an APPSA position.

The scheduling process

The timing of the recruitment process is determined by the director finance and administration and takes into account the availability of the other persons involved in the recruitment process.

Vacancy Announcement

The vacancy announcement is made through a notice of vacancy sent to the appropriate media, partner organisations, the MOHS, stakeholders and others. It is also announced in the main newspapers and published on the APPSA website. The announcement will be made after approval by the director finance and administration.

The notice of vacancy shall contain the following elements:

1. A summary description of the position
2. The profile of the candidate (education, experience, skills required)
3. The documents that have to accompany the application
4. The address to which the application has to be send
5. The deadline for applications
6. The date and place of the test and / or interview
7. Conditions of employment

A vacancy will be published at least two weeks before the closing date of the vacancy.

All current APPSA staff is also free to apply for the externally published vacancies.

Screening / selection of files

Applications must be submitted to the secretariat. They must be registered, numbered and then sent the same day to the director finance and administration.

The selection of applications is based on the analysis of letters and curriculum vitaes. A comparison of the characteristics of applicants with the job requirements (training, experience or expectations) will result to a first selection and elimination of candidates.

The non-certification of certificates and diplomas results in the elimination of the bid.

The selection of records must be made by a recruitement committee composed of:

Positions of middle and higher management

- General manager
- The relevant director of department or if it is the departement of finance and administration, another director of departement
- The director finance and administration
- The internal auditor
- A member of the board of directors

For other positions

- General manager or a representative of the general manager
- The relevant department head
- The direct supervisor of the position
- The director finance and administration or a representative of the director

The screening test and / or selection

The screening test and / or selection is a written test in one or more general issues related to the knowledge and skills required.

The written test will cover the skill and knowledge areas required for the position and also cover the fundamental values of APPSA.

- The test must be prepared and corrected by a commission established for that purpose and designated by the Management.
- Applicants must all do the same test and at the same time.

The list of candidates selected for the interviews is posted at least one week in advance. Candidates who are on duty travel can be informed by telephone or email.

The interview

The interview should be prepared according to specific objectives. This is to assess knowledge, check the candidates consistency with the requirements of the position as to be able to judge the ability of the candidate and to detect his or her potential.

The composition of the interview team is determined, for each job interview, by the chairperson of the recruitment committee.

Selected candidates are called for interview. Succesfull candidates are informed as soon as possible.
Where several candidates for the same position pass the interview, they will be judged using their professional references or if that does not give an outcome, a new round of tests and interviews will be organised.
Unsuccessful applicants will not be notified personally but they are invited to enquire about the outcome one week after the interview.

Checking references
The professional reference will be checked before the hiring decision is made. †his is done by the designated member of the recruitment committee.

Hiring decision
The hiring decision is taken after the completion of the recruitment process.

Hiring Procedures

Principle
A newly hired staff must complete a number of formalities.

- Hiring is formalised by a letter of employment stating the position to fill, grading, remuneration and length of the trial period.

Procedure
To allow APPSA to develop a comprehensive personal file, following the hiring, certain formalities must be complied with:

1. The staff "identification sheet" has to be completed
2. The staff to sign a copy of the code of conduct
3. The staff member will pass a medical test and render the medical certificate to the employer. The costs of obtaining medical certificate shall be borne by the employee;
4. The staff member will provide the adminstration with the date of birth, Certificate of Nationality, Diplomas and criminal record, number of children.
5. Have two passport photos to a new employee for the business card and another for the staff record.

Assessment of performance during the probationary period
Two weeks before the end of the trial period, the staff's performance will be evaluated by his or her supervisor.
For middle and higher management
The annual evaluation form is used for this purpose and must be approved by the General Manager.
For other positions
A simple letter of recommendation will be written by the supervisor of the staff member to the general manager and the director finance and administration after consultation with the concerned director of department.

Annex 9 Terms of reference APPSA senior management

The terms of reference of the senior management positions are presented here. They are inspired by the terms of reference as they were developed and adopted in 2006 under the EU NPPU support project.

The first three positions are those of the proposed Technical Assistants. The terms of reference only describe their responsibilities vis-à-vis APPSA and not in relation to the donor or the firm they are employed by.

