

Analysis of the Pharmaceutical Supply System of the Nicaraguan Ministry of Health

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ACRONYMS AND ABBREVIATIONS

ANDIPROFA	Nicaraguan Association of Pharmaceutical Product Distributors
CIPS	Centro de Insumos Para la Salud (Center for Health Supplies)
COIME	Coordinadora Interinstitucional de Medicamentos Esenciales (Inter-institutional Coordination for Access to Essential Medicines)
DNIM	Departamento de Normación de Insumos Médicos (Directorate of Medical Supply Standards)
EU	European Union
FONMAT	Fund for Safe Motherhood and Childhood
FSS	Supplementary Social Fund
GDP	gross domestic product
IDB	Inter-American Development Bank
IMCI	Integrated Management of Childhood Illnesses
INSS	Nicaraguan Social Security Institute
LBM	Lista Básica de Medicamentos (Basic List of Medicines)
MIFIC	Ministerio de Fomento, Industria y Comercio (Ministry of Development, Industry, and Trade)
MOH	Ministry of Health
MSH	Management Sciences for Health
NFD	Nordic Development Fund
NGO	nongovernmental organization
PAHO	Pan American Health Organization
PFSS	Proyecto de Fortalecimiento del Sistema de Salud (Project to Strengthen Health Care)
PMSS	Programa Modernización del Sector Salud (Health Sector Modernization Program)
PROSILAIS	Support to Local Health Systems Development Project (Proyecto de Apoyo a SILAIS)
PVO	private volunteer organization
RPM Plus	Rational Pharmaceutical Management Plus Program
SAAS	Sistema Alternativo de Abastecimiento y Suministros (Alternative Supply System)
Sida	Swedish International Development Cooperation Agency
SILAIS	Local Integrated Health Care Systems
SIMINSA	Sistema de Información de Ministeria de Salud (Ministry of Health Information System)
USAID	U.S. Agency for International Development
USD	U.S. dollar
VSM	Ventas Sociales de Medicamentos (Community Medicine Sales)
WB	World Bank
WHO	World Health Organization

EXECUTIVE SUMMARY

The Nicaraguan Ministry of Health (MOH) has been facing a crisis early this year in the shortage of medicines and medical supplies to treat the health problems covered by its health units. Some factors contributing to the current situation have been the practice of split purchases of medicines and medical supplies in past years; the reduction of the treasury budget for medicines and medical supplies this year; and the inefficiency created by technical and administrative procedures for planning, procurement, distribution, and use of medicines and medical supplies that require review and immediate updating.

Some aspects of pharmaceutical supply management have led to fragmentation of the procurement mechanisms. The multiplicity of donors and international agencies, which although contributing over 50 percent of the current budget for medicines and medical supplies, and even more with donations of products, also contributes to the increasing complexity of coordinating the activities carried out. Each project of the donors and international agencies has a distinct policy emphasis, with various sources of funding, in specific regions of the country (but which at times do not cover all health units of a SILAIS [Local Integrated Health Care System]), with budget releases at different times, and in the pharmaceutical supply area, with procurement and distribution processes that are different from those of the MOH's system.

However, the current projects of the financial credit agencies and some of the international agencies that contribute most to the medicine and medical supply budget of the MOH units will be ending their financial outlays committed in the current agreements, in particular those related to the subject of medicines, within one or two years. At that time, the funding for medicines at the MOH will see an abrupt drop if those projects are not renewed or new cooperation projects are not established. Given the current low level of economic growth in the country, it is difficult to suggest that an increase in treasury funding for medicines can supplement this gap in funding. In the last three years, the treasury funds for pharmaceutical procurement have decreased at an average rate of 5 percent annually, and there are no indications that the situation will improve in the next few years.

The efficiency that could be achieved by using public funds to improve the planning and procurement procedures to make them more cost-efficient will probably only make it possible to cover 20 percent of the financial gap that the decrease in treasury funds and outside funding will leave around the year 2005. Under these circumstances, the population not covered by MOH funds will continue to increase its out-of-pocket expenditures on medicines. In the case of the poorest groups, this may represent a proportionate decrease in funds intended for other consumer goods, such as food. Currently, a large percentage of the population already resorts to individual out-of-pocket expenditures to cover its medication needs even when coming to MOH health facilities for care.

The analysis presented in this document centers on recommendations for increasing the population's access to medicines through public-private initiatives and recommendations for increasing efficiency in the use of funds from the treasury allocated to the MOH and from

outside cooperation. Within the public-private initiatives, three alternatives merit special consideration.

The first is related to the expansion or creation of nonprofit social assistance pharmacies or medicine dispensing facilities that operate under a revolving fund system and make it possible to increase the supply of safe and effective medicines at a low cost. This initiative requires legal, political, and technical support. In the technical area, it is important to provide assistance so that the organizations that decide to offer this option can establish a cost-efficient central medicine procurement unit that supplies these pharmacies in a manner that enables them to be self-sufficient. The various modes that this type of intervention takes in different countries (networks, chain, franchise) and the working conditions (single or shared pharmaceutical management) are discussed in the recommendations.

The second alternative refers to the private pharmacies that currently operate as franchisees inside hospitals and health centers and therefore have a captive population that pays for the products they sell. The role of the MOH as a regulator can enable these pharmacies to benefit from the low prices that the MOH obtains for its facilities provided the increase in the sale price is limited to supplementing its operating expenses and maintaining the revolving fund of these pharmacies for reinvestment. Even by adding a profit margin to these products, making cost-recovery possible for the hospital's current costs, the price would not be as high as the cost of medicines in pharmacies that are exclusively private.

The implementation of both concepts requires legal and regulatory amendments and political lobbying; therefore, those activities should begin as soon as possible. This way, policies of greater magnitude that may favor the segment of the population that needs it most and that may be sustainable over time may compensate for the anticipated decline in the flow of public funds.

The third alternative is related to the support that can be provided to the MOH to increase the efficient management of its resources. The following aspects should be considered—

1. **Public bidding for the procurement of supplies and medicines that guarantees the offer price for a minimum of one year.** This differs from the current situation in which the bidding is for smaller quantities, given the lack of budget available for a larger purchase. The recommendation is to improve the capacity to plan the medicine and medical supply requirements to determine the level of the annual requirements for each product, which makes negotiation possible. This way, providers would estimate their operating and sale costs based on this volume, but with the possibility, if a larger quantity is needed, of the same price being offered. While the current planning has some deficiencies, it can serve as the minimum amount of products for which the price will be established. According to the experience of the first year, planning for the next year would be based on the actual consumption and its adjustment for the months in which there were no funds to order to products. Planning requirements for a year is also convenient for the providers, which would have the opportunity to plan their imports or production, and would be able to meet the needs of the units in installments. Knowing the minimum volume of finished products or raw materials that would require importation for MOH use may also help suppliers obtain products at a better price from their parent companies or the firms they represent.

The negotiation of prices would not involve immediate deliveries of the total volume negotiated. The purchase terms can set the delivery period according to the storage capacity of the health units.

A variation of what currently occurs would be for the health units to issue purchase orders according to their needs throughout the year after the central level has established the purchase prices and awarded the purchases to specific vendors. Purchase orders would be sent to the vendors awarded the contract.

This planning of needs with individual orders from the units when they need the product may also favor cooperation projects, whose fund disbursement schedules rarely coincide with that of the MOH and are subject to outside factors. Having negotiated the price through the MOH Purchasing Unit, the cooperation projects, which manage their own funds, could simply issue their purchase orders to the authorized vendors with no need for new bidding to supply the units they support.

2. **Conducting a detailed analysis of operating costs of the current supply systems.** This type of study would be very useful in providing information on the advisability of adopting one system or another and in determining the advantages and disadvantages of the following alternative supply models, which are described below—
 - Purchases that include distribution of the product to health units: Currently, the Programa Modernización del Sector Salud (Health Sector Modernization Project; PMSS), through its Alternative Supply System (Sistema Alternativo de Abastecimiento y Suministros; SAAS), is purchasing medicines and supplies whose prices include the direct delivery of the product to the facility. Although an initial analysis made with data collected during the visit to the country in July appeared to point to lower purchase prices obtained by SAAS than the prices obtained by the MOH Purchasing Unit, data provided by the Purchasing Unit during the November 2002 visit showed the contrary. In other words, the purchase prices obtained by the Purchasing Unit are much lower than those obtained by the SAAS, which can be explained because the latter include the cost of distribution to the facility. However, this consultation did not compare the total operating costs of both systems. The costs of the customs clearance procedures, storage, inventory management, and distribution to the health units, activities that are actually carried out by the Center for Health Supplies (Centro de Insumos Para la Salud; CIPS) with a budget allocated by the MOH, should be added to the MOH purchase price. It is essential to perform a more detailed evaluation that incorporates all operating costs in both systems so that, using empirical data, the MOH can decide whether the SAAS system with direct delivery is more profitable than maintenance of MOH's current warehouse and distribution system.
 - Comparison of the cost to the MOH of the systems specified above with the Prime Vendor method of contracting a private company to manage the logistical system of consolidating orders and distribution: In this logistics system, relations between the health units and the different vendors awarded contracts in price bidding would be simplified by centralizing the orders and consolidating the shipments to each health unit, avoiding administrative procedures that each health unit would have to carry out to

request orders of the medicines and medical supplies it requires. The health units would place monthly or bimonthly orders (according to their storage capacity) with this Prime Vendor. The design and maintenance of an information system that enables the Prime Vendor's work would be its responsibility; therefore, the MOH would not incur higher expenses but would have access to the information for management decisions. Although companies in Nicaragua currently perform distribution functions for both pharmaceuticals and other products, their logistical capacities and the possibility of adjustment to manage pharmaceuticals as well as the interest of these companies in competing in the contracting of these services should be explored in greater depth.

- Decisions regarding the distribution of donations: Given the large volume of donations in kind that the country continues to receive, these donations could be distributed through the Prime Vendor channel, if this is the option decided upon. If the Prime Vendor mode is not selected, a private distribution company could at least be contracted for this work because the volume of donations gives rise to one of the highest operating and stock management costs of the system, including costs for losses caused by expiration and waste.
- Necessary investments: If it is decided to maintain the current MOH storage and distribution system, investments must be considered, which will be necessary to improve the infrastructure of the current system of warehouses, the information system, and rapid movement of the products to maintain a lower volume of stock and increase efficiency at a reduced cost. The staff skills and infrastructure of the SILAIS, municipality, and local health unit warehouses require investment to obtain improvements, independent of which system it is determined to use. However, by choosing the direct delivery system, and if the direct delivery of orders is staggered over the year in small volumes to the health units, neither the central warehouse nor the health units will have tight storage problems, decreasing the costs of stock management and waste that large volumes of products entail.
- Establishment of a program to guarantee quality in the management of medicines and medical supplies: The need to establish a quality guarantee program is vital and independent of the storage system selected. The possibility of organizing a quality guarantee program involves fitting out health unit, municipal, CIPS, or Prime Vendor warehouses. Adequate scheduling of taking samples from lots to be distributed to the health units can be carried out, both on the vendor and Prime Vendor levels. It will be necessary to provide technical assistance to the MOH to develop this program.
- Mechanisms for the procurement of specific products: One last recommendation for reducing the price of some key products is the simultaneous use of other mechanisms made available to the country by international organizations (regular international purchases and through regional revolving funds), as is the case for antimalarials, antiretrovirals, and antitubercular medicines through the Pan American Health Organization (PAHO), which collectively could involve savings of up to 30 percent relative to the current pharmaceutical bill.

INTRODUCTION

Background

The Nicaraguan MOH is experiencing difficulty in providing medicines and medical supplies to its health facilities. In the initial months of 2002, stock-out levels of nearly 70 percent were reported for medical supplies on the Basic List of Medicines (Lista Básica de Medicamentos; LBM), and in the case of medicines in particular, the percentage was close to 74 percent. Those products that were available were in scarce supply for three months (DNIM, 2002). The supply problems experienced in the last year have been reflected in the stock-outs of the facilities, especially those on the second level of care.

For this reason, the MOH requested the support of the U.S. Agency for International Development (USAID) Mission in Nicaragua to tackle this problem. USAID/Nicaragua mobilized the technical resources of the Rational Pharmaceutical Management Plus (RPM Plus) program of Management Sciences for Health (MSH) to perform an assessment and consultation to address the situation. USAID/Nicaragua is interested in supporting the MOH in evaluating options that would allow it to improve and reinforce its supply system, not only during this crisis, but also to enable providing sustainable medium- and long-term solutions.

Objectives of the Consultation

1. Analyze the pharmaceutical supply system in terms of adequate needs for the different processes, such as levels of funding; selection and quantification of needs for products to purchased; procurement methods and legal bases that support the processes of procurement; receiving, storage, and distribution of the medicines to the health facilities; storage in the health facilities; distribution to the facilities; appropriate prescribing and use of the medicines.
2. Analyze the viability of options for improving the supply system and the interventions necessary to put them into practice.

Methods Used in the Study

The group of advisers visited the country between July 15 and August 2, 2002. Before and during the visit, RPM Plus consultants reviewed information available from previous studies, legal and technical-administrative documents, and established policies that regulate the supply of pharmaceuticals in Nicaragua and specifically at the MOH. Then, they interviewed employees of the MOH, from private industry, and from other institutions that run health projects. The following techniques were used to compile the information—

- Review of documents from prior consulting engagements, from consultants of both bilateral and multilateral organizations, and of policy documents.

- Analysis of routine statistical data and health indicators and of pharmaceutical policies that the MOH maintains.
- In-depth interviews of employees from the different offices and divisions of the MOH, and employees of outside agencies or projects that have a pharmaceutical component.
- Obtaining reports on registration, mechanisms for planning needs, recent tender specifications documents, and purchase prices for the last three years from the different MOH procurement methods.
- Visits to some hospitals in the Managua area to gather information on availability and stock-out levels, budget allocations, type of medicines where most funds are invested, inventory management, distribution and prescription of medicines. Information was gathered for a group of essential tracer medicines for the major conditions that the hospitals must treat. The tracer medicines selected were from the LBM of the MOH and also included in the collection of data that the MOH carried out in 2001 in SILAIS facilities (health centers and health posts). The hospitals where this information was collected were selected based on the convenience of proximity, given the short period allotted to gather the information.

The preliminary report on the findings was circulated among MOH employees to prepare a workshop to analyze the options. The workshop was held on November 21, 2002, with the Minister of Health, Lic. Lucía Salvo, her advisers, and directors of the different divisions of the MOH present.

Plans were made to follow up on the options established. Work groups were assigned to follow up each of the activities defined as being a priority.

FINDINGS

Funding of the Health Sector

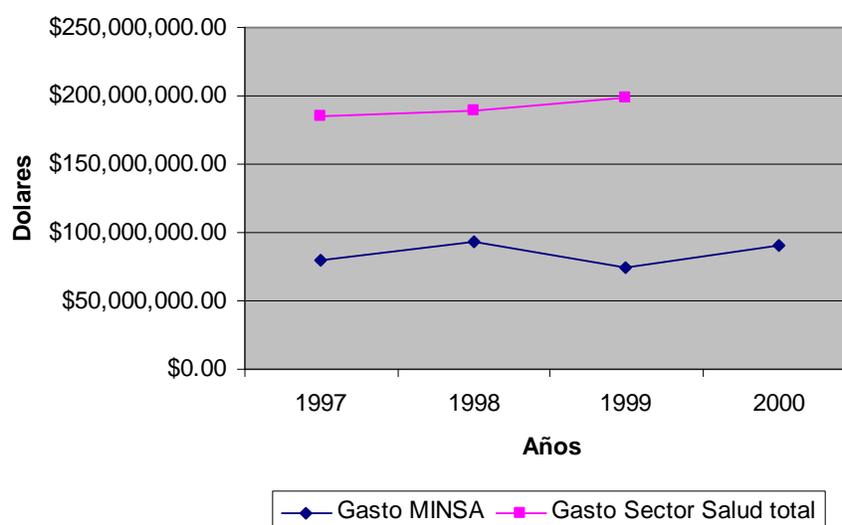
Between 1997 and 2000, the Nicaraguan government allocated 10 to 11 percent of the Republic's general budget to the MOH, which in terms of the treasury budget allocated to health, represents 93 percent of its health funds, leaving only 7 percent for the other institutions that provide services and fall under the Ministry of Defense, Department of the Interior, Nicaraguan Social Security Institute (INSS), and others. Although the health expenditures (public and private) as a percentage of the country's gross domestic product (GDP) were 43 percent in 1999, treasury spending on health (originating from treasury funds) represented only 3.4 percent of GDP that year, which suggests that the remaining 39 percent comes from cooperation funds and financial outlays of the population (MOH, Cuentas Nacionales en Salud, 2001a).

