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**Essential Drugs Concept Paper
for USAID/Nicaragua**

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CONCEPT PAPER

USAID/Nicaragua
Essential Drugs Project

ESSENTIAL DRUGS CONCEPT PAPER

NICARAGUA

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**CONCEPT PAPER
USAID/Nicaragua Essential Drugs Project**

EXECUTIVE SUMMARY

The health care system in Nicaragua has experienced a decline in resource availability and service over the past few years. The new government finds itself in a period of transition, with the economic situation critically depressed. Eastern Bloc imports, donations, and favorable credit terms from suppliers have sustained the health care system in the past. Thus, the current decline in Eastern Bloc imports and donations together with an increasing commercial debt for pharmaceuticals and medical supplies (over \$17 million), has resulted in a significant reduction in the supply of pharmaceuticals. Alarming, even hospitals and health centers are experiencing shortages of basic medicines and medical supplies. Hospitals are also experiencing shortages of consumable medical supplies, laboratory equipment/supplies, and medical equipment. They are functioning at a marginally adequate level of service. The Nicaraguan Health Care System needs a 'jump-start' to be revived.

Politically, health care is viewed as a critical human need (along with food, clothing, and shelter). Pharmaceuticals and medical supplies serve as a symbol of health care to the population. Shortages of these essential treatment tools signify to the country's population a breakdown in the health care system. In addition to the political harm to the government, the absence of medicines results in prolonged treatment requirements, exacerbation of illnesses, and even unnecessary death. Health care workers become discouraged because they are not able to treat the patients that come to them. They lose the patient's confidence and their prestige in the community is diminished.

The ability to provide reliable access to quality pharmaceuticals is hampered by many factors. Foremost is the lack of financial resources. Although there are many collateral problems (eg. warehousing, distribution, cold chain, misprescribing, etc.) these problems are resolvable through traditional technical assistance and educational interventions. Because therapeutic mismanagement however contributes so significantly to the allocation of scarce pharmaceutical resources, the financial

constraints must not be addressed independent of the need to reinforce the infrastructure which supports the rational selection, distribution and use of pharmaceuticals in Nicaragua.

The logistics solutions are understood in-country. The solutions include identifying new supply sources (U.S. manufacturers and private sector local distributors); accurate determinations of quantities to be procured, efficient procurement planning, development of clear specifications and bid procedures; modern warehousing practices, efficient distribution systems, computerized and up-to-date inventory control processes; security of commodities (theft and loss reduction) procedures; hygienic dispensing practices; and of course reliable and consistent sources of funding.

The therapeutic solutions are less well understood in-country. These solutions include improving diagnostic processes, selecting drugs of choice for treatment, prescribing and dispensing of appropriate quantities, identifying drug induced illness, and educating patients in appropriate use.

Analyses of the situation of the pharmaceutical sector in Nicaragua revealed the need for:

- improving the availability of medicines at all levels of the health care system
- improving logistics systems
- improving regulatory processes involving the registration, licensing, and oversight of medicines available on the market in Nicaragua
- improving access to current medical/pharmaceutical information
- improving and extending the management information system
- human resources training and development

- developing strategies for self-financing of pharmaceuticals
- exploring the feasibility of increasing the participation of the private sector in production, distribution, and dispensing activities
- exploring the feasibility of using 'traditional' remedies

Logically, an important ingredient in achieving success in a pharmaceutical sector revitalization scheme, is hard currency availability for imports, local industry modernization, and raw materials for production. But the 'weak link' of pharmaceutical logistics must concomitantly be strengthened. Donations of pharmaceuticals by USAID with a corresponding fortification of internal capacity in the pharmaceutical sector, will achieve high visibility and have significant long-term social/political/financial impact.

An immediate and short-term infusion of pharmaceuticals and medical supplies will help fill the pipeline and alleviate the critically low availability of treatment tools. This infusion of pharmaceuticals and medical supplies needs to be well-identified as US-donated. In addition to the immediate impact of the donated commodities, USAID/N will improve the chances of lasting impact if technical assistance is provided to improve the logistics system. Health and economic evaluations, studies, human resources training, and technical assistance in the areas of logistics, therapeutics, and financing will also provide long term impact on the pharmaceutical system and minimize the possibility of dependence on donations.

