# Basic Design Study Report on The Establishment Project of The Pharmaceutical Development Center in Lao People's Democratic Republic

March, 1984

Japan International Cooperation Agency



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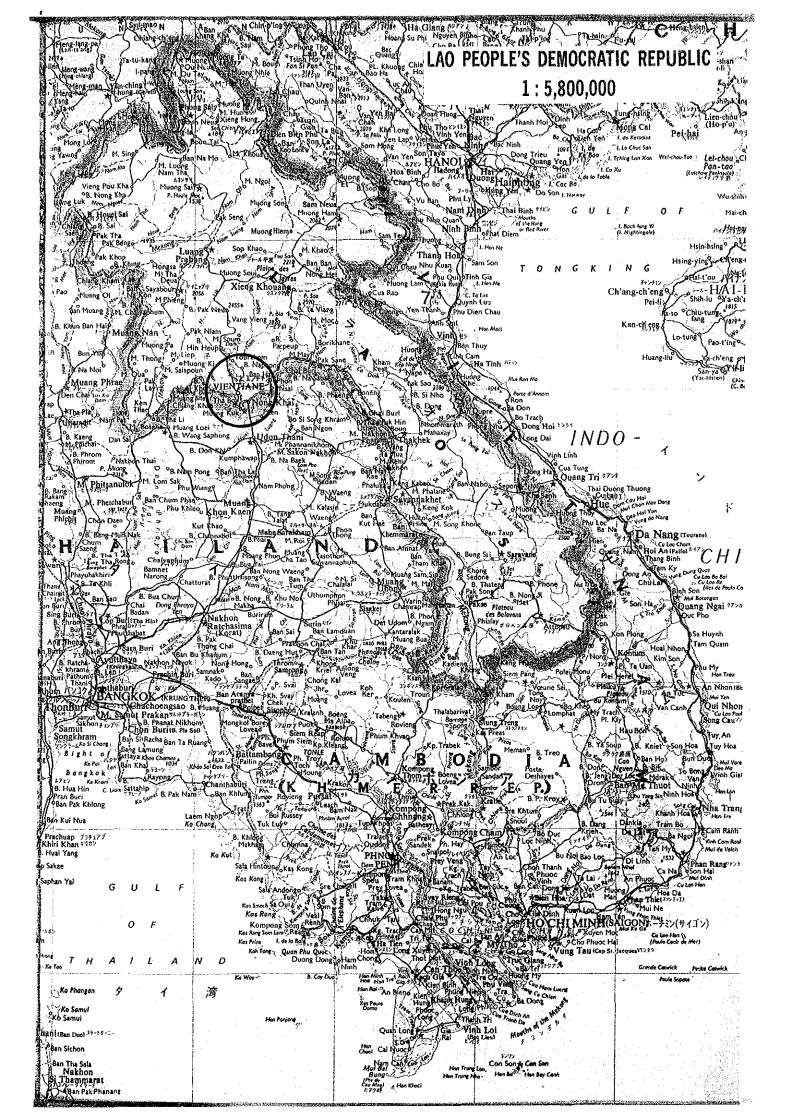
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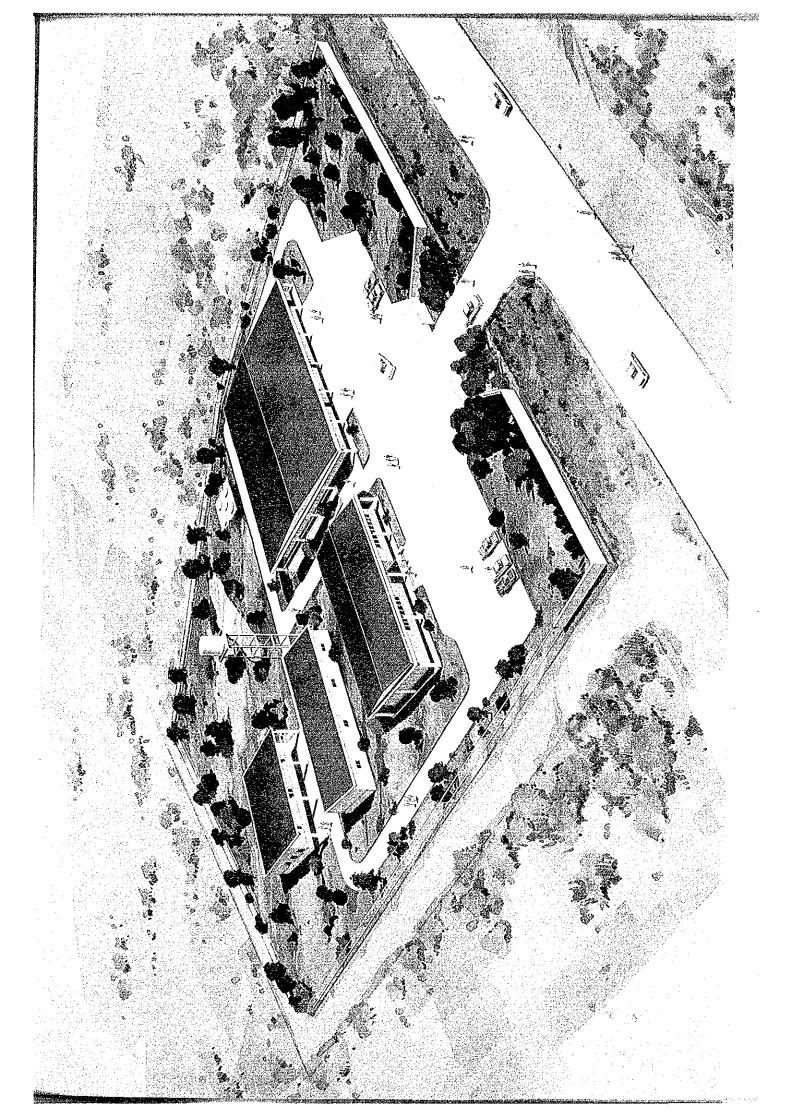
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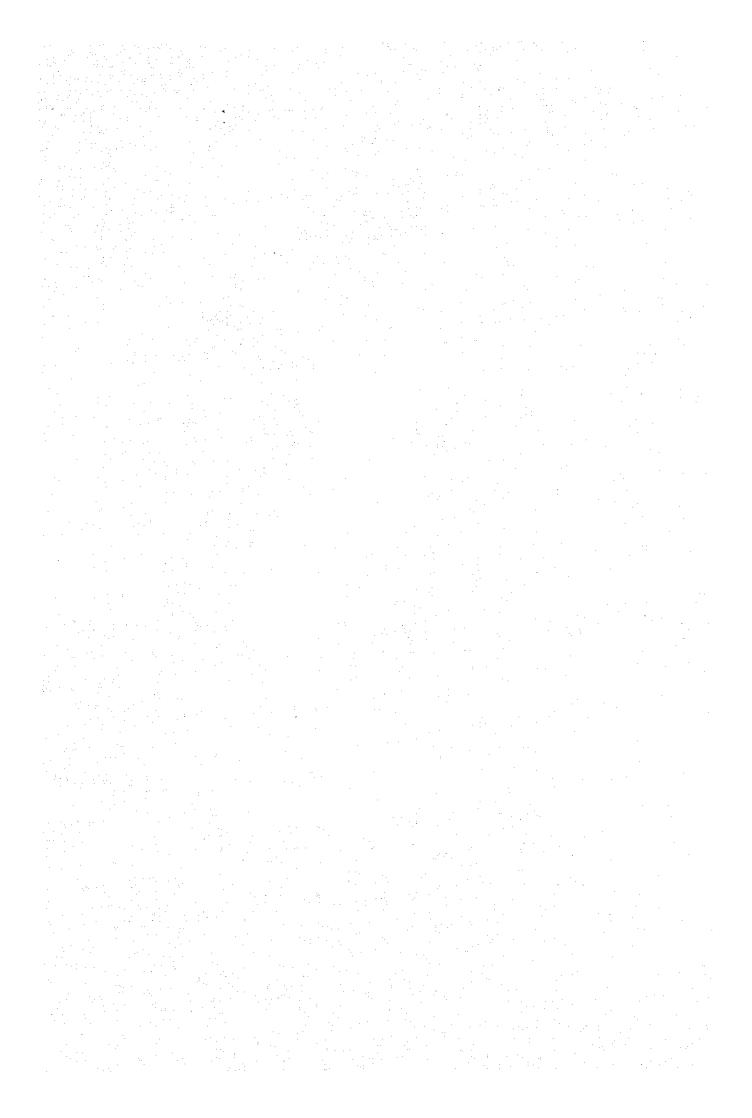
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### PREFACE

In response to the request of the Government of the Lao People's Democratic Republic, the Government of Japan decided to conduct a basic design stady on the Establishment Project of the Pharmaceutical Development Center and entrusted the stady to the Japan International Cooperation Agency (JICA). The JICA sent to Laos a study team headed by Mr. Minoru Ishida, Second Economic Cooperation Division, Economic Cooperation Bureau, Ministry of Foreign Affairs from October 9th to 28th, 1983.

The team had discussions with the officials concerned of the Government of the Lao People's Democratic Republic and conducted a field survey in Vientian. After the team returned to Japan, further studies were made and the present report has been prepared.

I hope that this report will serve for the development of the Project and contribute to the promotion of friendly relations between our two countries.

