Pharmaceutical Management Needs Update Appraisal in Albania
Trip Report

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Printed: August 2006

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This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Recommended Citation

Witt, Hella. 2006. *Pharmaceutical Management Needs Update Appraisal in Albania.* Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

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ACRONYMS

AGREE	Appraisal of Guideline for Research and Evaluation
CPG	Clinical Practice Guidelines
DoC	Drug of Choice
HII	Health Insurance Institute
MoH	Ministry of Health
NCDC	National Centre of Drugs Control
NCQSAHI	National Centre of Quality, Safety and Accreditation of Health Institutions
PHC	Primary Health Care
RPM+	Rational Pharmaceutical Management Plus
WHO	World Health Organization

BACKGROUND

In 2001 Management Sciences for Health, Rational Pharmaceutical Management Plus (RPM Plus) Program made a reconnaissance/assessment visit to design a program of activities. The areas of work proposed included: (1) improving provision of drugs used in hospitals; (2) creating and implementing Standard Treatment Guidelines for general practitioners; and (3) improving the system of drug subsidies for ambulatory patients. After initial appraisal with USAID, RPM Plus decided to concentrate on improvement of drug use for general practitioners. An assessment of prescribing practices had shown that PHC providers did not have evidence-based information at hand to guide prescribing for patients attending PHC facilities. It was decided that a Drug of Choice (DoC) list should be developed to improve prescribing practice. The DoC list should complement Clinical Practice Guidelines (CPG) being developed with USAID funding by the PHR Plus program of Apt Associates Inc. for two districts in Albania.

A Drug of Choice list for a wide range of primary health care conditions was drafted. The pharmacological content of some drugs of the DoC list was incorporated into the Clinical Practice Guidelines, but the treatment recommendations for 60 other clinical indications of the DoC list remained a final draft. There was limited interest at the time [2001-2005] in drug procurement and treatment guidelines, and uncertainty whether the timing was right to continue until more progress had been made in primary health care and related health financing reforms. There was also confusion on how the DoC list would fit together with the DPG prepared by PHR Plus.

Purpose of Trip

The purpose of this visit in July 2006 was to investigate how MSH can use remaining funds to support efforts of the Ministry of Health to improve rational use of medicine or other interventions in pharmaceutical management. With emphasis on Primary Health Care, Ms. Witt wanted to familiarize herself with current policies and practices affecting medicine use for PHC conditions. The plan was to visit PHC facilities to observe pharmaceutical management and to meet with representatives from USAID, MOH, HII, the University of Tirana, and other relevant institutions to discuss possible interventions and collaboration. Although the initial focus was given to drug use in PHC, the USAID in Albania had requested to look broadly for pharmaceutical management needs. Possible interventions should be discussed with USAID and MOH, and activities agreed upon.

Scope of Work

- Discuss specific objectives and schedule of visits with USAID Albania
- Familiarize self with current policies affecting drug prescription in PHC
- Follow-up on guideline development for PHC conditions
- Meet with representatives of the Ministry of Health (including Pharmacy Department, Drug Control, Institute of Health Insurance), to discuss plans and achievements in promoting Rational Use of Drugs
- Visit health facilities to learn about pharmaceutical management at PHC facilities
- Discuss possibilities for collaboration with representatives of the University of Tirana and other relevant institutions
- Propose options for interventions to improve pharmaceutical management and agree with USAID and MOH on activities that should be supported with the limited funds remaining from USAID/Albania's commitment to RPM+
- Plan next steps

ACTIVITIES

1. Discuss specific objective and schedule of visits with USAID Albania

Ms. Witt met with Dr. Zhaneta Shatri, USAID Health Specialist, to identify areas in which RPM Plus could contribute to improving pharmaceutical management and the use of drugs. Zhaneta emphasized that the activities should be limited in scope so that they can be completed with available funds of about USD 120,000. It is not necessary to continue with previous RPM Plus activities, but rather assess the needs identified by stakeholders of the new government. Dr. Shatri facilitated contacts with key MOH and HHI stakeholders, and Ms. Witt added other meetings with stakeholders of pharmaceutical management. The University was not thought to be of prime importance at this time though it might be useful at a later stage.

2. Familiarize self with current policies effecting medicine prescribing in PHC

An inquiry at the Pharmacy Department of the MOH revealed that a drug policy, per se, has not been developed for Albania. The former Health Policy Unit at the MOH has been dissolved. In the new organizational structure a General Department for Policy and Planning has been established comprised of three sub-departments. Some officers at the MOH, however, did not perceive this new structure as a policy developing body at present. Drug management is guided by the Drug Law rather than by a policy or set of regulations. The head of the Pharmaceutical Department of the MOH said that HII defines the criteria for drug distribution. The WHO country office considered the Health Strategic Plan a substitute for a health policy, but the pharmaceutical part in the strategic plan is small.

3. Follow-up on guideline development for PHC conditions

Ms. Witt met with Leonard Deda who worked with MSH in 2001-2002 in producing a "Drug of Choice List" manuscript. He said that the pharmacological part of some drug treatment recommendations was incorporated in the Clinical Practice Guidelines, but that the draft DOC list included treatment guidelines for 60 other clinical conditions which were not finalized due to problems with piloting. The treatment guidelines would need to be revised if the DoC list was to be used.

The 23 Clinical Practice Guidelines for PHC conditions developed by PHR Plus, Abt Associates were implemented at pilot sites. They are used in the training of family doctors, but are not yet endorsed by the Health Insurance Institute (HII) as a guide for drug prescribing in PHC. A summary of discussion with Dr. Marcel Reyners, URC, on the introduction of CPG is included in the Annex.[1]

[1] USAID/Albania's health sector activities (Strategic Objective 3, *"Improved Selected Primary Health Care Services in Targeted Sites")* are focused almost entirely within a contract with University Research Co., "Improving Primary Health Care in Albania" and a supportive Task Order with John Snow, Inc., "Albania Family Planning Project". The mission wants RPM Plus activity in Albania to closely converge with the on-going strategy.

4. Meet with representatives of the Ministry of Health (including Pharmacy Department, Drug Control, Institute of Health Insurance), to discuss plans and achievements in promoting Rational Use of Drugs.

Meetings were conducted with the Deputy Minister of Health, the Head of the Pharmaceutical Department, the Head of the Department for Quality of Services, the Health Insurance Institute, the Centre for Drug Control, World Bank, WHO, URC, and the Head of the Pharmacology Department, and the University Centre Tirana.

5. Visit health facilities and get familiarized with pharmaceutical management at PHC facilities

Polyclinic No. 8 in Tirana was visited. Record keeping and information management, challenges with prescribing were discussed with the Head of the facility and the HII Director of PHC services. Hospital pharmaceutical management was investigated at the Maternity Hospital in Tirana and Lezhne Hospital. The visit at Lezhne Hospital was recommended by the Deputy Minister as one of the better functioning hospitals.