The solutions proposed to address Nicaragua's pharmaceutical supply problems must be comprehensive due to the interrelationship of pharmaceuticals with all aspects of the health care system. Pharmaceuticals have the capacity to harm as well as to treat illness. Mismanagement of pharmaceuticals translates into additional costs within the health care system and contributes to loss of productivity.

Furthermore, lack of access to potable water, adequate sanitation, and hygienic habits, malnutrition, a high birth rate, and transmission of disease by insect vectors causes significant morbidity and mortality, thus leading to increased requirements for pharmaceuticals. Social and cultural factors also influence the way health care is

sought out and received. Deficient or outmoded technical and medical training can cause iatrogenic (physician-induced) morbidity and mortality.

Setting realistic expectations for the impact that a more accessible and rational pharmaceutical system can achieve, is a requisite for the success of any pharmaceutical policy reform initiative.

OVERVIEW OF THE PHARMACEUTICAL SECTOR IN NICARAGUA

The pharmaceutical and medical supply system is under the responsibility of the Direccion General de Abastecimiento Tecnico Material of the Ministerio de Salud. At this time, the supply system is in a transition phase. Previously, management of the pharmaceutical and medical supply budget was decentralized. Hospitals in Regions II and III had both the authority and responsibility for management of its institution's budget. Regional Directors were responsible for their own budgets. COFARMA, the state-owned pharmaceutical corporation procured all pharmaceutical products for the country (both public and private sectors) through imports and local suppliers. They sold pharmaceuticals to hospitals, health regions, popular pharmacies, and private pharmacies. With the new government, COFARMA has become the procurement and distribution arm of the Ministry of Health. MINSAs hospitals and health regions will no longer purchase their medicines and medical supplies from COFARMA or local suppliers. They will be sent, in theory, what they need from MINSAs/COFARMA. Private distributors will now procure from or represent manufacturers in Nicaragua and sell to the government or to private pharmacies.

Nicaragua is divided into six health regions and three special zones (zonas especiales). There are close to thirty hospitals, three polyclinics, 21 health centers with beds, 87 health centers without beds, 468 health posts and 28 'farmacias populares'. Each of these entities dispense pharmaceuticals. The 'farmacias populares' were intended to provide pharmaceuticals at low cost to the public. These pharmacies will become MINSAs pharmacies or will become private pharmacies. Approximately 380 private pharmacies are registered. There are MINSAs warehouses in each region and at the central level. Some are in extremely poor condition.

MINSAs has followed the WHO policy of essential drugs. It has been progressive in its creation of a Lista Basica (national essential drug list). Following ministerial

resolutions, in 1986, the creation and procedures for revision of the Lista Basica was defined. A drug formulary was published in 1988. The Lista Basica has not been revised since that time. In 1988, collateral basic lists were developed for each of the MINSA priority programs. The Lista Basica also classifies the medicines by level of use within the health system. The Lista Basica needs immediate review, updating, publication, and distribution.

Although Comites Farmacoterapeuticos were organized at the hospital level to promote the rational use of pharmaceuticals, very few are functioning. Where they have functioned, they have demonstrated an improvement in quality of care and savings of scarce economic resources. These Comites should be stimulated and supported to continue their mission.

There are 17 pharmaceutical manufacturers in Nicaragua. It has been estimated that these manufacturers are only producing at 30% of capacity. 99% of raw materials are imported. These manufacturers are reported to be able to produce 104 of the 320 products on the basic drug list. Unfortunately, their production planning and organization is suboptimal. Their technology is becoming obsolete. The personnel require training in 'Good Manufacturing Practices'. The product formulations and product lines need to be improved or modified. PAHO has developed courses directed to the private sector on 'Good Manufacturing Practices'. In the past, PAHO presented several seminars for the Nicaraguan manufacturers.