The position of the General Manager

Necessary qualifications

A qualified manager with at least 10 years of experience managing a small to medium size enterprise (profit or not-for-profit) in the health sector. The candidate has to demonstrate good leadership and have excellent communication skills. A postgraduate degree is required. A degree in Business Administration or Pharmacy is an advantage.

Responsibilities

- Exercise the overall management responsibility of APPSA
- Ensure the development of the overall standard operating procedures manual
- Develop the five-year strategic plan
- Develop and apply the annual business plan (action plan + budget)
- Ensure that strategic and annual business plan objectives are achieved
- Ensure that APPSA is a financially sound operation
- Establish excellent relationships with the APPSA clients
- Develop and implement the management information system with the necessary data, indicators and ratios
- Routinely report on the data, indicators and ratios to the board of directors, the MOHS and the stakeholders
- Supervise the Directors of the Department, the internal auditor and the quality assurance pharmacist
- Ensure the implementation of policies and decisions taken by the Board of Directors
- Take responsibility for financial viability and sustainability of the organisation
- Responsible for the donor contacts and donor reporting
- Legally represent APPSA vis-à-vis the Government of Sierra Leone, the local councils, hospitals and other clients, donors, aid agencies and all third parties, within the limits of the power delegated by the Board of Directors
- Represent APPSA in court and in all legal matters
- Attend the meetings of the Board of Director and assume the secretariat for such meetings

- Recommend wages, salaries, benefits, bonuses and various other remunerations for the staff members in conformity with collective agreements

The position of Director of the Procurement Department

Necessary qualifications
Experience in medical and pharmaceutical procurement. Minimum qualification B.Pharm Hons, with postgraduate qualification or experience in procurement of pharmaceuticals.

Responsibilities
- Develop and implement procurement plan
- Determine the needs of the APPSA clients for medicines, medical consumables, laboratory reagents etc.
- Adopt good procurement practices and procedures for international local procurement services of pharmaceuticals, operate WHO's certification scheme on pharmaceuticals
- Establish good professional relationship with the Pharmacy Board of Sierra Leone and ensure that APPSA follows their requirements
- Establish data base of recognized and reputable suppliers, particular manufacturers
- Develop and prepare tender documents
- Establish professional relationships with quality control laboratories
- Introduce and ascertain quality assurance notions in APPSA procurement
- Manage international logistics
- Manage clearing processes
- Establish professional relationship with Customs and the NRA
- Organisation of administrative procedures for the speedy clearance release of goods from customs, transfer of the goods from the port of entry to the NPPU ware houses
- Routinely supply procurement management information data to be included in the management information system

The position of Director Storage and Sales Department

Necessary qualifications
At least 10 years of experience in storage and logistics in low-resource settings. A Pharmacy degree is an advantage

Responsibilities
- Develop and implement receipt, storage, picking, packing, sales and distribution procedures
- Organise available stores in the most "space-efficient' way
- Ensure implementation and continued application of good storage practices and good distribution practices

- Plan and organize deliveries to clients by best (most cost/effective) available means
- Ensure the availability of essential medicines in the health facility times
- Determine and establish orders from the clients with approved
- Ensuring timely issue of items ordered to customers
- Control of delivery of items ordered to the clients
- Provide tools for stock management to the clients if requested
- Monitor and supervision of the order distribution to the clients
- Routinely supply receipt, storage, sales and distribution management information data to be included in the management information system

The Position of Quality Assurance Pharmacist

Qualifications

A pharmacy degree with post-graduate training in quality assurance or equivalent in quality assurance working experience. Work experience with quality control testing in laboratory settings as well as with quality assurance principles in and throughout systems.

Responsiblities

Manager Quality Assurance (MQA) is responsible for the quality of all medical products procured, stored and distributed by APPSA.

The MQA is accountable to the General Manager. The MQA has delegated responsibility for the release of products for distribution.