I wish to express my deep appreciation to the officials concerned of the Government of the Lao People's Democratic Republic for their close cooperation extended to the team.

March 1984

Keisuke Arita

President

Japan International Cooperation Agency

### ABBREVIATIONS

ADB : Asian Development Bank

GMP: Good manufacturing practice

GNP: Gross national product

IMF : International Monetary Fund

JIS: Japanese Industrial Standards

LPG: Liquefied petroleum gas

PVC: Plyvinyl chloride

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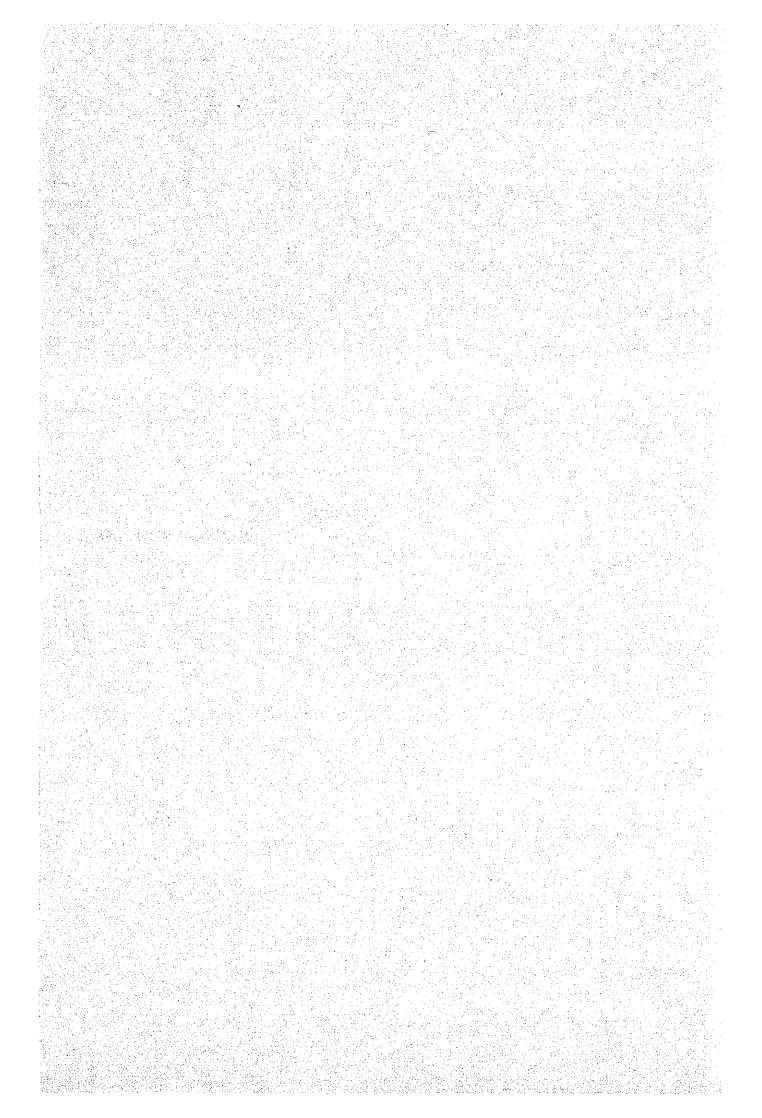
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GENERAL OUTLINE



### GENERAL OUTLINE

The Lao People's Democratic Republic has established the "First Five Year Plan (1981 - 1985) for the Development of Society and the Economy" in order to rebuild the country from the damage inflicted by long years of conflict. Strenuous efforts are being made to construct a new nation with the objective of establishing secure economic foundations and of raising the standard of living of the people in Laos. Among the public health activities designated by this first five-year plan, production of drugs centered on the active utilization of indigenous medicinal plants and the domestic production of essential drugs form the basis of the activities to improve the public health care which is itself one of the five major activities for the development of society. The government of the Lao People's Democratic Republic has requested the Government of Japan for financial cooperation to establish a pharmaceutical development center so that this production of drugs may become a reality.

In response to this request, the Government of Japan, through the Japan International Cooperation Agency, dispatched a basic design study team to Laos in October 1983 following on from the preliminary survey of June 1983. The study team discussed concretely the details of request with the representatives of the Government of Laos and carried out on-site surveys into the local conditions in Laos such as medical care, medical supplies, public health, medical improvement schemes of the government in order to propose the basic design. The study team also carried out field surveys on the four proposed sites, then decided on the project site by discussing the matter with the government of Laos. Furthermore, the study team investigated the conditions for supply of construction materials and equipment in Bangkok, Thailand, as well as the construction conditions in Laos.

The study team analyzed the results of its findings after returning to Japan and compiled the Basic Design whose outline appears below.

Construction Site: Thadua Road 8 km, Vientiane, Laos

## Principle Buildings and Facilities

| Mar | nufacturing Building                                 |                      |
|-----|--|----------------------|
| One | e-storied steel-frame structure:                     | $1,198 \text{ m}^2$  |
| Adn | ninistration Building                                |                      |
| One | e-storied steel-frame structure:                     | $338 \text{ m}^2$    |
| Cru | ide Drug Building                                    |                      |
|     | e-storied steel-frame structure:                     | $294 \text{ m}^2$    |
| Uti | lity Building  |                      |
| One | e-storied stee-frame structure:                      | 300 m <sup>2</sup>   |
|     | Total:   | 2,130 m <sup>2</sup> |
| Pri | ncipal Equipment                                     |                      |
| 1)  | Production Equipment for Crude Drugs                 | 1 set                |
| 2)  | Manufacturing and Inspection Equipment for Infusions | 1                    |
| 3)  | Manufacturing and Inspection Equipment for Ampoules  | 1                    |
| 4)  | Manufacturing and Inspection Equipment for Tablets   | 1                    |
| 5)  | Equipment for Quality Control                        | 1                    |
| 6)  | General Facilities and Equipment                     | 1                    |

The construction of this center requires 23 months, including 7 months for the Exchange of Nots, detail design and selection of the construction company, and 16 months for the construction work.

The drugs manufactured at this center will make it possible to improve significantly the current shortfall in the demand for drugs by hospitals. A major contribution can also be expected in improving the

conditions of public health care in Laos by effective use of domestic resources.

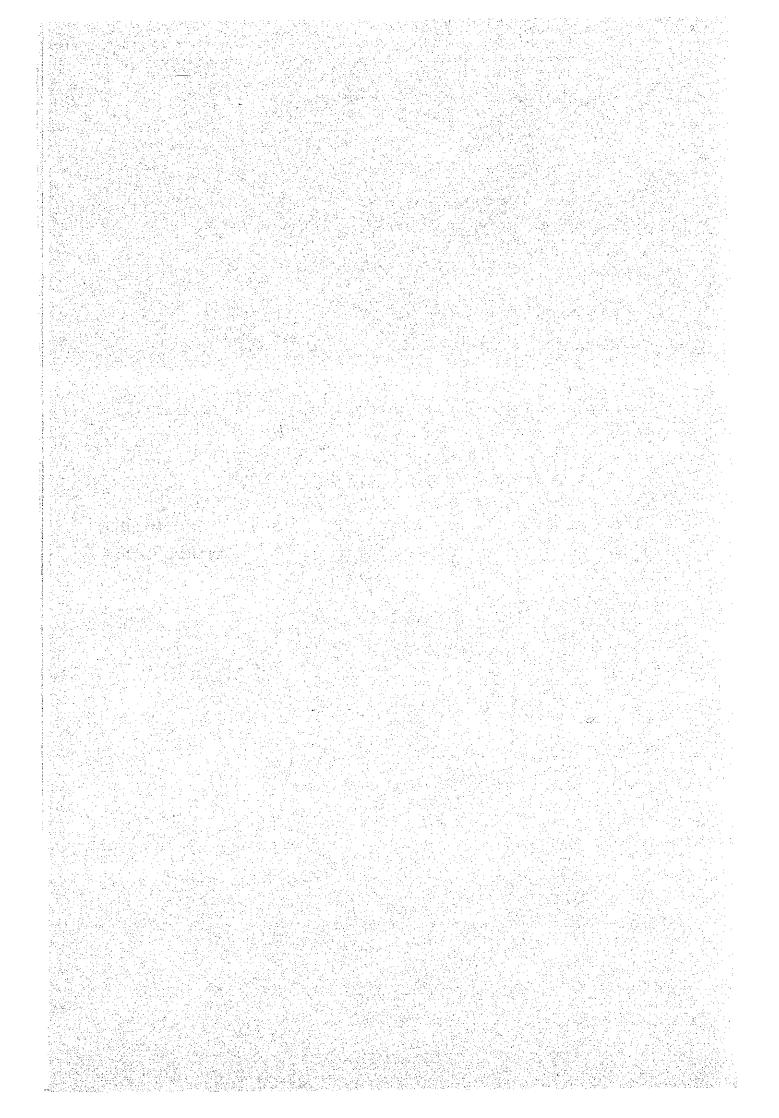
In order to ensure smooth operation of this center after its construction, it is essential to ensure a stable supply of raw materials. Concerted efforts by the Government of Laos to supply raw materials are also necessary.

