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SUPPLY AND DEMAND MANAGEMENT FOR INPATIENT PHARMACEUTICALS

TECHNICAL REPORT

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ACRONYMS

EEHR	Enabling Equitable Health Reforms
EML	Essential Medicines List
FEFO	First Expiry First Out
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
HTA	Health Technology Assessment
HII	Health Insurance Institute
MEF	Médecins Sans Frontières
MIS	Management Information System
MOH	Ministry of Health
MSH	Management Science for Health
QKKB	Qendra Kombetare e Kontrollit te Barnave (National Centre of Drugs Control)
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
WHO	World Health Organization
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

BACKGROUND

Most of the public hospitals in Albania are reported to experience a mismatch between supply and demand for pharmaceuticals. This problem appears systemic. It is well recognized by medical staff, the staff of the Ministry of Health (MOH) and Health Insurance Institute (HII). It is raised and reported by media, and expressed as a general concern by the public as well as patients and their relatives.

For example, many regional hospitals report shortages of some essential pharmaceuticals well before the end of their fiscal year. As a result, hospitalized patients do not receive drugs to which they are entitled to by law. Hospitalized patients are often urged to acquire drugs on the market in order to secure proper treatment.

KEY FINDINGS

A number of areas have been identified presenting weak systems that may have both a direct or indirect impact on the availability, affordability and/or quality of medicines, or a mix of these, within the hospital settings.

Most importantly, to a varying extent, the issues identified result in determining the following effects on the Albanian Inpatient Pharmaceutical System:

- Implicit rationing;
- Unnecessarily high cost of medicines;
- Discontinuous availability of hospital medicines;
- Uncertainty on the level of quality of medicines;
- Inequality amongst users;
- Operational inefficiencies;
- Unnecessary challenges in Hospital Financing.

RECOMMENDATIONS

In order to correct these outcomes, nine practical recommendations with relevant priorities have been identified in a number of Pharmaceutical Management areas. Specifically, the recommendations apply to Pharmaceutical Policy, Regulatory, Stock and Inventory Management, Pharmaceutical Financing and Procurement.

These are presented in details in Section 4. However, it should be noted that Pharmaceutical Management works well and deliver the desired outcomes only if/when all its activities are well interconnected harmonized and coordinated.

Therefore, in order to guarantee a continuous supply of affordable, effective and good quality products to patients in Albanian Hospitals, it is necessary to intervene and correct all weaknesses identified in this analysis. The partial implementation of recommendations may not guarantee a proportional corresponding improvement in the overall functioning of the system.

I. INTRODUCTION

The Enabling Equitable Health Reforms (EEHR) project is a five-year USAID funded initiative to increase access to essential health services for the poor by supporting the implementation of health care reforms in Albania. EEHR provides technical assistance and resources to assist key stakeholders in the application of reforms at the national level and helps develop and field-test approaches and tools that support implementation of reforms in selected sites.

The project encourages the involvement of all key stakeholders in policymaking and planning, and supports an evidence-based policymaking process. It implements interventions increasing the capabilities for management and administration at two regional hospitals and one tertiary hospital.

The project also enhances the capacity of the Ministry of Health to use information for improved policy and planning at the national and regional level, and works to involve non-state actors in the oversight of the health system in order to make it more responsive to the needs of customers.

I.1 BACKGROUND OF ACTIVITY

Most of the public hospitals in Albania are reported to experience a mismatch between supply and demand for pharmaceuticals. This problem appears systemic. It is well recognized by medical staff, the staff of the Ministry of Health (MOH) and Health Insurance Institute (HII). It is raised and reported by media, and expressed as a general concern by the public as well as patients and their relatives.

For example, many regional hospitals report shortages of some essential pharmaceuticals well before the end of their fiscal year. As a result, hospitalized patients do not receive drugs to which they are entitled to by law. Hospitalized patients are often urged to acquire drugs on the market in order to secure proper treatment.

In order to improve this situation, by identifying weaknesses in the pharmaceutical management system and proposing pragmatic remedies, EEHR through its implementers Abt Associates has commissioned the present analysis, which is focused on the management of pharmaceutical supplies in three public hospitals, two Regional secondary-care hospitals (in Lezhe and Korce) and one tertiary-care Maternity Hospital in Tirana (Queen Geraldine Hospital).

EEHR will then seek to field-test the proposed solutions in consultation with the MOH and HII.

I.1 METHODOLOGY AND THE CONSULTANT

The consultant has conducted a general review of the Pharmaceutical Sector in Albania, through a review of all relevant existing reports discussing issues affecting the accessibility, availability, affordability and quality of medicines in the country (including alleged issues around corruption), with a special focus on supply and demand issues affecting the inpatient system at two secondary and one tertiary-care hospitals.

Dedicated meetings were then organized with the relevant actors in the Pharmaceutical Sector to discuss their policies, operating approach or procedures (where available), their roles and responsibilities and their perspectives on the supply issues – mainly stock outs - currently experienced for inpatient pharmaceuticals.

Finally, the consultant visited the three hospitals and reviewed the Pharmacy Services operating systems and structures in order to identify the reasons that may be behind the unavailability of inpatient pharmaceuticals.

2. OBJECTIVES

This report is not intended to be a systematic and comprehensive assessment of the Albanian National Pharmaceutical System¹.

However, this report intends to provide an analysis of the existing system for managing inpatient pharmaceuticals in Albania, and to identify areas where existing operational procedures that are critical to guarantee an uninterrupted supply of affordable, effective and good quality medicines may be too weak and therefore in need of improvement.

The key findings of the analysis are presented in Section 3 here below. Practical recommendations and priority interventions will be presented in Section 4 of this Report.

3. FINDINGS

In general, Pharmaceutical Systems involve a number of different functions, which are covered by relevant Institutions, Agencies and Authorities within - or connected to - the Ministry of Health. Countries may then have different operational structures depending on several factors, of which many are outside purely technical considerations and relate heavily on political, cultural and socio-economic development.

As a general consideration, the consultant has noted a significant influence of politics on the direct, routine operational functions in the Health Sector. The majority of people interviewed involved with the management of hospital services emphasised that they had covered their role for a limited time and that they were expecting to move to other functions within the Health Sector with the newly appointed government. It was explained that this high turnover is quite normal in Albania and that it represented a great challenge from a managerial perspective, preventing any process improvements around efficiency and effectiveness of hospital services.