Thus, treasury expenditures on health have been decreasing over the years, as can be seen in Table 1 and Figure 1.

Table 1. MOH Health Expenditures as a Percentage of Total Health Sector Expenditures

Expenditures on Health	1997	1998	1999
MOH expenditure	\$89,180,000.00	\$105,500,000.00	\$82,000,000.00
Total health sector expenditures	\$205,800,000.00	\$213,500,000.00	\$218,500,000.00
MOH expenditure as a percentage of health sector expenditures	43%	49%	38%

Source: *Cuentas Nacionales en Salud, 1997–1999 Report*, Ministry of Health, December 2001.



[Dolares = Dollars, Años = Years, Gasto MINSAs = MOH expenditures, Gasto Sector Salud total = Total health sector expenditures]

Figure 1. MOH Health Expenditures and Total Expenditures of the Health Sector (USD)

Between 1997 and 1999, health expenditures, taking into account all service providers (MOH, INSS, Police, Army, and private), were concentrated on greater investment in hospitalization services and medical supplies¹ (MOH, Cuentas Nacionales, 2001a). Medicine expenditures as a proportion of health expenditures in these institutions did not vary significantly in recent years; they have been maintained between 13.59 percent in 1994 and 12.36 percent in 1999 (MOH, Baseline, 2001b). In the public sector, half the expenditures on health were for hospitals (50 percent), while a little over a third went to outpatient care (35 percent), and 13 percent to medical supplies. Of private expenditures, 56 percent is used for medical supplies and 31 percent for hospitalization in the private sector (MOH, Cuentas Nacionales, 2001a).

The contribution of international cooperation agencies has been and still is extremely significant in terms of funding health expenses in Nicaragua. In 2000, the treasury budget allocated to the MOH was 91.2 million U.S. dollars (USD), representing a little over 10 percent of the total USD 875 million of the national budget. However, an additional amount representing 67 percent of the total MOH budget (USD 61.4 million) was contributed by international cooperation agencies to pay health expenses (MOH, Baseline, 2001b). Private funding, that is, the portion of family income that households designate to fund their health expenses, was estimated for this same period at 61 percent of total health sector expenditures, with households contributing over 50 percent and other entities (social security, private insurance, nonprofit organizations) contributing the remaining 11 percent (MOH, Cuentas Nacionales en Salud, 2001a). Table 2 below shows the percentage distribution of the funding sources of the health sector in the years 1997–1999.

Table 2. Health Sector Funding Sources 1997–1999

Funding Sources	1997	1998	1999
Public	28.6	31.6	25.7
Private	60.5	57.3	64.2
International cooperation	10.9	11.1	10

Source: MOH, *Cuentas Nacionales en Salud, Informe 1997-1999* [National Health Accounts, 1997-1999 Report], December 2001.

Pharmaceutical Expenditure and Funding

The private pharmaceutical market in Nicaragua has increased from USD 51 million in 1996 to USD 55 million in 1998 (PAHO/WHO, 2002), to USD 60 million in 2000. However, these amounts do not include over-the-counter medicines (MOH, Baseline, 2001b). Over-the-counter products are defined by the Medicines and Pharmacies Act as ones that are sold without requiring a prescription and whose use does not present a great risk to the population (Law 292, 1998). Sales of these products are significant, which means the reported value of the pharmaceutical market is underestimated.

¹ The term “medical supplies” in the reports reviewed refers to replacement, laboratory, and nursing equipment and medicines.

Citing a publication of the pharmaceutical market (IMS 2000), the MOH study on baseline indicators of pharmaceutical policy reports that in 2000 the estimated value of pharmaceutical sales in the private sector and purchases made by public sector (including purchases with funds from outside cooperation) reached USD 14.30 per inhabitant, of which USD 12 came directly from the user's pocket and USD 2.3 from the public sector (MOH, Baseline, 2001b). The public sector amount comes from the sum of the treasury budget for medicines of the MOH (USD 6 million) and funds from outside cooperation (USD 6.8 million) corresponding to the year of the study. However, the estimate in this study was made assuming that the MOH must grant 100 percent coverage to the population, when the population covered by social security and others adds up to nearly 20 percent.

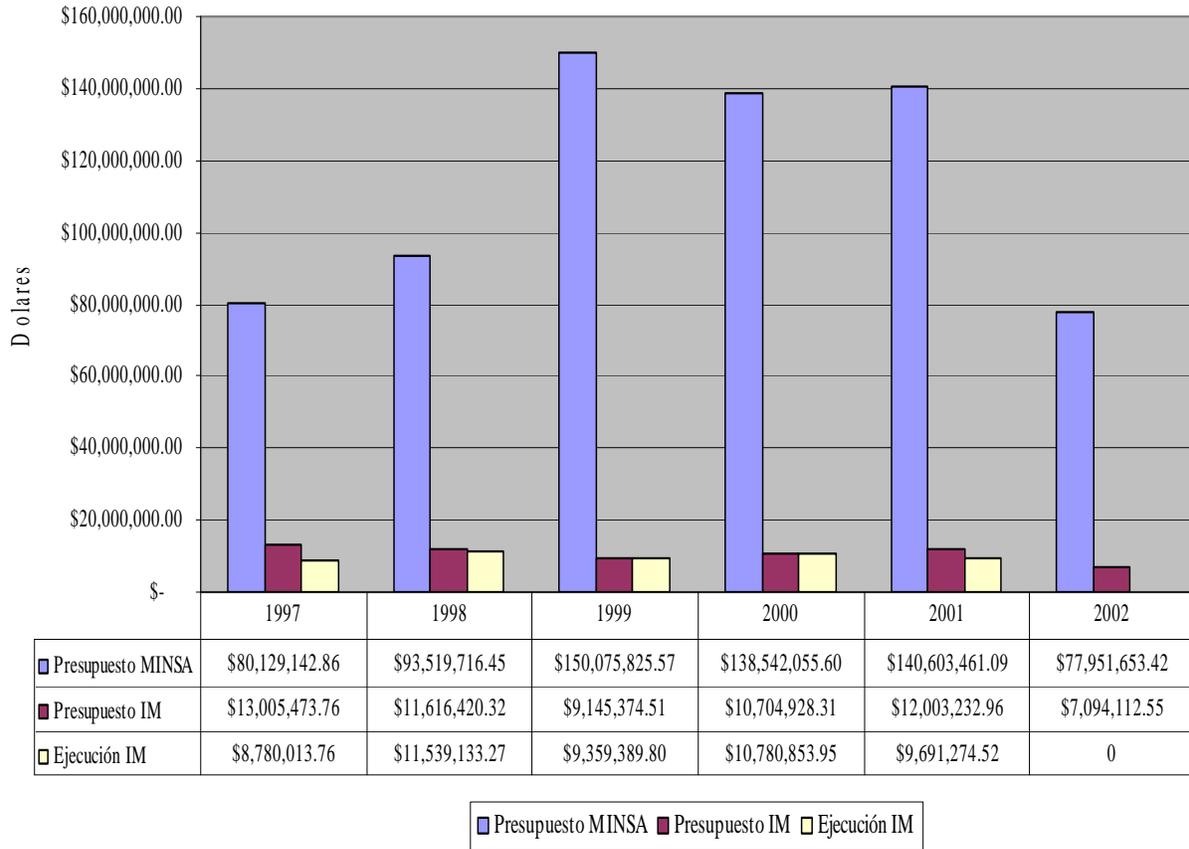
Because of discrepancies between the budget allocation reports that the Directorate of Medical Supply Standards (Departamento de Normación de Insumos Médicos; DNIM) handles and the reports obtained from the MOH Finance and Administration Office, it was not easy for the consultation team to prove through the documentation provided the budget figures allocated and spent. The difficulty also lies in the fact that in some reports, amounts in córdobas were used and in others, dollars for the same year, and different exchange rates were used, which would explain the discrepancies. In addition, comparisons over the years were hindered by changes in the form of reporting, which in some years was the full amount for medicines, periodic replacement equipment, and laboratory reagents, all under the heading of medical supplies (IM in Spanish) with no differentiation, whereas in the last year, it is itemized. This year also includes under this heading expenses for blood, which are paid to the Red Cross, and contracting a clinical analysis laboratory at a hospital in Managua, which is not reported for other years.

Taking these difficulties into account, to put together Figure 2, data were used from the DNIM, the exchange rates used for each year in the Cuentas Nacionales en Salud study (MOH, Cuentas Nacionales, 2001a), and the spending level of the budget according to the documentation from the MOH Budget Office. Depending on the data source that is used for the calculation, in 2001 only 73 percent (DNIM data) or 80 percent (Budget Office data) of the amounts budgeted for the planned purchases of medicines and medical supplies was spent. The fact is that less medicines and supplies were purchased than planned, and there were also unpaid debts from the only tender process that was conducted in the later months of 2000 and whose products entered the system during the first half of 2001. In addition, more purchases were not made in 2001 because of the challenge of the sole tender process brought by the vendors.

The budget estimated for medicines and medical supplies in 2002 is USD 10.74 million, of which USD 7.5 million (67 percent) would be intended for medicines exclusively. This means a reduction of 39 percent compared with the 2001 budget.

Of the funds planned for medicines and medical supplies (USD 10.74 million), 42.3 percent comes from treasury sources and 57.7 percent comes from outside cooperation. However, considering only the medicines area, 72 percent of the USD 7.5 million comes from outside cooperation sources, indicating the strong dependence on outside funding for this area. The largest source of the outside cooperation amount for medicines comes from the PMSS, which contributes 78 percent of total outside cooperation (or 56 percent of the total of the treasury and cooperation investment in pharmaceuticals). During the November 2002 visit, it could be

confirmed that although part of the PMSS funds had been earmarked for a purchase of medicines and medical supplies made previously, the payment and delivery of products would not take place until 2003, which may change the estimated percentage intended for consumption that year.



[Presupeusto = budget, IM = medical supplies, Ejecución = spending, MINSAs = MOH]

Sources: MOH Budget Office 1999–2002, DNIM, Cuentas Nacionales en Salud [National Reports on Health] 1997–1999

Figure 2. Total MOH Budget, Medicines and Medical Supplies Budget, and Spending of Medicines and Medical Supplies Budget

Table 3. 2002 Medicine Budget Treasury Funding and Outside Cooperation

Source of Funding	USD	%
Treasury (Primary and Second Level Care)	2,122,231	28
PROSILAIS/ASDI (Primary and Second Level)	250,000	3
Supplementary Social Fund/AID (26 hospitals)	432,280	6
European Union (Primary Level)	522,000	7
PMSS/WB/SAAS (21 health centers, Managua)	1,000,000	13
PMSS/IDB/SAAS (32 hospitals)	1,132,217	15
PMSS/IDB/SAAS (28 hospitals)	2,050,000	27
Total	7,508,728	100

Source: MOH/Office of Health Services/Health Resources Office.

Note: This budget does not include the value of the medicine contributions that several cooperation agencies and NGOs make.

IDB = Inter-American Development Bank; PROSILAIS = Support to Local Health Systems Development Project; WB = World Bank.

Too little spending on purchases in 2001 has caused a marked supply shortage in medicines and medical supplies since the middle of that year. So in July 2001, during the study conducted by the MOH (MOH, Baseline, 2001b), it was found that 95 percent of the 40 medicines and medical supplies used in the study as tracer supplies was available at health centers and posts. At the CIPS warehouses, the availability of these products was 90 percent. At the same time, 83 percent of the 600 patients interviewed who received a prescription were able to obtain the medicines prescribed at health facility pharmacies on the day of the visit. With regard to days with no inventory in the previous 12 months, the SILAIS units had a supply shortage for the tracer medicines and medical supplies 30 percent of the time. At the CIPS, the supply shortage level in the 12 months prior to the study was determined to be 8 percent of the tracer products.

According to DNIM reports, the stock-out situation intensified beginning in September 2001. The new administration found in January 2002 that 70 percent of the medicines and supplies on the LBM (and 74 percent of medicines) was zero and that those with stock on hand had hardly enough stock for three months (MOH, 2002b). The supply problems experienced in the last year have been reflected in facilities' supply shortages, especially in those on the second level (hospitals). During the first months of 2002, following the emergency purchases made by the new administration, the medicine and medical supplies level increased, but the speed with which they were used left a certain level of stock-outs at the units.

During the current year, the first procurement process with special procedures that was initiated did not succeed in calling a large number of vendors because of the unpaid debts (DNIM personal communication). These debts were honored in March 2002, nearly a year after the delivery of the products (personal communication, Ing. Jorge Arias, ANDIPROFA).

Pharmaceutical Procurement in the MOH System

Definition of MOH Pharmaceutical Requirements

Because of the budget limitations and the legal provisions that prevent the MOH from generating funds through revolving fund systems for medicines and medical supplies in MOH health facilities, the MOH has had to choose only certain conditions for which medicines will be provided free of charge (Law 423, 2002). These conditions are related to programs that cover maternity, children's health, and recently two chronic conditions (hypertension and diabetes). In the case of hospitalizations, it is established that all hospitalized patients will receive medicine at no charge, but it is reported that in the health facilities, priority is given to the so-called critical paths (from emergency to intensive care; from the operating room to post-op, etc.). As a result, the rest of the hospitalized patients purchase their required medicines and supplies at private pharmacies that are franchisees in the public hospitals and that do have the medicines.

It is established that each health unit identifies its medicine and supply requirements for the year based on medicine consumption, the morbidity that was handled in the unit the previous year, and subtracting its remaining stock. Officials from the DNIM acknowledge that this procedure has weaknesses, in particular because of a lack of records on all diagnoses that apply to each patient. In general, a complete record of all consultation reasons for each patient is unlikely to exist because of the system of recording outpatient visits, in which until just recently no clinical files were kept by patient, but rather presumptive consultation diagnoses were noted on loose sheets for each visit according to corresponding order. What is most commonly found, as reported, is a record of only one consultation condition, although the patient has two or three conditions for which medicines were indicated (for example, diarrhea and scabies).

In addition, the consumption data are limited because stock-outs in previous years prevent certainty in knowing how much the actual consumption would be if the products were actually available. Previous consulting reports done for the PMSS (Castaño C, 2002; Private A, 2001) noted that the health units do not appropriately select what they request and that planning is based on information that is quite inadequate. Another aspect included in these reports is that the scope of the LBM results in scarce funds being diluted to order little-needed products. More common yet is health units simply repeating their planning from the previous year without even considering their remaining stock.

Once the planning is done for the year, it is compared to the budget that will be required to pay for it. At this time, the DNIM adjusts proportionately the requests of each SILAIS to what can be supplied with the funds available and assigns the amount converted into monetary value. This annual estimate is divided by the 12 months of the year to supply the health units equally each month. This is what is called the Fixed Fund, which the CIPS uses to distribute medicines. The Fixed Fund is not related to the periods of the year or seasons when there are more cases of a health problem than in other periods, and it does not consider the actual demand of the population. Consequently, some units lack some products in some months, whereas other units have more than they need. This also results in the fact that even when products are in a warehouse, units do not want to receive them because they would "exceed" their budgeted Fixed Fund.

DNIM employees are exploring various mechanisms for adjusting the identified needs of the health units, but they need to coordinate with the planning system of the various programs and Health Services Office. One of the measures being implemented to adjust the estimate is the use of adjusted consumption, that is, taking the consumption data on days when the products were present at the unit so that potential consumption can then be extrapolated as if the product had been present every day of the month or year. Even so, a new adjustment is not made for possible increases in needs caused by population growth. Nor is this estimate adjusted by the amount of stock still present in the facilities and warehouse.

Problems with estimates and inadequate planning of needs contribute to inefficient use of financial resources, which are already insufficient. This, added to the difficulty of determining actual needs, even further reduces the amount of medicines that reach the facilities. The resulting stock-outs in recent years have contributed to the purchase of medicines in private-sector pharmacies by patients considered to be in the priority population.

Planning is more complex for the DNIM, which has to establish what it plans to purchase with the funds from each of the outside cooperation projects, based on the funds committed for the year but not yet available. In addition, each project has a specific beneficiary population, and the pharmaceuticals requested are specific to the conditions that are supported. This requires greater refinement to estimate the needs of each supply and distribute treasury funds and those from the projects for each while avoiding duplication by two projects or budgetary funds. In general, the DNIM tries to ensure that the financial resources that will be used for the supply will be complementary so it can distribute the supply resources fairly in all health units in the country (the SILAIS, or units, not supported by outside cooperation receive a larger proportion of treasury funds).