Furthermore, at the same time as a supply of raw materials is established, pharmaceutical technicians and skilled workers should be secured to staff the new center, and a fund for running, maintaining and managing the center should also be made available. Another important element necessary for the smooth running of the center is the Technical Cooperation of the Japanese Government with respect to pharmaceutical technologies. If possible, a long-term dispatch of Japanese specialists would be desirable to assist in quality control and the transfer of production technology. Even if such dispatch proved difficult, specialists should be dispatched for short periods and the proposed Lao staff should be trained in Japan before the start of operation of the new center.

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# CHAPTER 1 INTRODUCTION



### CHAPTER 1: INTRODUCTION

Lao People's Democratic Republic attained its current administrative structure in December 1975 after long years of conflict and turmoil. The country suffered a great deal of damage due to this conflict, resulting in delayed economic development in regions outside of the capital, Vientiane, which is unable to rise out of subsistence-level economic conditions. Since the establishment of the current administration, the government has been embarked on policies of establishment of secure economic foundations stabilizing the nation's livelihood with the ultimate goal of building a socialist economy. While receiving assistance from various countries, the government has promoted the development of agriculture and industry, and socialist improvements to the economy. In spite of this, undue haste to attain the goals set down by the three-year national plan for the years from 1978 to 1980 gave rise to a disparity with the actual conditions of society and had the adverse effect of slowing down principal economic activities.

For these reasons, such measures as the liberalization of the distribution of goods were taken as a review of the policy and the results of these moves, together with continuing good harvests from 1980 to 1982, gave rise to new prospects for selfsufficiency in food supplies. During this period, the First Five Year Plan for 1981 to 1985 also went into effect. The fundamental goals of this plan are the improvement of the standard of living of the citizens and the establishment of secure economic foundations. On the social level, the plan aims to improve the conditions of public health and hygiene and to make a determined effort to popularize education. There are three elements considered as urgent in improving the conditions of public health — upgrading of medical facilities, overcoming the shortage of medical personnel and establishing a sufficient supply of essential drugs.

With this background, the Government of Laos has planned the construction of a pharmaceutical plant as a means of improving the present situation of domestic drug production, in which approximately 95 % of the domestically consumed drugs are said to be imported, mainly by relying on foreign assistance. Therefore the Government of Laos has requested the Government of Japan for financial cooperation in order to construct the pharmaceutical center.

In response to this request, the Government of Japan, through the Japan International Cooperation Agency, dispatched a preliminary study team to Laos between June 26 and July 5, 1983 to confirm the details of the request as well as to investigate the background to the plan and has been studying ways in which cooperation could be provided for the plan. Based on the results of this preliminary survey, a basic design study team, headed by Mr. Minoru Ishida of the Second Economic Cooperation Division, Economic Cooperation Bureau in the Ministry of Foreign Affairs, was dispatched to Laos from October 9 to 28, 1983.

Investigations conducted by this team included,

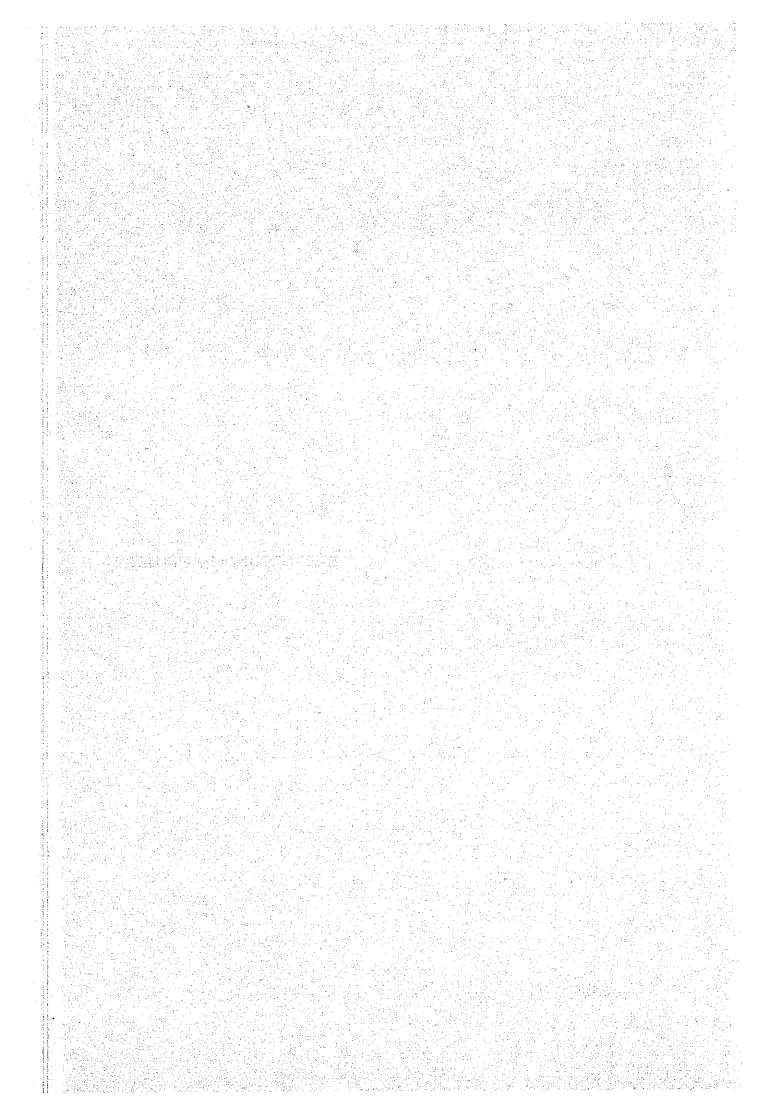
- 1) Supplementary survey to the background of survey conducted by the preliminary study team.
- 2) Clarifications of the details of the request.
- Selection of the project site and investigation of construction conditions.
- 4) Study of local construction conditions and of conditions for transportation of materials and equipment.
- of Laos. Minutes regarding basic items of the plan were signed and these were confirmed by both sides.

These minutes of meetings, together with the list of members of the study team, the list of the representatives concerned from the Government of Laos, and the schedule of the survey are attached in Appendices 1-4.

This report was compiled after analysis of the minutes of meetings,

data obtained from field surveys and materials collected on site, and includes a consideration of the suitability of the plan. The basic design contained here is of a scale, and with facilities most appropriate to the project.

CHAPTER 2
BACKGROUND TO PROJECT



CHAPTER 2: BACKGROUND TO PROJECT

### 2.1 General Conditions

### 2.1.1 Natural conditions

Laos is located in the center of Indochina and is an inland country surrounded by Vietnam to the east, Cambodia to the south, China to the north, Burma to the north-west and Thailand to the west. The country occupies a long, narrow strip of some 1,000 kilometers in length, and lies at a east longitude between 100° and 107°, and a north latitude between 14° and 22.5°. The total area of 6,800 square-kilometers is roughly equivalent to that of Japan's main island, Honshu.

Geographically, almost all of Laos lies in the highlands of the Annam Ranges which lead south from the Yunnan Plateau. The only flat lands are those around the Mekong and part of its tributaries. Arable land does not exceed more than 8 % of the total land area. The highlands of northern Laos consist of mountainous regions around the level of 2,000 meters, with Phu-Bia being the highest point at 2,818 meters above sea-level. This fact places a severe impediment on the development of transportation. In the south, the gentle plateau which runs from the Annam Ranges along the Vietnamese border to the Mekong is 2,100 meters at its highest point.

Climate is governed by the tropical monsoons. The rainy season runs from May to October when the temperature is relatively high. Rainfall is approximately 1,500 mm. The dry season is from October to April. The weather is rather cool until February, but this gives way to an almost unbearable heat during March and April. Humidity remains quite high all year round.

The capital, Vientiane, is on a plain by the side of the Mekong

at 170 meters above sea-level. Appendix 5 contains meteorological data for the city. There are no records of earthquakes in Laos, and the officials of the Lao government concerned had never experienced an earth-quake.

### 2.1.2 Social conditions

The population of Laos is 3.85 million (Source: 1981 materials of the Government of Laos), with a population density of 16 persons per square kilometer that is low among the countries of Southeast Asia. The population consists of more than 60 different ethnic groups. The Lao clan, which accounts for about 50 % of the total population, are mostly engaged in rice cultivation in the lowlands of the Mekong basin. Most of the rest of the population is involved in burnt field cultivation in the moun tain regions.

The majority of the population are devout believers in Hinayana Buddhism which was brought from Cambodia in the 14th century. Buddhism is an integral part of the national lifestyle, and Buddhist philosophy lies at the base of most thinking. The government has imposed a policy on the Laotian Buddhism circle to enlighten the people according to the socialist party's instructions. However, it has not banned the religion.

In addition to limiting geographic conditions as an inland country, the economical development of Laos has also been retarded by historical, social and economic causes. Particular influence has been exerted on the construction of the Lao economy by the decrease of the labor force, the damage to cultivation and the destruction of natural surroundings resulting from the long-term conflict, and by the confusion which accompanied the transfer of power to the new administration.

Laos remains a developing country with a GNP per capita of less

than U.S.\$100. Two-thirds of gross domestic product is accounted for by the agricultural sector, while 85 % of the total population is engaged in agriculture. Particularly most of the regional societies are natural economies of self-supply and self-sufficiency centered on village units. The cities and towns rely on neighbouring Thailand for many of their consumer goods. On the other hand, the main sources of foreign exchange are by exporting hydroelectric power and timber.