- Develop and implement the APPSA quality assurance SOPs for all pharmaceutical goods covering every step in the PSM process that is APPSA's responsibility: order purchase, receipt, sample selection, laboratory tests, batch release, batch tracking, storage, distribution and after-sales service
- Develop policies and associated action plans for the pharmaceutical quality assurance taking into account national developments in legislation
- Describe the role of APPSA quality assurance department in the short and longer term in the regulatory context, including the conditions and appropriate functional quality assurance unit for its future role (infrastructure, equipment, personnel, documentation, procedures and protocols)
- Approve or reject medical products based on results of analysis and testing
- Maintain contacts with relevant authorities (PBSL) on the quality
- Assist with the prequalification of suppliers and pharmaceutical goods
- Monitor the quality of the storage and distribution of goods (?)
- Maintain national and international contacts with peers to ensure that APPSA is aware of the latest developments in quality assurance through information sharing, access to literature and participation in meetings

The Position of Internal auditor

Responsibilities

- Assist in the development of the standard operating procedures
- Supervise the department activities according to the standard operating procedures
- Evaluate suggested changes in the standard operating procedures
- Continuously evaluating internal controls and make suggestions for improvements
- Systematically analyse the business processes, identify the organizational problems and recommend solutions.
- Coordinate the evaluation of reports from other departments and MD
- Assist in the preparation in collaboration with the other members of the management team of the strategic plan and the annual business plan
- Prepare the reports and follow up the executive of decisions and recommendations of management meetings
- Organise internal audits
- Organise and supervise "rolling" and annual inventories
- Report on the inventory results
- Assist in the execution of external audits

Annex 10 APPSA code of conduct

APPSA code of conduct for the employees and board members

The code defines accountabilities for decision making and subjects decision makers to specific financial disclosure requirements.
(c) The code is of obligatory compliance and consequences are administrative or criminal.

APPSA's objective:

APPSA pursues its vision and objective while respecting:

1. The national laws, rules and regulations;
2. The policy of the MOHS;
3. The National Essential Medicines List;
4. The principle of generic medicines using INN;
5. The WHO and, where possible, ISO norms

Principles that form the basis of APPSA's functioning:

1. Transparency in all aspects of management: financial, pharmaceutical, human resources and in its relationships with its clients, suppliers and partners;
2. Responsibility: to clients, suppliers, authorities, partners and employees;
3. Quality: of its products and services.

APPSA confirms that its work is based on the assertions that are presented below.

APPSA respects the law and will maintain a high professional standard of care.

Interpretation:

1. APPSA complies with the national law, regulations, standards and policies of the medical and pharmaceutical authorities by the letter and the spirit;
2. APPSA nor its employees or members of its statutory bodies will break the law while exercising activities for APPSA;
3. APPSA accepts and underlines the ethical principles of the pharmacy profession;

4. APPSA does not work under conditions that could compromise the freedom to exercise their professional judgment or cause a deterioration of quality services;
5. APPSA does not enter into arrangements with suppliers that could affect or impair its independent professional judgment or its right to choose or pre-qualify a supplier;
6. APPSA establishes a professional relationship with its clients and suppliers which also involves honesty, integrity and respect;
7. APPSA ensures that the information it provides to clients and suppliers is accurate, understandable so that clients and suppliers can make rational decisions;
8. APPSA keeps, in principle, any information about clients and suppliers confidential. Confidential information may be disclosed only when authorized by the client or supplier or when required by law;
9. APPSA ensures that knowledge of the pharmacy staff is up to date by providing access to the Internet, subscriptions to pharmaceuticals magazines and reference publications and participation in conferences and / or training and demanding that they actively engage in continuing pharmaceutical education.

APPSA keeps as its main motto the quality of its products

Interpretation:

1. APPSA has specialized knowledge about medicines, medical equipment and laboratory reagents and uses his knowledge to ensure that its customers receive the best products;
2. APPSA provides products that are effective and consistent with quality standards as defined by WHO and respecting the Sierra Leone legislation. APPSA makes an effort to ensure that the products it provides have a good ratio "cost effectiveness" and that pricing is made in a transparent process;
3. APPSA provides a policy for monitoring the quality of its products and does not distribute these products whenever there are doubts about safety, efficacy or quality;
4. APPSA ensures the destruction of drugs and other pharmaceutical products that are expired or no longer safe for sales for any other reasons

APPSA ensures that relations with its customers, suppliers and partners are fair and transparent

Interpretation:

1. APPSA is not prejudicial to its customers or suppliers because of their nationality, sex, race, color, ethnic or social origin, genetic features, language,

religion or belief, political opinion or other opinion, membership of a national minority, property, birth, disability, age, sexual orientation or marital status;

2. APPSA guarantees the principle of equality in the treatment of requests from clients and in making decisions. The customers in the same situation are treated equally. In cases of unequal treatment, the employee shall ensure that it is justified by objective characteristics of handled case;
3. The APPSA employees recognize that reverse information is essential to maintain and improve the quality of services offered to customers and partners. They make an effort to share this information with colleagues and heads of departments;
4. APPSA employees ensure the security of computers, software and computer data.