3.1 BACKGROUND INFORMATION ON THE PHARMACEUTICAL SYSTEM

In Albania, the Pharmaceutical System is mainly publicly funded and coordinated. The Ministry of Health (MOH) or its Public Agencies are directly responsible for registration, regulation, policies, planning, financing as well as the procurement of medicines for public hospitals.

Medicines prescribed by general practitioners and family doctors in public health centres are sourced through the retail pharmacy network and subsidized to patients through a national insurance scheme managed by the Health Insurance Institute (HII).

Private sector pharmacies and suppliers, including wholesalers, importers, manufacturers and distributors are therefore also part of the pharmaceutical system, whether they contract with HII under the national insurance scheme or with public hospitals following MOH public procurement.

A National Essential Medicines List (EML) exists in Albania and it was lastly updated in 2011. There are currently 464 medicines on the EML. The selection of medicines for the EML is not undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is not in place.

¹ For more information on the Albanian Pharmaceutical Sector, please refer to the WHO Pharmaceutical Country Profile. The World Health Organization (WHO) in 2011 has supported all Member States to develop Pharmaceutical Country Profiles (PCP), including Albania. PCPs provide data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector, aiming at compiling all relevant, existing information on the pharmaceutical sector and making it available in a user-friendly format.

STGs for the most common illnesses are produced and endorsed by the MOH in Albania. These were last updated in 2010. Specific STGs cover secondary care (updated in 2010) and paediatric conditions (updated in 2010).

However, based on the interviews held with various players at the MOH and in the three Hospitals visited for this analysis, most STGs have been developed but are not systematically used by physicians.

3.2 INPATIENT PHARMACEUTICAL MANAGEMENT SYSTEM

Pharmaceutical Management comprises a chain of activities that need to be well aligned, interconnected and coordinated to guarantee the continuous availability of good quality, affordable medicines to patients.



With regard to inpatient pharmaceuticals in Albania, the key activities are described here below:

Financing

Hospital financing is based on historical expenditure. The MOH allocates to each Hospital an annual budget based on the previous year expenditure and then adjusted by inflation. On average, around 40% of Hospital budget is then allocated by each Hospital to the expenditure of medicines.

In general, hospital management has consistently reported that financing is considered to be below the actual need and that at the time of budgeting significant cuts have to be made to the originally planned amount required to carry out services, including pharmaceuticals. The lack of any flexibility between budget lines has been also reported as a cause of concern. It appears that funds cannot be moved from one budget line to another in order to deal with unexpected higher costs in some services using savings that may be generated in others. This is perceived also as a disincentive to improve efficiency in areas where potential savings could in fact be made.

Product Selection

The list of medicines required by Public Hospitals was initially drafted by the University Hospital Centre in 2005. This list does not appear to have been aligned with the EML. In the last quarter of each fiscal year, Public Hospitals are then invited to submit a list to the Directorate of Hospital Planning (MOH) for the coming year, proposing changes based on their need. However, there are no procedures to attempt at consolidating a national list.

In addition, existing STGs and Treatment Protocols do not appear to play any role in the selection, planning and quantification of the hospital medicine list.

Finally, the systems does not seem to involve hospital pharmacists in the selection of medicines, in the rational use of drugs and in optimizing formulations and pack sizes suitable for hospital use. Currently, pack sizes can only be chosen from those registered by the local Regulatory Authority (QKKB²) upon application by pharmaceutical companies or their distributors.

Planning and forecasting

Hospitals conduct a planning and forecasting exercise for medicines on an annual basis based on their estimation of needs. After submitting the list of medicines to the Directorate of Hospital Planning, a dedicated Working Group at the Pharmaceutical Department of the MOH estimates the average price for each product on the lists submitted by hospitals and sends this information back to them. Hospitals then calculate quantities based on their allocated budget.

Once these quantities have been defined, they are communicated back to the Directorate of Hospital Planning (MOH), who consolidates all information received from Public Hospitals into a final list that is submitted to the Procurement Department of MOH.

Technical Specifications

The Directorate of Hospital Planning drafts technical Specifications for all products on the hospital lists, with some (inconsistent) input from hospitals. In case needed, a dedicated Working Group usually from the Mother Theresa Hospital in Tirana is formed in order to provide technical advice. There appears to be no formal guidelines or criteria regulating this Working Group.

Public Procurement of Medicines

Until 2004, the procurement of pharmaceuticals for hospital use was centralized within the MOH. This process was then decentralized, with hospitals being given the right to procure pharmaceuticals directly using the national public procurement regulations. However, a Cabinet of Ministers decree returned the process to a centralised system for 2013, allocating the procurement process back within the Procurement Department of MOH.

The objectives of this change were to increase the purchasing power of the current budget by seeking economies of scale in medicine supplies, to harmonize the availability of medicines throughout the national public hospital system and to tighten the control over the procurement process, thus reducing potential abuse/corruption.

The Procurement Department conducts annual tenders for all products included in the finalized hospital list and – most importantly - for the fixed quantities estimated by hospitals based on their approved budgets.

While the fiscal year goes from January to December, the procurement process can start only once the budgets have been defined, that is normally in January. In 2013, the procurement process closed in June.

² National Centre of Drugs Control (NCDC)/ Qendra Kombetare e Kontrollit te Barnave (QKKB).

The “Commission for the Evaluation of Offers” conducts the evaluation of tenders. This commission comprises 3-5 members nominated directly by the Minister of Health and it is established at the time of preparing tenders. Reportedly, the criteria for membership include experience in procurement and knowledge of medicines. Usually, the Minister selects members between employees of the MOH, although this has not been reported to be a formal requirement.

The Commission conducts the Technical and Financial evaluations of offers and awards the contracts. As a final step, the Minister signs off the final evaluations.

Inventory Management (MIS)

Inventory Management is computerized in Korce and Lezhe Hospitals, while in Queen Geraldina Hospital is based on the sole use of a manual register. Korce and Lezhe use a MIS software that was developed over 10 years ago by a local Software Company in Tirana and that was financially supported by Médecins Sans Frontières (MSF) who supposedly provided also the technical expertise for its design.