The new administration in Laos places its major economic objectives on the establishment of a socialist economic system. During its initial period, this administration emphasized the nationalization of major companies involved in the domestic distribution of goods and of financial organizations and the formation of collective farms. This rapid adoption of socialist economic policies, however, brought turmoil to the economic and social order. Combined with both droughts and floods during 1977 and 1978, this led to a reappraisal of economic policies, and as a result, new economic policies including currency reforms and the liberalization of the distribution of goods have been established. Following to the three-year plan for social development put into effect from 1978 to 1980, the First Social and Economic Five Year Plan outlined the goals of improving the standard of living and the establishment of secure economic foundations.

Particularly high priorities have been given to the expansion of agricultural output, the development of transportation and communications infrastructures, the promotion of industry using domestically produced raw materials and the development of domestic energy sources.

Since 1980, agricultural output has been steadily progressing with annual increases in crops of one million tons. Together with the 14.7~% increase in industrial output, this has made a

large contribution to raising the level of the gross domestic product. Furthermore, the total distance of roads in Laos doubled in the period between 1975 and 1982. While the total for transactions in the commercial sector during 1982 was 40 % higher than that in 1980, some two-thirds of that total was in the private sector, which led to the difficulty of sufficient price controls and contributed to a fall in the value of the kip.

Although this economic growth since 1980 has proved a certain improvement in the financial situation, it has also led to a rise in prices, financial debt, and is unable to avoid the deficit in the balance of trade. For some time to come, foreign aid will continue to hold the key to the construction of the Lao economy.

Under the First Social and Economic Five Year Plan, the government has directed a great deal of its energies in the social sphere into improvement of the conditions of health care and into the popularization of education.

In the area of education, the rate of attendance at primary schools during 1982 was 50 % higher than that in 1976, and the rate of literacy amongst persons between the ages of 15 and 42 had also risen from 40 % in 1974 to 85 %.

While health care has been improved at the regional level, in the number of medical centers and hygiene workers, the situation is still insufficient to adequately satisfy the existing demand. There is a shortage in particular of essential drugs, medical facilities and medical workers. Any rapid improvement in these conditions is most desirable.

# 2.1.3 Administrative organization

The central administrative agencies of Laos are run by the Ministerial Council comprising the prime minister (chairman), deputy prime minister (deputy-chairman), ministers, deputy-ministers, the chairmen and deputy-chairmen of the various committees, the Governor of the Bank of Laos and so on. Reforms of the administrative organization were carried out and some of the ministers and deputy ministers were replaced in August 1982.

Appendix 6 shows the organization of the Ministry of Public Health under whose jurisdiction the Pharmaceutical Development Center falls.

### 2.2 General Conditions of Medical Care

#### 2.2.1 Medical administration

Medical administration in Laos falls under the responsibility of the Ministry of Public Health. The organization of this administration is illustrated in Appendix 7 which was presented by the government of Laos.

In regard to the medical care service system in Laos, there are inadequacies of the facilities and equipment, and the number and quality of medical personnel need to be improved. Furthermore, medical facilities such as hospitals and health centers are short of medical equipment and spare parts.

Although the need for strengthening of the regional organization and the delegation of power to regional authorities is adequately recognized, because of various problems in the central organization and in the intermediate managing system, it is very difficult at present to undertake expansion or improvements of the medical services administration agencies in order that medi-

cal services in both central and regional areas be increased and unified.

As outlined above, the system of medical administration in Laos is inadequate at present. Nonetheless, the long-term outlook is considerably brighter under the present situation in which the education and training systems for medical personnel have been gradually improved.

# 2.2.2 Medical facilities and medical personnel

All medical facilities in Laos are government run and the principal facilities are hospitals and health centers. There are 119 hospitals, four in Vientiane, one in each of the 13 prefectures and 102 in the districts, and 603 health centers in towns and villages.

The number of beds per prefectural hospital is between 100 and 200, between 20 and 50 per district hospital and between three and six per health center. The total number of hospital beds is 10,736.

The average number of patients using these medical facilities every month is 320,000, of which half, or 160,000, are admitted to hospital. In addition to the above, a medical university hospital (of approximately 150 beds) is being constructed in the Vientiane vicinity with the assistance of the Soviet Union.

#### 2.2.3 Composition of diseases

Although, there are not sufficient data regarding the overall composition of diseases in Laos, the following facts were obtained by studying the medical records of the largest hospital in Laos, the Mahosot Hospital, for the order of prevalent diseases.

- (1) Gastro-intestinal diseases (dysentry, cholera, diarrhoea etc.)
- (2) Respiratory diseases (bronchitis, pneumonia, pulmonary tuberculosis)
- (3) Malaria
- (4) Cerebral meningitis
- (5) Endemic tropical diseases (protozoosis, filariasis, elephentiasis etc.)
- (6) Calculus (renal calculus, urethral calculus, gallstone etc.)
- (7) Dengue fever (outbraks in two-year cycles)
- (8) Tonsillitis, colds, etc.
- (9) Helminthiasis (Gastro-intestinal H, pulmonary H. hepatic H, etc.)

This composition of diseases is of a typical pattern in which the condition of hygiene and nutrition are insufficient. The first three diseases occur with particular frequency, while the highest mortality rates are for cerebral meningitis and dengue fever. The mortality rate amongst patients admitted to the Mahosot Hospital is 5 % and it rises to 11 % amongst children.

Factors affecting to the lowering of the average life expectancy in Laos include shortcomings in the health care organization such as the shortage of health care services, insufficient immunization measures, lack of medical facilities and the shortage of drugs. As of September 1982, the average life expectancy was 46 years, while the mortality rate amongst babies under one year of age was between 175 and 200 per every 1,000.

#### 2.3 Pharmaceutical Administration and Condition of Pharmaceuticals

#### 2.3.1 Pharmaceutical administration

It is possible to say that in Laos pharmaceutical administration has not been established like that in Japan or other developed countries.

In Laos, the major responsibility of the Ministry of Public Health which takes care of the pharmaceutical administration is to secure the supply of drugs which are in low quantities. Accordingly, neither enough inspections have been made to determine the efficacy or safety of drugs, nor is there any law such as a pharmaceuticals law to specify the handling of drugs. Drugs are administered to a certain extent by regulations which specify drugs whose import is forbidden or which authorize private pharmacies, and it is hoped to strengthen these regulations in the future.

Purchasing plans for drugs and raw materials are drawn up by the Central Pharmaceutical Company; these plans are then authorized by the Ministry of Public Health and the State Planning Committee.

#### 2.3.2 Demand for drugs

At present, it is difficult to determine with any accuracy the actual demand for drugs in Laos, though it is estimated to be U.S.\$5 million annually (1.5 dollars per person).

On the other hand, the supply of drugs is reckoned to be worth between two and three million dollars and these drugs are composed of \$500,000-worth produced domestically, 2 % of which are imported with the government's foreign currency, and 98 % of which come in aid from various countries, principally the coun-

tries of Eastern Europe. In addition, illegal imports from Thailand estimated to almost equal these imports under control, are meeting a part of demand, accordingly, the shortage of drugs is not necessarily so severe at present.

However, further considerable amounts of drugs must be imported so that various policies for normalization of medical care can be put into effect.

Although from the point of view of the current supply-demand balance, drugs on the market outside the government control are not in extreme shortage. Given the very nature of this market, the drugs which are available are not necessarily those which are essential, rather those drugs are imported which are easy to import and which sell well. Drugs like infusion therefore, whose unit price is low and which entail a high transportation cost, are in short supply and this fact constitutes an obstacle to policies for health care involving diseases such as malaria, stomach damage, respitory diseases and diseases endemic in the regions.

Another area in which the structure for the distribution of drugs and their market is inadequately organized is the conditions of transportation and distribution of drugs in the regions.

# 2.3.3 Domestic production and imports

Domestic production of drugs in Laos is limited to the approximately 25 items manufactured at the existing pharmaceutical factory which is controlled by the Ministry of Public Health, and the few crude drugs produced at the Crude Drug Research Center, as well as the infusions prepared by the pharmaceutical facilities within the central and regional hospitals. Of these production facilities, equipment within the hospitals which were provided with mainly Chinese assistance, most of it is not in operation. The scale of production of infusions at hospitals is between 120 and 400 liters/day.

Most of the legal imports are the raw materials for use in the existing factories or in the pharmaceutical departments of hospitals, and the drugs imported as finished products are in small quantities after those items of aid are excluded.

Although, items of drugs imported outside the control are all kinds merchandized within Thailand of numerous and diverse nature, most of the drugs imported into Laos are limited to low-priced items or those with well-known brand names and virtually none of the latest drugs available are imported by these means.

# 2.3.4 Procurement of raw materials and distribution of products

Apart from water and electric power which are available locally, all of the raw materials necessary for the existing drug factories are imported (including items provided as aid by various countries).

Naturally, the principal raw materials for drugs such as quinine, aspirin and sulfaguanidine are imported. In addition, items from such basic materials as salts for injections, glucose, corn starch, lactose and white sugar to bottles, bags, paper, ink, ampoules and capsules are also totally imported. Items such as bottles which can be used again are recycled for such reuse. Acids, alkalis, butane gas, solvents, reagents and other items of consumption and secondary materials, analytical instruments and their spare parts all depend completely on imports. Accordingly, there seem to be occasions when production activities are brought to a halt by shortages arising when imports of these basic materials slow down.

The pharmaceutical products are distributed through the Central Pharmaceutical Company mainly to the national hospital and health centers, with some also going to national pharmacies. Although, it is reported that these pharmaceutical products

meet from 60 % to 70 % of the demand from these agencies, in reality the situation is estimated to be much more severe.

