BASIC DESIGN STUDY REPORT

ON

CONSTRUCTION PROJECT
FOR
PHARMACEUTICAL FORMULATION CENTRE OF ESSENTIAL DRUGS
IN
THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

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JAPAN INTERNATIONAL COOPERATION AGENCY

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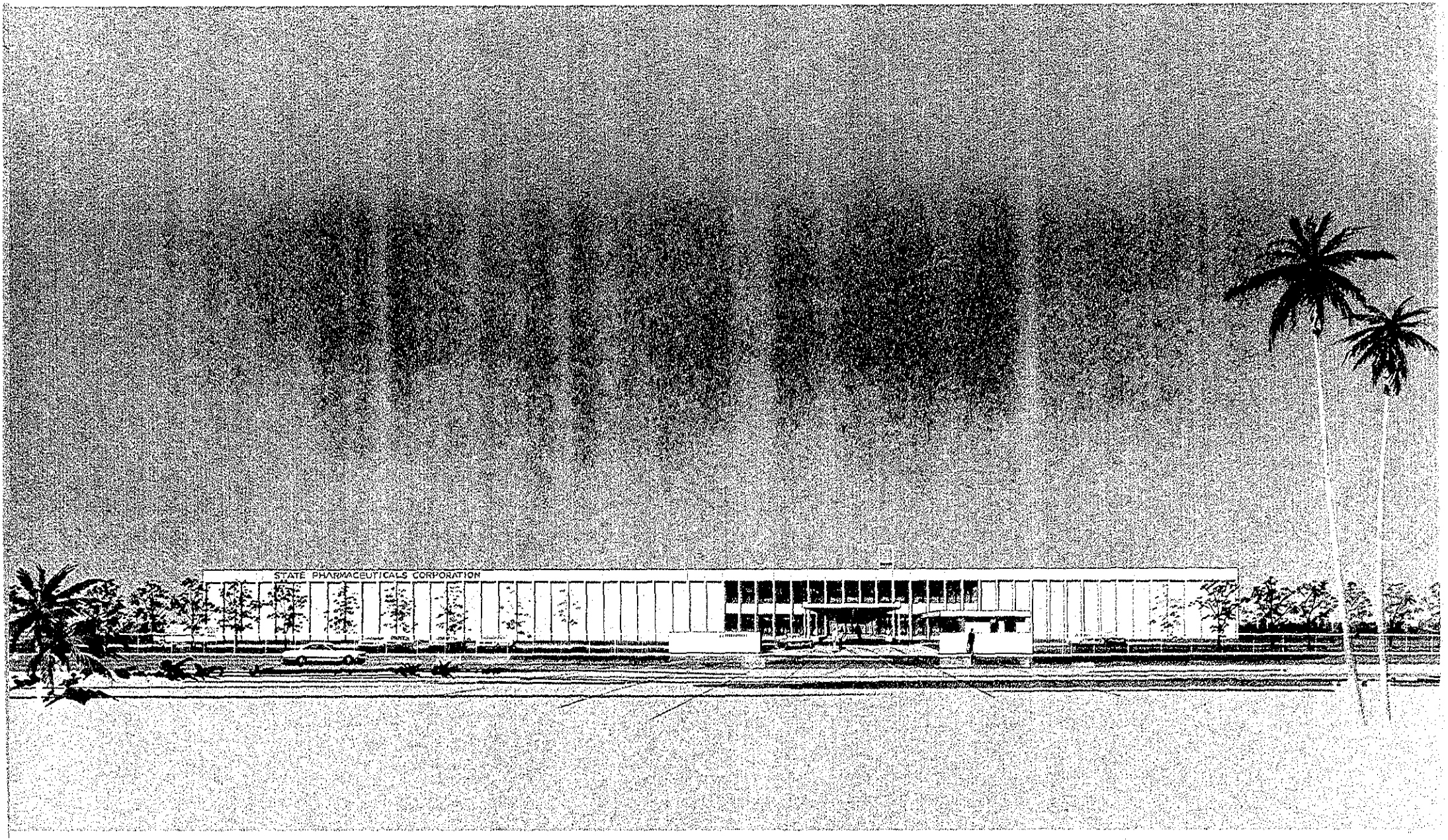

STATE PHARMACEUTICALS CORPORATION

PREFACE

In response to the request of the Government of the Democratic Socialist Republic of Sri Lanka, the Government of Japan decided to conduct a Basic Design Study on the Construction Project for Pharmaceutical Formulation Centre of Essential Drugs and entrusted the study to the Japan International Cooperation Agency (JICA).

