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PROJECT SUMMARY:

THE RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT

A Component of

THE HEALTH FINANCING AND SUSTAINABILITY PROJECT

BACKGROUND

Adequate pharmaceutical supplies are a precondition to the success of most strategies for improving health status in developing countries. Money spent on drugs and other medical supplies is one of the largest expenditures in public sector health systems; only personnel costs are higher. In most cases, pharmaceutical purchases represent the single greatest health-related drain on foreign exchange.

Even so, the resources available for pharmaceutical supplies are seldom equal to needs. In recent years, a number of factors have conspired to constrain ever more severely the financial resources available for these vital commodities. Slow growth or even contraction of economies in developing countries has diminished local capacity to purchase necessary supplies, while population growth and the onslaught of AIDS have dramatically increased demand. In the meantime, the collapse of the Soviet Union, with the urgent needs of its former republics, has increased the claims on donor support.

Any hope of improving health status, or even maintaining current levels, requires using the scarce resources available for pharmaceutical supplies as efficiently as possible. Unfortunately, inefficiency is common in public sector drug supply systems, which reduces the therapeutic benefit of expenditures by as much as fifty per cent. The constraints to effective management are startlingly similar from country to country:

- In many developing countries, systems for licensing and controlling drug products are absent or inadequate, leading to situations where poor quality or even counterfeit products are prevalent, and where unproven and outmoded products are widely marketed.

- The types and quantities of products selected for purchase and use are often poorly matched to epidemiological need. In many cases, expensive drugs are bought and used, when lower cost items would provide the same or greater therapeutic benefit.

- Procurement methods are frequently outmoded; poor planning and the absence of competitive procurement practices constrain cost efficiency. The results are high prices, wastage of resources, and procurement of products which do not meet established standards.

- Public sector logistics systems tend to function inefficiently, plagued by poorly maintained records, inadequate management information, substandard storage facilities, and bottlenecks in distribution. The results are substantial losses from deterioration, expiration, and theft, combined with shortages of frequently used items, and over-stocks of those in low demand.

- Even after reaching clinical facilities, waste continues. Doctors and other care providers frequently manage drugs inappropriately. Common problems include prescribing drugs not justified by diagnosis, prescribing too many drugs, and dispensing drugs in sub-therapeutic doses. In most instances, these prescribers and dispensers lack current unbiased information on the drugs they are using.

- Finally, patients seldom have useful information as to the proper use of the drugs they receive, diminishing still further the chances of good therapeutic results.

PROJECT MISSION

In response to the urgent needs summarized above, the United States Agency for International Development has developed the Rational Pharmaceutical Management project as a component of the Health Financing and Sustainability Project. The RPM will provide a focus for work in the pharmaceutical sector to be carried out by the Office of Health of the Research and Development Bureau (R&D Health).

R&D Health designed the RPM as two separate cooperative agreements to support institutions that will work in close collaboration. The Pharmaceutical Management Cooperative Agreement (C.A.) was awarded under competitive procedures to Management Sciences for Health (MSH) as No. HRN-5974-A-00-2059-00, with the work to be carried out by the Drug Management Program (DMP). The Pharmaceutical Information Cooperative Agreement was awarded to the United States Pharmacopeia (USP) as No. HRN-936-5974-A-00-2052-00.

The mission of the RPM is to enhance sustainability and reduce waste by promoting managerial efficiency and improvements in the allocation and use of resources in pharmaceutical systems. The RPM will employ a carefully selected set of interventions, including:

- Policy dialogue and reform
- Long and short term technical assistance
- Automation of information management
- Specialized training
- Applied research
- Information dissemination

PROJECT CONTENT

The RPM will focus on the following three priority technical areas:

1. Establishing and automating drug registration systems;
2. Rationalizing procurement and inventory management in the public sector; and
3. Expanding drug information resources and promoting rational drug use.

In support of this work, the Pharmaceutical Management Cooperative Agreement will provide:

- Indicator-based assessments of the pharmaceutical sector to be used for setting priorities and planning projects;
- Policy analysis and dialogue to identify areas where policy change will enable sustainable reforms in management systems;
- Long-term and short-term interventions to promote and support managerial reforms in the three priority technical areas;
- Training workshops, in support of technical interventions;
- Adaptation and installation of locally appropriate management information systems for drug registration, procurement and inventory management, drug use analysis, and drug information storage and retrieval;
- Studies and operations research to examine the causes of problems in pharmaceutical management, as well as the impact of interventions aimed at changing inappropriate behavior;
- Communications and social marketing programs aimed at policy makers, health care providers and consumers; and
- Dissemination of information on lessons learned and key issues arising from implementation of technical interventions.