APPSA ensures that its employees and members of statutory bodies are working for the interests of the enterprise

Interpretation:

1. APPSA ensures that its employees are conscientious, correct, courteous and friendly in their relations with customers, suppliers and other partners. In their responses to various correspondence, telephone calls and letters, APPSA employees strive to be as helpful as possible and respond as completely and accurately as possible to questions;
2. APPSA ensures that the behaviour of members of its team and its statutory bodies are never guided by personal interests, family or national or political pressure. APPSA employees and members of statutory bodies do not take part in a decision in which he or his kin has a financial interest. The members of statutory bodies can work for 12 months after resignation of APSSA statutory bodies;
3. APPSA asks its employees and members of statutory bodies to release or waive any interest that may create conflict of interests with APPSA;
4. APPSA employees are banned from working in a pharmaceutical-profit or nonprofit or take responsibility of such a pharmaceutical company while under contract APPSA. They are also banned from working for a supplier of APPSA while under contract with APPSA;
5. Business relationships with close relatives (family, friends) whose interests may conflict with those of APPSA are prohibited.
6. Any gifts or contributions from any provider to employees or members of APPSA Statutory Bodies will be handed to the secretariat. The acceptance of gifts such as T-shirts, caps, etc. cannot be considered as a problem if they are offered free of charge and not for the purpose of influencing a business decision;
7. APPSA managers can serve on boards of other NGO's or associations, but they must take care to inform the board of directors;
8. Employees and members of statutory bodies should take care of the APPSA

properties and not use them for strictly personal objectives. If an employee has doubts he should check with the Human Resources Manager;

9. APPSA grants sometimes medicines as gifts to partners and customers. It will ensure that these donations are given in the transparency and fairness to beneficiaries.

Annex 11 Framework contracts

A framework contract is a contractual arrangement that provides an efficient, cost effective and flexible way of procuring supplies that are needed continuously or repeatedly over a period of time. The framework contract provides a means of reducing procurement costs and time for supplies which are needed on a regular basis. Typical examples include:

- office stationery;
- spare parts for routine vehicle repairs; and
- commonly used medical supplies, such as bandages.

A framework contract also provides a means of having supplies "on call", where they might be needed urgently, but where the quantity and timing cannot be defined in advance. For example, malaria drugs might be needed to deal with a sudden outbreak of the disease, but the size and timing of any outbreak cannot be known in advance. The existence of a framework contract would allow a Procuring and Disposing Entity to respond quickly to the emergency, without resorting to direct procurement, which is likely to result in higher prices, due to the lack of competition.

Framework contracts should not normally be used for supplies which are only required occasionally, or which could be purchased by a single lump sum contract. Where the quantity of supplies and the times they are needed is well defined in advance, a lump sum contract is more appropriate.

Benefits of Using a Framework Contract

When used in appropriate circumstances, a framework contract can offer a number of benefits:

- Reduced time and resources spent on procurement, as the Procuring and Disposing Entity only has to conduct a single bidding process and place a single contract to be able to order supplies whenever they are needed, rather than conducting a separate procurement process each time e.g. 12 separate call-off orders could be placed on a monthly basis under a single framework contract covering a period of one year.
- Bidders' time and effort in preparing bids or quotations is reduced. A greater number of Bidders should be interested in the contract, as a single bid will result in guaranteed business for a long period of time.
- Lower prices should be obtained, as by aggregating requirements, a larger contract is offered, which is more attractive to providers, resulting in more competitively priced bids.
- The lead time for delivering supplies can be reduced, as there is no need for a procurement process for each order. Minimum response times for delivering the supplies can be included in the contract.