The software provides basic and essential functions in stock management. It records actual stock levels for all hospital medicines identified by generic name, pharmaceutical form and dosage. It also records the total level of stock received and volume dispensed for the period and the relevant cost per unit and total cost. Finally, it provides the opportunity to generate reports that can be used for planning, quantification and cost estimates.

Contracting & Distribution

Once Tenders have been awarded, all hospitals are required to contract with the selected suppliers for the products they had planned for in their hospital list and for their respective quantities. Hospitals tend to consider this step as just another bureaucratic requirement, as they can hardly negotiate on any conditions.

Most importantly, contracts are signed on fixed quantities determined at the time of budgeting and do not allow any flexibilities in supply/demand variations. Based on these contracts, suppliers then distribute inpatient pharmaceuticals directly to hospitals.

The Regulatory Authority (QKKB) is responsible for monitoring distributors and wholesalers, ensuring that they comply with Good Distribution Practices (GDP).

Rational Drug Use

In Albania, a number of Treatment Protocols appear to have been developed for the main disease and clinical conditions (104) in 2009-10 but are not systematically used by hospitals.

There appears to be no formal process to involve clinicians, nurses and pharmacists in promoting and monitoring adherence to treatment.

No Pharmacovigilance activities appear to be in place and functioning in Albania. QKKB is currently in the process of designing and implementing a Pharmacovigilance system in the country.

Accounting Capabilities

In each hospital ward, prescriptions are prepared each day by the nurse, except on Fridays, when the systems allows for multiple dispensing to cover for the week-end.

Prescriptions are prepared in 3 copies by the wards, and signed by the Doctor on duty. The Chief Pharmacist signs the prescription and keeps one copy for filing once the products on the prescription list have been dispensed and entered into the MIS System, where applicable.

The nurse receiving the dispensing checks the products against those ordered, countersign the prescription and keeps one copy for filing. The third copy goes to the Hospital Financial Services

with a report from the MIS software (where applicable) including the list of drugs dispensed, their quantity, unit cost and total cost.

Financial Services keep their own separate records, using their own accounting methodologies and software. In other words, the two systems are not interfaced. However, all three hospitals confirmed that they reconcile records with Pharmacy Services at the end of each month through a manual exercise.

The MIS System used in Lezhe and Korce records the unit price and total cost of each product in stock and reports on volume and cost of drugs received, volume and cost of drugs dispensed and of stock on hand. The Maternity Hospital keeps all records in a paper-based Register and all reports have to be manually compiled when requested.

No coding system appears to be in place to serve as unique identifier for each product.

3.3 HOSPITAL PHARMACY SERVICES

Lezhe Hospital

The Regional Hospital in Lezhe has 162 beds and cover the need for secondary care within a population of 220,000, which may reportedly grow to as much as 700,000 during the summer months.

The Pharmacy Services are provided by 4 staff, one Chief Pharmacists, two Pharmacists and one Assistant.

- **Receipt & Storage**

No written **standard operating procedures** (SOP) appear to be available.

No dedicated area exists for **receipt and visual inspection** of stock delivered to the Hospital before its acceptance.

The **dispensing** area appears to be adequate in terms of space, although storage equipments (cabinets, shelving etc) could be improved, as well as security, which appears to be very basic. The office is separated and requires pharmacists to continuously exit the dispensing area to access files and – most importantly - the computer where prescriptions need to be entered into the Management Information System (MIS).

The storage **area** is clearly insufficient for the volume of stock managed by the Hospital and in a separate building from where the Pharmacy Dispensing area is located.

The **security** level is quite basic, as the door of the storeroom is simply locked and the key held by the Chief Pharmacist.

The storage **conditions** are very poor and definitively below any acceptable level. The room is small, dark, not aerated, not adequately cleaned and without any temperature monitoring and/or control system. It is highly likely that temperature and humidity levels will go above those required for the medicines stocked in this room several times during a calendar year.

No proper storage **equipment** is available. Medicines are not rationally organized but simply put on or under old tables and cabinets without any apparent order. The Chief Pharmacist stated that “he knows where to find medicines” and how to keep expired stock separated.

Medicines are indeed grouped together and separated by each other and by expiry date but due to the limited space available, it may be challenging to maintain this separation if/when new stock arrives or if other staff needs to access stock. A quick inspection confirmed a basic separation of **expired stock**, which is not clearly understandable from a first sight.

The Chief Pharmacist confirmed that nobody is allowed to enter the room, that he is the only one responsible for moving and organizing stock in the storage area and that he has never been on holiday for many years.

Packaging/labelling of medicines appeared to be in line with legal requirements (a label indicating the duties paid for Hospital medicines and a simple red stamp on the outer box indicating “for hospital use only”). Some packs did not carry any of these and were presented to the consultant as “donations”.

- **Inventory Management**

MIS is computerized. No **stock cards** or bin cards appear to be in use in any area dedicated to the storage of medicines.

- **Stock-outs**

At the time of the visit, the following pharmaceutical products were reported to be out of stock and therefore unavailable to patients in need:

1. Ranitidine 50mg-5ml ampoules
2. Nifedipine 10mg tablets
3. Cefatoxime 1gr bottle
4. Ceftriaxone 1gr bottle
5. Paracetamol 1gr ampoules
6. Insulin ord. vials

Korce Hospital

The Regional Hospital in Korce has 510 beds and cover district level services for a population of 230,000.

The Pharmacy Services are provided by 5 staff, one Chief Pharmacists, three Pharmacists and one Assistant Pharmacists.

- **Receipt & Storage**

No written **standard operating procedures** (SOP) appear to be available.

No proper dedicated area exists for **receipt and visual inspection** of stock delivered to the Hospital before its acceptance. The entrance hall of the building where the Pharmacy Service is located is used for this purpose.

The **dispensing** area appears to be adequate in terms of space. The office is separated but communicating directly with the dispensing area and the first-floor storage area, thus staff access to files and – most importantly - the computerized MIS system are easily accessible.

The storage **area** is split in two separate floors in the same building. On the ground floor is the office of the Pharmacy Service, the dispensing area and a separated storage area with many cabinets storing all medicines in a reasonably good order. This storage area is spacious, very bright and adequately equipped for its purpose. All pharmacists can move freely around a big table in the middle of the room used by pharmacists when filling prescriptions.