6. Discuss possibilities for collaboration with representatives of the University of Tirana and other relevant institutions

At a meeting with Prof. Gizim Bocari, chief pharmacologist of Tirana University, the possibility of involving the pharmacological department in the development or review of treatment guidelines was discussed.

7. Propose options for interventions in pharmaceutical management and agree with USAID and MOH on activities that shall be supported

On July 22, 2006, a mid-term debriefing was held with Zhaneta Shatri and Gary Merritt, USAID. At that time most investigations had concentrated in the area of rational drug use, the initial focus of the investigations. Dr. Shatri suggested to also look into an in-depth assessment of hospital procurement and options analysis, so that interventions can be picked up by another agency.

After the meeting Ms. Witt visited two hospitals to discuss hospital pharmaceutical procurement and hospital pharmaceutical management. Nobody was available at Fupharma during the visit. A final briefing was held with Gary Merritt before departure. The proposed options for intervention are laid out under Recommendations below.

FINDINGS

In Albania, physicians operate in public hospitals, polyclinics, and health centers, while the pharmaceutical sector is mostly privatized. Primary health care is provided at health centers and polyclinics; hospitals provide secondary care. Drug management for primary and secondary care differs in all management aspects (procurement, storage, distribution, use, financing mechanism and management).

Drug management in PHC

Medicines for PHC are managed by private pharmacies that procure them from private wholesalers. They serve prescriptions, but prescription-only drugs also are easily obtainable over-the-counter. Patients treated at polyclinics and health centers in need of medicine receive a prescription and collect the medicine from a private pharmacy. When the patient is covered by the National Health Insurance Institute (HII), the pharmacy will be partially or fully reimbursed for the price of the medicine. The patient pays the remainder out of pocket. The HII covers:

- 100 % reimbursement for children 0-12 months, the fully invalid, veterans, orphans, pensioners, the blind, TB patients, and cancer patients;
- Partial reimbursement for employees, the voluntarily insured, partial invalids, social welfare clients, children > 1year, students, pregnant women, maternity cases, and active-duty soldiers. Reimbursable drugs are categorized into therapeutic classes, for which reimbursement levels of 50 – 80% are defined;
- No reimbursement for other patients and for drugs not reimbursed by HHI.

For most patients the percentage reimbursed is calculated on the index price--the lowest retail price of a generic drug. War veterans and the fully invalid veterans can be prescribed any brand without co-payment.

HII also pays the salaries of PHC physicians, but not of nurses or other personnel working in health centers and polyclinics. A drug budget is determined for each PHC doctor in order to contain spending. The budget is individualized and differs according to former spending and the number of war veterans and invalids. A list of reimbursable medicines is made available to the PHC physicians by the HII.

A drug formulary is the other guidance used by the physicians. The drug formulary is outdated and the HII has asked a specialist of the Teresa Hospital to comment on the current form. HII uses this list to restrict prescribing. The diagnosis for which the drug is prescribed should be listed in the compendium. Most General Practitioners do not have treatment guidelines available that could guide them in diagnosis and treatment of patients. In 2005 the PRO Shëndetit project trained physicians in Berat in Clinical Practice Guidelines, and is currently training physicians in Lezhe, Shkodra, Korca and Diber.

Some drugs on the reimbursable list of drugs can only be prescribed under certain conditions or need to be approved by a specialist. The system requires the PHC physician to request a specialist's advice. The PHC physician fills a referral form in which he or she can recommend a certain drug to the specialist. The specialist may, however, prescribe another drug or a specific brand. This often causes conflict when expensive brands or drugs are prescribed. Patients get confused when they receive another brand than that prescribed by the specialist. It also happens that patients visit the specialist first and want to have the prescription endorsed by the PHC physician. Direct-to-consumer advertisement by the pharmaceutical industry also generates demand and places pressure on physicians.

The list of reimbursable drugs is updated every year by a committee set up by Order of the Minister. Before the last elections, about 70 drugs were newly included on the list, many of which were very expensive. The committee also decided that drugs for pensioners should be 100% reimbursable. These measures resulted in an increase in spending on drugs, and the HII ran up a USD 10 Million deficit in 2005. The deficit was finally covered by the Government, and HII has introduced a number of measures to restrict the use of drugs, e.g. certain drugs on the list of reimbursable drugs can only be prescribed under specified conditions. HII carries out controls at pharmacies and patients to counter the abuse of the reimbursement system by false prescription that are not dispensed. Although the crisis in drug financing has been overcome for now, worries remain on how to contain drug costs.

Drug management for secondary care

Hospitals and specialized polyclinics provide secondary care for patients. Health personnel at hospitals and pharmaceuticals are paid by the MOH. Procurement for hospital pharmaceutical supplies is centralized. The different hospital departments prepare their requests for one year and hospital management decides on a comprehensive list of requirements for one year, which is sent to the Department for Hospital Services at the MOH. The MOH department receives requests from all hospitals and engages in negotiations with the hospitals on drugs and quantities to be procured. Hospitals, however, feel that they have little say in final procurement. Supplies do not meet their needs; one hospital suggested that only 60% of requirements are supplied.

Every year a drug procurement committee is set up by order of the Minister to manage hospital procurement of pharmaceuticals. Fupharma, a shareholding company with 70% of shares held privately and 30% by the state,is contracted for storage and distribution. Fupharma distributes the full annual quantity of a drug in one single shipment which causes storage problems at some facilities.

Hospital ward supplies are ordered and supplied daily. Pharmacists do not serve individual patients or check their treatment cards. The pharmacist may, however, participate in regular control visits where documentation of patient treatment is verified.

Drug procurement was stated by many sources as a major problem. Unavailability of drugs at hospital pharmacies results in high out-of-pocket payments at private pharmacies.

The World Bank has proposed a Health System Modernization Project[2] which includes a component of Hospital Governance and Management (base cost US$ 1.1 million). The proposal includes the development of the regulatory framework to support the move of MOH hospitals to the status of autonomous public health entities. A pharmaceutical management component is not indicated in this component.

Drug regulation

The National Centre of Drug Control (NCDC) was established in 1965 as a laboratory for drug control. The Centre is organized in six sectors: registration, inspection, laboratory, information, jurisdiction and administration, and financing. Main areas of work are drug registration, inspection, and drug analysis. The NCDC is not financially independent, and the Director did not know what legal status the NCDC would have in future.

In cases when the MOH wants to import a drug that is not registered, the Department of Pharmaceuticals at the MOH will register them. These registrations are meant to be valid for a limited period of time after which the drug should be formally registered or withdrawn from the market. The MOH is issuing import licenses for drugs and negotiates drug prices with the manufacturers.

The drug law was first developed in 1994. The current status of the drug law did not become clear from the interviews. The Director of the Centre of Drug Control referred to a new law from January 2005[3]. The chief of the pharmacological chair, University of Tirana, indicated that there is a need to review the drug law, but the Minister didn't consider this a priority. The Deputy Minister indicated that there are issues with the drug law and drug registration.

Most of those interviewed expressed a keen interest in bringing the Drug Law into conformity with European standards, but this would require further investigation of the status of the current law to identify areas that are insufficiently addressed.