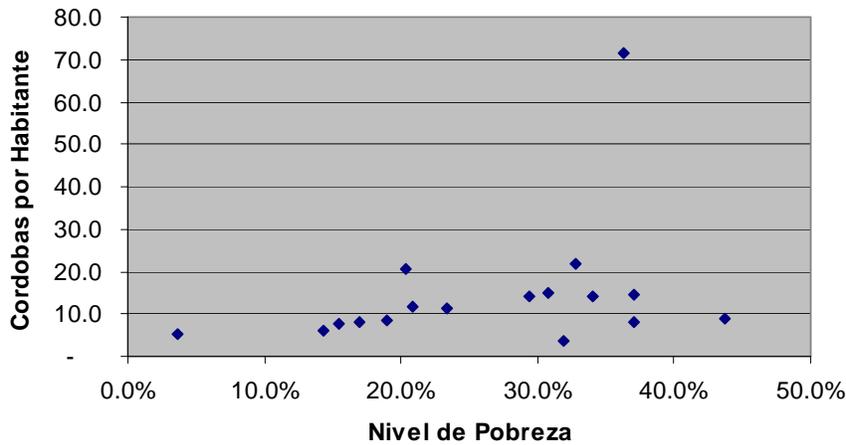
Possibly because of a greater concentration of some projects on the hospital level, in the last few years, hospitals have been more favored in the distribution of the MOH medicines budget. As seen in Table 4, the treasury funds budget for the primary level (SILAIS) has been decreasing since 1998 while it has increased for hospitals.

Table 4. Distribution of the Medicines Budget, 1998–2001

Unit	1998	1999	2000	2001
Hospital	48%	60%	59%	64%
SILAIS	52%	40%	41%	36%
Total	100%	100%	100%	100%

Source: Finance and Budget Office, MOH 2002.

In an attempt to improve the DNIM's planning system, its employees reported that to compensate for social inequalities, the distribution of funds allocated in 2002 took into account poverty criteria. However, analyzing the budget allocated for medical supplies according to the poverty level as shown in Nicaragua country reports, a trend to support or not to support populations with high poverty levels is not seen, as shown in Figure 3.



Source: Planning data from DNIM 2002 and poverty-level data from INEC 2001.

[Córdobas por Habitante = cordobas per inhabitant, Nivel de Pobreza = poverty level]

Figure 3. Budget Allocated per Inhabitant for Medical Supplies According to Poverty Level of SILAIS

The emergency situation for medicines has required much attention from the DNIM staff; therefore, its work has been geared toward planning needs, but without the ability to dedicate time or efforts to monitoring the deliveries and quality of the products. In past months, given the supply shortage, medicines have been purchased through a series of emergency purchases. From January to July 2002, the DNIM has participated in 13 purchasing programs. Three of these were carried out with treasury funds. The others were made with funds from the PMSS through its SAAS and through the MOH Purchasing Unit with funds from the Supplementary Social Fund (FSS/USAID), from PROSILAIS (Swedish funds), and from the European Union (EU) Project to Strengthen Health Care (Proyecto de Fortalecimiento del Sistema de Salud; PFSS). They have also planned needs for purchases with funds from UNICEF and the World Bank (DNIM, 2002). These emerging work demands will certainly continue over the course of this year, hindering the appropriate planning of needs for a larger-scale national purchase.

Procurement Process

The MOH Purchasing Unit is responsible for negotiating purchases for MOH needs. This includes carrying out medicine and medical supply procurement processes according to the rules of the Law on Government Contracts and the needs consolidated by the DNIM.

Normally, four methods are contemplated in the Law and Regulations of the Law on Government Contracts (Law 323, 2000) for the MOH to make its medicine purchases. The form selected depends on the volume, urgency of the purchase, and other factors. The four categories are described below—

1. Purchase by Quote: Used for purchases of at least 100,000 cordobas (USD 7,886 at the exchange rate on the date of Law 323), this category involves obtaining price quotes from

a minimum of three vendors. It must be approved by the Minister of Health. Then, an evaluation committee makes a comparative analysis and the final decision. Invitations to participate in the price quote may be made by mail, e-mail, or fax.

2. **Restricted Bidding:** This category is permitted for purchases between 100,000 and 700,000 cordobas (USD 7,886–55,205). The period for submitting proposals is 25–30 days. The Bidder Registry is used to select who will receive an invitation. When there are less than three or more than five registered bidders, the invitation must be made through advertised bidding. The invitation to participate may be made by mail, e-mail, or fax, but must be recorded in writing.
3. **Bidding through Registration:** The purchase amount in this category varies between 700,000 and 2.5 million cordobas (USD 55,205–197,160), and the period for submitting offers is 25–30 business days from the invitation or call for bids. Participation is by invitation to all registered vendors, through communication sent to the address indicated in the vendor registry. If there are more than 10 vendors, the invitation may be made by the advertised bidding method. In this type of bidding and in the restricted type, there may or may not be a discussion of basic bid terms and conditions with all potential bidders that obtained the bidding information.
4. **Advertised Bidding:** This is bidding open to all registered vendors through public invitation in newspapers with broad national circulation. It is used for purchases over 2.5 million cordobas. The period for submitting proposals is 30–45 business days from the publication of the call for bids. Law 323 permits international advertised bidding when consistent with national and institutional interests.

A Bidding Committee is formed for all bidding categories, which is composed of the coordinator of the MOH Purchasing Unit, the Minister’s legal adviser, the head of the financial office, the director of the pharmaceutical area, and often a specialist in the specific materials that are to be purchased. If necessary, this committee may form a subcommittee to provide advice during the process. The subcommittee may include a person from the DNIM, a pharmacist, and another technical expert.

In any of these bidding processes, prequalification methods may be incorporated, procedures with two or more evaluation steps, with price negotiation, with Dutch auction, with funding granted by the contractor, and even partial or continued deliveries accompanied by a schedule of partial payments, taking into account the satisfactory receipt of each of the partial deliveries. All these methods are possible pursuant to Law 323 on Contracting.

Advertised bidding processes can require about six months to be completed. Law 323 stipulates that purchases must be made only with Government Vendors registered with the Department of the Treasury and Public Credit, independent of the situation and cost of the product. This legal argument was used to avoid making emergency purchases with treasury funds through PAHO in the first half of 2002.

There are exceptions to this provision for “*purchases of goods or services, which are funded through government loans, international organizations, outside cooperation agreements, or which are based on international conventions, treaties or accords*” (Law 323, 2000). In addition, purchases and contracts in emergency, security, or public interest situations are excluded from the process. These are the legal foundations that cover the competitive bidding that the PMSS carries out with different requirements and procedures through the SAAS and the emergency purchases made in the first half of 2002.

As explained previously, the release of funds from projects to purchase medicines and medical supplies does not coincide with the release of funds from the MOH or between them. The administrative procedures used by the MOH Purchasing Unit to date have been related to the need to limit the volume of purchases to the amount of funds available, which has required in the past making several purchases during the year; therefore no economies of scale have been realized in the purchases. Product deliveries have always been for the full amount in a very short period after winning the bid. At this time, and following the consulting visit in July, the Purchasing Unit has decided to establish a mechanism for partial delivery of products, which will commence with the bidding in December of this year. The payment procedure has been and continues to be centralized through the Department of the Treasury and Public Credit once the products are received by the CIPS and the Ministry Finance Department approves the orders received.

The largest purchase made by the MOH Purchasing Unit took place in March of this year through a process called Purchase Excluding Regular Procedures. This involved purchase through the quote mechanism but for volumes that should normally be procured through advertised bidding. It was carried out in three phases, the first two for medicines and the third phase dedicated to medical supplies only. In Phase I, the purchase of medicines for 25 million córdobas² was planned, but because of the vendors’ difficulties providing the products in the short periods in which the placement of the products in a warehouse was requested (15 days), as well as the delays in payment of the preceding year’s purchase, the MOH Purchasing Unit was only able to obtain the amount of 10 million from 11 vendors. Phase II involved 25 vendors and was more successful because 70 percent of the products bid on was purchased.

It is estimated that these purchases will cover supply for May to September of this year, since they are only half (48 percent) of the supplies planned by the health units to cover the needs for the year, as can be seen in Table 5. This will certainly cause a new supply shortage before the end of the year.

² Exchange rate at the time of this study USD 1 = 14.02 córdobas.

Table 5. Codes Allocated in Purchases Made January–June 2002

Area	Codes Planned	Codes Bid on	% Planned Bids	Codes Allocated	% Allocated Bids	% Allocated Planned
Medicines	204	163	79.9	95	58.3	46.6
Clinical Laboratory	204	182	89.2	150	82.4	73.5
Replacement Equipment	388	203	52.3	141	69.5	36.3
TOTAL	796	548	68.8	386	70.4	48.5

Source: Data from the MOH provided by the Medical Supply Office.

Parallel to the purchasing system of the MOH through its Purchasing Unit, there are two more modes of purchase—

1. **Through the PAHO/WHO supply system:** PAHO/WHO offers member countries two ways to purchase pharmaceutical products and medical supplies.
 - **Reimbursed Purchases:** The regular supply system of the WHO in Washington through its Purchasing Services Unit makes purchases on behalf of a member government, which funds them in their entirety, to obtain items for the health program whose purchase in the country is difficult. The country has to make a deposit of funds that covers the amount of the supplies plus freight and insurance charges. In addition, a service charge is added on the net value of the products (3 percent).

At this time, the PROSILAIS project uses this mechanism (with Swedish cooperation funds) to supply its facilities in rural areas with essential medicines. This system was also used this year for emergency purchases with USAID funds for the Supplementary Social Fund, from ASDI-PROSILAIS, UNICEF for its national Women and Children's network, and for two more epidemic-prevention funds. The total amount spent through these emergency purchases from January to April was USD 870,000, and 73 vital medical supplies were obtained. The procurement process lasted less than four months until their arrival in port. However, for emergency purchases with treasury funds made in 2002, this mode was not used because of the legal argument that the MOH cannot make purchases through PAHO with treasury funds because it is not registered in the country as a government vendor (La Prensa, 2002).

- **The Strategic or Revolving Fund** implemented by PAHO in September 2000, which Member States voluntarily join for purchases of antiretrovirals, antituberculosis medicines, antimalarials, and leishmaniasis medicines. The country also has to deposit funds equal to the amount of the purchase in an investment account of the participant, and the amount of the purchase also includes the cost, freight and insurance, any quality control tests necessary, and an “investment charge” equal to 3 percent of the cost of the products purchased. Income from the 3 percent investment charge is deposited by PAHO in a central reserve account. PAHO contributes 0.50 percent of this amount to fund public health programs, but 2.5 percent is kept in the reserve account to cover PAHO's

administrative costs and other expenses related to the fund. If at the end of each calendar year, the reserve account exceeds USD 500,000, the surplus is credited to the respective investment accounts of the participant countries, in proportion to the supplies purchased by each participant during the period in question. All funds deposited into a country's investment account may be used to make purchases. PAHO has yet to make any purchases under this method for any of the member countries.

- There is a third mechanism, which has been in existence for a long time, the **Revolving Vaccine Fund** managed by PAHO of which Nicaragua has been a part, making its purchases for this purpose through this mechanism for several years now.
2. **The Alternative Health Supply System (SAAS)** was started by the PMSS and funded by the Inter-American Development Bank (IDB) and the World Bank (AIF) through the Institutional Strengthening component of the Project to Support the Ministry of Health in Modernizing the Hospital Network. For the SAAS, the bidding specifications include placement of the products in the health units through direct delivery (SILAIS and hospitals). Although the SAAS initially served only a reduced number of 13 health centers and posts (WB funds) and 7 hospitals (IDB funds), currently and given the emergency, the last purchase was intended to cover the needs of the country's 32 hospitals.

Calls for bids by the SAAS are conducted in accordance with the legal terms by which the donor organization is governed, whether the funds originate from the financial resources of the WB or the IDB. The condition is that the bidding must be international and public, although according to reports of staff involved, bids generally end up being through the representatives of international laboratories registered in the country. The terms of both types of bidding include a plan for staggered delivery to each of the facilities, so that bidders can consider this expense in their financial offer.

There are some differences between the terms that the WB uses and those of the IDB. For example, countries eligible for the purchase (countries of origin of the bidding companies) are different, depending on the origin of the funds, as are the forms to be completed, delivery periods, and various technical specifications. In the case of the World Bank, terms are governed by the Procurement Rules with loans from the IBRD and credits from the AIF of 1995 (PMSS, 2001). They establish the appropriate assignment of the prices of the goods, depending on whether they are produced in the purchasing country or imported. In the case of products produced in the country, it is requested that the production price be itemized (components and raw materials used, or assembly, or those previously imported and in stock in the country), additionally, the price of the domestic transport, insurance, and other local costs specific to the delivery of the goods to their final destination. For imported products, it is requested that the CIF cost be specified, or border CIP or destination agreed upon in the country, plus the price of the domestic transport, insurance and other local costs inherent to transport of the goods from the port of entry to their final destination, and the price of the services, if any. In this document, however, it is stipulated that the buyer shall grant the preferential margin to goods produced in its country. However, this clause is excluded from the bidding information in the document reviewed. Payments by product delivered must be made within 30 days from the date the invoice is presented. The Project Implementation Unit

is responsible for payments, unlike payments for purchases with treasury funds, which are handled by the Department of the Treasury and Public Credit.

In the case of international public bidding with funds from the IDB, the buyer is called the borrower, because in reality the purchase funds are part of a loan that the country receives under contract. Bidders can be individuals, private entities, government organizations, or any combination of the former. The nationality of the bidders must be (citizens or residents, or be registered as firms in) from countries eligible to offer their products. Eligible countries are all the member countries of the IDB, which include Japan, the United Kingdom, European countries, Norway, Denmark, Slovenia, Finland, Croatia, their territories and dependent areas, and almost all countries of the Americas, except Cuba. The goods must also be transported on vessels whose owners are registered in the eligible countries.

As in bidding with WB funds, in IDB bidding, it is requested that the prices of the goods be itemized and quoted in accordance with the Incoterms published by the International Chamber of Commerce in effect on the date. In addition, they must list the costs of tariffs, sales, or other taxes payable and applicable to the purchasing country.

At this time, over 50 percent of the funds for medicine purchases in this program have been spent. Of the USD 4.6 million in funds from the various agencies of the Modernization Project of the Health Sector (WB, which includes among others the AIF, IBRD, Nordic Development Fund or NFD), USD 1.2 million has already been spent on purchases and USD 1 million is in transit, that is, to be paid as soon as the products have been delivered. This means that only USD 2.4 million remains until the end of the project in 2003. Of the IDB Project to Strengthen the Hospital Network, which began with USD 6 million, USD 2 million and USD 2.9 million were spent in the last bid, which covered the entire hospital network due to the emergency, leaving only USD 1.1 million until the end of the project in 2004.

The SAAS has also been providing medicines and medical supplies to health service providers in the private sector that participate in another component of the PMSS funded through the IDB Modernization of the Hospital Network project called FONMAT (Fund for Safe Motherhood and Childhood). FONMAT is a funding plan for contracting local private health care providers to ensure mother-child care in remote areas of the country. Part of the medicines required in the package of services that are not readily available on the municipal level are bid on through the SAAS. To date, two large bids have been conducted for FONMAT. Providers deliver medicines and supplies on the municipality level based on a delivery schedule, and they are paid for them once the recipient acknowledges receipt of the product. The other mechanism is for medicines that are not as difficult to purchase on the local level, through which contracted health care providers can purchase them directly, based on three price offers. The costs of this last method are recognized as part of the cost of the project (personal communication, Emmanuelle Monin, IDB).

The payment mechanism that the SAAS uses has recently changed because of the recommendations of an evaluation conducted in late 2001. Although not much delay occurred in hospitals in processing product receipt orders to the PMSS Implementation Unit

so that providers are paid for their products delivered, there was much more difficulty obtaining these original orders from centers and posts on the primary care level. This resulted in a change in the procedure so that payment to providers begins when the provider brings to the Implementation Unit the copy of the purchase order and receipt signed by the facility warehouse manager, thereby reducing the period for payments to providers.

Because of the brief period in which the SAAS has existed and been in operation, an evaluation of the effective aspects of the system was scheduled for September of this year by a mission of banks. However, when the workshop to discuss the results of this consultation took place in November, there was still no date established for the evaluation group's visit. It is essential to compare the costs of the system to the costs of the MOH's regular supply system to make pertinent decisions and select the most cost-effective model appropriate for the MOH.

Despite the fact that certain modifications were made to make the purchasing terms more flexible, members of the Nicaraguan Association of Pharmaceutical Product Distributors (ANDIPROFA) note that the bidding processes (in the MOH or SAAS mode) continue to require from importers a series of requirements more specific to a producer (bioequivalence, bioavailability) than a distributor. Although technical specifications of all purchasing modes are adjusted to the technical specifications defined by the DNIM, this is mostly seen in relation to the bids made by the PMSS Implementation Unit with IDB or World Bank funding sources (personal communication, ANDIPROFA).