The bulk of the medicines stock is kept on a separate storage room on the first floor. This stock is accessed only when stock levels on the ground floor are low. The room appeared quite full but reasonably well equipped with shelves where cartons are lined up. Due to lack of space in the storage room, cartons of less-sensitive items are piled up on the stairwell.

The **security** level is quite basic and revolves around simple door locks. Keys are held by the Chief Pharmacist.

The storage **conditions** are just acceptable. However, no temperature monitoring and/or control system appears to be in place. It is possible that in this site temperature and humidity levels may at times go outside the range required for medicines.

Storage **equipment** appears just adequate in terms of cabinets and shelving. There are no trolleys to move cartons and no lift to move stock between the two floors. A reasonable attempt at separating medicines by alphabetical order and batch number is in place, although not always consistently implemented. **Expired stock** appears to be clearly separated.

Packaging/labelling of medicines appeared to be in line with legal requirements (a label indicating the duties paid for Hospital medicines and a simple red stamp on the outer box indicating “for hospital use only”). No packs were noted not complying with these requirements.

- **Inventory Management**

MIS is computerized, using the same software used in Lezhe Hospital. No **stock cards** or bin cards appear to be in use in any of the storage rooms (first or second floor).

- **Stock-outs**

At the time of the visit, the following pharmaceutical products were reported to be out of stock or with less than 1 month worth of stock:

1. Tranexamic acid
2. Diazepam vials
3. Prometazine
4. Calcium Chlorine
5. Dopamine
6. Heparin sodium
7. Amiodarone vials

Queen Geraldina Maternity Hospital

This is a tertiary-care Hospital located in Tirana, thus covering the need of the capital and an estimated wider population of around 1 million. It has 240 beds and performs around 7000 deliveries each year.

The Pharmacy Services are provided by 3 staff, one Chief Pharmacists, one Pharmacists and one Assistant Pharmacists.

- **Receipt & Storage**

No written **standard operating procedures** (SOP) appear to be available.

No proper dedicated area exists for **receipt and visual inspection** of stock delivered to the Hospital before its acceptance. The entrance hall of the building where the Pharmacy Service is located is used for this purpose.

The **dispensing** area appears to be adequate in terms of space. The office is separated but communicating directly with the dispensing area and storage area.

The storage **area** is relatively spacious and adequately equipped for its purpose in terms of shelving. Storage space did not appear full. Stock is well separated by therapeutic group, expiry date and batch number.

The **security** level is quite basic but the whole space has only one access and thus easily controlled and locked when necessary.

The storage **conditions** are acceptable. However, no adequate temperature monitoring and/or control system appears to be in place. It is possible that in this site temperature and humidity levels may at times go outside the ranges required for medicines.

Storage **equipment** appears just adequate in terms of cabinets and shelving. **Expired stock** appears to be clearly separated.

Packaging/labelling of medicines appeared to be in line with legal requirements (a label indicating the duties paid for Hospital medicines and a simple red stamp on the outer box indicating “for hospital use only”). No packs were noted not complying with these requirements.

- **Inventory Management**

MIS is completely manual. Pharmacists record receipt, stock levels and dispensing using a manually filled, paper-based Register. No **stock cards** or bin cards appear to be in use.

- **Stock-outs**

At the time of the visit, no pharmaceutical products were reported to be out of stock.

4. RECOMMENDATIONS AND PRIORITIES

Based on the findings of this analysis, a number of areas have been identified presenting weak systems that may have both a direct or indirect impact on the availability, affordability and/or quality of medicines, or a mix of these, within the hospital settings.

Most importantly, to a varying extent, the issues identified result in determining the following effects on the Albanian Inpatient Pharmaceutical System:

- Implicit rationing;
- Unnecessarily high cost of medicines;
- Discontinuous availability of hospital medicines;
- Uncertainty on the level of quality of medicines;
- Inequality amongst users;
- Operational inefficiencies;
- Unnecessary challenges in Hospital Financing.

In order to correct these outcomes, particular attention should be paid to the Pharmaceutical Management areas outlined in this Section.

4.1 PHARMACEUTICAL POLICY

National Standard Treatment Guidelines and Protocols aim at ensuring a standardized level of care throughout the country, at harmonizing hospital medicine lists and help predict consumption and promote equity in the health sector.

In Albania, a number of Treatment Protocols appear to have been developed for the main disease and clinical conditions (104) in 2009-10 but are not systematically used by hospitals.

This has a clear impact on both availability and affordability of inpatient pharmaceuticals. Furthermore, different treatment approaches may have different level of cost-effectiveness, potentially resulting in higher costs with no apparent greater health gains. Due to the limited budgets in health care systems, such cases typically end up denying effective treatments to patients affected by the same or by other diseases.

- **Recommendation I:** The systematic use of Treatment Protocols should be implemented at secondary and tertiary care level, consistently to the efforts being made in primary care.

Priority: High (to be followed up as soon as possible).

Proposed Approach: A methodology for developing and updating Treatment Protocols appears to be in place, as well as the necessary leadership, which was identified in the past under the overall direction of MOH. However, it is critical to also identify a suitable link between Treatment Protocols and the national Essential Medicine List (EML). Treatment Protocols should be implemented in Hospitals through their Therapeutic Committees.

- **Recommendation 2:** Hospitals should establish independent Therapeutic Committees.

Priority: High (to be followed up as soon as possible).

Proposed Approach: Therapeutic Committees should have as main goal the rational and cost-effective use of medicines through a collaborative drug management involving all health workers. The Committee will be responsible for defining its own specific objectives on an annual basis.

The membership of Therapeutic Committees should reflect all stakeholders: physicians, nurses, pharmacists, patients and hospital management. Nominations should not necessarily follow a hierarchical approach.

Chiefs of Hospital Services should nominate candidates amongst physicians, nurses and pharmacists. Hospital Directors should nominate candidates from their respective Hospital Executive Management Team. Local patient groups should nominate their candidates.

The Hospital Board should select the best candidates based on their knowledge, qualification and expertise. Where Hospital Boards are not yet in place, the Hospital Management Team should take up this task. Members of the Therapeutic Committee should be elected for 2-3 years and their membership should not exceed 2 consecutive mandates. Members should be required to operate within a consultative framework within their represented Hospital Services. Chiefs of Hospital Services must commit to facilitate implementation of all decisions made by Therapeutic Committees as part of their Terms of Reference and performance appraisal system.