Promoting rational drug use

In the current situation Ms. Witt found no functioning structures to promote reforms favoring more rational pharmaceutical management and drug use. Drug and Therapeutic Committees are not functioning. The Clinical Practice Guidelines (CPG) appears to be in use only by the Pro Shëndetit Project for the training of general practitioners. The CPG was produced by the Department of Family Medicine with USAID's earlier PHR Plus Program. Although different sources indicate a need for evidence-based treatment guidelines, the CPG are not yet endorsed on a national level.

Interest in improving health care services at the national level can be seen in the establishment of the National Center of Quality, Safety, and Accreditation of the Health Institutions (NCQSAHI). Established in September 2005 as a center with technical and professional

[2] Document of the World Bank. Report No: 33415-AL. Project Appraisal Document on a Proposed Credit of US$ 25 Million Equivalent to the Republic of Albania for a Health System Modernization Project, October 31, 2005
[3] Uncertainty remains which law the director referred to.

autonomy in its decision making process, the NCQSAHI is to support the MOH in the implementation of the long-term national health strategy. The NCQSAHI has four divisions, one of which is concerned with Health Information, Technology Assessment, Evidence-Based Medicine, and Practical Clinical Guidelines. The Director of the Center would like support in the establishment of an evidence-based system for health care guidelines, not limited to drug prescribing.

The biggest component of the World Bank proposal for a Health System Modernization Project is on Improving PHC Service Delivery (base cost US$ 9.6 million). One of the subcomponents targets the development and introduction of clinical guidelines for most common diseases. The Project envisages foreign consultants to assist in the preparation of guidelines for the diseases lacking protocols.

The Health Insurance Institute is interested in treatment guidelines for primary care which can be used to monitor prescribing in PHC. The Director of HHI considers it important to have the Pharmacology Department of the Medical School and specialists from the Mother Teresa University Hospital involved in development of the treatment guidelines as their expertise is most recognized in the country.

CONCLUSION

Interviews conducted showed that most problems in pharmaceutical management require a system approach and policy commitment. MSH assistance would be effective only insofar as the MOH is willing to take ownership. Three areas of interventions have been identified in which MSH could assist to improve pharmaceutical management. The potential outcome of a support in the respective areas is discussed below.

1. Improving drug prescribing in primary health care

Drug use and cost containment are key challenges for improving PHC services delivery. A need for improving patient treatment and rational prescribing is recognized by some key stakeholders (e.g., Dep. Minister, Director of NCQSAHI, and Director of HII). The Director of NCQSAHI proposes the establishment of an evidence-based system for drug prescribing and patient care. In the past USAID invested in this area through PHR+ for the development of the Clinical Practice Guidelines for PHC conditions. The guidelines were prepared in collaboration with the Department of Family Medicine and are currently used in the training of family physicians in USAID's IPHCA. They are, however, not yet accepted at the national level. The guidelines, and the process of preparing them, must be endorsed by the MOH, but there is currently no institution in place working to promote evidence-based prescribing guidance. Support in the development of an evidence-based system can improve patient care and rational use of medicine.

2. Improving drug availability at public hospitals

Hospital services are reported to suffer from significant supply disruptions for some items, whereas other items are overstocked. The current system doesn't allow hospitals to actively plan and manage their supplies. Often when the MOH tenders for hospital supplies, bids for expensive medicines are received while no offers are made for less costly drugs. Hospital pharmacists indicated that they must ration medicines which are in short supply. The General Secretary mentioned that a review of the hospital procurement system is planned. Improved hospital procurement could significantly improve availability of medicines at hospitals for all patients requiring emergency care.

3. Improving drug quality assurance

There is said to be no official drug policy and the Centre for Drug Control considers adaptation of (Western) European legal and regulatory standards to be a high priority. Besides supporting a larger, integrative political objective, adopting European standards almost surely would result in improved drug quality assurance.

Recommendations

As the preparation of treatment guidelines is a long process, and as USAID has already invested in the development of Clinical Practice Guidelines, Ms. Witt strongly recommends further USAID assistance to promote the adoption of existing pilot guidelines as part of national policy. This requires that the MOH, NCQSAHI, HII, and the Pharmacology Department of the School of Medicine reach agreement on the priority and the process. Collaboration with the PRO Shëndetit Project will be beneficial to the process as the project has an in-county presence and uses the guidelines in the training of family physicians.

The endorsement of treatment guidelines at the national level appears more likely if a committee for evidence-based medicine and guidelines is constituted, given a clear mandate, and made effective in the budgetary and financial disbursement (i.e., political) system. This may be a long process. The likelihood of success depends, from the beginning, on commitment and ownership by the MOH. Appraisal of existing guidelines, with special focus on the Clinical Practice Guidelines, could be the first activity on the agenda. Further testing and adaptations of the guidelines may be required to assure consistency with the list of reimbursable drugs and the drug formulary.

Depending on the readiness of key stakeholders to directly embark on the implementation of national treatment guidelines, a first step could also be the development of a drug information center. Training could be provided on drug information and development of evidence. Also, for treatment guidelines, the first objective should be the promotion of good patient care and prescribing. In a second step, the Health Insurance Institute could use the guidelines as a managerial instrument to promote and monitor prescribing by the HII.

MSH might support USAID's health sector strategy by assisting GoA to:

1.a. establish a drug information center to provide training and equipment, including computers, internet access, and reference materials.

and/or

1.b. establish a national guideline committee to promote rational prescribing, including training of committee members, and facilitation of work group meetings for the adaptation of Clinical Practice Guidelines

and/or

2. carry out an assessment of hospital procurement followed by an options analysis and presentations for building consensus. The General Secretary indicated that hospital drug procurement is going to be revised. MSH could support the process of drug selection and quantification, help explore options and promote decisions about procurement mechanisms, as well as storage and distribution services. The MOH and possibly other relevant authorities would guide the assistance to assure the relevance of findings for decision making. Steps would

include: designing the assessment tools and approach; data collection and analysis; and, facilitating workshops for appraisal and decision-making about options models.

and/or

3. help adapt Albanian drug law to European standards[4]. If the MOH and USAID chose to make this area priority, MSH would need to make available European drug regulations and facilitate a sustained process of reviewing them (perhaps especially concerning drug registration and import regulations) for which one or more external facilitator(s) may be required. It is likely that European Union health agencies present in Albania could be enlisted in this effort though this was not explored during this consultancy.

Adjustments to Planned Activities and/or Additional Activities

The emphasis of the exploratory visit was anticipated to be on the promotion of rational drug use. As support to hospital drug procurement was indicated as a potential area of work, hospital drug management was investigated at two public hospitals.

[4] A follow-up with the Centre of Drug Control is necessary to specifically define the scope of support needed and mode of collaboration as this is required for the development of an action plan.