The sources of pharmaceutical supply are imports, local production, donations, and multilateral projects. Financing for imported products came from lines of credit, agreements with socialist countries, supplier credit, barter, and liquid foreign exchange. There is currently a commercial debt of \$17 million. The pharmaceutical and medical supply budget for 1991 is estimated to be \$21.6 million (approximately \$5/capita). This represents 26% of the overall health care budget. Close to \$10 million are earmarked for imports and \$12 million for local production.

Pharmaceutical prices are not currently being regulated. MINSA contemplates formulating a pharmaceutical pricing policy and regulations, in conjunction with the Ministry of Finance, Customs, and MINSA.

The private sector is an important provider of care, particularly ambulatory health care. In addition to private pharmacies, there are clinics, hospitals, and

laboratories. Approximately 90% of physicians maintain some type of private practice. Nicaragua has a system of overlapping care from the primary care system, private physicians, and public hospitals. Patients may go to a private laboratory to have a test done, take the results to a government hospital or health center, receive pharmaceuticals from the government, supportive care from a private clinic and surgery from a public hospital. (Health and Revolution).

The subsidized prices of drugs in 'farmacias populares' and the availability of drugs at no cost for certain special programs (such as tuberculosis, venereal disease, malaria, maternal-child health, aged, etc) stimulated many forms of black market activity. MINSA drugs were found on private pharmacy shelves and sold at the 'mercados'.

Antibiotics make up 60% of imported medicines. People have a tendency to take antibiotics for only a couple of days, rather than a full course of treatment and thus dangerous resistance is created. Especially, now with the high cost of medicines, and increasing shortages there is drug rationing. The number of prescriptions dispensed annually has been estimated to be nine million, with each prescription containing three to five products. As in many societies (including the U.S.), there is intense pressure on medical practitioners to over-prescribe. Most Nicaraguan physicians receive minimal training in pharmacology and are unprepared to make appropriate choices. The large volume of patients and poor diagnostic capacities result in overprescribing as the most expedient solution for the overworked clinician. (Health and Revolution).

'Traditional' remedies are used throughout the world to treat major and minor ailments. These remedies come from plants, roots, herbs, fruits, etc.. Nicaragua is rich in plant life and has an extensive vademecum of remedies that have been used for centuries. Recently, there has been a movement by WHO and naturalists to re-examine the value of 'traditional' remedies. Nicaragua would be an ideal country to systematically evaluate the risk/benefits of these 'traditional' remedies and identify those that provide a beneficial (and economical) alternative to modern pharmaceuticals. The promotion of those beneficial 'traditional' remedies would increase the capacity of the country to supply medical treatment to the population.

COFARMA, the state-owned pharmaceutical and medical supply corporation, has become the procurement and distribution arm of the Ministry of Health. It has extensive warehousing capability at the central level. A computerized inventory control system is being implemented. The distribution system needs to be reviewed. In the past, each region and hospital would have to arrange transportation to pick up their supplies from COFARMA. For procurement planning, each region furnishes a list of their annual requirements to COFARMA. COFARMA compiles all the lists and develops a national procurement plan. While COFARMA is aware of the stock levels in their central warehouses, products in transit, and donations, they are not aware of stock levels at the regional warehouse, hospital, health center, and health post level. This results in defective procurement estimates and plans.

As with many developing countries, it is difficult to determine actual consumption patterns, morbidity patterns, and unsatisfied demand. The diagnostic and consumption statistics are not carefully collected and tabulated. This leads to excesses or shortages of pharmaceutical supplies, with misutilization or losses due to deterioration or expiration.

The most recent attempt at a bid solicitation was thwarted due to a misunderstanding about where the funding would come from for the procurement. Bids have been analyzed by ATM/MINSA and consideration is being given to proceeding with the procurement using other funds. However, legal issues may arise. Precise specifications and favorable contract clauses were not included in the bid solicitation.