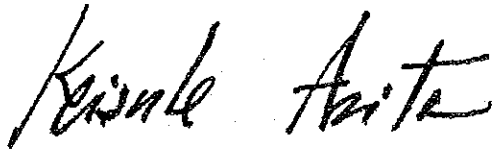
JICA sent to Sri Lanka the Phase I Study Team from 5th to 17th March, 1985, which was followed by the Phase II Study Team, headed by Dr. Masatoshi HARADA, Head of Pharmacognosy and Phytochemistry Division, National Institute of Hygienic Sciences, Ministry of Health and Welfare, from 8th to 27th July, 1985.

After the Phase II Team returned to Japan, further studies were made and the present Report has been prepared.

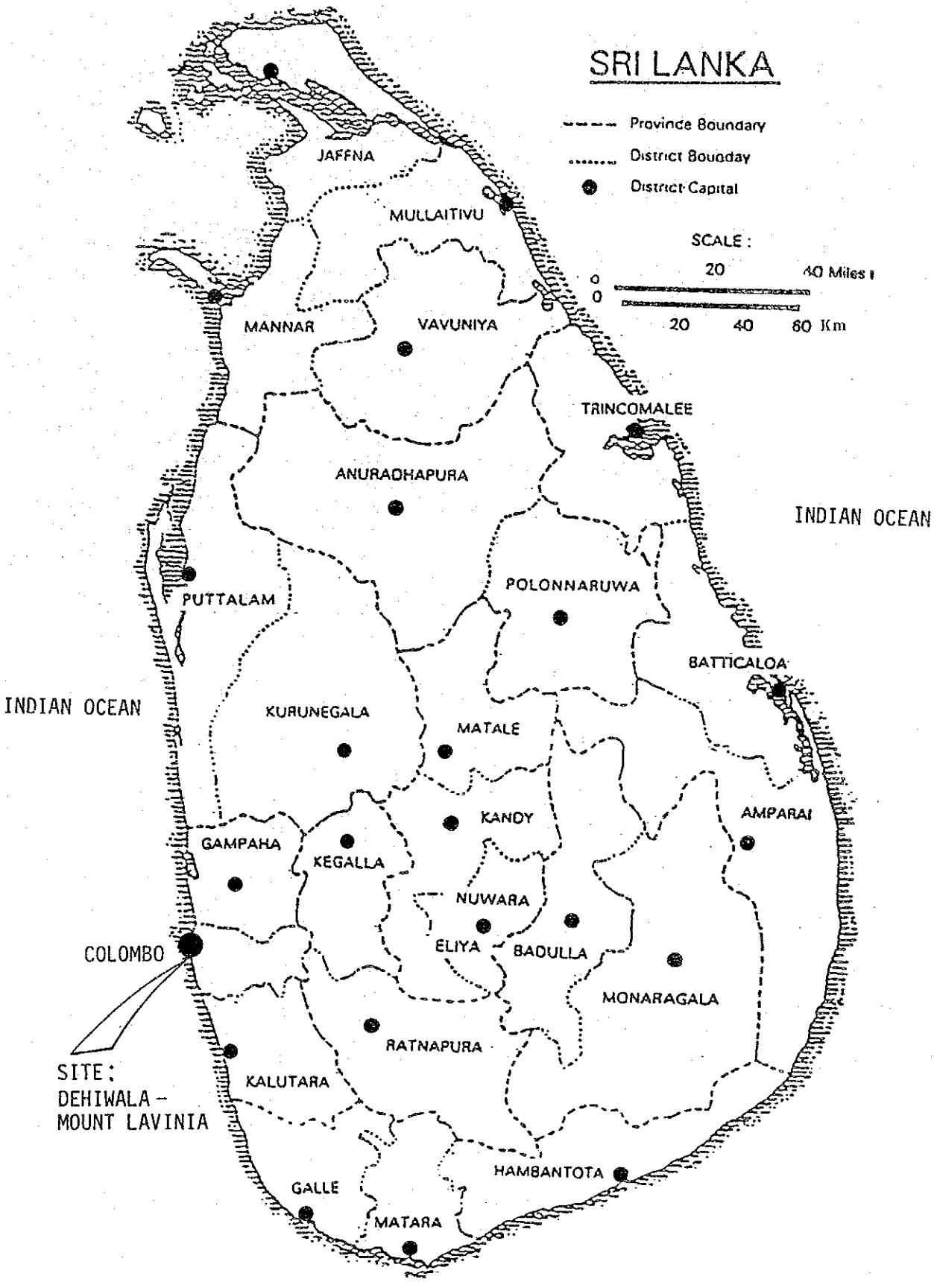
I hope that this Report will serve for the development of the Project and contribute to the promotion of friendly relations between our two countries.