NEXT STEPS

Immediate Follow-up Activities

MSH and USAID should agree on how to address the Deputy Minister and Director General of the MOH to select among the priority areas for MSH support. Depending on the agreed working area, MSH will contact respective partners directly to work out the strategy of collaboration.

(See Annex 3 for Action Plans and estimated budgets of the proposed activities.)

ANNEX 1. PERSONS MET AND FACILITIES VISITED

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ANNEX 2. DISCUSSION POINTS WITH PERSONS MET AND RECOMMENDATIONS FOR RPM PLUS INTERVENTIONS

Meeting with Isuf Kalo, Director of the National Centre of Quality, Safety and Accreditation of Health Institutions (NCQSAHI)

The National Centre of Quality, Safety and Accreditation of Health Institutions was introduced by the new government to improve quality of services. The Centre is responsible for quality standards and accreditation of hospitals but has very little staff. At the time of visit there was only one other officer employed at the NCQSAHI. The Centre's objectives are to support the MOH in the implementation of the long term national health strategy in the following fields:

- Continuous Improvement of the Albania Health System Quality
- Education and training of healthcare professionals and promotion of Quality Culture
- Systematic re-licensing of healthcare professionals in the public and private sector
- Design, dissemination, and monitoring of clinical guidelines for best practices for healthcare professionals
- Accreditation of the public and private Healthcare Institutions
- Strengthening patients' roles as key actors in the healthcare system
- Minimization of risks and errors in healthcare institutions to increase safety of patients and healthcare professionals
- Assessment and selection of the most cost-effective Health Technologies
- Identification, collection, and use of scientific evidence for best medical practices
- Establishment of sustainable links and technical coordination between the MOH and its partners, institutions, and national and international organizations in the above subject areas.

Prof. Kalo stressed three main problems in pharmaceutical management and general health services in Albania:

- inadequate policy and regulatory framework for procurement
- limited knowledge of health professionals
- poor standards of integrity (of health professionals)

A main problem is the influence of pharmaceutical companies who influence prescribing practice by providing financial incentives to physicians. Leading specialist often prescribe expensive drugs. Clinical practice guidelines are important, but they need to be evidence based. The process of developing guidelines needs to be up to date. Direct consumer advertising is also used

to create demand. Privatization has brought an influx of new drugs, which is good as such, but there is no control. He has helped found the medical foundation, Hippocrat, to promote the integrity of doctors. The foundation tries to promote good prescribing practice by awarding and making public doctors that are well performing.

Prof. Kalo thinks there is a need to make changes at the system level rather than carrying out small projects. The policy unit at the MOH was not functioning effectively.

Most prescriptions are made in Primary Health Care centres. Specialist make recommendations, but they cannot prescribe drugs to be reimbursed by the Health Insurance Institute. The HII receives 10% of the global budget of the health system. They pay salaries for physicians, but not for nurses, laboratory, premises, or maintenance. Prof. Kalo was critical of the Health Insurance Institute for monitoring only financial cost, but not clinical outcome. He wants them to monitor whether medical targets are reached. He asks for changes in treatment guidelines to be evaluated when costly drugs are used and suggests measuring outcome indicators for such interventions. When this is not possible the process should be monitored.

Prof Kalo mentioned a pilot for health financing in Berat, where the local administration is receiving all funds for PHC. He is not clear of the indicators monitored. The number of prescriptions has increased, but he wondered whether this is a good indicator of positive outcomes.

Drug use in the primary health care setting is challenged by the process of drug selection and prescribing. Three committees are defining drug selection in PHC:

- A committee responsible for drug registration
- A Committee responsible for drug pricing
- A committee deciding on the inclusion of drugs into the reimbursement list

The problem is that some people are members of all three committees. The new government has changed this, but poorly-informed, opinion-based drug selection prevails. There is no committee concerned with the use of drugs.

The influence of the pharmaceutical industry is also seen in the fact that some drugs are 80% more expensive than in neighboring countries (e.g., Slovenia, Macedonia).

DTC committees are not working at any level even if they should exist in theory.

The majority of prescriptions are in PHC (polyclinics and HC). Specialists working in these facilities can prescribe drugs, but their prescriptions need to be signed by a PHC doctor. PHC drugs are bought from private pharmacies and reimbursed by HII. It happens that physicians write prescriptions which are not supplied by the pharmacist but are reimbursed by the HII. Physicians and pharmacist share the ill-gotten gains. It is also possible for patients and pharmacists to make this deal. Transparency and accountability are lacking.

Prof. Kalo would like support for building up a system for evidence-based medicine including drug policy to guide drug use, outcomes, and costs. The AGREE collaboration (Appraisal of Guidelines for Research and Evaluation) could set the standard for a guideline development group. The challenge he sees is how to build and empower such a system, which might be something similar to NICE (National Institute of Clinical Excellence in the UK). He suggests that MSH could help in developing an evidence-based system in Albania.

Prof. Kalo recommended contacting the former Secretary General of the MOH, Ruki Kondaj, who is currently studying pharmaceutical policy in Albania.

Meeting with Nazmi Alibali , Head of the Pharmaceutical Department, MOH

The Director of the Pharmaceutical Department of the MOH, Nazmi Alibali, described his department: there are two units, one working with drug pricing, the other with inspections. The Pharmaceutical Department provides import licenses for drugs when they are not registered at the Centre of Drug Control. The drug pricing unit collects data on drug prices in the region. Drug prices negotiated with the drug companies are stable for one year.

A drug committee (of up to 20 people) at the MOH develops a list of reimbursable drugs. Different commissions work on a group of diseases and treatments. The committee includes scientific authorities as well as the Director of HII and two other specialists of the HII.

There is no specific Drug Policy in place. Policies are expressed only in the drug Law. The law allows procurement form the EU, Japan, Switzerland, Austria, USA and countries of south-east Europe, under the condition that a drug has been in use at least two years in the country of origin. The Health Insurance Institute develops policies for drug reimbursement. Pharmacies are reimbursed monthly. Last year the GoA had to reimburse HII for USD 15 million (other sources said 10 million) caused by overspending. Some drugs are generic. For patented drugs they look for alternatives.

Hospital supplies are distributed by Fupharma, which is 35% state owned; the rest are private shareholders.

Nazmi Alibali said that material support is needed more than technical support. He identified the following areas requiring support:

- Laboratory equipment – many drug analysis are not done
- Capacity building at central level – e.g. a study tour to learn how things are organized in developed countries
- Treatment for rare diseases or for patients that need expensive treatment; e.g. by establishing collaboration with organizations such as Red Cross International

Meeting with Ms Elavana Hana, Director of the Health Insurance Institute (HII)

The HII has 90 employees at the center. There are 12 regional offices and 4 agencies in charge of controlling family doctors in polyclinics and health centers.