An alarming observation was made of the state of pharmacy practice in the MINSA system. Pharmaceuticals were stored in open containers, thus exposing them to high temperatures and humidity and contributing to rapid physical decomposition with loss of potency or creation of dangerous decomposition products. The transferring of products from the original bottle into these open storage containers destroys audit trails critical to responding to serious product recalls and monitoring for out-of-date medicines. It was observed in one MINSA pharmacy that four different capsules and four different tablets were in the same open container. (Hooper's Oct 1990 report).

In general, the dispensing of pharmaceuticals is suboptimal. There is a lack of bottles or prescription vials to dispense medications. The products are usually dispensed in a clear plastic bag or paper cone. No written instructions are provided on a label or the bag. Rarely, are instructions given verbally. Up-to-date pharmaceutical references are not widely available to pharmacy personnel.

Although prescriptions are required, the prescription form is not standardized and not maintained on file. The prescription is essential for creating an audit trail for pharmaceuticals dispensed. If the prescription form were standardized, the information could also be used for utilization review purposes.

The law regulating pharmacy practice is antiquated. A revision has been worked on and would be worth revisiting. Recently, MINSA waived the requirement for registration of pharmaceutical products. This may cause a proliferation of products of suboptimal safety or efficacy on the Nicaraguan market. MINSA's 'FDA-like' office lacks sufficient numbers of trained staff for oversight of pharmacists, pharmacies, manufacturers, and product integrity.

USAID/N GOALS AND STRATEGY

USAID/N's overall goal is to assist the Government of Nicaragua in the revitalization of its health care system. This revitalization will impact on the public and private sectors. Nicaragua must develop cost effective health care delivery mechanisms. Pharmaceuticals and medical supplies are the primary tools for delivery of health care. Absence of these tools, mismanagement of these tools, or suboptimal quality of these tools will cripple the health care delivery system. USAID/N strategy is to assist in the optimization and rationalization of the use of these tools, and to enhance the capacity of the Government of Nicaragua to finance and manage these tools.

AREAS OF SUPPORT

Given the status of the MINSA system of pharmaceutical supply, an immediate area of support by USAID is in procurement of pharmaceuticals to 'prime the pump'. Concomitant with this commodity support must be technical assistance in the following areas:

Administrative Functions

- MINSAs staff training and efficiency
- Product Selection
- Methods of quantity determination
- Methods of procurement
- Regulatory issues

Distribution/Warehousing

- Levels of distribution
- Distribution plan
- Inventory control
- Warehouse and distribution security

Pharmacy

- Pharmacist/technician training
- Use of standardized prescriptions
- Dispensing
- Labeling
- Storage
- Inventory control/ordering

Medical/Clinical

- Treatment guidelines
- Prescription monitoring/drug utilization review
- Clinical pharmacology training for physicians
- 'Traditional' Remedies Benefit/Risk Assessment

Financing Issues

- Cost-recovery
- Self-financing

EXPECTED ACHIEVEMENTS

USAID/N will in general expect to reach certain goals with its investment in the revitalization of the pharmaceutical and medical supply system, such as:

1. Improved availability of pharmaceuticals and medical supplies in pharmacies throughout the country.
2. Improved qualitative and quantitative assessment of rational pharmaceutical needs and use patterns.
3. Improved procurement planning, bid process, specification development, bid analysis and tracking.
4. Improved warehousing, distribution, inventory control, and security systems.
5. Improved pharmacy operations and dispensing practices.
6. Improved regulatory processes for registration, licensing, and oversight of medicines available on the market.
7. Improved manufacturing practices (moving towards adoption of 'Good Manufacturing Practices') by local manufacturers and increased participation by local manufacturers in the supply of medicines and medical supplies.
8. Increased activity and efficiency of the national quality control laboratory.
9. Development of a local capability for pre-packing of unit of use quantities of pharmaceuticals.
10. Implementation and evaluation of self-financing strategies for pharmaceuticals.
11. Development and implementation of utilization review and cost containment programs for pharmaceuticals.
12. Improved control over black market sales of pharmaceuticals.
13. Rational integration of 'traditional' remedies into the clinical treatment of patients.

SPECIFIC RECOMMENDATIONS

1. Exigency procurement of pharmaceuticals and medical supplies (Prime the pump). Estimate \$10 million for first year.

Possible Suppliers: USPHS, VA, specialized pharmaceutical procurement agent.