I wish to express my deep appreciation to the officials concerned of the Government of the Democratic Socialist Republic of Sri Lanka for their close cooperation extended to the teams.

October, 1985



Keisuke ARITA
President
Japan International Cooperation Agency


SRI LANKA
Province Boundary
District Boundary
District Capital
SCALE :
20
40 Miles
0
0
20
40
60 Km
JAFFNA
MULLAITIVU
MANNAR
VAVUNIYA
TRINCOMALEE
ANURADHAPURA
INDIAN OCEAN
PUTTALAM
POLONNARUWA
BATTICALOA
INDIAN OCEAN
KURUNEGALA
MATALE
KANDY
AMPARAI
GAMPAHA
KEGALLA
NUWARA
ELIYA
BADULLA
COLOMBO
MONARAGALA
RATNAPURA
SITE:
DEHIWALA -
MOUNT LAVINIA
KALUTARA
HAMBANTOTA
GALLE
MATARA

ABBREVIATIONS

AIJ	The Architectural Institute of Japan
BP	The British Pharmacopoeia
BS	British Standards
CDDTAC	The Cosmetics, Devices and Drugs Technical Advisory Committee
CEA	The Central Environment Authority
CEB	The Ceylon Electricity Board
DQCL	The Drug Quality Control Laboratory
E/N	Exchange of Notes
GMP	Good Manufacturing Practice
JICA	Japan International Cooperation Agency
JIS	Japanese Industrial Standards
MOH	The Ministry of Health
MRI	The Medical Research Institute
MSD	The Medical Supplies Division, the Ministry of Health
NFC	The National Formulary Committee
NQCL	The National Quality Control Laboratory
ORS	Oral Rehydration Salts
QC	Quality Control
SPC	The State Pharmaceuticals Corporation of Sri Lanka
UDA	The Urban Development Authority
USP	The Pharmacopoeia of the United States of America
WHO	The World Health Organization

Exchange rate: 1 rupee = 8.7 yen (as of August 29, 1985)

SUMMARY

SUMMARY

With primary health care as the key approach the Government of the Democratic Socialist Republic of Sri Lanka (the name of state hereinafter abbreviated to Sri Lanka) is implementing a programme of reorientation of health care delivery system in the country to achieve acceptable level of helath for all its citizens by the year 2000. In particular, various problems concerning supply stability and qualities of essential drugs for the primary health care (e.g., supply of substandard drugs not of uniform quality, delay in supply) are pointed out. At present, these essential drugs are all imported from abroad, and almost all of the problems that are pointed out are seemingly derived from this full dependence on import in supply of such drugs.

With this situtation in the background, the Government of Sri Lanka decided that the Pharmaceutical Formulation Centre of Essential Drugs should be established to produce essential drugs within the country. In consequence of this decision, the Government of Sri Lanka requested the Government of Japan to extend a grant aid for implementation of this project.