In the past HII management was without a policy and lead to a 10 million debts. The reason for this was that 72 drugs were put on the reimbursement list of 2005 which had a huge financial impact. Also pensioners received 100% coverage of drug expenses up from 80-90% in 2003. As the HII has to fulfill their contracts with third parties (private pharmacies) the Ministry of Finance stepped in to avoid insolvency. The Ministry of Finance also increased HII budget about 10%. This is not sufficient to cover drug cost according to HII Director Elvana Hana. The HII has introduced a patient fee of 100 Lek (about 1 USD) for each prescription. This co-payment generates about USD 200000 per year, covering approximately 5% of drug costs. Physicians were unhappy about this measure as patients now formally pay the money which they previously used to tip the physicians for their services. The HII also changed the prescription forms. Since 2006 prescriptions are written in two copies, one of which is sent to the regional HII office. This allows the HII easier follow up on patients (if they have received the drug) and to check if the medication correlates with the diagnosis. A drug compendium is used to check whether the indication is listed under the indications of the drug. Internal audits were implemented. 15 persons of the HII have to control 800 pharmacies, 2000 doctors and 800000 patients treated, and two pilot projects.

The HII takes the responsibility to monitor finances and expects the MOH to monitor the quality of services.

In the HII pilot project in Berat, where the HII is the only source of payment for PHC services is most advanced. Two other similar pilots were HII paid the salaries of specialist started in Tirana in 1998 or 1999 but was not that successful. Single source payment shall now be piloted in Durres and Berat. In Durres the pilot project has lead to improved infrastructure and an increase of physicians' salaries, but did not lead to better services. There were not enough quality data of the outcome.

One problem of the pharmaceutical system is that hospitals don't have drugs.
Patients don't have an ID card. The implementation of patient IDs will be addressed by the World Bank.

The HII has currently no means to control prescribing electronically. Prescriptions include drug codes and the diagnosis but these are not transferred into the electronic system.

Drug cost containment is a big challenge to the HII. A committee of 21 persons decides on the inclusion of new drugs into the list of reimbursable drugs. Many committee members are specialists from the University Hospital in Tirana, only three members are from the HII, so they are easily outvoted.

In 2005 the previous government had increased profit margins of wholesalers and pharmacies to 18% and 33% respectively. These margins were set back to the old level now, which are still very high (12% wholesale margin, 29% pharmacy margin, calculated on the CIF price).

About 50% of drugs prescribed are patented.The MOH is trying to negotiate drug prices with the manufactures, but this is difficult particularly for patented drugs.

Some 1900 medical preparations are reimbursable, of which 19 are not registered at the Centre of Drug Control. The MOH also licenses some drugs, which should thereafter be registered officially or be excluded from reimbursement.

The HII has managed to reduce false prescribing by improving control. (Patients are visited and asked, if they have received the prescribed medicines.) In the process some doctors and pharmacists have been excluded from the reimbursement scheme.

Ms. Elvana Hana suggested the following areas to improve pharmaceutical management:

- Provide training to the reimbursement department, the pharmaceutical department of the MOH, directors of medical departments and specialists. Drug economic understand lacking and should be addressed to these groups
- Develop treatment protocols
- Develop mechanisms to limit drug selection for reimbursement

Ms. Witt discussed the use of treatment guidelines for guiding PHC prescribing in a second meeting with the Director of the HII. Ms. Hana considers it important that the University pharmacological department and leading specialists are involved in the development of treatment guidelines. The influence of the pharmaceutical industry is strong and it has been difficult to engage individual specialists in the development of evidence based guidelines. The HII is hoping to develop guidelines for PHC conditions in the future.

Meeting with Zamira Sinoimeri, Deputy Minister

The Deputy Minister, Zamira Sinoimeri, explained that Albania wants to follow EU standards in drug regulation. They have to be cautious with the quality of drugs. The drug law needs to be reviewed as well as procedures for drug registration.

A body for policy decisions needs to be established between the MOH and HII.

There are 51 hospitals in 36 districts. Hospital supply is a big concern. When central tendering for hospital supplies are done, bids for the high priced medicines are received, but cheaper drugs may not be procured. Contracts with winners of previous tenders were extended.

The pilot project in Durres, where single source financing was tried, was not convincing.

The Deputy Minister was concerned about the number of private pharmacies. Pharmacy licensing requirements ask for 100 m distance between pharmacies, but pharmacies have found a way to get licensed even when they fell short of that target distance.

Prescribing is guided by pharmaceutical protocols first developed in 1996. PHR+ developed guidelines for PHC conditions, which is now being followed up by Pro Shëndetit.

Asked about the Policy Unit of the MOH (which could not be found) the Deputy Minister explained that the Policy Unit was established in 2000. Five people were hired, but the work was not well integrated. Assistance in policy development is needed from the World Bank.
The Dep. Minister explained the new organizational structure of the MOH. The Minister of Health and two Deputy Ministers are overseeing three general departments with their sub-departments, which includes a Department of Policy and Planning:

1. Department of Supportive Services
    a. Human Resources
    b. Legal Affairs
    c. M&E

2. Department of Policy and Planning
    a. Hospital Services
    b. PHC
    c. Pharmaceutical Department

3. Department of Economics
    a. Budgeting Department
    b. Investment
    c. Procurement

In addition there is the new Centre of Quality of Services at the MOH.

The Institute of Public Health is the technical branch of the MOH. It is an implementing agency working, e.g., in environmental control and immunization. The Institute also has a department of Policy Development, but it is not functioning.

Local governments are not much involved in pharmaceutical management, but buy some emergency drugs and supplies like alcohol and bandages.

The MOH is reviewing the basic law on health. They will include a National Commission on Health.

The World Bank is working in health system development and primary health care. Little is done about hospital drug management. Some hospitals had previously received support from Pharmacists Without Borders (PSF), but the project has ended. She recommended visiting one of the better organized hospitals (Berat, Durres, Mother Teresa University Hospital, Lezhne).

Meeting with Vladimir Margjeka, Director of the National Centre of Drugs Control (NCDC)

The Director of NCDC has worked four years for the HII. He is a member of the procurement committee for hospital procurement, working also on drug reimbursement and tendering. Members of the Department of Planning (MOH) are involved in the procurement of drugs. He thinks too many human resources are involved, drugs are lacking in the hospitals.

A pharmaceutical policy is missing but there is a need for such policy. Albania has had a free market since 1990. In 1994 pharmacy services were privatized. They had some support in legislation. Drug pricing is a big issue. He thinks that the schemes used are correct. When things go wrong, it doesn't mean that the schemes are wrong.

The Centre was established in 1965 as a laboratory for drug control. They were involved in regional planning to supply facilities with medicines. Regional laboratories existed and the inspection role was not big.

In 1994 the drug law was developed. The Centre for Drug Control became responsible for the registration of drugs, inspection, laboratory analysis, and microbial analysis. In 2005 work on a New Drug Law started (?). The NCDC should have a special status, but this is not implemented. The NCDC should self administer their funds, but until now it is MOH budget, and registration fees. Changes in the licensing and inspection process is envisaged.