2. Refine/update the Essential Drug List and Medical Supply List. This should include some cost-benefit analyses for newer, higher priced therapies.

Possible Suppliers: PAHO, Contractor Expert in drug formulary development.

3. Critical assessment of shortages by conducting a nation-wide survey of quantities-on-hand. Particularly, at the regional and health center levels.

Possible Suppliers: Local independent surveyors.

4. Develop an estimated demand for pharmaceuticals based on a combination of historical consumption statistics and available morbidity data. This can be performed on a sampling basis. WHO/Geneva may have software for estimating pharmaceutical requirements.

Possible Suppliers: MINSA, with technical assistance from PAHO, or Contractor Expert.

5. Implement a prescription based dispensing policy and use prescriptions to validate/audit dispensing of medicines and construct patient profiles for analysis of prescribing patterns and utilization review.

Possible Suppliers: MINSAs, with assistance from USAID for printing; USPHS or Contractor Expert to assure that form design is complete and useful for all purposes (auditing, utilization review, prescribing patterns).

6. Redistribute pharmaceuticals and medical supplies from overstocked locations to short-stocked locations.

Possible Suppliers: MINSAs.

7. Fully automate the inventory control system, beginning at the central level and expanding to the regional levels.

Possible Suppliers: Local software development companies with some direction from an expert in computerized inventory control.

8. Analyze existing distribution system and assign additional vehicles to regions, or change delivery routes, or begin or expand deliveries using COFARMA vehicles from the central level to the regional levels (hospitals and health centers).

Possible Suppliers: PAHO or Contractor Expert in pharmaceutical distribution.

9. Implement or strengthen security measures/procedures to reduce losses.

Possible Suppliers: MINSAs, with assistance from USAID auditors.

10. Develop and implement improved procedures for pharmacy management and dispensing.

Possible Suppliers: USPHS, PAHO, Contractor Expert in pharmacy practice.

11. Develop pharmaceutical treatment guidelines and train health professionals.

Possible Suppliers: PAHO or Contractor Expert in therapeutics.

12. Expand/implement cost-recovery mechanisms for pharmaceuticals.

Possible Suppliers: Contractor Expert in cost recovery mechanisms for pharmaceutical benefit programs.

13. Determine the feasibility of implementing physician specific prescribing budgets (indicative budgets).

Possible Suppliers: Contractor Expert in pharmaceutical economics.

14. Conduct an economic evaluation of all pharmaceutical benefit interrelationships in light of health, economic, social and political risks.

Possible Suppliers: Contractor Expert in pharmaceutical economics.

15. Develop regulations governing the registration, import, sales, use, and distribution of pharmaceuticals.

Possible Suppliers: PAHO, FDA, or Contractor Expert in pharmaceutical regulatory systems.

16. Strengthen human resources capacity through team building, training, and professional development.

Possible Suppliers: PAHO or Contractor Expert in training.

17. Strengthen the local production capability through intensive technical assistance in 'Good Manufacturing Practices', production planning, product formulation, packaging, development of Central American export opportunities.

Possible Suppliers: PAHO or Contractor Expert in pharmaceutical manufacturing/formulation.

18. Provide a revolving loan fund to finance updating of manufacturing equipment and acquisition of raw materials.

Possible Suppliers: USAID/N.

19. Evaluate conditions at central and regional warehouses. Provide limited (air extractors, air conditioners, lights) improvements to warehouses.

Possible Suppliers: Contractor Expert in warehousing. USAID.

20. Determine the extent of the use of "traditional remedies. Systematically evaluate the chemical composition, benefit/risk, and possible role of the traditional remedies in the MINSA health care delivery system. Promote use of beneficial traditional remedies. Evaluate export opportunities.

Possible Sources: WHO, Contractor Expert in Pharmacognosy/pharmacology.

