Terminal Evaluation

Asia

1. Outline of the Project

Country:
Philippines

Project title:
The Project for the Preparation and Publication of the Philippine Pharmacopoeia

Issue/Sector:
Health/ Medicare

Cooperation scheme:
Expert Team Dispatch Program

Division in charge:
Southeast Asia Division, Regional Department I (Southeast Asia and Indochina)

Total cost:
106 Million Yen

Period of Cooperation
1 March 1999 - 28 February 2002

Partner Country's Implementing Organization:
Department of Health (DOH), Bureau of Food and Drugs (BFAD)

Supporting Organization in Japan:
Health, Labour and Welfare Ministry,
National Institute of Health Science, Japan

Related Cooperation:
Grant Aid; "Project for Establishment of Food and Drug Laboratories
Project-type Technical Cooperation; "Food and Drug Testing Center"
Expert Dispatch

1-1 Background of the Project

In the Philippines, there has been no Pharmacopoeia of its own (Pharmacopoeia is a regulation to assure adequacy of a medicine's description and quality, which set standards, test method, preserving method, available period, package, etc. of the widely used major medicines. Each country defines its own pharmacopoeia depending on its situation). Therefore, the Philippines has not only set U.S. Pharmacopoeia as the official standard, but also the pharmacopoeia of England, Europe and Japan as the official references. As a result, difficulties have arisen in maintaining consistency of administrative direction on medicines. Moreover traditional herbal medicines to have no quality standards. Based on the request made by the Department of Health (DOH) and Bureau of Food and Drugs (BFAD), the Government of Japan commenced cooperation for the preparation of the Philippine Pharmacopoeia (PP) in March 1999.

1-2 Project Overview

For the establishment of the Philippine Model Pharmacopoeia, policy and procedure of its settlement is clarified and the Model Monographs of pharmaceutical products and herbal medicines as well as Model of General Test Methods and Reagents are established at BFAD. Through these activities, techniques are transferred to the staff of BFAD, Philippine Pharmacopoeia Organization (PPO), and its technical working group (TWG).

(1) Overall Goal

1) Philippine Pharmacopoeia is published.
2) Philippine Pharmacopoeia Organization is established in DOH for the preparation and continuous improvement of the pharmacopoeia.

(2) Project Purpose

The model of a Philippine Pharmacopoeia is made.

(3) Outputs

1) The policy, management and process in establishing a Philippine Pharmacopoeia are clarified.
2) Necessary facilities and equipment are utilized for development of the model of the Pharmacopoeia.
3) Model monographs of selected pharmaceutical substances and preparations (products) are made.
4) Model monographs of selected medical plant materials (and products) are made.
5) Model of General testing Methods and Reagents are made.
6) Methodology for continuous evaluation of Pharmacopoeial materials and formulation of monographs are prepared.
7) Information on the Philippine Pharmacopoeia is provided to the persons concerned.

(4) Inputs

Japanese side:

Long-term Experts	2	Equipment and Facilities	44 Million Yen
Short-term Experts	12	Local Cost	0.6 Million Yen
Trainees received	5		

Philippine Side:

Counterparts	10
Local Cost	

2. Evaluation Team

Members of Evaluation Team

Team Leader/Technique Evaluation: Kouichi SHUDOU, Director General, National Institute of Health Science, Japan
Evaluation Planning: Shuhei UENO, Staff, Planning Division, Regional Department I (Southeast Asia and Indochina)
Evaluation Research: Kanji HOSHINO, Sowa Consultants, Ltd.

Period of Evaluation

28 January 2002 - 9 February 2002

Type of Evaluation:

Terminal Evaluation

3. Results of Evaluation

3-1 Summary of Evaluation Results

(1) Relevance

The establishment of the Philippine Pharmacopoeia was in line with the priority placed on medicines in the range of the national health care policies such as "the National Drug Program (1987)" and "the Philippine Health Sector Reform Agenda (1999)". As mentioned, since the Philippines has set the pharmacopoeia of US, England, Europe and Japan as the official reference, difficulties in conducting a consistent administrative direction on medicine as well as various adverse effects had been observed. Therefore, from the view of upgrading the quality of medicine, establishing the Philippine Pharmacopoeia met the Philippine social need of upgrading welfare for its citizens. Judging from above, the Project has high relevance.

(2) Effectiveness

The Model Monographs was completed, for 17 pharmaceutical products and 32 medical plants and would be submitted to the Executive Board of PPO for its approval. Hence, the Project Purpose has been accomplished. The Model Pharmacopoeia was composed of (1) General Test Methods and Reagents, (2) pharmaceutical products and (3) medical plants, and each of them was settled as the outputs. These contributed to accomplishment of the Project Purpose.

(3) Efficiency

The Inputs of both the Japanese side and Philippine side were appropriately implemented except for the points indicated below. Overall, most of the inputs contributed to achieving the Outputs of the Project, which led to efficient implementation of the project.