The NCDC has the following sectors:
Registration, inspection, laboratory, information, jurisdiction and administration, financing
For registration dossiers will be evaluated within six months. After six months the application goes to the Nomenclature Commission, which investigates the clinical evidence. A proposal for registration is given to the Minister who signs. The members of the Nomenclature Commission are assigned by the Minister, the meetings take place at the NCDC. Five specialists of the University are part of the committee. Regulations for the registration of drugs are from May 2005. There are regulations for specific procedures, non-reimbursable drugs.

3200 drugs are registered and 6-700 are reimbursable.

Inspectors check import license of registered drugs. Import licenses are given by the MOH, this was formerly a responsibility of the NCDC.

The NCDC approves the conditions of wholesalers and pharmacies. The NCDC center and six inspectors in the regions inspect 1000 pharmacies in the country. They want to strengthen the inspection sector.

There is no post-marketing surveillance in Albania, which the Director of the NCDC considers a gap. The objective for this year is to set up a centre for surveillance and develop a surveillance system.

Overall, the Director thinks that the schemes used are good, but the will is missing.

[It was difficult to understand the structure and developments in drug control from the comments, and the issues may not be presented fully correctly here.]

Meeting with Lorena Kostallari, Country Operations Officer, World Bank

The World Bank is starting its third project in Albania. The first project completed in 2001 concentrated on improving infrastructures and equipment of hospitals, health centers, and health posts in two regions. The second project (ended in January 2005) was designed to support the pilot testing of a new organizational set-up in Tirana region and physical upgrading of facilities in the capital region. The new (third) proposed project will further shift emphasis from reconstruction towards support for structural reforms. The emphasis is on PHC, health financing, governance issues and hospital management. The World Bank activities will work together with URC in training.

Pharmaceutical management is not addressed, but technical assistance to the HII is included. The WB will train HII staff, develop a personal card for health insurance, and provide some support for the development of a Management Information System. The WB provides some ongoing technical assistance for HII policy development.

Meeting with Dévora Kestel, Head of WHO Country Office

WHO in Albania doesn't work on a specific contract, but helps the MOH prioritizing areas for donor cooperation. WHO worked with the WB on a pharmaceutical assessment of which she provided a copy. As there is no drug policy, the strategic long-term plan of the MOH serves as a policy. An action plan has to be developed from the strategic plan. Planning in pharmaceutical management is very little addressed in the strategic plan, and she suggested that MSH could support that area.

Meeting with Marcel Reyners, Service Delivery Technical Officer of PRO Shëndetit

The University Research Co. (UCR) is implementing the Pro Shëndetit Project, aiming at improving quality of services in PHC. This project supports training for the general physicians in the 5 focus prefectures (total approximately 550 - 600). The current World Bank grant hopefully will support this training in future in the seven other prefectures so that all of the 1500 physicians may be trained.

The training is part of a comprehensive framework for training to certify them as Family Doctors. The training aiming at upgrading knowledge and skills takes 28 sessions given on 14 weekends (Friday and Saturday). In their training they use Clinical Practice Guidelines, which have been prepared by the PHR Plus project. 28 guidelines have been introduced, 23 were initially prepared and 5 others developed at a later stage.

The Pro Shëndetit Project also supports clinical auditing in the focus prefectures, including medical drug use as prescribed by the guidelines in the handbook. The experience so far shows that it is very difficult to change drug use patterns. Clinical auditing looking for the compliance with the hypertension guidelines showed that multiple drugs are prescribed instead of recommended monotherapy, that the doctors/specialist prefer more expensive drugs, and that doses are not appropriate to effectively lower blood pressure to normal level. Mr Reyners suggest to make more use of wall charts to guide physicians prescribing.

The project is working with HII representatives to start clinical auditing of the clinical practice guidelines in the 5 prefectures.

Marcel Reyners recommends that practical training in rational drug use should be part of the undergraduate training of general practitioners.

Meeting with Leonard Deda

Dr. Deda was previously a member of the Nomenclature Commission and served as an in-country coordinator for MSH. A visit was arranged to discuss the development of the Drug of Choice list. Dr Deda informed Ms. Witt that the pharmacological part of some drugs of the DoC list was integrated in the Clinical Practice Guidelines prepared by PHR Plus. Guidelines for more than 60 additional conditions were prepared. He was supposed to do a field test, but this failed as physicians would not have the knowledge to judge the adequacy of the guidelines. At this stage he considers the guidelines outdated.

Dr. Deda explained the function of the Nomenclature Commission. The law on drugs requests the creation of the Nomenclature Commission as an advisory commission to the MOH. The Minister appoints the members, many of them pharmacologists or professors of medicine. The Nomenclature Commission makes recommendations for the registration of drugs, especially on new molecules, for the reimbursement list, for the OTC list, and procurement.

Meeting with Sokol Dedja, General Secretary, Ministry of Health

The General Secretary was visited to understand his view on pharmaceutical management needs and potential support by the MOH. The General Secretary mentioned the USD 10 million debt accumulated by HII between 2004 and 2005 and he sees a threat that this could happen again. The HII and MOH tried to develop a new list of drugs, but they await data from the HII for the first months of 2006.

For hospital procurement the Department of Hospital services goes through the requested list of drugs and their quantities received form the hospitals. The information is shared with the Mother Teresa Hospital in Tirana. The procurement commission reviews the list and sends it back to the Department of Hospital services, which makes the final decision. The procurement of pharmaceuticals is managed by the procurement committee and supported by the secretariat of the procurement sector of the MOH.

Hospital procurement mechanisms are going to be revised. The MOH continues with centralized drug procurement, but this may change in 2007, when hospitals might procure by themselves. A major decision on this issue will be made in 2007. Currently an ad hoc commission at the MOH is managing drug procurement for hospitals. Tenders are suffering lack of competition. When 100 drugs shall be procured, bids are only received for half of them. It is possible that drug selection will continue to be decided by the MOH in a decentralized procurement system. A major decision on hospital procurement is expected for 2007.

The General Secretary would like MSH to support the MOH Department of Pharmaceuticals to get better price information from the regions. He thinks that lower drug prices would benefit all patients even when they have to pay them out of pocket. Ms. Witt suggested that such activity would benefit from regional collaboration. WHO might be better positioned to start such a process through their country offices, while MSH doesn't have such a presence.

Treatment guideline development would fall under the responsibility of the General Department for Policy and Planning at the MOH. The position of the General Director of this department is not yet filled. Also the department of Public Health and the Department of Family Medicine should be involved.

The Secretary General didn't see any obstacles for MSH supporting the development of treatment guidelines, investigating hospital procurement.

Meeting with Prof. Gezim Bocari, Head of the Pharmacological Chair, Medical University of Tirana

Besides being the Head of the Pharmacological Chair, Prof. Bocari also chairs the Nomenclature Committee. In the discussion with Prof. Bocari he repeatedly raised concerns about prescribing practice and corruption. He knew that Clinical Practiced Guidelines have been prepared, but was critical that the Pharmacological Department hasn't been involved in their development. However, he sees a need to introduce treatment guidelines and his department would be able to adapt treatment guidelines from a credible source for Albania. The possibility of reviewing the existing Clinical Practice Guidelines for introduction at the national level was discussed. Prof. Bocari would prefer preparing treatment guidelines from scratch, but he might be convinced to work on the existing CPG as well.