According to pharmaceutical industry representatives, emergency purchases have increased the price of products, partially because of the airfreight of small amounts of medicines and partial shipments to facilities, which were required to cover the stock-out crisis. This could explain the results of the price comparison presented later.

Purchase Prices

The ability to obtain competitive purchase prices was explored for the different MOH purchasing modes. The purchase prices obtained by the MOH in its Purchases Excluding Regular Procedures made between March and June of this year were used as a basis for comparison. These were compared to the median of international bid prices included in the *International Drug Price Indicator Guide* compiled by MSH, the MOH purchase prices for a smaller-scale purchase in 2001, the emergency purchase made by PAHO for the MOH in the same period of this year, and various purchases through the SAAS. For each of the comparisons, the products to be compared were chosen based on identical ingredients, doses, concentrations, and presentations. To facilitate the comparison, unit prices were used (tablet, capsule, etc.) and for medicines in solution, by milliliter, or by 5 ml for the oral route.

In the case of comparisons with international prices, 48 products were analyzed for which data were available in both sources (MOH purchase and *International Drug Price Indicator Guide*). Given that for some medicines, the prices obtained by the MOH were lower than the median of the international bid prices and the purpose of this comparison was only to see how much could

be saved if there were access to the more competitive international market, only the products whose reported price in the guide was lower than those obtained by the MOH were considered.³

The result summarized in Table 6 suggests that if the MOH had access to more competitive markets comparable to those presented in the MSH guide, it would have saved approximately 25 percent of the funds it spent in its last purchase. As a more concrete example, with only what would have been saved in the purchase of tablets, it could have purchased 46 million additional tablets. In any case, access to truly international price competition (possibly through regional consortiums with other countries or using PAHO-type mechanisms) has the potential to achieve great savings for the same purchase or for larger volumes for the same amount of money.

Table 6. Average Potential Savings with International Bidding Prices

Average total savings if prices comparable to the <i>International Drug Price Indicator Guide</i> had been obtained	25%
Potential extra purchase with total funds saved if prices were obtained in international bidding	94,774 vials 1,369,685 capsules 4,405 bottles 5,698 suspension bottles 44,778 tablets (pills) 46,050,051 tablets

Estimating the indicator in the usual manner, that is, by calculating the difference between the median of international prices and the MOH purchase price as a percentage of the median of international prices,⁴ the MOH obtained prices for the comparable group of medicines that were on average 86 percent over the median of the prices reported in bids for the 2001 year. Annex 2 presents a table by product, showing both the savings and the price differential percentage used in this comparison.

The method used to make a similar comparison for the Baseline study conducted by the MOH for products purchased in the year 2000 differs from the comparison made here in that the indicator used in the Baseline study was calculated using the price average from the list of international vendors and not the median of prices obtained by countries that contributed to the guide in international bids, as is the suggested procedure. For comparison purposes, it is recommended to use prices obtained in bids that actually occurred and not those from the list of vendors because they may differ depending on the market. It is also recommended to use the median and not the average because the average is more likely to lean toward extremes if there are very expensive or very cheap products among the different sources of data. With this reservation, it is seen that, for the previous year, the MOH purchase price was 264 percent over

³ Products whose median international price in the guide was higher than that obtained by the MOH were considered as zero earnings to estimate how much money could have been saved by purchasing at a lower price. This method differs from the traditional one used by MSH to estimate the price differential indicator, which takes into account both prices over or under the reference of comparison, resulting in a balance among all prices, which is used for comparisons with different purchase methods within the country.

⁴ $\frac{\text{MOH Price} - \text{International Price}}{\text{International Price}} \times 100$

the international vendors list price (year 2000), which could suggest that the MOH has improved its ability to negotiate prices.

The mode of purchase may have a significant effect on prices that can be obtained for the medicines the system requires. The table presented in Annex 3 shows the comparison of the purchase prices of the MOH in March 2002 with the purchase made by PAHO during the emergency between April and May of the same year. Despite the fact that the comparison involves only eight products, one can see that PAHO purchased the same items at prices 34 percent lower than the prices obtained by the MOH (Figure 4). If the percentage is obtained taking as a base the price obtained by PAHO (100 percent), this difference would be expressed as the MOH obtaining prices 29 percent higher than those obtained by PAHO, which can be explained by the scale on which PAHO works and by the comparative advantage of its negotiation power for certain products such as antimalarials. There is no doubt that access to the regional market is a major factor in obtaining these lower prices. This difference is presented in graph form in Figure 5.

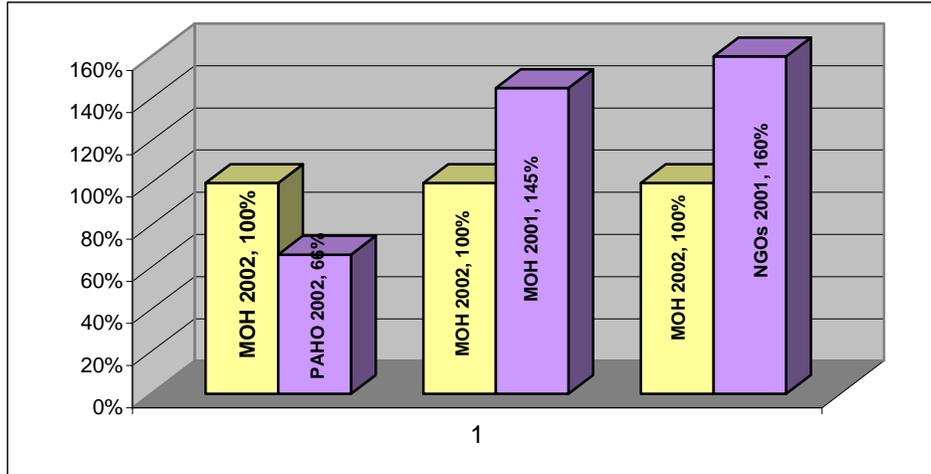
The disadvantage of smaller-scale purchases and the restricted access to national vendors is shown clearly in comparing the MOH purchase prices in its Purchase Excluding Regular Procedures to purchase prices from the year 2001 for a lower volume. Prices of the MOH purchase in 2001 for the same products were 44 percent higher than the MOH purchase prices this year. If the difference is expressed as a percentage of the cost of the small MOH purchase, the prices of the larger MOH purchase this year were on average 18 percent lower than those of the small purchase of last year (see Annex 4).

A comparison was also made of the prices obtained by the MOH in its purchase this year with the prices obtained through a joint purchase of five nongovernmental organizations (NGOs), members of the Interinstitutional Coordination for Access to Essential Medicines (Coordinadora Interinstitucional de Medicamentos Esenciales; COIME). In late 2001, these NGOs made a consolidated purchase of 122 products for community pharmacies and health posts of their projects. The purpose of this last comparison is to observe the differences when purchases are made on the national market by priority.

The prices obtained by the five NGOs in late 2001 were on average 60 percent higher than the prices obtained by the MOH in its purchase in early 2002 (Figure 4). When the price difference is expressed as a percentage of the purchase prices of the NGOs, the MOH obtained prices on average 21 percent lower than the prices obtained by the NGOs the previous year (Figure 5). However, despite the disadvantaged purchase of the NGOs, a study conducted for the EU's Project to Strengthen the Health Sector reports that they offer the public pharmaceuticals 2.7 times cheaper than those of the private pharmaceutical market (Quintón S., Arauz L., 2000); therefore they still fulfill their role of giving the population the cheapest medicine. Details of the comparison can be seen in Annex 5.

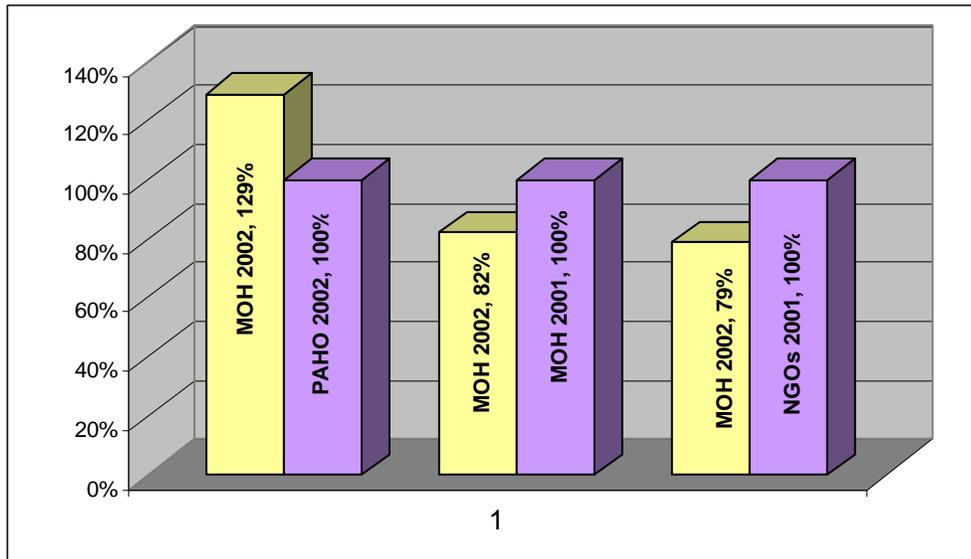
Figures 4 and 5 summarize the results of this comparative analysis. For Figure 4, the MOH 2002 purchase was taken as the comparison point (100 percent), establishing the differences with the prices obtained through the other organizations or methods as a percentage of the prices obtained by the MOH. In Figure 5, the differences are illustrated based on the prices obtained through

other purchase methods (the denominator—100 percent—is the others), and the estimate reflects the prices obtained by the MOH in its last purchase as a percentage of the prices obtained under other methods or by other buyers. As stated previously, for each comparison, only the medicines common to both purchases are used; therefore, comparisons were not made between the other methods.



Note: $\frac{2002 \text{ MOH Purchase} - \text{Comparison Purchase}}{2002 \text{ MOH Purchase}} \times 100$

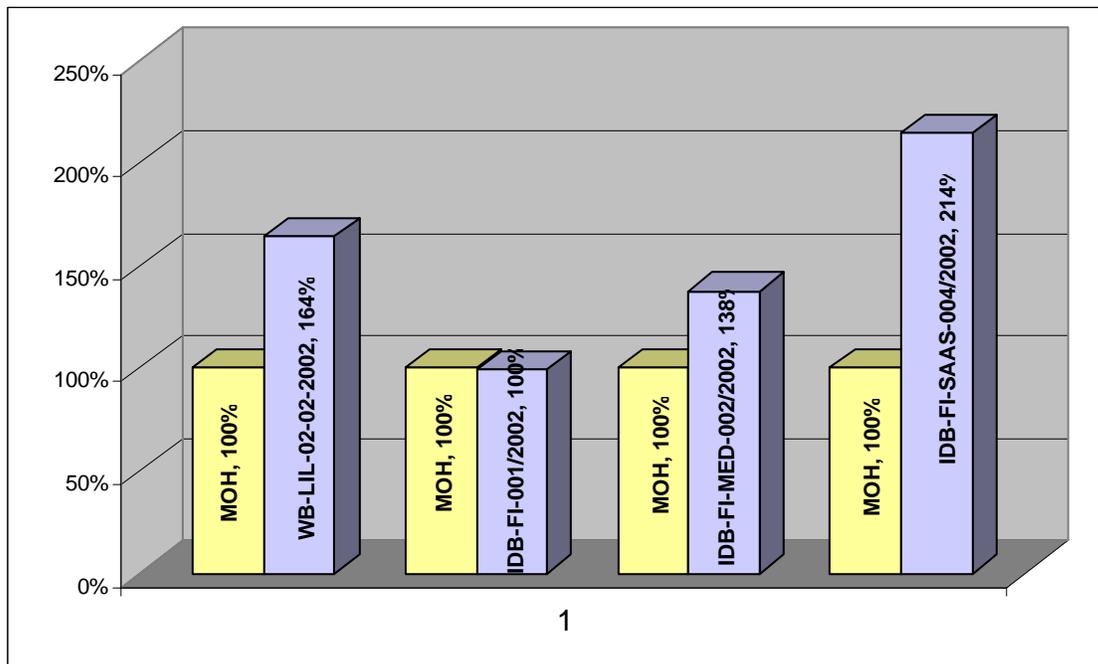
Figure 4. Purchase Prices under Different Purchase Methods as a Percentage of 2002 MOH Price



Note: $\frac{2002 \text{ MOH Purchase} - \text{Comparison Purchase}}{\text{Comparison Purchase}} \times 100$

Figure 5. Purchase Prices under Different Purchase Modes as a Percentage of Purchase Prices of the Compared Group

The data obtained during the fieldwork visit for a purchase made through the SAAS with funds from the IDB for all hospitals in the country in this same year appeared to indicate that the SAAS had acquired comparable products at prices lower than those obtained by the MOH that year. However, during the second visit (November 2002), the MOH Purchasing Unit had obtained more complete data on several purchases made by the SAAS with various funds. Reworking the analysis with these more complete data shows that the SAAS obtained purchase prices that were similar or between 37 percent and 114 percent higher than the Purchasing Unit in Its Purchase Excluding Regular Procedures (see Figure 6 and details in Annex 6). It is important to remember that the prices obtained by the SAAS include the cost of placing the product in the health facility, whereas the price used by the MOH is CIF (which does not include clearing customs, storage, and distribution).



Note: $\frac{2002\text{ MOH} - \text{Comparative Purchase}}{\text{Comparative Purchase}} \times 100$

Figure 6. 2002 MOH Purchase Prices Compared with Several Purchases through the SAAS

The results of these comparisons point to the fact that planning of requirements, which makes it possible to negotiate purchase prices with better terms, can reduce prices as the MOH Purchasing Unit is doing at this time, compared with what occurred the prior year. Curiously, the different prices offered to the MOH and SAAS are not related or correlated to the purchase volume. It is possible that the payment terms and bidding conditions influence the price more than the volume to be purchased. Measures that make it possible to use international bidding mechanisms (such as purchases through PAHO or access to competitors on the international market) may improve even further the use of limited financial resources.

Storage and Distribution of Medicines

With the exception of the medicines and supplies funded by the PMSS through the SAAS, all other supplies and medicines originating from treasury funds, funds from projects, or outside cooperation and donations are stored and distributed by the CIPS. The CIPS is an entity directly under the Ministry Office of Health.

According to the information gathered, over 90 percent of the purchases through the MOH Purchasing Unit come from representatives of foreign manufacturers. Therefore, one of the major functions of the CIPS is clearing customs, for both purchased and donated products. Japanese Cooperation and Project HOPE are donors of large quantities of medicines and medical supplies, which are brought to the country and placed in port so that the CIPS can get them out of customs. For this purpose, the CIPS has a Customs Clearance Unit and a warehouse in customs (*bond*). This way, the products do not pay tariffs (internally) or import duties, in accordance with Law 292.

The CIPS performs the duty of receiving supplies, checks the invoice against the purchase order, reviews the specifications of the product to corroborate they are consistent with the purchase order, and performs a physical count of 100 percent of the products received. Once the products are inspected, this information enters its information system and goes to one of its warehouses. The CIPS sends the invoice, purchase order, entry sheet, and import sheet (if applicable) to the MOH Financial Unit. The Financial Unit sends these forms and its approval to the Department of the Treasury and Public Credit so that it can make the payment. According to the information reported, the payment period is not long because it is made through a bank transfer. The bank can issue checks to the vendors once the CIPS has confirmed the delivery to its warehouses at the port or in the capital (personal communication, Lic. Rocha). It must be kept in mind, however, that vendors were not paid for the 2000 purchase until March of this year. This delay suggests that although the administrative process may be fast, other factors such as a lack of treasury funds can contribute to slow payments, and therefore, affect the participation of vendors in future MOH purchases or the terms of the offer.

The storage system is “first in, first out” (FIFO). The CIPS has five warehouses divided into sections according to the type of product. After products enter the warehouse, the Quality Control Unit staff takes a sample from each of the lots deposited and sends the samples to the National Medicine Quality Control Laboratory. The CIPS also has an Inventory Control Unit, a team of five people who periodically perform a check of the information system, inventory cards, and physical count of the supplies according to a schedule.

Because health facilities do not have an information network system, the staff has to take its requisitions (needs requisition forms) to the CIPS. The quantity that is delivered to each facility is consistent with the duly assigned quantities established by the DNIM of the MOH in the annual planning or Fixed Fund. If there is a lack of products, the CIPS delivers a limited amount and notifies the facility when the product comes in.

The health units of Managua and the surrounding area normally go to the CIPS to put in their orders. The same staff of the unit is present when its request is prepared and they must confirm

on site the quantity and type of product that is delivered to them before it is loaded on the CIPS truck. According to the information from the staff of hospitals in Managua, staff “protects” the truck until it makes the delivery at the respective hospital.