The Pharmaceutical Information Cooperative Agreement will be responsible for:

- Expanding the USP Drug Information data base to include commonly used non-U.S. products, including those found on the WHO Essential Drugs List;
- Adapting USP drug information formats for use in developing countries; and
- Assisting countries in using the USP data base to produce locally appropriate drug information materials.

TECHNICAL ASSISTANCE WITH CORE AND ADD-ON FUNDING

Working through the two cooperative agreements, the RPM will allocate core funding for *long term interventions* in the three priority technical areas identified above. The countries in which the long term interventions will take place will be determined on the basis of formal assessments and deliberations with R&D Health and USAID mission staff. The primary selection criteria will be the presence of remediable deficiencies and, very importantly, evidence of the political will required to carry out measures for change.

The long term interventions will be managed through a combination of periodic visits by RPM staff and consultants, coupled with on-going local technical assistance provided by host country firms. Emphasis will be placed on skills transfer and collaborative work with local counterparts. The RPM will provide appropriate computer equipment to support these interventions.

It is projected that core funds will support six initial country assessments plus a total of six long term intervention activities. The actual distribution of the six long term interventions will be managed pragmatically, depending on AID priorities and on needs. For example, it is possible that two countries will each have three activities, or that three countries will each have two.

Short or long term technical assistance to countries that are not part of the core funded RPM activities portfolio will be financed by "add-on" funds from USAID missions or regional bureaus. Add-on funds from missions may also be used to supplement core funding in the countries where long term interventions take place.

PROJECT START UP ACTIVITIES

During the first six to nine months, the RPM will be primarily occupied with two assessment activities which are critical to the project's long term success. They are:

- The Technical Opportunity Assessment
- Six country-level pharmaceutical sector assessments.

Technical Opportunity Assessment: AID has mandated that the RPM collaborate closely with other international agencies and organizations working in pharmaceutical management. In order to do this, RPM and R&D Health staff must be familiar with the activities that other organizations are currently undertaking or planning. Unfortunately, there is no current single repository of information on world-wide development activities related to pharmaceutical managment which would allow A.I.D. and the RPM to extract information on opportunities for collaboration with other donors.

Such a repository would potentially have real value to A.I.D. and to other agencies. Therefore, during the first three to six months after setting up shop, the RPM will gather input on the feasibility of developing and maintaining a pharmaceutical management database. The types of information to be incorporated into such a data base could include:

- Development activities in Pharmaceutical Management sponsored by various donors and agencies;
- Tools available for Pharmaceutical Management, such as computer software, training modules, procedures manuals and drug information materials;
- Opportunities and constraints in specific countries.

Specific uses of the data base could include:

- Identifying gaps in the drug management support services currently being provided;
- Identifying specific country opportunities for development assistance;
- Contributing to project design work.

Agencies and organizations whose input might be used in building the data base, and who will be contacted to discuss the process and the feasibility, include:

- Major international agencies, such as WHO/Geneva, PAHO, UNICEF and the World Bank;
- Bilateral donors such as DANIDA (Denmark), DGIS (Holland), SIDA (Sweden), and others;
- AID bureaus, missions and projects;
- MSH programs, projects, collaborating institutions and consultants;
- US Government agencies, such as FDA and the Public Health Service;
- AID contractors;
- NGOs;
- Universities and Research Institutes;
- US Pharmacopeia and American Public Health Association advisory panels.

If preliminary discussions with other agencies indicate that the construction of a pharmaceutical management data base is feasible, and is a worthwhile endeavor, the RPM will help establish an inter-agency working group to guide the process of developing and maintaining the data base. Once in place, the data base would be available for access by all participating agencies.

Country Assessments: The RPM will undertake six country assessments for the purpose of identifying candidates for long term assistance. RPM and R&D Health staff will work closely with USAID missions to identify the assessment countries. The assessments themselves collect data using standardized indicator-based surveys, derived from instruments developed for the Eastern Caribbean Regional Pharmaceuticals Management Project and by the LA/C Health, Nutrition and Sustainability Contract. It is currently estimated that three to four weeks will be required for RPM teams, plus counterparts, to complete each assessment. The target date for completing this work and choosing the long term intervention countries is August 1993.

RPM OFFICES AND STAFFING

PHARMACEUTICAL MANAGEMENT COOPERATIVE AGREEMENT

MSH will provide all of the core staff for this C.A. through its Drug Management Program, which has opened an office in Arlington, Virginia to serve as both the RPM project office, and the DMP headquarters office. The DMP will also maintain an office in Boston. Responsibilities of individual staff members are summarized below.