In response to this request, the Government of Japan decided to conduct the basic design study for the proposed project and sent to Sri Lanka the basic design study (Phase I) team from 5th to 17th March, 1985 and the basic design study (Phase II) team from 8th to 27th July, 1985 through Japan International Cooperation Agency (JICA).

In Sri Lanka, essential drugs are at present supplied to the public sector and the private sector by the State Pharmaceuticals Corporation of Sri Lanka (SPC) which is responsible for supply of the essential drugs under the control and direction of the Ministry of Health. Although there are a number of private pharmaceutical manufacturers in the country, none of these local manufacturers are producing essential drugs because these drugs have only low profitability. Thus, SPC is compelled to depend fully on import for supply of the essential drugs. It is reasonable to conclude that the major problems concerning supply of the essential drugs for the primary health care in Sri Lanka cannot be solved unless the essential drugs are locally manufactured by SPC. Thus, the need and feasibility of constructing a national pharmaceutical formulation centre for essential drugs for primary health care in Sri Lanka may be emphatically asserted.

As a result of the discussion with the concerned persons on the part of Sri Lanka during the basic design study at Phases I and II, it is considered reasonable and justifiable to set the scale of this project as follows.

General Drugs	Tablets	32 items	427.5 million tablets/year
	Capsules	4 items	25.3 million capsules/year
Penicillins	Tablets	3 items	54.4 million tablets/year
	Capsules	2 items	51.4 million capsules/year
	Bottled powder	2 items	9,000 litres/year
		43 items in total	

For implementation of this project, Sri Lanka is carrying out such preparatory works as land acquisition, preparation of protocols (i.e., description of technical know-how for pharmaceutical manufacture), budgetary preparation, etc.

The proposed site for the projected Formulation Centre is already secured in the industrial estate located in Dehiwala-Mt. Lavinia. Although the site requires a little preparation in earthwork, infrastructure is almost ready for serving the site. In addition, SPC already has the drug storage and distribution facilities adjoining the proposed site.

The project of the Formulation Centre is outlined as follows.

(1) Building Facilities

The Main Building	:	One storey (in part, two storeys), reinforced concrete structure General drug manufacturing rooms, penicillin manufacturing rooms, quality control rooms, office rooms, canteen, etc.	4,229.8 m^2
The Utility Building	:	One storey, reinforced concrete structure Boiler room, water supply system, sewage treatment system, etc.	293.8 m^2
The Guardhouse	:	One storey, reinforced concrete structure Guard room	15.0 m^2
External Work	:	Car park, etc.	-
		Total floor area	4,538.6 m^2

(2) Equipment

Production equipment	:	Necessary equipment for pretreatment/ weighing, granulating, tabletting, sugar coating/film coating, packaging, bottle washing/drying, capsule filling and powder bottling
Non-production equipment and implements	:	Transportation equipment, in-process instruments, maintenance equipment, formulation improving equipment, etc.
Quality control instruments	:	Instruments for physicochemical and biological experiments and general analyses

To implement the project it will take 4 months for detail design, 1.5 months for tendering and contracting and 16 months for construction. Financially, the work to be undertaken on the part of Sri Lanka is estimated at about Rs. 10-million (¥88-million).

In consideration of the nature of a pharmaceutical manufacturing plant, the hardware, such as facilities and equipment, of the project will be provided and delivered to Sri Lanka after confirmation of their performance.

Establishment of the Formulation Centre is expected not only to solve the major problems of essential drugs described in the opening paragraph, but to have great effects (e.g., foreign exchange saving, increase in employment opportunity, increase in technological know-how of pharmaceutical manufacturing, stimulation of supporting industries such as packaging and printing) on the society and economy of Sri Lanka. On the other hand, the annual balance estimated for the Formulation Centre in stabilised production showed that the Formulation Centre would have financial feasibility. As for employment of the staff for the Formulation Centre, SPC is planning to take effectual measures to insure stable employment of the key personnel.