For facilities in other parts of the country, deliveries are made according to scheduled routes every two months. At six decentralized SILAIS, the CIPS makes deliveries directly to health units because neither the SILAIS nor the municipality has a warehouse. At the 11 remaining SILAIS, delivery of orders for the entire SILAIS is made to SILAIS warehouses or municipal warehouses according to availability.

With regard to inventory management, the study conducted by the MOH reports that only two products were consistent in terms of physical count and adjusted records in the health units in the sample. However, in reviewing the estimate of the indicator, we found that the incongruence between the physical count and the adjusted records (by arrivals and exits since the completion of the last Kardex or loading card) of the warehouses surveyed was only 1.2 percent of all units of the products, denoting quite efficient inventory management in these units. This, in a certain way, invalidates the perception of employees on the central level that the health units or SILAIS have no inventory management capacity.

Despite the reported efficiencies achieved during transition administration of the CIPS at the beginning of this year, there are still improvements that officials should consider if they decide to maintain the operation of the CIPS in the role it plays at this time. The information system is one of these aspects that require improvement. The DNIM staff does not have immediate information on the stock (purchases or donations) to enable it to make decisions. The information system that the CIPS runs was reported to be slow and dependent on a series of programs to obtain the information that is required. The DNIM needs a network connection to whatever system is operating in the medicine warehouse because of the high volume that is handled at the CIPS and the cost it represents. It would be ideal to have a connection also with the SILAIS and municipal warehouses.

In the case of the alternative supply system (SAAS), products are delivered by vendors directly to the health units, and the deliveries are staggered over the periods agreed upon in the contracts. There were some payment issues during the first year the system was in operation because the original purchase order had to be sent back to the PMSS Implementation Unit to begin the process of payment to the vendor. After an evaluation visit in late 2001, it was decided that the vendor would obtain a copy of the purchase order, signed by the warehouse manager of the health unit, and that this document would serve as a basis for initiating the payment process with the Implementation Unit until the original arrived, thereby accelerating the payments. The other difference from the MOH system is that the PMSS Implementation Unit makes the payments directly, unlike the Department of the Treasury and Public Credit, which could make payment in this alternative system more flexible.

During the visit to hospitals in Managua, some concerns were expressed with regard to the large-volume deliveries of the last emergency purchases through the different systems—

1. The hospitals' warehouses lack the appropriate environment to enable them to receive larger volumes from vendors, especially of products that occupy a large amount of space (such as bottles of intravenous fluids). This appears to have been a problem because, due to the supply shortage, the last purchase of the MOH and IDB supplied intravenous solutions, which because their volume, had to be placed in rooms without appropriate storage conditions. This can be resolved by planning deliveries appropriate to the storage capacity of the units as well as their capacity to use the medicines.
2. Hospital pharmacy managers believe that there is not sufficient experience or staff to make an itemized receipt of deliveries from vendors when the volume is very large. However, a good quality assurance program that includes training and a system for sampling lots upon their arrival in port or at the producers' or distributors' warehouses may improve this situation.
3. With regard to the SAAS quality control system, the DNIM staff expressed concern because it fears the systematic shipment of samples to the quality control laboratory that the CIPS carries out has not been replaced by a mechanism that permits systematic sampling in the facilities that have direct delivery. In a SAAS progress report, it is mentioned that a sampling of 45 percent of the lots delivered was taken for quality control. A good quality assurance program has to be designed and put into practice for either of the two systems in use, and it must include quality control of lots prior to their delivery to the health units—not be after they arrive at the health unit—where the medicine needs to be consumed almost immediately.

The advantages and disadvantages of each of the purchase and delivery models must be considered to determine which would be the right system for the MOH to keep in the context of its new role in the health sector. The decision on the system that will prevail must be the product of a detailed cost analysis, which will be conducted by the same financial organizations in September of this year. If based on empirical evidence, the benefits of the SAAS are demonstrated, the MOH would have to consider alternatives for the storage and distribution of medicine donations, which the CIPS currently administers. One alternative to consider is bidding to contract a private organization that could be charged with the immediate distribution of donations. Importers, for example, in addition to having distributors that they contract to distribute their products on the private market contract with local couriers and the Nicaraguan Post Office, especially for the distribution of their products to remote areas. This reduces their operating costs because they do not need to have their own fleet of vehicles or staff for this work.

A presentation of the preliminary results of a study on the logistical management of products in health units of eight SILAIS conducted by the John Snow, Inc., DELIVER project in July 2002 reported that the six essential medicines used as tracers for the mother-child program in health centers and posts were available, and amoxicilline was the only one that might have been out of stock. The presence of these products was explained by the existence of donations. However, the consulting team collected information from the local staff regarding a decision (it is not clear if from the central or SILAIS level) not to complete Kardex cards in health posts, or record donations, to avoid responsibility for the expiration of products (presentation of DELIVER 2002

findings). Apparently, recording donations that they receive directly can affect their right to receive supplies because this donation would be counted against their Fixed Fund.

The Population's Access to Medicines

The insufficient public funds to provide medicines and supplies to MOH health facilities and the consequent supply shortage have been compensated for in recent years by an increase in families' out-of-pocket expenses to obtain medicines. According to the MOH baseline survey (MOH, Baseline, 2001b), 15 percent of the 600 patients interviewed in primary care-level health units paid some amount for the medicines they received at MOH units. Although the Law on Medicines and Pharmacies (Law 292, 1998) establishes that medicines provided by the MOH are exclusively for the priority programs and that, therefore, no patient should pay for these medicines, health facilities request contributions from patients to compensate for the chronic supply shortage of the health units.

The real problem is that given the supply shortages in the health units where the public must receive the free medicines for some priority programs (mother-child, especially), patients inevitably end up buying medicines in the private sector. A study on the demand for health services in Nicaragua in 1996 revealed that the purchase of medicines outside the institution visited (public and private) was the largest expense category for outpatient curative care, representing between 44.9 percent and 89 percent of the total expenses in all facilities (MOH/MSH/IDB, 1996).

A method that the MOH is implementing to make medicines available in its units is to grant private pharmacies the right to sell medicines in MOH facilities as a franchisee. These pharmacies are primarily in the outpatient care area, but they also have the role of selling medicines and other supplies to hospitalized patients who are not considered to be in the critical paths or programs to receive free medicines.

These pharmacies are working with a system of revolving funds. It was not clear to the consulting team what agreement with the facilities' administration enables the hospital to use part of the earnings on medicines to contract staff or other goods and services, but it was reported that this occurs. These pharmacies, however, because of their private nature, are not supplied by the consolidated purchase that the MOH makes. As a result, patients of hospitals and centers that have this type of franchisee buy pharmaceuticals at a commercial price as in any other pharmacy. The staff of the hospitals visited mentioned that the prices of the medicines that are sold in these pharmacies are even higher than those in regular pharmacies. Because of the location of these pharmacies inside the hospital, the population treated in the hospital may believe that the prices will be more favorable than if they went outside the hospital for medicine. In other words, these pharmacies are working with a practically captive population.

It appears that the for a pharmacy franchisee to invite bids arose because of the existence of a limitation in Law 292 (Article 113, Chapter III, Title VII, p. 4498). This article prohibits sale to the public of pharmaceutical specialties intended for the MOH, thereby preventing these health

units from attempting to maintain a fund that enables them to resupply themselves with medicines for the use of the public that they serve.

Although the Regulation of Law 292 in its Chapter XII, Article 78, clearly establishes that the national pharmaceutical policy of Nicaragua includes among its purposes “increasing the accessibility of the population to medicines,” a tendency exists among civil servants to continue to maintain that the population is entitled to “free” medicines when, in daily practice, the population has to resort to buying it in the private sector. The prohibition on sale of medicines at MOH facilities requires patients to purchase them at franchisee pharmacies or outside the hospital, without considering whether a small payment from patients who are not in priority groups, even with a certain subsidy from the government making it possible to assume the cost of the purchase process, may contribute to generating funds to guarantee that essential medicines are available in the health units.

Another example of alternatives that the units use to generate funds is the so-called “separate services.” Public hospitals have adapted areas of their infrastructure for the admission of *private* patients, whether covered by their own funds or by insurance, including social security. The accounting of this system of separate services is carried out by the hospital’s administrative staff, and the services are provided by the same hospital staff, theoretically at times that do not conflict with the the government contracting. However, no other alternative exists than to use the same resources as other MOH patients, such as operating rooms and emergency equipment; therefore, there must be clear descriptions of the priority for using the resources when there are competing needs for them. Despite the fact that everything points to the MOH subsidizing many of the services that are offered to patients in these separate facilities, and that possibly those benefiting most are the provider physicians who receive direct payment from the patients for their services, the fairness and efficiency with which this system operates exceeds the purposes of this consultation. It does not appear probable that the income for these services is used to purchase medical supplies.

To illustrate how unfavorable it is to the Nicaraguan population to have to turn to the private market to resolve its health problems related to medicines and medical supplies, we are presenting some price comparison figures from the private sector. A study conducted by Health Action International in Latin America in 2001 revealed, for example, that ibuprofen costs eight times more in Nicaragua than in Brazil, despite the fact that the product compared in Nicaragua was not the original brand product (AIS, 2001). Wide price ranges between brand-name and generic medicines reported by this study in Nicaragua are also a sample of the imperfections of the Nicaraguan market, which in the end affects those who are poorest (see Table 7).

Table 7. Price of Brand-Name and Generic Medicines in Nicaragua (USD × 100 units), May 2001

Medicine	Original Brand	Lower-Priced Similar Brand	Lower-Priced Generic	Higher-Priced Generic
Amoxicilline 500 mg cap.	0	15.1	11.3	12.8
Captopril 25 mg tab.	0	0	57.4	0
Ceftriaxone 1 g inj.	1592	1116	1607	0
Ciprofloxacin 500 mg tab.	0	162.6	75.4	113.2
Dicloxacillin 100 mg cap.	181.1	24.5	15	22
Fluconazole 150 mg cap.	1766	0	558	966
Gentamicin 80 mg/2 ml inj.	0	52	26	56
Ibuprofen 400 mg tab./gra	0	181	45	56
Omeprazole 20 mg cap.	196.1	215.1	22.6	183.8
Sulfamethoxazole/trimethoprim 800/160 mg tab.	0	7.5	6	0

Source: AIS. Precios de Medicamentos en América Latina [Medicine Prices in Latin America]. Mimeographed. May 2001.

Another illustrative comparison is between MOH purchase prices obtained and sales prices of products to the public in the commercial sector. It is important to take into account that the MOH purchase price is CIF (cost, insurance, and freight) and does not include import payments (the MOH is exempt). Neither does it include the costs, including the staff, that the MOH absorbs in the processes of clearing customs, maintaining its customs warehouse, maintaining and operating its central and SILAIS warehouses, inventory management, and distribution (vehicle maintenance and recurrent expenses) until the product reaches the user. These costs were not determined by the current consultation because the MOH management team believed another consultation would need to be conducted by the PMSS team. To determine the real cost to the MOH of bringing the product to the user, all these costs must be taken into account and added to the CIF price of the product. Without adding these costs, the comparison presented here is only illustrative to indicate the price differences with the commercial sector and how much the user would have to pay when the health facilities cannot resolve his needs.

The MOH study (MOH, Baseline, 2001b) found that the prices of medicines in private pharmacies were on average 394 percent higher than the average purchase prices of the MOH for equivalent products obtained in purchases for the year 2000. Because commercial pharmaceutical services were not surveyed during the current consultation, the highest price permitted by the Ministry of Development, Industry and Trade (Ministerio de Fomento, Industria y Comercio; MIFIC) obtained through its Consumer Protection Department was used for comparison.⁵ These MIFIC amounts are derived from the sum of certain percentages of the CIF price of the product: 6 percent for importation to the country; 35 percent for the operating costs of the representatives or distributors in the country, which would be the price that is offered to pharmacies; and a 30 percent markup added by the pharmacies for sale to the public. In the case

⁵ Based on Ministerial agreement 052-97 (MIFIC) and Law and Regulation No. 182, MIFIC controls prices for pharmaceutical products in the private sector.

of generic products, the import fee is the same (6 percent), but the additional percentage for the sale of the importer or distributor to the pharmacy is 30 percent. The markup at the pharmacy for sale to the public can go up to 35 percent, possibly with the expectation that pharmacies will have a better profit margin, given the lower price of the product, and thus not be discouraged from offering the generic product. These markups, which increase the cost of the product to the public by 71 percent of the CIF price, are the maximums that one could find in the private market.

These prices were compared with the purchase prices obtained by the MOH in the first two phases of the Purchase Excluding Regular Procedures made between April and June of this year. For products for commercial sale, the median was used instead of the average of the products on the market to avoid distortions by brand-name products, which could have a much higher value than generics. As can be seen in Table 8, the group of products compared ended up being 1,070 percent higher in commercial pharmacies than the CIF price obtained by the MOH.⁶

Table 8. Comparison of Median MIFIC-Controlled Prices to MOH Purchase Prices, 2002

Products	2002 MOH Purchase Price (USD)	MIFIC Median Price (USD)	<u>MOH – MIFIC</u> MOH
Albendazole 100 mg/5 ml suspension, 10–20 ml bottle	0.07	0.9789586	–1299%
Amoxicilline 500 mg capsule I	0.037	0.3773181	–920%
Benzatinic benzylpenicillin-G 1,200,000 IU, sterile powder IM	0.21	1.9486448	–828%
Captopril 25 mg tablet	0.03	0.3077746	–926%
Ceftriaxone 1 g freeze-dried powder IM, IV	1.34	19.388017	–1347%
Chloroquine phosphate 250 mg tablet	0.028875	0.0599144	–107%
Clotrimazole 100 mg vaginal pessary	0.0712	0.4265335	–499%
Diazepam 10 mg/2 ml solution, 2ml IV	0.12	1.3109843	–992%
Diazepam 5 mg tablet	0.0088	0.2378745	–2603%
Phenytoin (diphenylhydantoin sodium) capsule 100 mg	0.0097	0.0991441	–922%
Glibenclamide (Glyburide) 5 mg tablet	0.0057	0.2047076	–3491%
Ibuprofen 400 mg tablet	0.0115	0.1287447	–1020%
Ibuprofen 400 mg tablet	0.0115	0.1180456	–926%
Lidocaine chlorhydrate (w/preserving agents) 2% injectable solution	0.45	2.0192582	–349%
Metronidazole 125 mg/5 ml suspension 100–120 ml bottle, oral	0.4312696	3.3519971	–677%
Paracetamol 100 mg/1 ml solution, 15 ml bottle	0.3182596	1.0506419	–230%
Paracetamol 500 mg tablet	0.0079	0.0734665	–830%
Paracetamol 500 mg tablet	0.0079	0.042796	–442%
Primaquine phosphate 15 mg base tablet	0.024465	0.2902996	–1087%

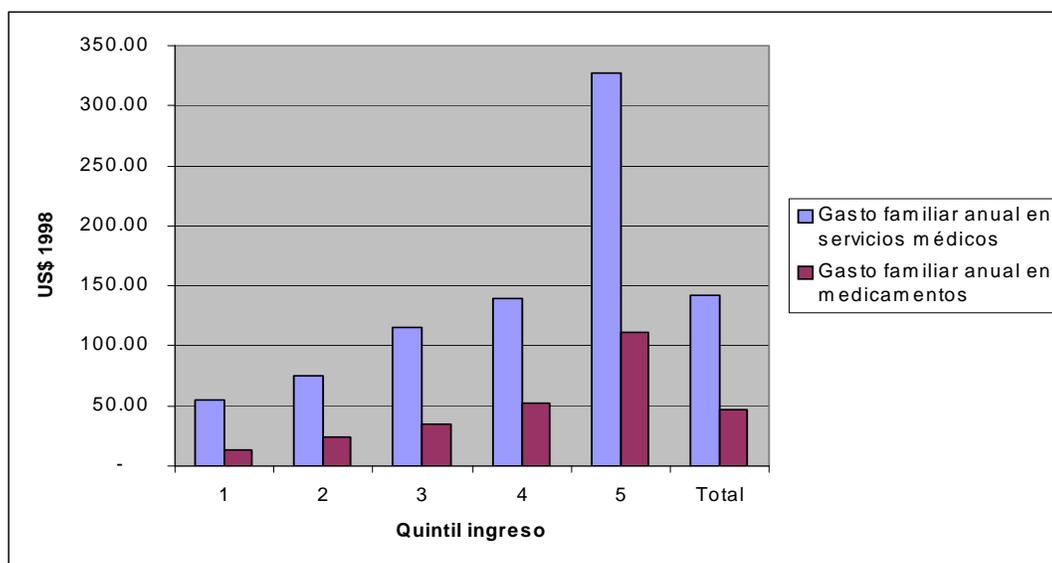
⁶ Obtained by subtracting the median public sale prices on the private market from the purchase price of the MOH and estimating the percentage that this difference represents from the MOH purchase price. The negative sign indicates that the median market price was higher than the MOH purchase price.