Prof. Bocari indicated three pharmaceutical management areas that need to be addressed:

- Treatment guidelines for the most important diseases need to be implemented. They could be adapted from a credible source
- The drug law needs to be adapted according to European guidelines. Prof. Bocari said he had addressed the Minister concerning the development of a new drug law, but the Minister didn't see this a priority
- The development of a data base for all drug products in the country would help in drug control. All pharmaceutical products would need to be marked with a bar code so that their identity and legal status is manageable at all times. He has already suggested this intervention to the Minister, who didn't consider this his current priority.

Visit at a Polyclinic No 8 in Tirana

A visit to a polyclinic in Tirana served to get familiarized with the current prescribing system at PHC facilities. Ms. Witt met with the Dr. Neritan Kellici, Director of the facility, who also practices as a pediatric family doctor. Luftar Zebi, Director of PHC Service Department, HII accompanied the visit.

General practitioners are orientated on treating either children or adults. Salaries are low and depend on the area and the work (rural or urban, pediatric or adult). One family doctor generally serves a population of 800 to 1500 children or 2000 to 3000 adults. Use of PHC services is considered low, only 74 of 1000 registered inhabitants visit family doctors in his area.

The physician had two drug lists on his desk, the list of registered drugs and the list of reimbursable drugs.

Drugs on the list of reimbursables are listed with their generic names, followed by the list of branded preparations registered in Albania. The unit cost of the cheapest brand provides the index price. There are very big differences between unit costs of the different brands (e.g. 300% difference between the index price and the most expensive brand of ranitidine tablets). PHC physicians have to prescribe with the generic name. The insurance institute reimburses a certain percentage of the index price. If the patient requests another brand, he or she has to pay the difference (at the private pharmacy). Reimbursable drugs are categorized into therapeutic classes, for which reimbursement levels of 50 – 80% are defined.

The PHC physician uses three different classes of prescriptions:

- 100 % reimbursement for children 0-12 months, full invalids, veterans, orphans, pensioners, blinds, TB patients, cancer patients
- Partial reimbursement for employees, voluntary insured, partial invalids, social welfare, children > 1year, students, pregnant women, maternity, soldiers
- No reimbursement for other patients and for drugs not reimbursed by the Insurance Institute

For most patients the percentage reimbursed is calculated on the index price. War veterans and full invalids can be prescribed any brand without co-payment. This naturally causes high drug expenditure for this patient group, as confirmed by the HII specialist.

The HII sets a drug budget for individual PHC facilities. The drug budget is negotiated form last year's budget and the number of veterans and full invalids served at that facility. The drug budget of the family doctor visited was e.g. 226000 Lek for reimbursable drugs.

At the polyclinic work medical specialists of gynecology, surgery, and cardiology. The specialists cannot directly prescribe medicines for reimbursement through the HII. They were allowed doing so 2-3 years ago, but then did not want to sign a separate contract with the HII, due to the restrictions imposed with the contract. PHC doctors however have to refer to a

specialist when they want to prescribe certain restricted medicines or when they want to get specialists opinion. Specialist may not follow the recommendation of the PHC doctor and usually prescribe with brand names. It is then difficult to convince the patient afterwards that another brand presents the same drug. It also happens that patients visit directly a specialist and then asks the PHC physician to sign it.

The HII is currently working on a new contract with the specialists.

HII has recently improved the system for information management. The facility keeps a register of patient visits, in which the doctor writes the patient name and code, the diagnosis and the drugs prescribed. The polyclinic keeps patient files, and the family doctor also has a patient file with the medical history of each patient he serves. Patients do have a patient card xxx. Prescriptions are made in double, which one copy send to the regional HII office and the other going to the pharmacy. The physician writes the diagnosis as well as the diagnostic code on the prescription. The codes follow the ATC system.

Each medical preparation has a distinct code. This is written by the pharmacist on the prescription, when reimbursable drugs are dispensed.

The physician does not have any treatment guideline, and said he would really need one. He uses a vademecum developed in the late 90ties, which lists drugs, their indication, side effect, contra-indications. There is no guideline starting with a medical assessment or a diagnosis. When mentioning the CPG prepared by the faculty of Medicine and Faculty of Family Doctors, the HII Director for PHC services said, he has seen them recently and liked them a lot.

Visit at the Maternity Hospital Tirana

Two pharmacists at the Maternity Hospital manage drug supplies for the hospital. They have 163 items is stock, many of them medical supplies.
Every day the Head nurse of each department comes to the pharmacy with a list of drugs and supplies required for the inpatients. Patients don't get supplies to take home when they are discharged. The drug request form of the wards comes in two copies, the original is sent to the economic department of the hospital, the copy stays at the pharmacy. The pharmacist serves the prescription, when there are no shortages and these are no luxury items. If the department asks e.g. for an additional antibiotic, they may inquire if this is indeed needed.

The pharmacists do control the wards, but this doesn't happen very often. The pharmacist is usually content with the signature of the department chef.

The MOH tenders ones a year for hospital supplies. Each hospital has a budget for drug procurement. The facility receives the list of registered drugs and the different department chefs indicate the amount of drugs they need. The pharmacist adds requested quantities up and subtracts quantities still in stock. She may adjust quantities with respect to former monthly usage and calculates drug costs with a reference price. This list is first going to hospital administration,

where some adjustments may be made, when the budget is too high. The list is then sent to the Department of Hospital Services at the MOH.

A procurement committee at the MOH carries out the procurement. The winning manufacturer signs a contract with the hospital. Supplies are received by Fupharma, which is responsible for storage and distribution of drugs. The Maternity Hospital receives all drugs in one go. The pharmacists indicated no problem with storage space. Thee are no shortages with drugs, if at all this may happen with medical supplies. When supplies are used up earlier, they request additional supplies from the MOH. The supplier who has won the bid for one drug provides the drug with the same price. In case this supplier cannot deliver, the hospital can make direct procurement with allocations from the MOH. The hospital can also purchase items for rare diseases directly, when the cost is lower than 100,000 Lek. The pharmacist could not tell how often this is done, but suggested this is rarely the case.

The pharmacist mentioned however, that the faculty did not prepared them for the administrative responsibilities they have, and they would like to improve their knowledge by learning from neighboring countries, how administration functions there, what are their roles and rights, how to communicate, what literature to use, etc.

The pharmacist stated that there is rarely a shortage of supplies.

Interviewing a physician of the same hospital the pictures presented differently.
Problems were seen in stock-outs particularly of medical supplies, which lead to interruptions in diagnostic procedures and a need to change treatment. When one antibiotic isn't available, they have to change the scheme. The standard of the items procured changes. Lack of continuity of supplies was a big problem to him. The physician did not trust the quality of some products. Storage conditions at the wholesaler and along the distribution lines are one concern. In his particular area of specialty, the physician also noted that there is a lack of pediatric formulations.