# 2.3.5 Inspection and quality control systems

Although products manufactured in the existing factories are subjected to quality control inspections based on independent Lao criteria, judging from the condition of the materials and equipment, it is considered that these inspections are limited in scope and that in some cases measurement of the specified amounts of even the main ingredients is not carried out.

Moreover, since most of the principal raw materials are provided as items of aid, it is surmized that the quality of the raw materials are unstable.

# 2.3.6 Medical personnel

Currently, all of the qualified pharmacologists in Laos, whose total number does not exceed 31, are persons who obtained their qualifications abroad.

These qualified persons are employed as government executives (the Ministry of Public Health) and as directors of pharmacology departments within the major hospitals. Excepting some of the government executives who are involved in the distribution networks of the drug factories, almost all of the responsible practising technicians are assistant pharmacists (numbering about 110) who were trained in the past within Laos. In 1981, a pharmacological department (with a five-year system) was established at the Vientiane Medical College and began training activities.

Consequently, the College will turn out the first 30 to 35 graduates in 1986. In order to secure personnel for the new center, advance on-the-job training should be carried out for

the new graduates from the pharmaceutical department together with the training of new workers for the new center at the existing No.2 factory.

# 2.3.7 Outline of existing pharmaceutical factories

The only drug factory at present in Laos is the No.2 Pharmaceutical Factory of the Central Pharmaceutical Company which is under the control of the Ministry of Public Health. (The No.1 Factory is not functioning at present.)

The No.2 Pharmaceutical Facotry was originally owned by the private firm, the Liberty Drug Company which was founded in 1969, this company was then acquired by the government and nationalized. The factory comprises the older building and warehouses of about 500 m<sup>2</sup> which have production facilities for injection, tablets, capsules, infusions and ointments, and an extremely compact prefabricated construction with an area of 128 m<sup>2</sup> which was provided with the assistance of the Dutch government and houses production facilities for infusions.

The equipment in the old building is of a small scale and it does not adequately fulfill the conditions as a manufacturing plant. Furthermore, use of the equipment has had to be halted because of its deteriorated condition and the shortage of components for repair. However, the efforts to somehow proceed with manufacturing, even with equipment such as this, are worthy of a great deal of respect and admiration.

The production facilities for infusions, although small, are unique. Inside the building, there is almost no space given to purposes such as transportation or storage which are not directly related to the manufacturing process, resulting in a highly functional arrangement. These facilities are particularly well suited to maintaining product quality and to the local condi-

tions. Although the grant provided by the Dutch government was between 1.5 and 2.0 million U.S. dollars, no provision seems to have made in this amount for necessary technology transfers after the completion of the facilities.

It is reported that roughly once every two years, maintenance and inspection of the equipment has been carried out by the Dutch government.

# 2.4 Plan for Improvement of National Health Care System

The plan for improvement of the national health care system covers the following five points which are concrete activities for the department of public health within the "First Five Year Plan for Economic and Social Development (1981 -- 1985)".

- (1) Action against contagious diseases
- (2) Improvement of basic health care services
- (3) Expansion and improvement of drinking water supplies and popularization of sanitary ideas.
- (4) Improvements to regional hospitals and renovation of equipment
- (5) Production of crude drugs from indigeneous medical plants, domestic production of the drugs which are currently imported, and reorganization of the distribution network.

These measures to improve medical care are deeply related to each other and it is not possible to achieve improvements in any one area independently.

Nonetheless, the most urgent needs in each area can be highlighted as follows.

#### (1) Activities related to contagious diseases

The five-year plan mentioned above makes the following concrete actions, as a part of the activities, as vaccinations against diphtheria, whooping cough, tetanus and rebella in children and pregnant women, and measures against illness related to diarrhea in the four urban regions of Vientiane, Luang Prabang, Savannakhat and Pakse where there is a high density of population and a stable supply of electric power.

The following goals have been set for rate of innoculations in these four urban areas between 1982 and 1986.

50 % of children aged 1 to be treated with a mixed type of three vaccines (for diphtheria, tetanus and whooping cough) and to be inoculated against BCG and rubella. 80 % of children between the ages of 6 and 8 to be inoculated against BCG. 50 % of women including pregnant women between the ages of 15 and 45 to be inoculated against tetanus.

As a fundamental practice, the above vaccinations are to be carried out by health-care service agencies. In Laos, however, with its high prevalence of diseases such as malaria and tuberculosis, simply performing vaccinations against these contagious diseases is not effective.

Organized activities are also necessary such as the securing of a stable supply of drugs which are effective against these diseases and the elimination of carriers of the diseases (insects such as mosquitoes and other animals) by the use of pesticides.

#### (2) Improvement of basic health care services

One concrete measure indicated by the Lao government for improving the basic health care services is to obtain the cooperation of the citizens to participate extensively in the running of these basic services, thereby setting up a grassroots health-care organization on a national level. Other

goals include the spread of vaccinations and of sanitary regulations at village level, and an emphasis on treatment of sickness among women and children in the regions.

(3) Expansion and improvement of drinking water supplies and popularization of sanitary ideas

The Lao government pays a great deal of attention in its plans for improvement of health care to the expansion and improvement of drinking water supplies and popularization of sanitary attitudes. A concrete example of this concern was seen in the fact that the deputy chairman and the secretary general were chosen from the Ministry of Public Health, although a representative of the irrigation board in the Ministry of Agriculture was appointed as the chairman when the Water Resources Committee was established and that a regional drinking water office has been set up within the Ministry of Public Health.

Actual goals for activities aim to supply 25 % of the regional population and 70 % of the urban population (27 % of the total population) with drinking water by 1986. These activities are to adopt simple methods in keeping with the actual conditions in the regional areas such as irrigation using bamboo pipes and the digging of wells and installation of hand-operated pumps. As a further element in the execution of these plans, more than 600 water-supply technicians are to be trained by 1986.

(4) Improvements to regional hospitals and renovation of equipment.

Regional hospitals are the mainstay of all activities for improving health care including treatment and preventative measures in the regions, as well as being the focus for training of medical personnel. In order that smooth progress be made with the improvements to health care, these regional hospitals should be improved and their facilities should be renovated

and upgraded.

The first five-year plan aims to increase the number of hospital beds from 10,736 in 1982 to 13,000 in 1985. At the same time, it is planned to renovate and to upgrade facilities at the Mahosot Hospital and at regional hospitals to improve the quality of health care and to meet the large demands.

- (5) Production of crude drugs from indigenous medical plants, domestic production of the drugs which are currently imported and reorganization of the distribution network for drugs.
  - In order to realize the aim of production of crude drugs from indigenous medical plant the following three measures are necessary. 1) Drawing up of a detailed list of drugs whose principal ingredients are obtained from medical plants.
  - 2) A survey to determine actual conditions such as the geographical distribution of such plants throughout Laos.
  - 3) Finally, strengthening of the Vientiane Traditional Medicine Research Center, where the staff engaging in these activities will be trained.

Next, in regard to imported drugs, it is desirable that efforts be made to increase effectiveness of foreign currency by shifting, as much as possible, the current imports of finished products with imports of semifinished products or raw materials. And the domestic products packed for practical use should be totally labelled in Lao.

It is recommended that the organization for the distribution of drugs also be restructured in order to secure a stable supply of drugs to the regions and to maintain the quality of drugs.

Strengthening of pharmaceutical training is another problem which cannot be overlooked as a means of raising quality standards for drugs.

# 2.5 Assistance Provided by Foreign Countries and International Organizations

Since the foundation of the Lao People's Democratic Republic, aid from the United States, formerly the source of the largest amounts of aid, has stopped, and aid from other Western countries has also diminished.

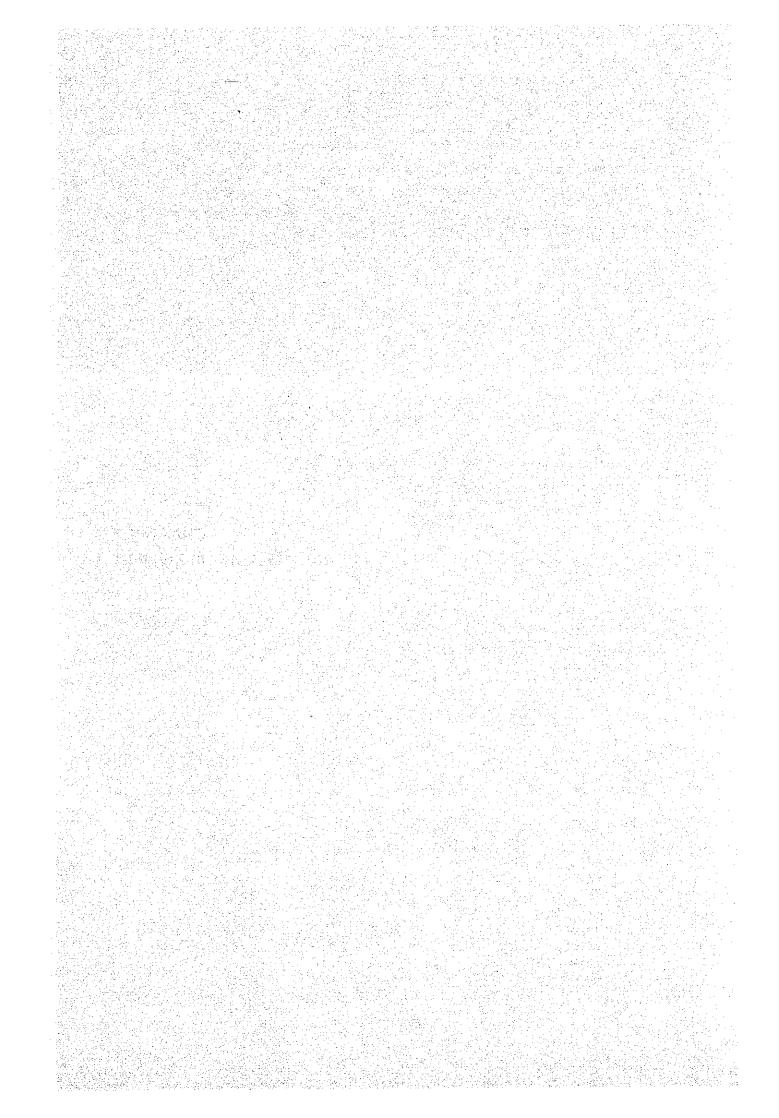
In place of these aid sources, communist bloc countries including the Soviet Union, Vietnam and the countries of Eastern Europe have become the principal source of aid for Laos. In addition to these communist countries, agencies of the United Nations, Japan, Sweden, and Australia have been providing a cosiderable level of aid. The Government of Laos is hopeful, however, of receiving even greater assistance not only from the socialist countries, but also from non-communist Western nations and the international organizations such as the IMF and ADB.