Therapeutic Committees should have the responsibility to implement Treatment Protocols and SOPs within their respective hospital structure, to promote evidence-based clinical behaviours, to design and implement a continuing-education program for clinical staff, to compile the list of medicines normally required by clinical services and to evaluate special cases requiring extraordinary treatments.

In addition, Therapeutic Committees may have a role in ensuring rational drug use within the hospital, including providing input on the selection of the most appropriate formulation and pack size of medicines, to promote and monitor treatment adherence and to gather and communicate data relating to Pharmacovigilance to the national Regulatory Authority (QKKB).

For more details and operational steps to follow on setting up and running a Hospital Therapeutic Committee (including Scope of Work, goals and objectives), it is recommended to refer to the practical guide developed by WHO, in conjunction with the USAID-funded Rational Pharmaceutical Management Plus Programme of Management Sciences for Health (MSH)³.

4.2 PHARMACEUTICAL REGULATORY ISSUES

Regulatory Authorities cover a critical role in ensuring that only medicines meeting the required standards of efficacy, safety and quality are imported and distributed in the country. Their role normally includes the responsibility to monitor that all institutions and organizations handling

³ Drug and Therapeutics Committee – A Practical Guide.

World Health Organization, Department of Essential Drugs and Medicines Policy, Geneva, Switzerland in collaboration with Management Sciences for Health, Center for Pharmaceutical Management Rational Pharmaceutical Management Program, Arlington, Virginia, USA.
<http://apps.who.int/medicinedocs/pdf/s4882e/s4882e.pdf>

pharmaceuticals for public use adhere to Good Manufacturing Practices (GMP), Good Storage Practices (GSP) and Good Distribution Practices (GDP).

It has been noted that a number of medicines packs stored in Hospital Pharmacies carry product information in a number of different languages. In discussion with the Albanian Regulatory Authority (QKKB), it has been explained that this is due to a lack of strict regulations around language. In addition, some of these medicines may have been imported in Albania using the flexibilities offered in the local legislation under “Exceptional Circumstances”. The consultant has not been able to obtain firm data on number and frequency around the use of such flexibilities but QKKB verbally reassured that this flexibility may only be applied 3-4 times a year for fixed quantities of medicines under the direct order of the Minister of Health.

In any case, the availability on the market of a high number of medicine packs carrying product information relevant to other countries and in languages other than Albanian, and perhaps English, may be source of considerable confusion to patients, create difficulties to prescribers, pharmacists and nurses and eventually expose patients to unnecessary risks.

Most importantly, medicines entering the Albanian market under “Exceptional Circumstances” have not been comprehensively assessed by QKKB and are not therefore required to be priced within the accepted international references, as it happens for all other medicines.

- **Recommendation 3:** The use of at least the Albanian language in product leaflets should become a strict legislative requirement in the marketing approval of all medicines. Other languages may be allowed in addition to Albanian.

Priority: Medium.

Proposed Approach: This is a small but important step in the chain of activities aiming at ensuring adequate rational drug use of medicines in the country. In addition, it would also make immediately recognizable any stock of medicines circulating in the country either through the process of “Exceptional Circumstances” or through potentially illegal channels.

- **Recommendation 4:** The use of Marketing Approval under “Exceptional Circumstances” should be limited to the minimum and only to those cases strictly meeting the exceptional circumstances criteria.

Priority: Medium - High.

Proposed Approach: While this type of approval has been reported being used “rarely”, it is difficult for this consultant to believe that each year 3-4 products have a real Public Health need to be imported urgently and in fixed quantities in Albania. Further investigations would be necessary to establish the exact size of the problem.

However, this is a highly political and sensitive matter, due to the potential financial interests that will be directly touched by this recommendation. Since it is the Minister of Health in person who has to sign the request for marketing approval under “Exceptional Circumstances”, it is quite clear that this system is exposing the Minister to potentially significant lobbying, political influence and financial pressure to get products approved through this route.

Therefore, it is evident that political will is indispensable to address this issue, which should be discussed at the appropriate political level, illustrating the risks for Public Health. Alternatively, this issue may also be tackled from a pure legislative side, as for most medicines it would be difficult to justify that they met the legal criteria of “Exceptional Circumstances”.

- **Recommendation 5:** Hospital medicines should be all required to be supplied in pack sizes tailored to those most suitable for hospital use, preferably in bulk packs (when appropriate), with the wording “Hospital Use Only – Not For Sale” clearly printed (not stamped) on the outer packaging, boxes and cartons.

Priority: High (to be implemented as soon as possible).

Proposed approach: While all recommendations in this report will contribute all together to significantly improve the management of pharmaceuticals in the country, this is by far the single, most important and most effective action that could be taken to correct a number of present issues. Hospital-only bulk packs would be likely to achieve the following:

- Minimize/eliminate the risks of leakages;
- Minimize/eliminate the risks of sale in the private or black market;
- Achieve cost-savings;
- Improve stock and inventory management;
- Improve adherence to treatment protocols.

The current requirements are not considered sufficient, as most pack sizes are the same as those on the retail market, with the exception of a small label and a red stamp on the outer box of medicines. The red stamp is most of the times not clearly readable and it can easily fade off with time and handling. In addition, the small label can be easily detached.

Rationalizing pack sizes should be a joint effort between Chiefs of Hospital Pharmacies, Regulators and Purchasing Institutions. There is no need to involve other health professionals such as physicians and nurses. However, there is also a role to be played by Therapeutic Committees, once they have been established.

4.3 STOCK AND INVENTORY MANAGEMENT

Adequate procedures, systems and structures for handling medicines ensure that patients receive an uninterrupted supply of affordable and good quality products. Pharmaceutical Management in the three hospitals visited present critical issues affecting the receipt, storage and inventory management.

The findings outlined in Section 3 of this report have a significant impact on the availability, accountability, affordability and quality of medicines. When medicines of recognized good quality are not available in the correct dosage form and quantity at the required time, patients may unnecessarily suffer financial and clinical consequences, resulting in unequal access to treatment, prolonged hospital stay, higher costs, undesired clinical consequences and reputational damage for the Public Health Sector.

- **Recommendation 6:** Pharmacy Stores should all comply in full with Good Storage Practices (GSP) as defined by the World Health Organization (WHO)⁴.