- Procuring and Disposing Entities can retain the benefits of competition, even where supplies are needed in an emergency situation.
- The Procuring and Disposing Entity can obtain benefits of scale without incurring the costs of holding stock or paying for a large volume of supplies up-front.
- Call-off orders can be placed and commitments made in accordance with the funds available.
- Once a framework contract is in place, the completion of call-off orders is a quick and simple process.

Disadvantages of Using a Framework Contract

- Although call-off orders can be easily placed, the overall framework contract must be managed, to ensure that individual orders and payments correlate and that the Procuring and Disposing Entity is meeting any financial commitment to purchase a minimum value of supplies.
- The Procuring and Disposing Entity may need to guarantee a minimum value of supplies, in order to obtain competitive bids. There is then a risk that it does not require the minimum value specified.
- It may be difficult to accurately estimate the quantity of supplies likely to be required. If actual requirements turn out to be higher than estimated, the Procuring and Disposing Entity may end up paying higher prices than necessary. If actual requirements turn out to be lower than estimated, Bidders may increase their prices or decline to bid for any subsequent framework contract.
- Framework contracts may favour larger providers, who are able to hold sufficient stock or import supplies quickly to meet the required response times. Smaller providers may be unable to compete for the contract.

Annex 12 Internal and external audit

Internal Audit

Definition:	Internal audit is an independent, objective assurance and consulting activity designed to add value and improve an organisation's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Role:	International accounting standards dictate that organisations in the public and private sectors have effective 'internal' audit. The internal audit department of any organisation, private or public, is very much an integral part of the management of that organisation and performs its work for and on behalf of the management. Internal controls are strengthened through the internal audit function.
Approach:	An audit plan is usually developed based on a risk assessment and updated at least annually. Senior management helps to formulate the plan. The findings and recommendations included in a standard internal audit report are reported to the management of that organisation. Management should then act upon these recommendations with the result that subsequent internal audits would begin by reviewing previous recommendations and whether or not management was seen to act in response. Internal audit is based on a systematic methodology for analysing business processes or organizational problems and recommending solutions.
Underlying concepts:	Internal Audit is based on the existence of internal controls, measuring compliance with these policies and procedures and recommending improvement actions to management. Internal Audit 'advises' management on issues that arise and whether follow-up action has been taken. It is an on-going process.

External Audit

Definition:	A periodic examination of the accounts and records of an entity conducted by an independent third party to ensure that they have been properly maintained, are accurate and comply with established concepts, principles, and accounting standards, and give a true and fair view of the financial state of the entity.
Role:	External auditors are independent of the organisation but are engaged by it. Their objectives are set primarily by statute and their primary client - the board of directors.
Approach:	Internal audit work is often relied upon by external auditors to help target the time limited external audit to areas of greatest control weakness and to avoid duplication. They should meet periodically on common interests; benefit from complementary skills, gain understanding of each other's work and methods; discuss audit coverage and scheduling; share reports and working papers and jointly assess areas of risk.
Underlying concepts:	External Audit is: an annual inspection of accounts and records; is performed by a body external to the organisation; is mandatory; can raise issues informally or formally in its letter to the senior management; is required to 'sign off' that the accounts give a 'true and fair view' of the financial position in the entity at that point in time.

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3. HSSP. Consultancy on the proposed legal status of the central medical stores operation. May 5-15 2004
4. Comments by the World Bank mission on the proposed national pharmaceutical procurement unit
5. Minutes of the third meeting of the ministry of health and sanitation of the proposed legal status of the central medical stores, held at the conference hall of the ministry Monday 28th October 2004 at 1:00pm
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8. Agreement between the government of Sierra Leone and the Central Procurement Unit (CPU) for the purchase, storage and distribution of medicines and medical consumables in Sierra Leone, Draft. 2004
9. The new CMS - Central Procurement Unit - Organogram and Job Descriptions
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11. Minutes One-day advocacy workshop for financial resource mobilization for the establishment of the national pharmaceutical procurement unit NPPU of the Ministry of health and sanitation. 30-11-2006
12. Re-final draft of revised health services cost recovery policy guidelines for Sierra Leone, second edition. 24-01-2007
13. Legal consultancy to advice the HSSP to develop a new legal status for the central medical stores. 24-05-2004
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