The ratio of aid from foreign countries for drugs which, as has been pointed out, are completely imported including the raw materials for those drugs produced domestically, to the imports obtained by Laos' own foreign reserves is placed at 98:2. (No actual figures for the respective values have been made public.)

The Lao government's organization for accepting foreign aid is the State Planning Committee which conducts overall coordination of foreign aid projects. The State Planning Committee has 18 departments which are responsible respectively for coordinating aid to the various government ministries and agencies. After aid project have been studied at ministerial level, the State Planning Committee administers the project and passes it on to a cabinet meeting composed of specified cabinet members. Projects which are approved by this cabinet meeting pass back to the State Planning Committee and are then reported to the embassy of the donor nation through the Ministry of Foreign Affairs. Contact between

the Ministry of Foreign Affairs and Western nations is handled by the second bureau. All negotiations with Western donor nations pass through this second bureau in the Ministry of Foreign Affairs.

# CHAPTER 3 OUTLINE OF PROJECT



# CHAPTER 3: OUTLINE OF PROJECT

# 3.1 Objectives of Project

In Laos, there are such factors to lower the average life expectancy as the disorganized nature of the health-care system with its shortages of health-care services, of measures for the prevention of disease, of medical facilities, of medical personnel and of medical supplies in addition to insufficient environment sanitation and lack of nutrition. The urgent improvement of both the quantity and quality of health care has been designated as an important activity under the first five-year plan as another means of securing the nation's economic foundations.

On the other hand, the supply of drugs in Laos functions under the unnatural conditions of a reliance for its greater part on aid from foreign countries and imports outside the government control.

Additionally, the amount of the supply of drugs, even including the foreign aid and imports outside the government control, is insufficient to meet the demand.

Shortages of the most essential drugs are particularly outstanding. The shortages of these essential drugs present major obstacles to raising the effectiveness of health-care activities, consequently, the elimination of drug shortages and the normalization of supply sources and distribution networks is indispensable to the attainment of the goals in the social development plan. One means of securing a supply of the most essential drugs which have a low profit margin when sold, and of ensuring effective use of foreign currency reserves is to import the raw materials for drugs which would then be manufactured internally making full use of domestic resources.

The objectives of this project, then, are the construction of the

"Pharmaceutical Development Center" with the necessary facilities for domestic production of drugs suited to the actual conditions of need within Laos and for producing and developing crude drugs using indigenous medical plants in order to achieve the goal set out above.

# 3.2 Project Orientation

# 3.2.1 Items and quantities to be produced

An objective determination of the items and quantities is difficult because of insufficient statistical data available to provide its basis. A decision has therefore been made by considering the details of the initial request based on the experience of the Lao Ministry of Public Health together with the judgement of the study team obtained from the survey materials.

During the preliminary survey, the Lao Ministry of Public Health indicated that it wished to produce one-third of total demand for drugs in Laos at the new center. A request was made, therefore, for facilities with production capacities of 750,000 liters per year of infusions, 20 million ampoules per year and 200 million tablets per year. As a result of discussions in which the conditions of procurement of raw materials within Laos and the shortage of trained pharmacists were taken into account, the Government of Laos proposed a modified request of the capacities to 100,000 liters/year of infusions, 5 million ampoules/year and 100 million tablets per year by reducing the amount of drugs to be produced. The Government of Laos has strongly requested that at least half of the above modified amount be secured.

With regard to the determination of the actual items and their quantities to be produced at the new center which is the basis of the basic design, it was explained to the Laotian side that a stable supply of raw materials by the Lao authorities is essential to the smooth operation of the new center, and that a plan sufficient for those imports is also necessary. The Laotian side indicated its understanding of these points.

As a result of these deliverations, the final request made by the Lao Ministry of Public Health list in Appendix 8, increaged the amount of infusion which needs urgent upply but requires comparatively less foreign currency and decreased the amount of the other items drags. The request has been recognized as an appropriate and realistic one which takes into such considerations as restriction of use in imported raw materials to meet the current financial and technical conditions in Laos, and restriction of items within those which urgently need to be produced domestically and those which can be produced with the current levels of technology in Laos.

The general outline of the items and quantities to be produced as appearing in the request is as follows.

- Plant Medicines (Traditional indigenous drugs)
   Berberine, Cacsalpinea sapan etc. equivalent to 60 ton gross weight of plant raw materials
- ii) Liquid transfusion (L.V.P) --- 150.000 liters/year

  Dextrose solution 5 %

  NaCl solution 0.9 %

  Dextrose 5 % + NaCl 0.9 % solution

  NaHCO<sub>3</sub> 1.4 % solution

|         | Procaine Hydrochloride | 1 & 2 %: 2 ml              |
|---------|------------------------|----------------------------|
| iv)     | Tablets                | 100 million tablettes/year |
|         | Quinine Hydrochloride  | 100 mg                     |
|         | Pyrmethamine           | 25 mg                      |
| ·.      | Tri-sulpha             | 500 mg                     |
|         | Sulphaguanidine        | 500 mg                     |
|         | Berberine              | 50 mg                      |
|         | Caesalpinea sapan      | 100-200 mg                 |
|         | Activated charcoal     | 500 mg                     |
| 75. 113 | Paragerique Elixir     | 100-200 mg                 |
| •       | Aspiring               | 500 mg                     |
|         | Paracetamo1            | 500 mg                     |
|         | Analgin (Sulphyrin)    | 500 mg                     |
|         | Antitussive            |                            |
|         | Antiacid               | 500 mg                     |
|         | Vitamin C              | 100 mg                     |
|         | Vitamin $B_1$          | 500 mg                     |
|         |                        | •                          |

# 3.2.2 Selection of project site

Of the three proposed construction sites indicated by the Government of Laos during the preliminary survey, the No.3 site in the north sector of the city was excluded as an inappropriate site. The current survey investigated the two other proposed sites, the No.1 site in the west sector of the city suburbs and the No.2 site in the southeast sector of the city suburbs, as well as the No.4 site in the west sector of the city suburbs which was newly proposed by the government during the current survey. The results of these on-site investigations, including comparisons of the various conditions thought necessary to the construction activities, are described in the table below.

Discussions were held with the Government of Laos on the basis of these investigations and the No.2 site, which proved superior to the other proposed sites in all aspects except conditions relating to the acquisition of this land, was selected as the project site.

The Lao Government is to complete the procedures for the acquisition of the No.2 site by the end of January, 1984, and has promised to undertake necessary site preparation prior to the end of April, 1984. The area of land adjoining the north-east corner of the site is also under negotiation for partial acquisition. Since part of this land is owned by the National Tobacco Company, negotiations for its acquisition have been made possible.

"The Regulation Concerning the Safeguard of the Road" was promuglated by the Government of Laos on September 13, 1983 and was informed to the study team after its return to Japan. The regulation prohibits the construction of a pharmaceutical factory within the area 100 m from the edge of the road. The study team asked the Government of Laos on the matter though the Japanese Embassy in Laos and received the answer that this prohibition is not to be applied to this pharmaceutical development center.