Priority: Medium-High (to be completed within 6 months).

Proposed Approach: In Lezhe, the Pharmacy Store is totally unacceptable, particularly in terms of space, conditions, equipment and security. However, work is currently undergoing to renovate a new storage space, which will comply with Good Storage Practices.

For Korce and Queen Geraldina Hospitals, general storage conditions, space and equipment appear barely acceptable. Chiefs Pharmacists should refer to the WHO Guidelines on GSP and make a detailed list of all requirements currently not met in their respective stores.

However, as a matter of priority, they should be immediately improved in terms of temperature monitoring and control. Appropriate thermometers recording min and max temperatures should be provided in all rooms where medicines are stored and temperatures should be regularly monitored and recorded. Appropriate ventilation and air-conditioning systems should

⁴ Guide to Good Storage Practices for Pharmaceuticals. WHO Technical Report Series, No. 908, 2003, Annex 9 (2003; 12 pages) <http://apps.who.int/medicinedocs/en/m/abstract/js18675en/>

be installed in order to maintain temperature and humidity within the required ranges at all times (7/7).

In Korce, additional space should be ideally identified, as less-sensitive stock is currently stored in the stairwell. Stock cards should be in use to record movement of stock between the two floors. In both Korce and Queen Geraldina hospitals, there is no proper space allocated to receive and inspect products on arrival, to quarantine stock and for expired and/or recalled stock.

- **Recommendation 7:** Written Standard Operating Procedures (SOP) should be developed, implemented and made available to train staff, monitor operations and document activities if/when required.

Priority: Medium-high (to be completed within 6 months).

Proposed Approach: The Chief Pharmacist in each Hospital should drive the process of documenting each activity in writing, consulting with, and receiving input from, stakeholders (doctors, nurses, pharmacists) if/when relevant. SOPs should cover all activities from receipt of stock down to the dispensing of medicines to patients, including the recording on patient files.

It would be desirable if the final SOPs could be harmonized where possible between the three hospitals, at least for all activities in common. Such exercise could potentially strengthen systems by sharing best practice and own experience.

SOPs, once in place, should be regularly updated once a year, or more frequently, if operative changes are implemented during the year. SOPs should then be made freely available to all staff involved with the relevant activities and be used as guidelines for training new staff, for defining staff roles and responsibilities and for monitoring staff performance. A copy of the current SOP should be signed and filed at the Hospital Director's office.

- **Recommendation 8:** Inventory Management should be improved to a more modern standard.

Priority: High (to be followed up as soon as possible).

Proposed Approach: Lezhe and Korce have a computerized system to monitor stock levels, record dispensing and report on cost. However, in Queen Geraldina Hospital, pharmacists still operate with a paper-based Register, which provide essentially the same information, with the exception of reporting capabilities, which are understandably more cumbersome and time consuming to provide when requested.

While simple and basic, these computerized systems do provide the barely minimum information normally required for good inventory practices. However, there is significant room for improving efficiency and effectiveness of Pharmacies' operations and for improving accountability.

Immediate, inexpensive and simple steps could be taken to improve the current inventory systems with some gains for the overall management of inpatient pharmaceuticals. These steps would require modifying the current software as follows:

- Include the possibility to record for each product, its batch number and expiry date. This would help optimizing the FEFO (First Expiry First Out) inventory management system currently in use.
- Include a "Unique Identifier" Coding System for each product. This would avoid possible mistakes and make reports more reliable and comparable. The same coding should then be used in the Hospital Costing Software, in order to improve financing and cost monitoring at central level.
- Include the possibility to record type, volume and cost of products prescribed, in addition to those dispensed. This simple enhancement would provide the important benefit of recording and reporting on actual need, which at present is in fact only

estimated based on dispensing. Furthermore, this would also give the opportunity to report and take into account unmet needs when planning and forecasting.

- Include the possibility to generate an additional reporting table, as outlined in Section 6, recording for each product over a given period: Opening Stock, Estimated Quantity Needed, Quantity Planned, Quantity Received, Quantity Prescribed, Quantity Dispensed and Stock on Hand.
- Provide a read-only interface with the Financial Department, in order to monitor deliveries, invoices and costs.
- Implement the same software in Queen Geraldina Hospital.

An alternative approach would be that of developing a completely new and modern software to be implemented in all Hospitals. Modern technologies offer undisputable advantages and could potentially significantly improve operational efficiencies, offering real time monitoring and enhanced inventory control. In addition, they could be directly interfaced with Hospital Wards to process prescription orders and with Financial Departments to monitor costs.

Such approach could rely on bar-coding systems, which offer the opportunity to reliably and accurately trace stock from the wholesaler warehouse down to dispensing at Hospital Pharmacy level. Such state-of-the-art system would provide the highest possible degree of security, accuracy, reliability, traceability, stock and cost controls. However, it should be treated as a project on its own, requiring significant and dedicated time, resources and efforts in the design, piloting, testing, training and implementation of the system.

4.4 PHARMACEUTICAL FINANCING AND PROCUREMENT

Efficient and effective financing and procurement systems are essential to maximize the health benefits for the population within the available resources.

Ideally, the main aim of these systems should be to improve the health status of the population through affordable treatments, while providing explicit criteria for rationing; aligning to epidemiological need; meeting patients' expectations, being equitable amongst users; and responding to the need of the most disadvantaged. In other words, the goal should be that of achieving the best possible health outcomes from public money spent on medicines.

Typically, inadequate financing of pharmaceuticals leads to inequity, implicit rationing within the health sector and higher out-of-pocket expenditure for patients, which in fact appears to be a significant problem in Albania.

On the other hand, inefficient procurement systems results in delays of pharmaceutical supplies, higher costs, corruption and ultimately waste of Public Health resources. When pharmaceutical expenditure grows out of control, it may crowd out other healthcare funding, thus creating further inequities and uncontrolled rationing.

In Albania, the current financing system for inpatient pharmaceuticals does not reflect actual health need. The quantification process is effectively driven only by the centrally-allocated hospital budget, which in turn is also not based on the estimated health need for the region, or on the epidemiological and demographical situation or even on the real historical consumption of medicines for each hospital (which at present cannot be measured).