1) A Long-term Expert returned to Japan because of a health problem, and a replacement expert could not be recruited for one year. The project progress was stagnated for five months until the dispatch of the Short-term Experts to fill the vacancy. In addition, in relation to the leave of the other expert of the first dispatch, delivery of the equipment was delayed with arising arrears in procedures.
2) There was only one full-time counterpart out of 10, which caused the difficulty of not taking enough time for the technical transfer, and sufficient effects could not be delivered.

(4) Impact

Through the activities of the Project, the importance of the Philippine Pharmacopoeia has become widely recognized among government agencies, pharmaceutical industries and medical departments of the universities, and they have come to share the objective to establish the Philippine Pharmacopoeia by 2004. There were also some positive and indirect impacts such as increased awareness of the importance of traditional herbal medicine, in the process of accomplishing the Project Purpose.

(5) Sustainability

Based on the Government of Philippines' strong will to enact the Philippine Pharmacopoeia by the year 2004, the budget and its implementing scheme have been secured. Therefore, the Model Pharmacopoeia settled by the Project will be utilized in establishing the new national standard. As for the maintenance and management of the Pharmacopoeia, the DOH as well as the Department of Agriculture, the Department of Science and Technology, research institutes such as University of the Philippines and pharmaceutical companies offered their cooperation, which shows that the supporting system has been organized after the revision of the Pharmacopoeia.

However, as this was the first time for the Government of the Philippines to establish the Pharmacopoeia, there remain some concerns on smooth management of committees and settling the policy on coming projects. In addition, the techniques for the testing of the Model Monograph necessary for the settlement of the Philippine Pharmacopoeia have not yet been fully transferred, so there remain some concerns on the technical aspect as well. Therefore, the counterparts also requested the extension of the cooperation of Japan.

3-2 Factors that promoted realization of effects

(1) Factors concerning Planning

The establishment of the Philippine Pharmacopoeia was a strong need of the Government of Philippines. As the result, the Project could enjoy support from BFAD.

(2) Factors concerning the Implementation Process

1) The succeeding expert to the one who returned due to a health problem, had experiences in the establishment and revision of the Pharmacopoeia in Japan, a stronger leadership ability as well as English proficiency. Thanks to his effort the Project made up for the delay and accomplishment of the Project Purpose was achieved.
2) The counterparts of BFAD as well as those in universities and pharmaceutical companies who will utilize the Pharmacopoeia in the future had been involved in the establishment of the Pharmacopoeia and had participated in the PPO. It has increased the likelihood of the utilization, maintenance and management of the Pharmacopoeia which would be settled by 2004.

3-3 Factors that impeded realization of effects

(1) Factors concerning Planning

N/A

(2) Factors concerning to the Implementation Process

1) The absence of a long-term expert and the six months delay of the equipment arrival hindered the outputs of the Project.
2) As there were only a few full-time counterparts, the necessary techniques could not be transferred fully and there remain some concerns for the technical sustainability.

3-4 Conclusion

The Project Purpose of completing the Model of the Philippine Pharmacopoeia was accomplished. As for the Overall Goal, which is the enactment of the Philippine Pharmacopoeia (by government decree), it has not been attained yet. However, the movement toward the publication of the Philippine Pharmacopoeia by the Government of the Philippines has been prepared and promoted after the project achievement in formulating the Model Monograph.

3-5 Recommendations

(1) The Government of the Philippines should organize the plan and immediately implement the validation of the Model Monograph for the settlement of the Philippine Pharmacopoeia. It is also necessary to spread the information on the Philippine Pharmacopoeia widely by promoting further participation of the academic organizations and industries involved.

(2) BFAD should secure the condition where the counterparts are able to work on a full-time basis in order to establish the division for the continuous revision of the Philippine Pharmacopoeia. In addition, BFAD should secure a sufficient number of counterparts and conduct trainings to maintain their technique level.

(3) The Government of Japan should support that the preparation of legislation procedures so that the Model Philippine Pharmacopoeia will be authorized.

(4) The Government of Japan should continue its cooperation through; (1) giving advice to the management of preparatory organizations and (2) giving advice and transferring techniques to the monograph testing of medicine for the settlement of the Philippine Pharmacopoeia in 2004.

3-6 Lessons Learned

(1) It is necessary for the accomplishment of the Project Purpose to follow the original input plan so that there will be no gaps in the dispatch of experts during the term of the project.

(2) The Project involved those who were in the pharmaceutical industry and pharmaceutical departments of universities and this brought about their support for the Project activities. In a project which aims at establishing institution or organization, it is crucial to involve external resources and beneficiaries not only to gain momentum but also to secure sustainability of the project result.

3-7 Follow-up Situation

For the settlement of the Philippine Pharmacopoeia in 2004, the Government of Japan has implemented Phase II cooperation of three years, which is (1) to give advice to the management of the settled preparation organization and (2) to give advice and to transfer techniques on the monograph testing of medicines.