Comparison Table for Proposed Sites

| Item                    | Site No.1  | Site No.2  | Site No.4   |
|-------------------------|--|--|---|
| Area                    | 4.0 ha   | 1.4 ha (2.0 ha)  | 4.0 ha  |
| Front road              | Being planned  | Total width 29.0 m (©) Paved width 9.0 m   | Total width 29.0 m © Paved width 9.0 m  |
| Frontage                | Will be selected from Other area of 11.0 ha  | 76.0 m (115.0 m)   | C 200 m   |
| Shape                   |  | Almost rectangular (O) 75.0 x 160.0 m (115.0)  | Irregular $\triangle$ = 200 x 200 m   |
| Location & surroundings | 7 km from the center of © the city. A ridge of a hill. Undeveloped. Industrial zone in the future. | 8 km from the center of O the city. Along a trunk road Developed. Being planned as an industrial zone. | 8 km from the center of O the city. Along a trunk road Undeveloped. Being planned as a light industry zone. |
| Undulation              | Almost flat  | Slightly sloped down from the front road   | Almost flat   |
| Vegetation              | Covered by grass   | Consists of grass Covered area and bush  | Covered by tall trees $\Delta$ with thick undergrowth   |
| Electric<br>supply      | being planned  | High-voltage cable Oalong the front road   | High-voltage cable along the front road   |
|                         | _  | _  | _   |

Comparison Table for Proposed Site

|           | the O  | ◁                                | (d                               | iter of $\bigcirc$   | ublic (                                      |
|-----------|--|----------------------------------|----------------------------------|--|--|
| Site No.4 | Water main along the front road will be completed in 1983. | O None, slightly undulated area. | O Along a trunk road             | 8 km from the centhe city.   | ∆ The Ministry of Public       Health        |
| 1 11      |  | 0                                | 0                                | O <sub>f</sub> o   | 48   |
| Site No.2 | Water main along the front road will be completed in 1983. | None, higher than<br>backarea.   | Near Port Thanaleng              | 8 km from the center of $\bigcirc$ 8 km from the center of $\bigcirc$ of the city. | Private owned, requires 3 months to purchase |
| Site No.1 | Being planned  | None, hilly area                 | Roads are being planned $\Delta$ | Roads are being planned $\Delta$   | The government                               |
| Item      | Water supply   | Drainage                         | Transportation                   | Commuting  | Ownership                                    |

Note: The figures in ( ) shows the total figures including the area located at the north-east corner.

#### 3.2.3 Production facilities

The items and quantities of drugs to be produced under this project are reasonable in light of the request which has to deal with extremely urgent problems such as the condition of pharmaceutical affairs and the current financial and technical conditions in Laos. When, however, further consideration is given to the conditions of procurement of raw materials, the state of foreign exchange reserves and the plans for training of personnel in Laos, it may not be necessarily appropriate to accept all the requests without modification. The following facilities which could maintain high operation ratio are considered to be most appropriate from the point of view of present condition in Laos.

The facilities to be planned are production equipment and buildings having nominal capability of handling for the requested amount of the four requested categories, crude drugs, infusions, ampoules, and tablets.

#### (1) Crude drug zone

A building containing working areas, storage space for raw material plants and space for preliminary treatment for production of raw materials such as active ingredients, extracts and powder from medical plants is to be constructed.

# (2) Infusion, ampoule and tablet zone

This building is to contain a standard set of integrated equipment for preparation, filling, sterilization and packing of infusions and ampoules, and a standard set of integrated equipment for tablets from their weighing to granulating, drying, tabletting, coating and packing.

These zones are to be planned in one building together with

the area for common use in consideration of efficiency for keeping the production circumstances, efficiency of equipment maintenance and initial construction cost. All the necessary building services such as airconditioning, electric power supply, water supply, lighting, drainage and the like are to be provided.

# (3) Administration and quality control zone

The quality control zone is to be housed in one building together with the general administration zone as an independent function for quality evaluation of both the raw materials and products.

The administration zone contains administrative offices, managers' offices and meeting rooms suitable for use by trainees.

# (4) Utility building and exterior facilities

A utility building and exterior facilities are to be provided as integrated receiving-distribution systems and concentrated treatment systems for energy supply, steam supply, water supply, drainage, etc. in order to operate these zones.

The minimum of in-site roads and parking lots necessary for the running of the center will also be provided.

# 3.3 Outline of Project Site

#### 3.3.1 Location of project site

The project site is located on the main road leading from Thanaleng Port, the major center for the transportation of goods to Laos, to downtown Vientiane (Thadua Road; total width: 29 meters, paved width: 9 m), at a point 17 kilometers from the port and 8 kilometers from central Vientiane. The site is in

an industrial zone in Vientiane's southeastern suburbs and is surrounded by a soap factory, a tobacco factory and a oil distribution station, etc.

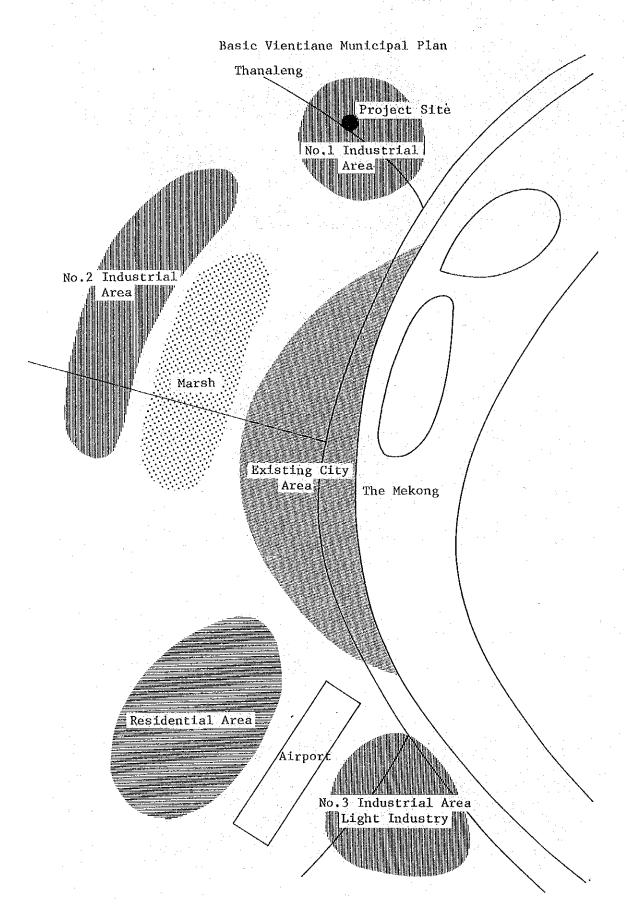
# 3.3.2 Vientiane municipal plan

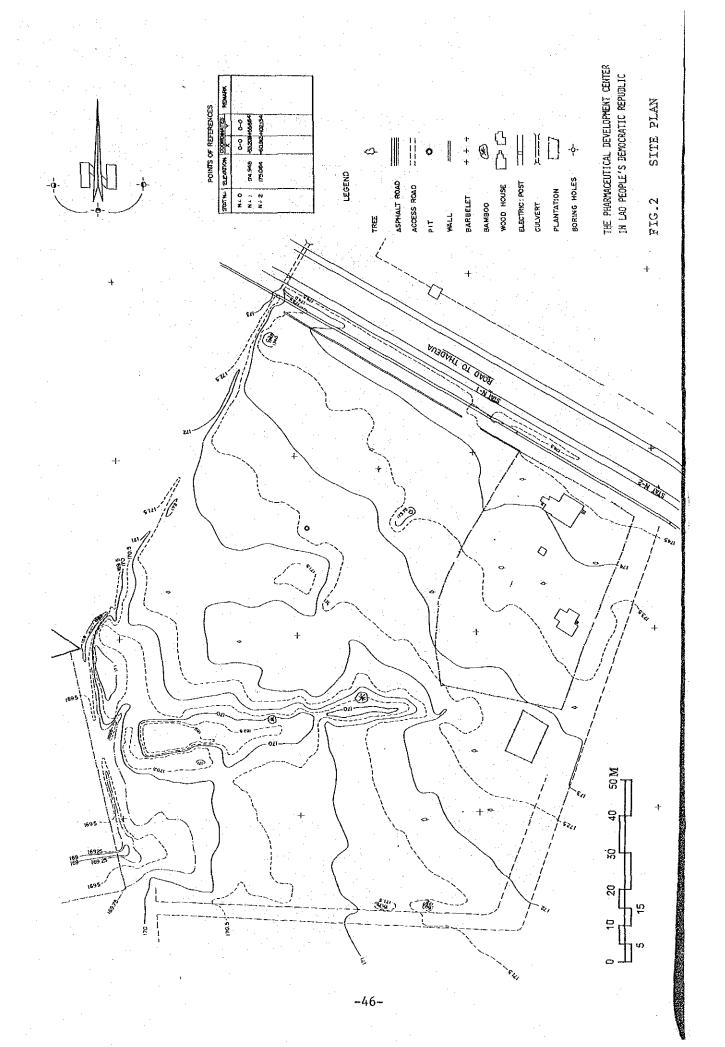
The basic structure for the Vientiane Municipal Plan was drawn up about 20 years ago by the French, but was abandoned without being carried out. With the advent of the new administration, there have been strong feelings that a basic plan for the Vientiane Municipal Plan should be drawn up independently by Laos itself. Such a basic plan, due to be released in 1985, is currently being compiled. Fig. 1 illustrates diagramatically the explanation which the study team was given by the Deputy Minister of Construction concerning the proposal currently being prepared.