Primaquine phosphate 15 mg base tablet	0.021735	0.0413695	-90%
Ferric sulfate + folic acid 60 mg + 0.25 mg tablet	0.0182	0.0663338	-264%
Trimethoprim sulfamethoxazole 40 mg + 200 mg/5 ml syrup 100 ml	0.32	12.104137	-3683%
Average Difference			-1070%

Source: MIFIC and MOH Purchasing Office 2002 data.

Using data from the National Survey of Household Incomes and Expenses 1998–1999, it is estimated that in relation to the level of income, the health expenses of the poorest quintile are greater (6.21 percent) than those of the wealthiest quintile (3.88 percent). Health expenditures of households are principally in the private sector (90 percent in 1999), which means they have to pay for medicines (INEC, 2001). On average, two-thirds of the households' health expenses (69 percent) are used to purchase medicinal products and 12 percent for medical consultations.

A direct relationship does not appear to exist between pharmaceutical expenditures and families' level of income (see Figure 7). In other words, the poor spend on medicines a percentage of their annual family consumption similar to what the higher-income population spends (1 percent), but in absolute terms, this expenditure is more significant to the poor. So, we see that while families in the poorest quintile spend an approximate average of USD 12.74 on medicines per year (23 percent of their health expenditures, or 1 percent of their annual family consumption), families in the wealthiest quintile spend USD 111.13 per year (34 percent of their annual health expenditures, or 1 percent of their annual family consumption).



Source: Based on data from the INEC: National Survey on Household Incomes and Expenses 1998–1999; Mecovi Project, Profile and Characteristics of the Poor in Nicaragua, February 2001.

[Quintil ingreso = income quintile; blue box = Annual family expenditures on medical services; red box = Annual family expenditures on medicines]

Figure 7. Family Expenditures on Health and Medicines by Income Quintile, Nicaragua 1998

The distances that the population has to travel for care or to receive a medicine from the MOH also contribute to the need to turn to pharmacies or private sector sales for medicines. The study on the demand for services reports that the time that a person must travel to reach an MOH health center is 44 minutes on average. For a health post, it is 23 minutes on average (MOH/MSH/IDB, 1996). The Nicaraguan Community Services Survey (ENCO 2001) reports that 69 percent of the women in Nicaragua have access to a location less than 2 kilometers away where they can buy or request birth control pills, while 73.5 percent report knowing of a location less than 2 kilometers away where they can buy or request an oral serum (INEC 2002). Although cooperation agencies and NGOs have promoted provision of both, 30 percent of the population still does not have access to these supplies. This lack of access is bound to be greater for other supplies and medicines. For example, 16 percent of women report that the closest health post is over 5 kilometers away from their home. This would be the closest level of care with essential medicines available. These data suggest that the government needs to consider strategies that enable the neediest population to have access to quality medicines through adequate dispensing.

Self-medication has also been documented in Nicaragua as a common practice, given the population's inability to access health services. The same demand for services study mentioned above found that only 6 percent of people who had had an acute health problem had sought some type of care. Of the 94 percent that did not report seeking care, over 45 percent self-medicated (MOH/MSH/IDB, 1996). This means that a large percentage of the population turns to the purchase of medicines to some extent to solve their health problems on a permanent basis.

Technical Cooperation and Financial Credit Agencies

Donor agencies actively contribute to the flow of funds for medicine supply. Most of them carry out activities on the operations level in specific geographic areas. Their cooperation programs usually include the purchase of medicines for the health programs they support. According to their care programs and consumption of medicines and supplies, they send purchasing plans to the DNIM, which along with the Purchasing Unit organizes the purchasing process with funds from these agencies.

In their eagerness to resolve the supply shortage problem, technical cooperation and financial credit agencies have contributed to creating a supply system that is complex because of its fragmentation and probably inefficient because of the loss of economies of scale. The continuing crisis has resulted in funds that should be used for investment (including for the very management of the planning and purchasing process) instead being used for recurring expenditures on medicines.

The World Bank and the IDB have been transformed into two major players in the public provision of medicines through the PMSS, which contributed from both sources 56 percent of the MOH medicine budget in 2002 and 86 percent of the budget contributed by outside sources. In addition to the funds to purchase medicines and medical supplies, the PMSS pays the operating expenses of the SAAS and expenses for contracting third parties in FONMAT, as described later.

Another large-scale initiative funded by the PMSS is the Ministry of Health Information System (Sistema de Información de Ministeria de Salud; SIMINSA). In early 2002, this information system started the installation of software on computers purchased with PMSS funds at pilot SILAIS. The flow of information to the central level already provides some consolidated data that makes decision making possible. Specifically, the supply module provides, among other things, information about consumption, inventory, income, and prices. The employees interviewed in the hospitals visited said the system is useful. However, informants from peripheral areas believe it is too complex to be handled in the health units. We will have to wait, however, for its full operation to assess its functionality and impact on the supply system.

The European Union, through the medicine component of its Project to Strengthen the Health System in Nicaragua, planned 2 million euros to be spent in three years. The coverage of the project is for the Matagalpa, Jinotega, Río San Juan, and RAAN SILAIS, which together have 25 percent of the country's population (PFSS, 2000).

The PROSILAIS project, which operates with funds from the Swedish International Development Cooperation Agency (Sida) and is technically supported by PAHO, supports six SILAIS (57 municipalities). Its work areas are children and women; therefore, its pharmaceutical demands are oriented toward care for these groups. Purchases for this project are made through the PAHO purchasing mechanism, but the needs are planned in accordance with the DNIM and PAHO. Medicines are brought to the country through PAHO mechanisms and placed in the CIPS warehouse.

The BASICS Project began its activities in Matagalpa and Jinotega but is currently working through the bilateral project of USAID PROSALUD, NGOs supported by USAID that comprise NICASALUD, and through private volunteer organizations (PVOs) that receive Title II funds. BASICS does not buy medicines, although some of its partner PVOs do so with other funds. Financial funds for the BASICS mission are planned to conclude in September 2002 (personal communication, David McCarthy).

The PROSALUD project, funded by USAID/Nicaragua, covers three SILAIS and 12 municipalities (4 in Jinotega, 6 in Matagalpa, and 2 in Boaco). Although it does not cover hospitals, there are 50 health units in these areas. The project does not cover pharmaceuticals, but at times, it receives donations in kind from the U.S. government and supports their distribution (personal communication, Dr. Alba Luz Solórzano).

Project HOPE, in contrast, donates medicines (in kind) to the MOH. Its coverage is mostly hospital related to strengthen the hospitals of Estela, Matagalpa, Boaco, and Chontales. There is also a primary health and child survival component. In 2000, about USD 5 million in products were donated between June and December. For 2002, Project HOPE donated USD 10 million in kind to the MOH. This amount is the value of the products on the North American market. Normally, the CIPS revalues the products according to the Nicaraguan market when it enters them in its warehouses. Donations can have two origins: (a) A donation of specific products that Project HOPE obtains in the United States is offered to the MOH, and if the latter accepts it, the products are brought to the country. (b) When the MOH expressly requests an item, the project requests it from the donor (personal communication, Ing. Francisco Torres, Country Director,

Project HOPE, Nicaragua, July 19, 2002). During 2002 (until July 2001) donated medicines valued at USD 3 million were imported. These medicines are received by the MOH and distributed through the CIPS (personal communication, Ing. Francisco Torres, Country Director, Project HOPE).

NICASALUD is a consortium of NGOs and PVOs that receives some funding from USAID/Nicaragua. This consortium was formed to channel funds dedicated to health programs in a more rational manner, promote collaboration between them, and avoid duplication of activities.

Japanese Cooperation is one of the biggest contributors of medicines and supplies in the form of donations in kind. Its cooperation is purely a donation and does not require reimbursement by the country. Pharmaceuticals are purchased from Japanese vendors. In general, they ask the MOH to plan needs, particularly in relation to IMCI, and through bidding in Japan, they obtain the products, which are brought to the country and stored by the CIPS.

The donations are normally converted to the value of similar products on the national market to avoid distortion in the value of the products received when counting the inventory. The CIPS staff reports that they do check donations and that their value enters the inventory. However, donations that arrive directly at the less-complex health facilities are not entered in their records (DELIVER, 2002). It appears that the SILAIS fear that if a record is kept of the value of this donation, the amount will be deducted from their budget allocation (Fixed Fund). With regard to these donations, no records are kept at the central level.

Private, Nonprofit Sector

Through different mechanisms, technical cooperation agencies and private nonprofit organizations have seen the need to develop a mechanism for medicine and supply distribution to the populations they serve. This has occurred in response to the need to have otherwise scarce quality medical resources reach the public at an acceptable price for its income level and to generate sufficient funds to buy the product and have it available.

The European Union's PFSS and PROSILAIS have attempted to support the existence of community medicine chests or pharmacies. The PFSS commissioned a study on the feasibility of a "Community Medicine Sales" (VSM in Spanish) facility (Quintón, S., Arauz L., 2000), but because of internal decisions and fund usage priorities, this project has not been implemented.

Since 1996, 20 nonprofit NGOs and 150 local projects formed COIME (an association of NGOs that conduct activities involving medicines) with the objective of promoting community alternatives for medicine supply. These projects have been united under the concept of "Community Medicine Sales." They currently include a network of approximately 300 nonprofit facilities, also known as Community Pharmacies, with coverage estimated at 500,000 inhabitants.

According to PFSS staff, one of the NGOs, the PROSALUD-Darío Association, has a warehouse for medical supplies that meets most technical storage criteria and an adequate record and control system. This appears to be the NGO that has advanced most in its purchasing negotiations and made a joint purchase with four other NGOs in 2001. This purchase made it possible to supply a total of 23 Community Pharmacies in remote locations of Matagalpa, Jinotega, Río San Juan, and RAAN. Twelve of these pharmacies belong to the PROSALUD-Darío Network and the 11 others to NGOs and organizations that dispense medicines under the same criteria.

Currently, legal provisions that appear to impede extension of the community medicine sales are being challenged. Although the definition of pharmaceutical facilities (Law 292, Title V, Chapter I, Article 59) contemplated only pharmacies and medicine sales posts, Article 54, Chapter VIII of the Regulation of Law 292 (Decree 6-99, 1999, p. 580) authorizes *“the opening and operation of medicine distribution facilities of nonprofit social projects, located in unstable urban areas where there are no facilities and in rural areas, authorized by the departmental pharmacy headquarters of the corresponding SILAIS, in coordination with the DNIM.”* This could be sufficient legal grounds for the operation of the VSMs or community pharmacies. However, because they are considered “pharmacies” and the discretion in the interpretation of the regulation lies with the SILAIS officials as to which pharmaceutical facilities can be authorized, there have been problems establishing this type of facility in some places. The primary obstacle is that each one of these community pharmacies is required to have a full-time managing pharmacist for the periods the facility is open. This appears to be impossible given the small scale of these facilities, which would have trouble generating sufficient funds to cover the wages required by law to pay one pharmacist per facility. One possibility, which must be explored, is shared management, that is, using one pharmaceutical professional for a determined number of community facilities. This would make it possible to guarantee supervision of the activities of the staff of these facilities, the quality of the products, and their manner of storage, distribution, and delivery to patients according to established standards. A pharmacist does not have to remain at a facility all day or always be the professional who delivers the products.

On the other hand, interpretations by regulatory officials at the MOH central level about modification of Article 9 of the regulations of Law 292 have contributed to limiting the expansion of the VSMs. The staff interviewed reported that because the officials believe that the community sales are supplied through donations of medicine, they should not be sold using revolving funds. However, the VSMs are actually supplied with medicines through purchases from mostly national vendors. Given the importance of their function in concentrating on marginalized populations, both geographically and economically, it is important to disseminate information on how these sales work to prevent legal repercussions that could affect their operation. This erroneous perception of how these facilities are supplied appears to have limited the financial and political support of the outside cooperation projects and contributed to the existence of opposition within the MOH to this initiative.

Local Distributors and Producers

The country has approximately 22 national medicine production laboratories. Their market is basically commercial pharmacies and sales posts, as well as NGOs, but they do not participate in MOH bids because they consider themselves disadvantaged vis-à-vis importers.

There are 83 importation and distribution companies for pharmaceutical products and medical supplies manufactured abroad. Both—producers and importers—distribute their products through a network of pharmacies and over-the-counter points of sale. As recorded in the Pharmacy Office Registry, there were about 1,115 authorized pharmacies in the year 2000 (MOH, Baseline, 2001b). Although there is no record of points of sale, at least one medicine point of sale is estimated for every 3,261 inhabitants in the country.

As of late 2001, there were 12,564 registered products, but products with expired health registrations had not been removed from the MOH Registry and Control database and many products were registered that were not being sold. The following table shows the rapid increase in the registration of medicines since the early 1990s. However, a number of products are still sold without being registered, as the baseline study of the MOH (MOH 2001b) confirmed in its survey of pharmaceutical facilities (17 percent of products not registered). Table 9 also makes it possible to identify a slight trend toward an increase in generic medicines on the market.

Table 9. Evolution of the Medicine Registry

Indicator	1993	1994	1995	1996	1997	1998	1999
Total number of pharmaceutical products registered	2,061	3,241	4,266	5,261	7,529	9,282	10,585
% brand-name medicines	87.28	84.01	80.89	80.93	71.20	74.04	74.08
% generic medicines	12.72	15.99	19.11	19.07	28.8	25.96	25.92

Source: Budget, Planning, Medicine Regulation and Accreditation Offices of the Ministry of Health.

ANDIPROFA is a group of 25 distributors that covers about 90 percent of the pharmaceutical market in Nicaragua (personal communication, Ing. Jorge Arias, ANDIPROFA). The member distributors of ANDIPROFA are also the largest vendors to the MOH. It is probable that the bidding requirements dissuade small producers, which prefer to sell their products on the private market. In fact, only 14 percent of the products included on the Basic List of Medicines (Nicaragua, LBM, 2001) are manufactured in the country (MOH, Baseline 2001b). The following table shows the progressive increase in the importation of pharmaceuticals.

Table 10. Value of Pharmaceutical Imports to Nicaragua, 1991–2000

Year	Thousands of Córdoba
1991	24,044
1992	32,785
1993	20,975
1994	31,012
1995	30,307
1996	51,595
1997	47,470
1998	49,591
1999	74,930
2000	61,782

Source: Sieca. Nicaragua: Importation of the top 10 products, http://www.sieca.org.gt/publico/CA_en_cifras/

The growth potential of the private pharmaceuticals market in the next few years is higher, in real terms, as public funds decrease. Emergency purchases and different bidding procedures and requirements are factors that add to the complex nature of establishing commercial relations with the public sector. For example, the emergency in early 2002 required vendors to deliver products 15 days after signing the contract (personal communication, ANDIPROFA). This discouraged participation in bidding, apart from a group of vendors who did not want to participate because they were owed money from a prior MOH purchase in late 2000.

MOH employees note that inefficiencies on the vendors' side also contribute to the system's supply shortage. Noncompliance of some vendors has been observed in the delivery of products at the contracted times. However, vendors argue that the reduced Nicaraguan pharmaceutical market prevents maintaining high volumes of medicines *in place*. They must be requested from the pharmaceutical company, which frequently does not have them available immediately either. On average, between 60 and 90 days are required to be able to make the delivery.

Likewise, MOH employees note that challenges from the industry are frequently improper and cause stock-outs. According to representatives of the pharmaceutical industry, the bidding in early 2001 was challenged for almost all items on the absence of technical criteria stipulated in the contract award. Since then, some challenges have been made, but they have been of specific items; therefore, they have not stopped the entire bidding process.

Private distributors argue that the prices they offer to the MOH are preferential because when they sell the government the majority of their products, the foreign pharmaceutical company places the products at a lower price than when they are offered to the private market. It was reported that the importer or distributor charges 1 to 10 percent for administrative expenses when it sells to the MOH (personal communication, Ing. Jorge Arias, ANDIPROFA).

Despite the negotiation difficulties of past years, a genuine interest is seen in the group of importers and distributors in continuing to expand their medicine market with the MOH. The same situation is not seen from the perspective of the national producers. Because they perceive that the system puts them at a competitive disadvantage, they do not enter the MOH purchasing processes.