Even improving the way consumption is recorded and then quantified to forecast volume and expenditure for the following year, it would most probably only reduce or minimize, but not eliminate, the chronic under-over stocking of medicines. This is because the pharmaceutical historical financing would need to be "reset" to reflect true consumption, once this becomes adequately and reliably recorded, and then adjusted by trends and by epidemiological and demographic data in order to produce some reliable forecasting. In addition, this approach would

also require specialist expertise in data analysis, epidemiology and forecasting that this consultant has not perceived being available in the Hospitals visited during this study.

Centralization and decentralization of the procurement system over the past several years has not provided any substantial improvement in terms of final outcomes. The availability, affordability and quality of hospital medicines have substantially remained the same through these changes. Furthermore, whether central or peripheral, the approach of procuring fixed quantities of medicines based on weak data and on historical financing not reflecting actual consumption does not provide the required flexibilities that must be taken into account at secondary and tertiary care level for special cases, rare diseases or even simply by normal fluctuations in epidemiology or demography.

Finally, both the centralized and the decentralized approaches have left several doors open in their operating procedures to potential private and political lobbying and influences that in any socio-economic context would lead to cost-inefficiencies and ultimately to corruption. These factors have become so embedded in the Albanian context that it would require significant time, efforts and resources to promote the cultural and habitual change required to bring it within acceptable levels. Most importantly, it would require a holistic approach that goes well beyond purely technical considerations for the health sector.

Virtually any Committee or Working Group involved with pharmaceutical management, from drafting Hospital Lists, to preparing Technical Specifications or – most importantly – to the evaluation of tenders, offer no clear separation of roles, no written criteria for selection of members and no explicit criteria for decision-making. If the current system is maintained, all Committees and Working Groups involved with Product Selection, Technical Specification and Procurement would need to be completely reconsidered and their Nomination Process and Operating Procedures redesigned from scratch.

The Tender Evaluation Committee alone is a notable example. Their members are too few (3-5) to minimize possible external influences, lobbying and/or corruption; they are nominated directly by the Minister of Health, which does not guarantee undue political influence in the process (be it real or perceived); they conduct both the Technical and the Financial evaluation of submissions at the same time (!), which does not comply with internationally accepted best practice in procurement; they operate without explicit written criteria where only the final cost is reported as being considered, which instead should be weighted against other important factors, such as capacity to supply, past performance, evidence of previous experience etc.

Therefore, for inpatient pharmaceuticals, the current financing and procurement systems in Albania are far from providing an ideal outcome and a high number of important corrections would indeed be required to improve them, to a point where this consultant believes it appropriate to recommend considering a completely different approach as a pragmatic, yet radical, solution to the chronic unavailability of affordable, good quality medicines in Public Hospitals.

- **Recommendation 9:** Inpatient pharmaceuticals should be funded through the Health Insurance Institute (HII).

Priority: High (to be implemented as soon as possible)

Proposed Approach: If this recommendation is implemented, then all the issues currently affecting the financing and procurement systems for inpatient pharmaceuticals would be transferred to a single operational framework, thus making it easier to follow up and address.

Furthermore, this approach would provide the possibility of moving away from the weaknesses identified under historical financing and fixed-quantity annual procurement; it would not have to rely only on the weak data around health-need and consumption at regional level; and it would provide the flexibilities required at secondary and tertiary care level for the supply of small and variable volumes of non-routine products.

Finally, under this model, the funding for inpatient pharmaceuticals would be harmonized with the funding system currently implemented for medicines at primary healthcare level.

Other important advantages of this approach relate to the possibility of implementing a more transparent and explicit rationing in the healthcare system. Already, the HII is able to declare the explicit criteria for funding pharmaceuticals at primary care level as well as the level of subsidies applied to each product.

For example, selected socio-economic groups enjoy a full reimbursement of pharmaceuticals (children <1 year old, elderly, military veterans) as well as selected patient groups affected by specific diseases (cancer, tuberculosis, people with severe disabilities, transplanted patients etc). Other social categories (children >1 year old, students, pregnant women, soldiers) or patients groups affected by other diseases or disabilities receive different level of subsidies.

The HII list of reimbursed drugs is modelled on the WHO Essential Medicine List (EML), to which a number of other products have been added based on priority diseases. The list also includes outpatient pharmaceuticals. In addition, some inpatient pharmaceuticals are currently already funded by HII for the Mother Teresa Hospital. In fact, based on the Albanian legislation, HII has already been designed to manage inpatient pharmaceuticals. Therefore, no legislative or policy changes are required to implement this recommendation.

By implementing this recommendation, the following effects on some of the key activities related to pharmaceutical management are expected:

- **Financing**

The financing of Regional Hospitals may still remain based on historical expenditure. However, two important differences would apply: 1) There would be no need to procure fixed quantities based on previous year weak consumption data; and 2) Hospitals would be in a much better position to adjust their stock based on actual consumption and manage their allocated budget according to recorded health needs.

However, under this approach there would be a one-off requirement to increase the annual hospital pharmaceutical budget to allow funding of “buffer stocks”, which at present do not exist at Hospital Pharmacy level. Typically, this would mean a one-off increase of around 25-30% on historical financing for inpatient pharmaceuticals.

- **Product Selection**

Product Selection would be carried out by HII, making sure that only products included in STGs and Treatment Protocols are listed in the schedule of inpatients pharmaceuticals. A link should be established between HII and the Working Group coordinating the development and update of Treatment Protocols.

- **Planning and forecasting**

With the recommended improvements to the MIS systems (Recommendation 8), Pharmacy Services would be able to record actual consumption for a period (for example on a quarterly basis) and adjust their forecasting for the year. With the possibility of implementing “buffer stocks”, the risk of running out of stock (or of overstocking) would be greatly minimized.

For example, if for a given product 100 boxes are estimated for a given year at the time of budgeting, the Pharmacy Services should plan to order 50 boxes at the start of the year (25 as expected consumption for the first quarter plus 25 as buffer stock). If at the end of the first quarter, 30 boxes of that product were actually prescribed then the Pharmacy Services should order 30 boxes for the next quarter (25 as expected consumption plus 5 to replenish its buffer stock level). However, at the same time, the original forecasting for the year should be adjusted (from 100 to 105). Similarly, if at the end of the next quarter, only 10 boxes were prescribed, then the following order should be 10 boxes (which would again

replenish stock for the coming 3rd quarter, 25 boxes as originally expected consumption + 25 as buffer stock). However, the original forecasting for the year should again be adjusted to consumption (from 105 to 80). Ideally, this approach of continuing adjusting forecast to actual consumption should enable Pharmacy Services to manage stock more effectively, avoiding both stock-outs and overstocking and therefore controlling expenditure more effectively. However, a “spending review” should be carried out at mid-year transferring savings from one budget line to another to respond to possible increased needs for other products.