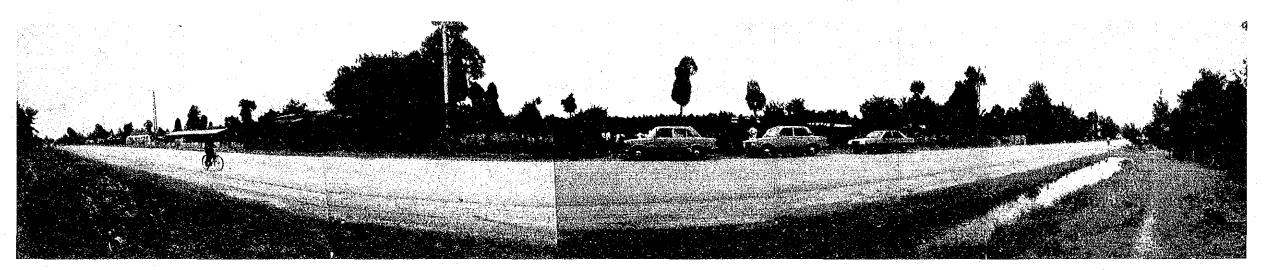
Under the terms of these proposals for the basic plan, the project site is contained in the first industrial district in the southeastern surburbs of Vientiane connected to with the port of Thanaleng which is the main base for import of goods from abroad. Already there are several factories scattered throughout this first industrial district. It is Laos' principal industrial area and has a relatively well-organized infrastructure with roads as means of transportation, electricity, water supplies and a telephone network. Together with the surrounding areas, this district will, in the future, be developed as a major industrial district.

# 3.3.3 Topography and soil-bearing capacity of project site

The topography of the project site is illustrated in Fig. 2. Although the details of soil-bearing capacity of the project site must await the results of the analysis of the soil investigations by boring carried out by the Lao Ministry of Construc-



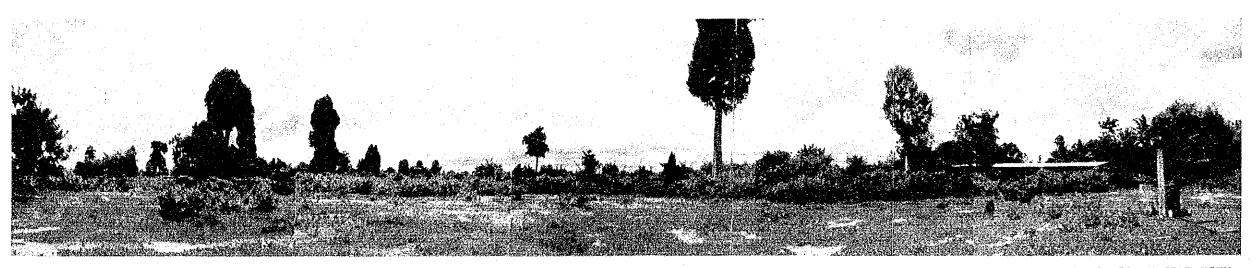




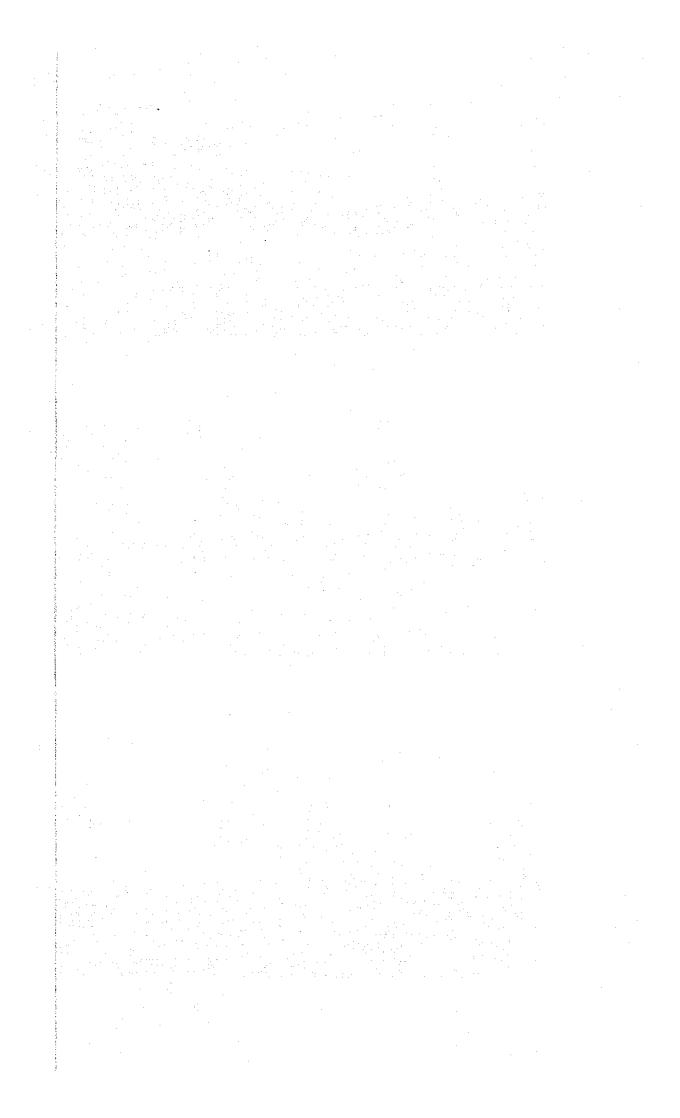
PROJECT SITE, VIEW FROM THE FRONT ROAD.



PROJECT SITE, NORTH SIDE VIEW



PROJECT SITE, SOUTH SIDE VIEW



tion. The results of preliminary surveys conducted by this study team are as follows.

Although the study team was unable to obtain geological data related to the site, as a result of observations of both the site and its surroundings, it appears that the site was on a plain formed in considerably olden times by accumulating layers of soil from the Mekong and by subsequent rises in the land mass and the soil is considerably hard. When measured with a cone penetration meter, penetration became impossible at a depth of about 30 cm. And the reading on the meter at that point showed  $250 \times 10^{-2}$  mm, which is equivalent to a soil-bearing capacity of  $14.9 \text{ t/m}^2$ . These results would lead to the conclusion that the current site for construction of the center has enough bearing capacity.

# 3.3.4 Infrastructure related to project site

#### (1) Electric power

Hydroelectric power due to the abundant water resources in Laos is both relatively plentiful and low-cost, and the country's sole domestically produced energy source.

Power transmission facilities for the project site already exist along the road running in front of the site. These are for 22KV,  $3\phi$ , 3W and have a maximum capacity of 2MW and supply to the construction site is 22KV. Accordingly, it is necessary to provide a substation in the site in order to use the electric power of this secondary voltage in this public power supply.

Existing power transmission facilities have ample capacity to serve as the power source for this project. The supply of electric power in Vientiane is relatively well organized. In particular, the construction site will be supplied by a loop trunk from the three generating stations at

Tchomcheg, Sone and Thanaleng. Power failures are likely for ten minute with intervals two or three times per month during the rainy season due to lightning.

# (2) Water supply

Although no water supply pipes are laid at present along the road in front of the project site, 200 mm water supply pipes are to be laid with the grant-in-aid from the Government of Japan for 1982.

During the construction of the new center, therefore, the public water supply will be available as the water source.

The water supply pipes are laid at a depth of 1.2 m and designed according to Japanese water-supply standards. A chemical analysis of the water proposed for supply to the new center appears in the following table.

Table for Chemical Analysis of Supply Water, 1983.

| 4. **                              |                        |                              |                    |    |
|------------------------------------|------------------------|------------------------------|--------------------|----|
|                                    | Max                    | Min                          | Average            | 0Ъ |
| РН                                 | 7.5                    | 6.2                          | 6.8                |    |
| Turbidity                          | 3 p.p.m                | 0.1 p.p.m                    | 0.2 p.p.m          |    |
| Color                              | 0.5                    | 0.1 p.p.m                    | 0.3 p.p.m          |    |
| Total Hardness                     | 130 p.p.m              | 60 p.p.m                     | 95 p.p.m           |    |
| Fe (a)                             | 0.1 p.p.m              | 0.01 p.p.m                   | 0.08 p.p.m         | -  |
| Mn                                 | 0.02 p.p.m             |                              |                    |    |
| Conductance<br>Ohm/cm <sup>2</sup> | 5200 Ω/cm <sup>2</sup> | $1800  \Omega/\mathrm{cm}^2$ | $3500~\Omega/cm^2$ |    |
| Ca <sup>+2</sup>                   | 80 p.p.m               | 30 p.p.m                     | 57 p.p.m           |    |
| Mg <sup>+2</sup>                   | 70 p.p.m               | 20 p.p.m                     | 45 p.p.m           |    |

Coliform group 2 (Ne'au)

Total bacteria General bacillus (total bacteria) = 35 max, 5 min, 20 average.

# (3) Drainage system

Except drain ditches along the roads in part of Vientiane's urban area, there is no drainage system in Laos for either soil water, general residential waste water or rain water. On the project site therefore, rain water and residential waste water will be drained away naturally from the low areas of the site. And the soil water and the waste water from the production process will need to be disposed of by seepage on site after primary treatment. There are no particular standards or regulations governing drainage systems in Laos at present.

#### (4) Telephone system

Although there are aerial telephone cables on poles along the road in front of the project site, the telephone circuit capacity is already saturated at present and there is not margin for further laying of new circuits. Investigations at the Telephone Company revealed plans to increase the telephone cables running along this road in order to handle 54 new circuits early in 1984.

If the number of circuits to be used in the center is restricted to around 5 by the provision of a private telephone exchange system and if application for early installation to the Telephone Company is made, these circuits will be available.

#### (5) Gas supply system

Since Laos has no public gas-supply system, imported LPG in cylinders would have to be used. However, it is recommendable to avoid using such LPG which is expensive and in unstable supply by replacing the gas-supply system with another energy like electric power, except for the ampoule sealing process.