At times, representatives of laboratories have a distribution company as a second investment, but not exclusively for its commercial companies. For distribution to the private network, distribution companies work as "intermediate distributors," to which import or manufacturing companies offer products at a specific price so they can offer and sell to the regions they serve. In parallel, importers and producers also have a small contingent of vendors specific to their companies that sell directly to the commercial pharmacies. If the customer is recruited by the distributor, the price is the one the distributor offers it. If it is recruited by the company's vendor, the importer or producer decides how to send the product to the location. They assume the costs of the distribution and any losses. On occasions, distributors belong to the same business group that operates a laboratory or importer. Distributors have sales agents in certain regions, and if they make the sale, the commission is theirs. In general, for urban areas, area distributors are used, and for remote areas, they contract the Nicaraguan Post Office. On occasions, they contract the distribution to private transportation companies (not necessarily specialized in pharmaceuticals) when the distribution is to public facilities.

DISCUSSION AND RECOMMENDATIONS

The acute pharmaceutical supply shortage in the first half of 2002 was the result of a convergence of problems afflicting the supply system and giving rise to the lack of large purchases in 2001. However, its complexity should not conceal the central problems of the MOH supply system and its effect on the population's access to medicines. Some of these problems are summarized below—

- Regular treasury funds are insufficient to cover even essential medicines, and there are no prospects for improvement of tax income in the short and medium term.
- Pharmaceutical procurement depends on over 50 percent outside funding whose availability depends greatly on donations. The loans that are funding the bulk of the medicine procurement will end about 2004, the disbursement period of current projects, if they are not renewed.
- More efficient use of financial resources that could be achieved through technical improvements in the planning, procurement and distribution, and stock management processes may be significant but insufficient to cover the gap that will be left by the decrease in treasury funds and the exhaustion of the funds from loans and donations.
- There are no defined plans to resolve the financial problems the MOH will face for the continued supply of pharmaceuticals.

Each of the supply phases analyzed presents current or potential future problems that can be affected by interventions. The RPM Plus consulting team believes, however, that the biggest current and future problem is insufficient financial resources to purchase medicines.

The following graphs present the current and projected situation of public funding of pharmaceuticals with three different assumptions about the population of the country to be covered. In all the graphs, the total budget required to supply the medicine requirements has been estimated according to the parameters used by MOH employees and stated by the Minister of Health in her speech to the Assembly Health Committee in July 2002, that is, assuming a very conservative figure of USD 5 per inhabitant per year of medicine. The difference is that in the first graph (Figure 8), it has been assumed that the MOH coverage is 100 percent, in the second graph (Figure 9) that the MOH coverage is 80 percent of the population, and in the third (Figure 10) that the coverage is 60 percent of the population of Nicaragua.

The amounts used correspond to the allocated budgets reported in official reports of the MOH up to 2002. The 2003–2005 budgets were projected based on the average annual growth of 2000, 2001, and 2002, equal to negative growth of **–5 percent** per year (in the year's dollars).

As can be seen, the proportion of funds from loans and donations to fund the recurrent expenditures on medicines has increased to more than 50 percent of the public expenditure on medicines in 2001 and 2002. The main projects (IDB and WB) will end their disbursements in

2003 and 2004; therefore, conservatively, a 50 percent reduction of these funds is estimated for 2004 and an additional 50 percent (of the balance) for 2005. A “0” reduction was not considered, given the possibility of cooperation funds coming from other sources. This was common to the three graphs.

Also common to the graphs was the estimate that optimized use of public funds (with the assumption that the suggested interventions are implemented) could represent the release of MOH funds (savings) on the order of 20 percent in 2003, 5 percent more in 2004, and another 5 percent in 2005 (total of 30 percent in the three years). If these theories are plausible and acceptable, the gap between the treasury fund and cooperation funds in 2005 to cover the needs of the **entire** population (Figure 8) would be USD 22 million, and optimized use of the public funds would be 7 percent of this amount (USD 1.6 million).

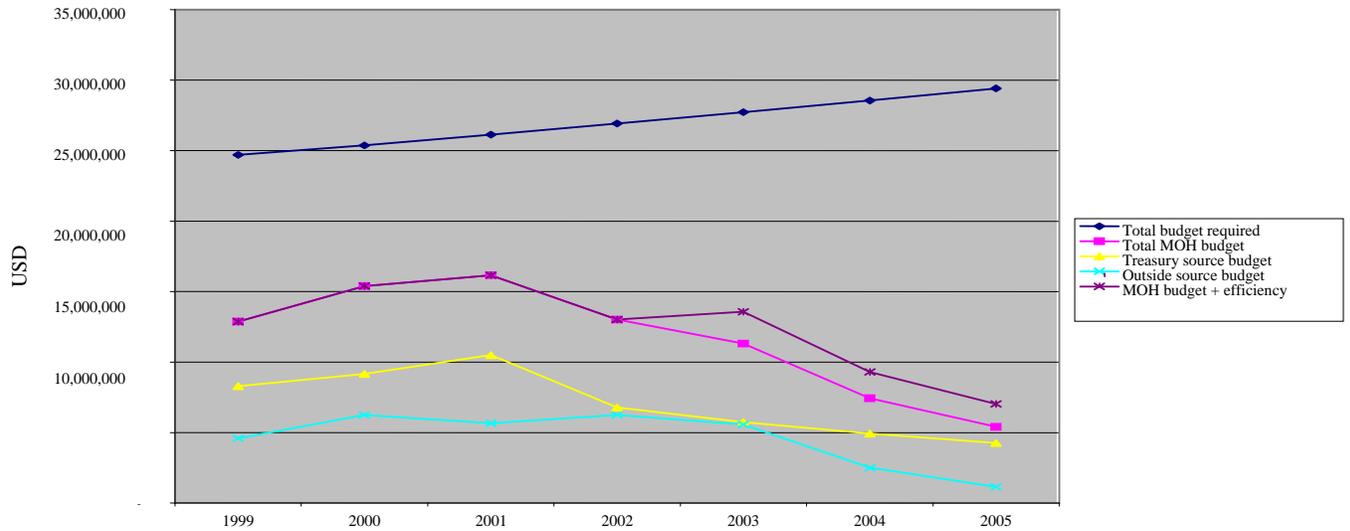
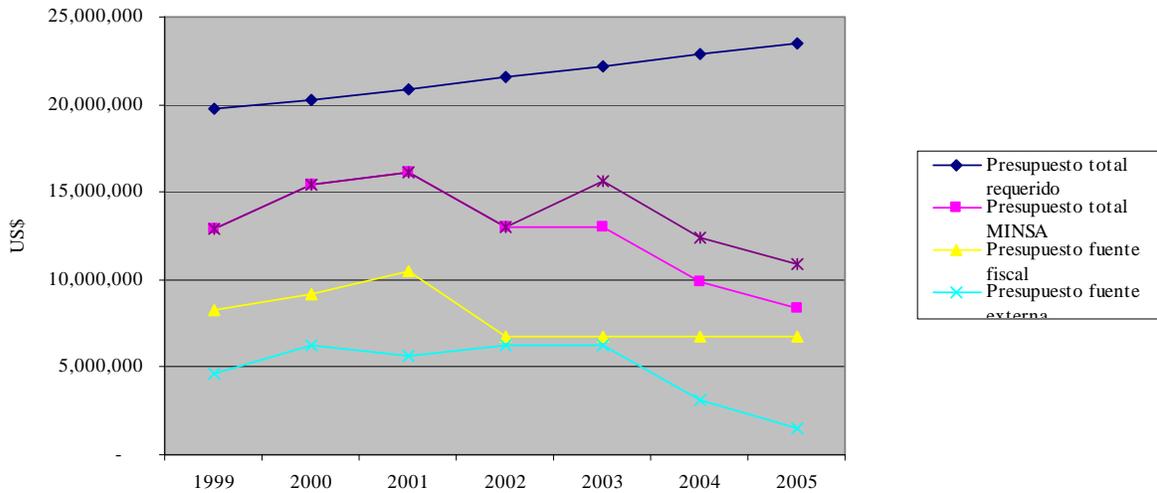


Figure 8. Medicine Budget, 100% Population Coverage, 1999–2005

If the exercise is repeated, but expecting to cover 80 percent of the population, the gap between the funds available and the requirements would be USD 12.7 million, and optimized use of the public funds would cover 19 percent of this amount, but the rest would still not be covered (Figure 9).



[Key: blue = Total budget required, pink = Total MOH budget, yellow = Treasury source budget, aqua = Outside source budget]

Figure 9. Medicine Budget, 80% Population Coverage, 1999–2005

If the estimate is made with 60 percent coverage, the gap between the budget available and that necessary would be reduced to USD 10.6 million, but even so, the optimized use of public funds would cover only 15 percent of this gap (Figure 10).

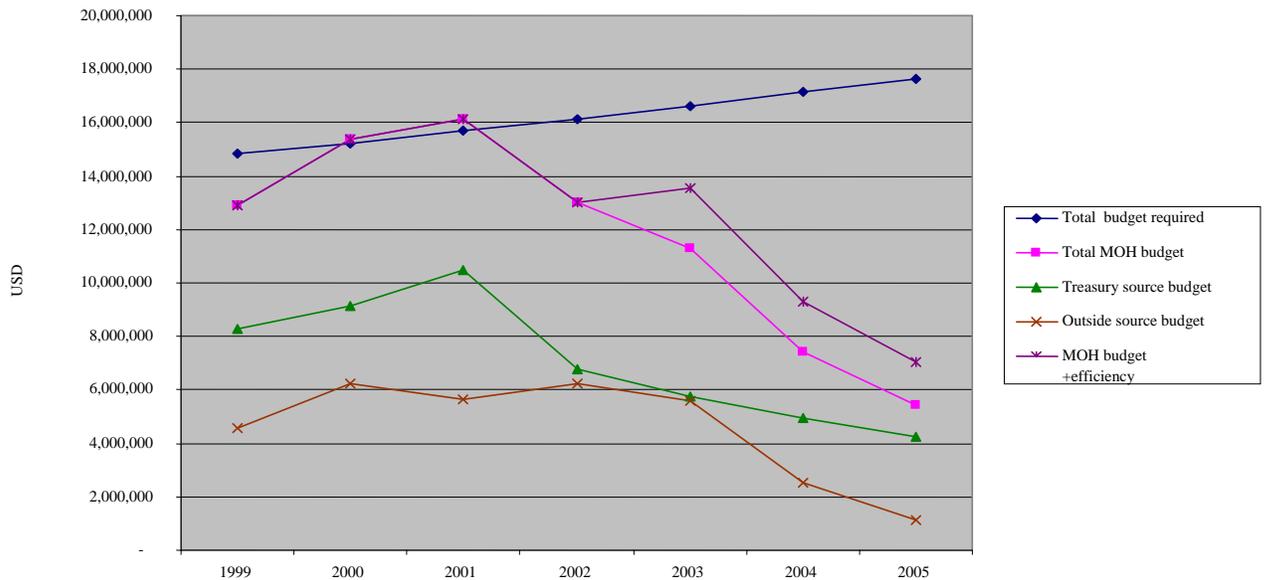


Figure 10. Medicine Budget, 60% Population Coverage, 1999–2005

Although predictable, the problem of scarce availability of funding and its intensification once the funds from outside cooperation projects are exhausted has not been receiving attention overall from the technical or political levels, possibly because of the intensification of the supply shortage and the need to take short-term actions. The predicted financial crisis can hardly be addressed with an increase in treasury funds. It is important, then, for the government to fulfill its governance role to optimize the use of the out-of-pocket funds that the citizens already dedicate to purchasing medicines.

In this sense, one must keep in mind that insufficient public funds have created de facto privatization of procurement of medicine. The real *privatization* arises from the fact that people now spend more out of pocket. Therefore, public intervention in private for-profit and nonprofit markets to increase the return from the funds that the population is already spending to purchase medicines is more than justified.

The problems presented separately in the previous sections are presented together in the diagram in Annex 7, which attempts to establish a priority order between past, present, and potential problems.

The alternative solutions, which are presented below, emphasize interventions that make it possible to address the problem of the access of the neediest population to medicine, in addition to presenting alternatives to ensure present and future funding through sustainable mechanisms. However, interventions are also considered in the areas of procurement, storage, and distribution that can optimize the use of the scarce public funds.

Improvements in Access to the Private Nonprofit Market

In this case, the role of the MOH is to head up the establishment of a legal and regulatory framework that permits the development of stores that sell essential medicines at a low cost and with assured quality.

Mechanisms that could be favored with regulations follow—

1. Essential medicines stores: These may be—

- **Nonprofit:** A variety of possibilities exist, which have already been tested or are being tested in various countries. Among the nonprofit programs, we have the example of Community Sales in Nicaragua, the Medicine Accessibility Program (Programa de Accesibilidad a los Medicamentos; PROAM) in Guatemala, the PRO-VIDA Medicine Service in Peru, and Essential Medical Supplies (Insumos Médicos Esenciales; IME) in Bolivia.
- **For profit:** These are in the form of chains of pharmacies and franchises. The chains belong to the same owner. One example of these is the Pro-familia chain of pharmacies of the Salvadoran Demographic Association, which has begun to establish these pharmacies to ensure the sustainability of its reproductive health services.

Franchises are being tested in other contexts, although there are still no results on their effect in terms of ensuring that needy populations have access to medicines. The Strengthening Health Enterprises Foundation in Kenya and the Ghana Social Marketing Foundation in Ghana are two examples that are currently being developed.

Some aspects that any of these alternatives must consider are—

- **Pharmaceutical management:** The objective of having a pharmaceutical professional in any of these models is to ensure the quality of the system; specifications of the products; appropriate storage and dispensing; and adequate patient education. However, a variety of models can be considered for facilities in remote areas and with little possibility of generating income. Pharmaceutical management can be established for a determined number of facilities in rural areas (10–20). This way, the pharmacist does not stay at a single facility during all service hours but rather oversees the quality of the pharmaceutical management in these facilities, provides staff training, ensures the quality of dispensing, and monitors storage and inventory control.
- **Mechanism to procure products with assured quality and affordable prices:** It is necessary for any of the modes selected to have technical and financial support that enables it to purchase safe, effective, and low-cost products. If the prices obtained are not low, it will merely replicate the commercial pharmacies' model of passing along the operating and purchase costs to the patients to maintain the service.
- **Service quality assurance mechanism (Good Dispensing Practices):** This component has to be in the design of any of the alternatives to bring low-cost medicines to the needy population. Otherwise, the credibility of the services and products would be diminished, leading to the failure of the strategy.
- **Self-sustainability:** In addition to appropriate procurement mechanisms, an important aspect is for these initiatives to use a financial system that enables them to regenerate the investment that is made. The sustainability of these mechanisms depends on having both funding and technical staff trained in improving the operating mechanisms and pharmaceutical management on all levels.

Taking these aspects into account for Nicaragua, the following recommendations should be considered.

Regulation of Pharmacies with a Social Function

In the short term, it is necessary to clarify, and if necessary amend, the regulation of the Medicines and Pharmacies Act to permit the operation of community pharmacies for social purposes managed by trained staff. These pharmacies would operate with a social function, be nonprofit, and use the revolving fund mode, which enables them to maintain sufficient funds to replace their stock and fund their operating costs. In the style of social projects that currently have community pharmacies or community medicine sales, they must have oversight mechanisms to ensure rational pharmaceutical management.

Law 292 has no provisions regarding the need for pharmaceutical management of community-project type facilities. Given the operating scale of these facilities, it is very difficult for them to have a full-time pharmaceutical manager, as the law requires. Senior officials at the MOH must consider the feasibility of these facilities being able to comply with Article 60, which is applicable to MOH facilities (of the same Chapter VIII of the legal regulation). This article permits the MOH, in performance of its programs by level of care, to authorize duly trained assistant health care personnel to **manage and sell** pharmaceuticals in locations where there are no health care professionals with a university degree. One more option is for NGOs to be able to have one pharmaceutical manager for a certain number of community pharmacies who can guarantee the operation of the community pharmacies or VSMs and the work quality of the trained, nonprofessional staff.

This team suggests that the existence of community pharmacy or VSM-type initiatives be made viable, which can fill the vacuum caused by the lack of resources of the MOH to provide pharmaceuticals to the population that lacks resources to be able to purchase them on the private market. Moreover, this possibility would increase the market of the national production industry and of the importers, adding consumers who do not participate (or partially participate by buying incomplete treatments) in the market at this time because of a lack of money.

An additional use of outside cooperation funds could be providing investment funds for “seed money” to start new community pharmacies. This would allow areas where there are currently no community pharmacies to benefit from support in organization, development of operating plans, adequate training on pharmaceutical management and dispensing practices, as well as adequate training in management skills, which would enable them to make the facilities sustainable.