Also, it should be noted that in case of any unexpected increase in demand for certain products due to either mismanagement of stock, unexpected epidemiological fluctuations or irrational prescribing that exceed any financial savings made on products used less than originally estimated, patients should never face lack of treatment under this approach, as the hospital would end the year running a deficit but the system would still allow to track need, order and supply the required product. In such cases, HII should follow up and investigate reasons for the deficit and implement the relevant corrective actions.

Similarly, for exceptional circumstances requiring rare treatments that could not be expected or planned for at the beginning of the year (as it could reasonably happen especially for tertiary care hospitals), the system would allow the immediate ordering of the required medicines (as long as included in the HII list) at any time during the course of the year, as it currently happens for the medicines prescribed at primary care level.

- **Technical Specification**

Since there would be no annual tenders, strictly speaking there should be no need to draft technical specifications for inpatient pharmaceuticals as it is currently done.

However, this activity would be replaced by that of including products into the Inpatient Pharmaceutical List of subsidised products. These will need to meet defined criteria for listing, as it is currently the case for outpatient and primary care medicines.

- **Public Procurement of Medicines**

The procurement of inpatient pharmaceuticals would be carried out by HII through listing products in the reimbursed schedule of inpatient pharmaceuticals.

However, the general considerations made around Board Committees, Technical Committees, Financial or Policy Working Groups would still apply for HII, since memberships, nominations, roles and responsibilities, decision-making and operating procedures would all need to be regulated by appropriate, rational and transparent written criteria.

It is recognized that this alone would represent a time and resource-demanding project on its own, requiring strong political commitment and support. It is therefore highly recommended that this work be initiated as soon as possible if Recommendation 9 is implemented. If not implemented, then the same work would still be required at MOH level for Committees and Working Groups connected to pharmaceutical policies and procurement.

In addition, while the framework offered by HII in terms of analysis and budget management should be greatly recognized as an important step forward towards a modern and effective way of managing pharmaceutical expenditure, it should also be noted that important activities appear to have just been planned but not fully executed, or performed in an incomplete, and thus potentially ineffective, way.

Specifically, only “External Reference Pricing” is currently applied and this even in a very limited and irrational way, as Suppliers are reportedly required to only “not exceed” prices of the same product marketed in Italy, Macedonia and Greece. The selection of these

countries as being in the same Region is not considered appropriate. Essential medicines are marketed in all continents by the same limited number of international and/or global suppliers who operate in a global market. Therefore, Albania should be strongly encouraged to benchmark against what is available on the global market.

Furthermore, at the moment, subsidies are the same for the same products and within the list of available suppliers prices may vary significantly between the cheapest and the most expensive option (see for example Omeprazole 20mg, which lists a generic supplier as the most expensive option, around 5 times the price of the branded option!⁵). Another example could be Amlodipine 5mg, which is listed at a price more than 20% higher than the 10mg option without any real clinical or technical justification. Similarly, it is difficult to accept that within the options listed under Amlodipine 10mg, the most expensive is 26 times (!) the price of the cheapest.

Beside dealing with these differences (not justified by the technical specification of products that are essentially the same), the introduction of Therapeutic Groups would allow the implementation of “Internal Reference Pricing”, which is based on the therapeutic comparison between different products (active ingredients) having the same or similar therapeutic effect and therefore deserving to be subsidized at the same level.

This approach too is not yet implemented by HII, thus forgoing 1) the possibility to act as a responsible “purchaser” of health gains rather than just a passive “payer” of products; 2) to provide financial and commercial incentives to suppliers to compete against each other; and 3) to achieve significant savings that could be used to fund either more expensive pharmaceuticals or additional health care, to the benefit of public health.

This approach would require the comparative assessments of pharmaceuticals, their added therapeutic value and their overall absolute health value (Health Technology Assessments - HTA) in order to recognize a fair level of subsidy, one that would be based on evidence of comparative effectiveness and relevant Economic Evaluation (cost-minimization, cost-utility, cost effectiveness analysis).

In this way, the system would achieve a high degree of transparency, of equity and of explicit rationing, providing at the same time the opportunity for open public discussions on funding priorities and allocation of limited health resources.

- **Contracting**

Under the HII model of funding, contracting would not be based on fixed volumes and will not be driven and/or constraint below the level of health need by the hospital budgeting process. As for primary care medicines, the system would allow reimbursement of inpatient pharmaceuticals mainly driven by health need.

While Public Hospitals would still be in control of their budget, with the possibility of improved Inventory Management they would be in a better position to manage expenditure. However, contracts between Hospitals and HII will have to provide incentives for Hospitals to generate savings that they could re-invest in other Services, provided that they could prove compliance with Treatment Protocols and responsiveness to Regional epidemiological needs. This could be a first step towards a form of performance-based funding.

As a consequence, accountability would also significantly improve under this approach.

⁵ See: List of Reimbursable Drugs (HII-2013), Alb.: LISTA E BARNAVE TË RIMBURSUARA (ISKSH – 2013)

5. CONCLUSIONS

As explained, Pharmaceutical Management works well and deliver the desired outcomes only if/when all its activities are well interconnected harmonized and coordinated. These activities work as a chain, where the overall strength is determined by its weakest link. Therefore, good outcomes can be expected only when all activities work at a reasonably good level and without any major weakness.

In order to guarantee a continuous supply of affordable, effective and good quality products to patients in the Albanian Hospitals is therefore necessary to intervene and correct all weaknesses identified in this analysis. The partial implementation of recommendations may not guarantee a proportional corresponding improvement in the overall functioning of the system.

6. TABLES

TABLE I: STOCK REPORTING TABLE

PHARMACEUTICAL PRODUCTS	OPENING STOCK	ESTIMATED ANNUAL QUANTITY NEEDED	ANNUAL QUANTITY PLANNED	QUANTITY RECEIVED	QUANTITY PRESCRIBED	QUANTITY DISPENDED	STOCK ON HAND