ECONOMIC AND POLICY ISSUES

The major issue to consider when donating commodities of any type is the possibility of creating a dependence on that donation. Commodity donations provide an immediate short-term solution to a lack of medicines. On the other hand, if the supply system is weak, if policies and procedures are non-existent, if steps are not taken to resolve the problems contributing to the medicines crisis, the donation of medicines may be entirely wasted. Nicaragua's pharmaceutical and medical supply situation is critical. The pipeline is emptying. Commodity support is urgently needed.

The Ministry of Health, however, must adopt a comprehensive health care sector policy. Goals and objectives must be clearly defined and communicated to the health care workers, patients and suppliers. This should include development of policy that protects the patient, the health workers, the Government of Nicaragua, and the private sector. Equitable solutions must be identified. Support of the health care system must be a cooperative endeavor including all parties.

The Government of Nicaragua must clarify its commitment to maintaining its financial/budgetary support of the health care sector, including pharmaceuticals and medical supplies, in the short-term; and increasing that budgetary support in subsequent years.

The Ministry of Health must commit its support to the improvement of the logistics systems. An important component of the logistics system is the integrity/security of the commodities. A commitment to decreasing the black market sales of pharmaceuticals should be seriously considered.

The Ministry of Health should clarify its position with respect to increased participation of local manufacturers. A collateral issue is the requirement for strengthened quality control surveillance by the ministry of Health.

The Ministry of Health should mandate use and storage of a standardized prescription form. Prescribing and dispensing standards must be developed and enforced.

The Ministry of Health must clarify its commitment to supporting cost-recovery/self-financing options, and cost-containment activities.

The budget developed by MINSA for pharmaceuticals and medical supplies is most likely severely understated. This is due to several factors: 1) Budgets were developed based on prior consumption statistics during times of shortages; 2) Hospitals in the Managua area handled their own budgets and when the budget was depleted they did not purchase supplies--now they will receive products from MINSA as needed; 3) The availability of previously unavailable products in itself will create demand; 4) Higher quality pharmaceuticals from free-market countries may be more expensive than the previously available Eastern Bloc products; 5) Pharmaceutical prices have increased at a greater rate than other health care costs worldwide; 6) Population estimates, and consequently demand estimates may be understated; 7) Refugees may precipitate unanticipated epidemics.

Additionally, the \$17 million commercial debt would suggest that creditor suppliers will not be willing to provide pharmaceuticals and additional extensions of credit. This will narrow the range of available suppliers.

The local pharmaceutical industry is currently estimated to be operating at 30% capacity. Some of the deficiencies identified are: obsolete technology, suboptimal production organization and planning, inefficient practices, obsolete product formulations, unappealing packaging, questionable pricing policies, diminished access to raw materials. It will be important to reinforce the local pharmaceutical industry. However, without intensive technical assistance in 'Good Manufacturing Practices' and improving efficiency, locally procured products will not be of adequate quality or of a competitive price.

It will be beneficial to explore the feasibility of Nicaraguan pharmaceutical manufacturers serving as contract manufacturers for multinational companies or allowing equity participation. These mechanisms lead to technology transfer.

The MINSA quality control laboratory has modern equipment and trained technical personnel. The potential exists for it to be a very effective quality control laboratory. However, the monitoring system must be defined. For example, policy must developed which indicates the types of products to be tested, the sampling methodology to be employed, the types of tests to be performed, the ranges of

acceptability of results, the on-going verification of the accuracy of testing procedures, and the efficient operation of the laboratory to maximize the number of drugs that can be tested.

Other issues to be considered relate to the willingness of USAID to provide financial support for improving physical infrastructure, maintaining staff, equipment procurement, transport, and other special activities.

Self-financing options for pharmaceuticals, such as pre-paid contributions, user fees, taxation, insurance, payment in kind, etc. should be explored. Although the challenges presented by Nicaragua's current situation may require use of more innovative solutions.

In summary, assistance to Nicaragua to prime the pump will provide short-term relief to the health care system. Additional assistance to ensure on-going financing, improved logistics systems, strengthened regulatory and normative policies, support for local manufacturing efforts, and therapeutic improvements will be critical to the long-term solution of Nicaragua's health care problems.