Support for Mechanisms to Procure Safe, Low-Price, Quality Medicines for Community Pharmacies

The regulatory capacity of the MOH could be used to establish access mechanisms through social programs that reduce the prices of medicines in the private nonprofit sector. If at a given time, the MOH assumes its governance role and becomes the principal price negotiator, it could provide the opportunity for community pharmacies to unite to benefit from these purchase prices. The Guatemalan government currently uses one example of this type of strategy in the Medicine Accessibility Program (PROAM), which utilizes government mechanisms that affect Social Security, the Ministry of Health, and Armed Forces Health, such as open contracting of prices for a determined volume. PROAM benefits from this open contract and places its supply orders through a revolving fund for community sale pharmacies, which operate in the different health facilities in the country and in areas where there are no formal service providers.

The inclusion of NGO community pharmacies in MOH quantifications will involve a potentially larger volume of purchases, which may reduce even further the prices obtained by the MOH. The economy of scale would result in lower-priced medicines for all parties. This could be attacked by the private sector, by claiming unfair competition, but insofar as the regulation of these facilities considers their nonprofit nature, their location at remote and neglected sites, and a list

of medicines restricted to essential medicines, their areas of operation would be clearly differentiated.

If the MOH in Nicaragua decides to use its governance role to push these types of programs, savings of up to 40 percent of the price of the medicine on the private market could be generated for families (conservative estimate based on the PROAM report, which has documented up to 50 percent savings compared with private pharmacy prices). Thus, the funds that the population of quintiles 1 and 2 would save on medicine purchases would be on average USD 7.40 per family per year. These funds could be used to purchase food, or alternatively to purchase medicine, with which the average spending on medicine of families in quintiles 1 and 2 would reach USD 26 per family, or approximately USD 4.80 per capita per year. Table 11 shows the details of this calculation.

Table 11. Health and Medicine Expenses (USD), by Income Quintiles

Quintiles	1	2	3	4	5
Annual family consumption	875.66	1,539.48	2,260.21	3,327.86	8,419.03
Annual family medical services expenditures	54.38	74.66	115.27	139.77	326.66
Annual family medicine expenditures	12.74	24.34	34.94	52.90	111.13
Average spending on medicines Q 1 and 2	18.54				
Spending on medicines as % of medical services	23%	33%	30%	38%	34%
Spending on medicines as % of annual family consumption	1%	2%	2%	2%	1%
Annual per capita expense	2.36	4.51	6.47	9.80	20.58
Savings on medicines if price is reduced 40%	5.10	9.74	13.98	21.16	44.45
Average Q 1 and 2 savings (poorest 40% of population)	7.42				
Potential spending capacity (total spending + Q 1 and 2 savings of)	25.96				
Total potential per capita annual spending	4.81				

Sources: Estimates based on data from INEC (National Institute of Statistics and Census), government of Nicaragua; Profile and Characteristics of the Poorest Populations in Nicaragua (National Household Income and Expenses Survey 1998–1999); Mecovi Project, UNDP/NIC/98/004 Project, February 2001.

If the MOH establishes that this mechanism is not possible, organizations that decide to establish community pharmacy facilities will have to form a team to be a purchasing unit, so that it can consolidate the needs of these types of facilities. This can provide savings to the participant institutions in the absence of other supply channels.

Given the legality of its existence, this central team would be able to receive technical support support from the international community in developing plans and mechanisms that enable it to work efficiently and use technically reliable mechanisms to carry out this work. Outside cooperation funds would make it possible to technically reinforce procurement consolidation efforts between the cooperating organizations, their projects, and NGOs. This appears to be a

more sustainable use of the additional funds that flow into the country, compared with the present recurrent expenditures for medicines to which they are being directed.

Examples of this type of program, which operate in parallel to the services that the MOH can provide, are the Pro-Vida Pharmaceuticals Service of Pastoral Health of the Episcopal Conference of Peru, and the Essential Medical Supplies (IME) group in Bolivia. Pro-Vida maintains a technical center that ensures provision of a reduced number of essential medicines to supply 3,600 stores of community groups throughout Peru, especially in the most remote areas of the Sierra and Amazonía. Both IME and Pro-Vida obtain medicines through international bidding and finance procurement through revolving funds from the sale of medicines in each pharmacy of the system. In the case of Pro-Vida, not all stores have a managing pharmacist, but there are requirements for opening a store in the system, which include training the staff on the management of medicines (storage, stock management, requirements for specific medicines), training to be able to resolve primary health care issues, in dispensing, and to provide patient education, among other things. Pro-Vida has developed its specific treatment formula for health promoters and has training modules that the MOH has also used in its institutional pharmacies under shared management with the community.

Mechanism to Reduce Prices in Health Unit Franchise Pharmacies

Another strategy to improve the population's access to medicines is to develop mechanisms that enable private pharmacies that currently have franchises in hospitals and health centers to be able to obtain preferential prices and thus get medicine to the public at a lower price. Acting in its governance role, the MOH can achieve this by entering into a contract with these pharmacies so that the prices of the products to be sold in there are negotiated with the group of products that the MOH would negotiate (if it adopts the mechanisms suggested below for its supply system). This way, the pharmacies that operate in hospitals would be supplied through the MOH Purchasing Unit and would operate in the revolving fund mode. However, their income would be limited to a profit margin for operating expenses and a lower margin to generate income to create a common fund for making medicine available to the indigenous population.

An important aspect is obtaining the approval of the administration of hospitals and health centers so they do not continue to see these pharmacies as a source of income to cover personnel and other expenses they currently finance through the earnings margin shared with the pharmacies under contract. For these purposes, separate mechanisms must be analyzed that do not place the entire responsibility for generating income to maintain and operate the hospital on a price increase in medicines. An alternative to supply through the MOH Purchasing Unit is for these pharmacies to organize to make joint purchases. While the feasibility of any of these mechanisms is being assessed, the need to make the legal modifications necessary for their operation must be considered.

MOH Procurement Process for Medicines and Medical Supplies

Various strategies are presented here for official consideration with the objective of increasing the efficiency of the financial resources available for medical supplies in MOH facilities. In the

first place, any decision that is made will have to be consistent with the policy of the new role of the MOH as a governance entity as set forth in the Health Law and with a long-term view.

Early negotiation with the Treasury and Legislative Assembly so that inflation and the buying power of the currency are considered in the budget allocation for the year 2003 is essential to improve somewhat the lack of treasury funds. Although the percentage of the public budget intended for health and the pharmaceutical budget in relation to MOH health expenditures is comparable to that of other countries, the financial problem arises more from an insufficient budget ceiling than from an imbalanced allocation between departments or inside the MOH. The economic growth of the country in previous years suggests that it will be very difficult to increase the budget significantly for 2003.

Centralized Price Negotiation with Decentralized Purchase Orders

One of the financial problems the MOH currently faces is that the allocated funds (both treasury and cooperation) are not available at the same time and are disbursed throughout the year. It is not possible to change this situation. Therefore, it is suggested that instead of procurement bids that require immediate payment upon delivery, thereby restricting the purchase to the amount of the budget immediately available, bidding be conducted to negotiate prices only and that these prices be maintained for a minimum of one year. In this way, facilities could place their purchase orders directly with the vendors awarded the contracts when they need products. This type of bidding is covered by Law 323 on Government Contracts.

For price bidding, it is necessary to have an estimate of the volume needed. Generally, it can be negotiated as a range within which the purchase will vary during the year, but the vendors will have to rely on the minimum needs estimated to adjust their production, importation, and operating expenses. If this estimate is not adequate initially, it can be adjusted the next year based on the actual consumption plus an adjustment for potential consumption if there are sufficient financial resources.

The implementation of this system would also benefit vendors because they would have the opportunity to schedule better their raw materials purchases or imports for production. It would facilitate importers having products in the country when they are requested. Because the price would be negotiated for a minimum purchase volume of each product, if the units require more than what is established, the demand for the vendor does not become unsustainable because the orders would be distributed throughout the year, unlike now, where the purchase volume is required 45–60 days after winning the award. This operation would be like private pharmacies requesting small orders to meet their needs, but the purchase would be made based on the price negotiated in advance by the central level. In the same way, funds from special projects would be used for the purchase when they are released, but the purchase prices would be those negotiated by the MOH.

Agencies cooperating with their projects would continue to have their outlays at the times permitted by their management, but the purchase scheduling needs would already have been consolidated when the price bidding was conducted. In this way, they can place purchase orders at the agreed upon price when their funds are released.

Methods to Consider to Reduce the Costs of the Supply System

The following alternatives are discussed—

- Adoption of a procurement model with direct delivery
- Adoption of a prime vendor model
- Maintenance of the current procurement and distribution model (MOH/CIPS)

Adoption of a Procurement Model with Direct Delivery of Products to the Facility

During this consultation, we could not perform a detailed analysis of the costs of the procurement and distribution system, taking into account not only purchase prices but also operating costs. The MOH is obtaining better medicine procurement prices than those obtained in the purchases through the SAAS, but the prices obtained by SAAS already include delivery of the product to that facility.

It is clear that the MOH needs to make a decision with regard to continuing its regular procurement system, which involves placing the product in the CIPS warehouse. If the MOH believes that it does not have sufficient information to make decisions, it must request a detailed cost analysis of both models immediately. Based on this, the MOH could decide to include in its bidding specifications prices that include placement of the product at the health unit.

Adoption of a Prime Vendor Model

The MOH can use the Prime Vendor system to prevent each health facility's pharmacy manager from having to place orders with each of the vendors awarded contracts in price bidding. Centralizing orders so that a company with good logistical management can be responsible for channeling orders to vendors, organizing orders to be sent to their final destination, and taking charge of distribution would save the system time and money. This will require clearly defining the role of a Prime Vendor to make contracts in open bidding.

Another benefit of contracting a Prime Vendor is that it could be responsible for the distribution of donated pharmaceuticals and supplies. They are the largest volume of products that the CIPS currently handles and have the greatest potential for expiring and increasing the stock management cost. With a Prime Vendor, donated products would reach the facilities almost immediately, with no need to store them for long periods.

The company that is contracted for this function must also implement a logistics information system that enables MOH officials and the health units to assess their medicine availability situation. This system would also work for donations.

Outside cooperation funds can be used to provide technical support to the MOH to establish the terms and specifications of this bidding and to provide technical support to the selected Prime Vendor in beginning its activities.

It is necessary to analyze the viability of this model, assessing the real capacity of some companies in the private sector to provide this service and the interest in openly competing to perform these functions. Potential bidders on the services can come from the group of pharmaceutical products distributors or from the companies that handle the distribution of products from foreign companies not related to pharmaceuticals, which could adapt their systems to accommodate handling pharmaceutical products. The Nicaraguan Post Office could be one of the companies to compete, since it now appears to play a major role in the distribution of pharmaceutical products, according to the information gathered from members of ANDIPROFA. However, all companies that carry out distribution work must adapt their operations capacity to handle pharmaceutical products, which may require refrigeration, and improve their capacities related to inventory management systems and information systems that permit modern logistical management, with no further use of warehouses.

Maintenance of the Current Procurement and Distribution Model (MOH/CIPS)

Following are the necessary improvements in the MOH supply system for any of the alternatives decided upon, and all the more if increasing efficiency of its management is to be attempted.

Technical Support at the MOH Central and Local Levels to Improve the Planning/Estimation of Medicine and Medical Supply Requirements

The central and local level staff of the MOH who participate in planning requirements can benefit from technical advice to improve their quantification system. The MOH must initially decide on limiting the products that it intends to provide according to the types of care it will consider as a priority. This will require finding substitutes for products used in treating less frequent diseases.

The new decentralized purchase order method will permit planning in the future based on the actual adjusted consumption of the facilities. Thus, it will not be necessary to plan distribution of products through a fixed monthly fund because the health units will be requesting what they actually need to cover their requirements for one or two months. The decentralized purchase order has the advantage that health facilities request only what they need, avoiding the distribution of medicines they do not need just because they are in the fixed fund, and avoiding inventory management at the SILAIS warehouses. At the same time, it would limit losses caused by expiration of medicines that may remain at the facility without being used.

To complement the planning of needs, it would be advisable to support the DNIM in performing its national physical stock count at the CIPS, SILAIS or municipal warehouses, and hospitals. This would provide better information to the central level, allowing the exchange products, immediate delivery of products to facilities that could use them before their expiration, and deduction of stock that has not expired from the necessary planning. If these data are actually available, it would be necessary to develop the technical skills that enable decision making at different times of the year and to develop a systematic program that enables these mechanisms to become part of the regular activities of the pharmaceutical coordinators at SILAIS and the central level.

Purchase of Specific Products through Cooperation Agencies

Purchases through national bidding must not be the only alternative for acquiring medicines. Some products for purchase can be acquired on international markets through cooperation agencies (PAHO for antimalarials or antituberculosis medicines, for example). This will also contribute to a healthy price competition on the local market. The method of combined purchases for several countries has the potential to reduce significantly the price of these supplies whose consumption can be easily projected.

Assessing and Improving the Local Capacity to Manage Stock and Fit Out Warehouses

Regardless of the mechanism the MOH decides to use—direct deliveries, contracting a prime vendor, or continuing with storage and distribution by the CIPS—substantial improvement will be necessary in warehouse management capacities, and in some cases, in the existing infrastructure of the network of MOH warehouses. For this purpose, funds can be used from international credit agencies to improve the infrastructure and from cooperation projects and agencies for training on stock management.

It is to be expected that if the decision falls on direct delivery or contracting a prime vendor, deliveries would be for volumes of medicines for no more than two months. This would somewhat reduce the immediate need to improve the infrastructure. However, it will still be necessary to train or provide refresher training to the staff who have already received training on aspects of stock management because the products will be moving more frequently, without having to be stored at the facility.

Establishing a Quality Assurance Program

Regardless of the procurement and distribution system decided upon, the MOH will need technical advice on design and implementation of a quality assurance program for management of the medicines and supplies that circulate through the system. In the first place, training for the warehouse and pharmacy staff will be required so they can perform their duties in the quality guarantee program. In this sense, they must confirm that deliveries meet technical specifications, verify the quantities of products delivered, and perform an adequate quality inspection of what is delivered.

The program must also establish when corresponding samples should be taken to analyze the quality of the products to enter the system. This can include taking systematic samples at vendor warehouses when the order has already been consolidated and is ready to be distributed, in port for importations, or at the Prime Vendor's warehouse (if this mode is implemented) when the orders are consolidated. Once samples have been taken at any of these locations, it is not as important to take samples of the medicines after they arrive at the facilities unless there is a complaint or report of quality issues upon receipt. However, medicines that arrive at the facilities are expected to be rapidly dispensed to patients, which would not leave sufficient time to establish systematic sampling on this level.

Reducing the Operational Capacity of the CIPS to Handle Other Purchases or MOH Supplies Exclusively

Savings on storage and distribution are possible only if one of the systems, in this scenario the CIPS, reduces its scale of operations. Its existence to handle donations may not be justified if a Prime Vendor is contracted, which would be responsible for their immediate distribution. Nor would its role in maintaining emergency stock, because large volumes of medicines would not need to be stored with the new staggered deliveries system. Its role would be maintained only for material or purchases of other types for the MOH, but its operating costs and the scope of its infrastructure would have to be reduced.

The possibility of franchising its role for management of distributions to private companies so that it generates income for the MOH and the current infrastructure is improved can also be analyzed.

Conclusions

After these options are presented to MOH officials, three committees will be formed to analyze the following actions. A summary of the duties of these committees is presented in Table 12. It is hoped that the conclusions these committees reach will determine the activities the MOH needs to perform to make the pertinent decisions.

Table 12. Agreements on the Strategies to Improve Access to Medicines in Nicaragua

Responsibility for Monitoring Agreements: Lic. Pedro Aguilar			
Actions	Time Periods	Coordinator	Participants
Analysis of the possibility of increasing access to medicines through mechanisms of public-private coordination (facilities that provide essential medicines for social purposes)	First organizational meeting and definition of plan of action during the week of 11/25/02	Dr. Canales (Primary Care Level)	Financial Administration, Medical Supply Regulation, Financial Administration [sic], Legal and Pharmacy Departments
Identify needs to evaluate more efficient supply models (procurement, distribution, and storage)	In the next 3 months	Dr. Narvaez (DNIM)	Legal, Financial Administration, and Purchasing Departments, CIPS, Information System, PMSS/SAAS, Quality Control Laboratory, Outside Cooperation and Planning
Parallel Agreement			
Analysis of the complete rules process and functions of the MOH relative to the different selection processes, planning needs, establishing budget and distribution ceilings, which enables improving the efficiency of the internal working procedures of the MOH to ensure that medicines actually reach the health units	Meeting to delegate responsibilities and define a work plan will take place on Monday, November 25	Lic. Pedro Aguilar (Ministry Office Advisor)	DNIM, Pharmacy, Regulation, Information Science, Legal, Health Services Departments?

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