Washington Office

James R. Rankin is Director of both the MSH Drug Management Program and the Rational Pharmaceutical Management project. He will be responsible for administration of the RPM and the DMP, and for overall supervision of long and short term technical assistance. He will manage relations between the DMP and AID, and between the DMP and other MSH programs and offices.

James A. Bates is Deputy Director and Technical Assistance Coordinator for the Rational Pharmaceutical Management project. He will have primary responsibility for matching requests for technical assistance with qualified specialists and for communicating with missions. He will also participate directly in technical assistance activities and be responsible for organizing RPM training activities.

Jean-Pierre Sallet is the MIS Coordinator for both the MSH Drug Management Program and the Rational Pharmaceutical Management project. He will be responsible for assessing MIS requirements for the RPM, for selecting hardware and software, and for supervising MIS technical assistance, including software development.

Jennifer Jones will be the RPM's Administrative/Financial Officer. In this capacity, she will be responsible for coordination of all RPM administrative support and financial tracking, in addition to supervising support staff.

Dr. Alexander van Ommen, DMP Program Associate, has played a key role in the formulation and field testing of DMP assessment tools. He will continue this work during the RPM's country assessment phase, and will provide technical assistance for both long and short term interventions.

Anthony Savelli, DMP Program Associate, has particular expertise in hospital pharmacy and pharmaceutical information systems; he has recent long-term experience as logistics coordinator for the Presidential Initiative for Humanitarian Assistance to the former Soviet Union.

Enriqueta Clark and *Julie Frye* will provide administrative support to the RPM and project back-stopping for long term RPM interventions.

Boston Office

Dr. Richard Laing is the DMP Drug Use/Training Coordinator. As Network Coordinator of the International Network for Rational Use of Drugs (INRUD), he will assist in establishing collaborative efforts between INRUD and the RPM.

Dr. Pradeep Goel, DMP Program Associate, is Director of the WHO-sponsored Project for Improving the Diarrhoea Treatment Practices of Retail Drug Sellers. An expert in operations research and study methods, he will provide technical assistance to the DMP in these areas.

Penny Caponigro will coordinate DMP administrative activities for the Boston office and provide support to INRUD, and *Jeanne Madden* will provide support services to DMP projects.

Other MSH Staff from Boston based technical programs such as MIS, Health Financing, Management Training, Population and Strengthening Health Services, as well as from MSH field projects, may be used for specific RPM assignments.

Consultants and Collaborating Institutions

More than thirty individual experts in various areas of drug management have committed themselves to providing services to the RPM. In addition, five institutions with substantial experience in the field have agreed to collaborate with the project on an as-needed basis. They are:

- Euro Health Group
- Academy for Educational Development
- Program for Appropriate Technology in Health (PATH)
- PharMark Corporation
- Social Sector Development Strategies Incorporated

PHARMACEUTICAL INFORMATION COOPERATIVE AGREEMENT

The United States Pharmacopeia will manage its RPM work from the USP headquarters in Rockville, Maryland. The following personnel will be involved in RPM activities:

Keith Johnson is the Director of the USP Drug Information Division, and will direct USP's efforts in the RPM. He will be responsible for liaising with AID and with MSH. He will also oversee all information development by USP staff and input from USP panels. Finally, he will participate in country assessments and design of drug information systems to be implemented at country levels.

Drug Information Specialists: USP will provide two full time drug information specialists with training in pharmacy or clinical pharmacology. They will be responsible for literature searches, development of information monographs, and revision of USP drug information materials into formats required by the RPM.

USP Expert Panels: USP develops its drug information materials through the volunteer efforts of 33 specialist advisory panels; all of the these panels will review and comment on materials which are developed by USP during the course of RPM activities.

The USP Panel on International Health will play a central role in the USP's contributions to the RPM. This panel is chaired by *Dr. Rosalyn King*, and has 27 members, with representatives from U.S. Government agencies (AID, FDA, and the VA), international agencies (WHO, PAHO, UNICEF), US and international universities and non-governmental organizations, and the US pharmaceutical industry. The panel includes members from Canada, Ghana, Cameroon, Jamaica, Mexico, Panama, Nigeria, Malaysia, Indonesia and the Netherlands Antilles. This panel will advise USP and the RPM as to priorities for development of drug information materials, in addition to reviewing the materials which are developed. It is expected that each international member will help identify additional reviewers in his or her country or region, and thus expand the network of comment on these important materials.

CONTACT INFORMATION

Any questions or requests for information about the Rational Pharmaceutical Management project should be directed to one of the following individuals:

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