Every year the physician writes a list of drugs requested for procurement. For new items put into the request he fills a separate form. The Department of Hospital Services provides feedback to the revised list, but not to the drug list the physician has originally requested.

Visit at Lezhne Hospital

At the Lezhne Hospital Ms. Witt met with the Director, Dr Pashk Gjoni,the Economical Vice Director, Sokol Vat, and the Pharmacist, Mark Marku, to discuss hospital drug management procedures and challenges. Lexhne Hospital has about 200 beds. The hospital as well as the specialist polyclinic next door are categorized as secondary care facilities for which drugs are procured by the MOH. Also the salaries of the physicians are paid by the MOH. The hospital suppose to provide pharmaceuticals free of charge to patients who are admitted to the hospital or are treated at the emergency and pediatric wards. The system does not foresee providing the patient with any supplies for the immediate time after leaving the hospital.

Once a year the MOH procures hospital supplies using an open tender. At the hospital the different departments come up with a list and quantities of drugs required for the next year. The pharmacist is not involved in drug selection, but compiles requests and may change quantities suggested based on previous use. Drugs are listed by their generic name. The hospital submits the final list of requirements to the Department for Hospital Services at the MOH. An open tender is carried out at the MOH to procure supplies for the next year.

Hospital pharmaceuticals procured by the MOH are stored and distribute by Fupharma. Fupharma is a shareholding company with 70% of shares hold by private shareholders and 30% by the state. Fupharma supplies only public hospitals. They stamp drugs as "for hospital use only", and do some quality control like checking for expiry and correctness of labels.

Drugs suppose to come 60 days after contracts are made with the winning bidder. But the whole process takes long and the hospital cannot plan for arrival of the drugs. The last request was made in December 2005 and supplies have not yet arrived (July 2006).

Asked about a drug budget, the health advisor said that they supposed to have a budget of 3500 Lek per patient for drugs and medical equipment, but these unit prices are not received. For 2006 the got about 60% of what was suggested by the hospital, averaging to about 2000 Lek per patient. After hospital request is submitted to the MOH there are sometimes negotiations, but they seem not to influence the outcome of the drugs purchased for the hospital.

Running out of supplies the hospital has recently procured some additional supplies. The hospital can procure pharmaceuticals from the same suppliers who won the bid in the previous year, but they found that 80% of the manufacturers don't respond to their request. In this case direct procurement is possible, but no more than 300000 Lek can be spent on drugs of the same therapeutic group. The hospital has to procure from Fupharma, but drugs are very expensive when bought directly (10 time more expensive was suggested). As an example, infusions bought that way, would only last for 13 days. The facility does not have an emergency budget for drugs.

The hospital manages a reference system so that doctors know what is in stock. As supplies are insufficient, patients have to buy medicines out of pocket. This is so common that records include a column for medicines purchased by the patient.

The different hospital wards keep some stock for emergency supplies. In addition the request medicines for individual patients treated in their department. Supplies to the wards are given out daily. The head nurse comes with a ward request for the patients treated in the ward. The ward request form is prepared in three copies, one of which is kept at the pharmacy, the other with the financing department of the health facility. The pharmacist enters the drugs issued into a daily drug register, which is added up at the end of the day. Daily quantities are entered into a monthly register and monthly consumption is again entered into a multiyear consumption register. About 215 different items are recorded at the pharmacy. Their records are ordered by the drug form. As supplies don't match requirements, the pharmacist is rationalizing some drugs so that they will last longer. Patients will not get the full amount of a medicine prescribed and it is hoped that the burden of out of pocket payment can carried equally among the patients. The pharmacist claims to know from experience how long supplies will last and which quantities to give to the

wards. Requirements change about 5-10 % from one year to the other. Pharmacy staff has no direct patient contact.

At the ward the medicine and treatment scheme for the patients are summarized in a "treatment book". Requirements are summarized and daily requirements requested from the pharmacy using a request form prepared in three copies. This request is signed by the chief of the respective department. The recording system appears to allow regular control of drug usage when the medication is administered as indicated.
Regular ward checks are done approximately once a month by the technical vice director and the economic section. The pharmacist sometime joins the team. In addition they check expiry of drugs kept at the wards.

No problems with drug quality have been noticed at the hospital.

The Medical Director identified only one big problem with pharmaceuticals at his facility, and this is the continuity of supplies. Pharmaceutical supplies don't meet their requirements and one cannot plan with it. The hospital makes annual requests for medicines, the last being made in December 2005. Until now (July 2006) only 10% of the pharmaceuticals have arrived.
The nurses were particularly concerned about people on welfare who are equally hit by the lack of medicines but cannot afford to pay for drugs out of pocket.

ANNEX 3. BUDGET ESTIMATES FOR PROPOSED ACTIVITIES

Plan of action and budget estimate for the assessment of hospital procurement options

Activity	Estimated cost
Study preparation • Identifying the scope of the assessment and potential options in collaboration with the MOH • Development of assessment tools • Reaching concurrence on assessment approach with MOH • Contract local consultant to carry out field assessment • Refinement of assessment tools according to inputs from MOH (One 1 week trip of external consultant required)	$36,000
Field assessment Data collection by local consultant at • up to 13 regional hospitals and specialty hospitals in Tirana • Fupharma • MOH departments involved in hospital procurement • 3 private wholesalers in Tirana Review of procurement records (national tenders) Report writing	$30,000
Data analysis and presentation • Evaluation of findings and option analysis • Workshop for option appraisal • Final report (One 1 week trip of external consultant required)	$29,000
Incidentals (Additional TA in the preparation or data collection phase may be required depending on capacity of local consultants)	$10,000
Total	**$105,000**

Plan of action and budget estimate for the establishment of a national guideline committee to promote rational prescribing, and facilitation of work group meetings for the adaptation of Clinical Practice Guidelines

Activity	Estimated cost
Establishment of a national committee for guideline appraisal • Reaching agreement among main partners on the need, scope, and regulatory requirements for the establishment of a treatment guidelines committee at the MOH • Design structures and the process of guideline development in collaboration with the National Center of Quality, Safety and Accreditation of Health Institutions • Conduct workshop with members from MOH, NCQSAHI, Health Insurance Institute, representatives of the Medical School and external consultants for appraisal of the recommended structure, and process of guideline development (One week trip for two external consultants required)	$48,000
Review of Clinical Practice Guidelines for national endorsement • Conducting training of committee members in guideline appraisal • (Endorsement of the guidelines committee and appointment of members by the Minister) • Ascertain consistency of drug recommendations in the CPG with the list of reimbursable drugs and the drug formulary • Technical review of drug treatment recommendations according to the agreed review process • (Endorsement of drug treatment recommendations by guidelines committee) (One 1 week trip for one external consultant required)	$32,000
Incidentals (If unforeseen obstacles prolong the appraisal process, additional TA may be required).	$10,000
Total Cost of Activities	**$90,000**

ANNEX 4. REFERENCES RECEIVED DURING VISIT

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