In consideration of all the above study results, it is concluded that the Formulation Centre project requested by the Government of Sri Lanka has sufficient reasons and significance to be immediately implemented under the grant aid programme of the Government of Japan.

To satisfactorily fulfill the objectives of the project are required harmonious and efficient connections of three factors: the grant aid, the technical cooperation, and the technical development on the part of Sri Lanka.

CONTENTS

CHAPTER 1 INTRODUCTION

CHAPTER 1 INTRODUCTION

With the primary health care as keynote, the Government of the Democratic Socialist Republic of Sri Lanka (the name of state hereinafter abbreviated to Sri Lanka) is now implementing a health and medical care improvement programme to substantiate its medical and related systems so that all its citizens will be able to receive much improved medical care by the year 2000. In this programme, the Government has a specific intent to implement its health and medical administration through improvement of preventive, curative and rehabilitative service systems.

In Sri Lanka, there exists on one hand a great demand for curative care while on the other hand various problems concerning supply stability, qualities, etc. of medical supplies, particularly essential drugs for the primary health care, are pointed out. These essential drugs are not good profit-making pharmaceutical products, and so they are hardly manufactured by large manufacturers but mainly by small manufacturers in the world. In Sri Lanka, the essential drugs are not manufactured at all and almost all of them are imports of which the sources are small manufacturers. Therefore, such small manufacturers of which the output is low by nature cannot be expected to supply drugs in time. This dependence on small foreign manufacturers cannot cope with emergency use in the case of occurence of infectious diseases. Further, qualitative problems cannot be avoided in many cases. Although products are inspected when imported, the eye of inspection cannot reach production. The poor package is liable to augment the qualitative problems and incur loss in the course of transportation. And, since the purchase of essential drugs is as a rule done by tendering, drugs are supplied from sources different from tender to tender. This causes different physiological reaction in patients because of different formulation, and confusion and psycological anxiety on medical/paramedical professionals and patients because of difference or similarity in the view of drugs.

With this situation in the background, the Government of Sri Lanka decided that the Pharmaceutical Formulation Centre of Essential Drugs should be established to stabilise supply and insure quality of essential drugs by producing such drugs within the country in lieu of importing them from foreign supply sources. In consequence of this decision, the Government of Sri Lanka requested the Government of Japan to extend a grant aid for implementation of this project.

In response to this request, the Government of Japan conducted through Japan International Cooperation Agency (JICA) the basic design study (Phase I) from 5th to

17th March, 1985 and the basic design study (Phase II) from 8th to 27th July, 1985 to supplement the study at Phase I. Through these studies at Phases I and II, the Japanese study team investigated and ascertained the general background, the matters contained in the request, the proposed organisation for the project implementation and the proposed project site, and thereafter conferred with the representatives of the concerned agencies of the Government of Sri Lanka with respect to the basic conditions of the project. Matters agreed during such conferences at Phase I and Phase II are recorded in the two minutes of discussion which were signed between Dr. (Mrs.) L.G. Jayewardene, Chairman of the State Pharmaceuticals Corporation of Sri Lanka (SPC) and Dr. M. Harada, Leader of the Japanese Basic Design Study Team. The organisation of the study teams, the diary of the teams, the minutes of discussion and the list of persons concerned in Sri Lanka are attached as Appendix I to this report.

This present Basic Design Study Report describes the basic design appropriate for implementation of the proposed project by studying justification for the project on the basis of the basic design surveys at Phase I and Phase II previously mentioned.

CHAPTER 2 BACKGROUND OF THE PROJECT

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2.1 General Situation of Medical Care in Sri Lanka

2.1.1 Primary Health Care

At the WHO (World Health Organization) International Conference on Primary Health Care held in Alma-Ata, USSR in 1978, it was decided among other matters that all governments should formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health system with the aim of attaining an acceptable level of health for all the people of the world by the year 2000.

On this decision, the Government of Sri Lanka began to implement a programme of improvement of health and medical care system in the country to achieve acceptable level of health for all its citizens by the year 2000 with the primary helath care as the keynote.

Activities undertaken under the primary health care include those aimed at primary, secondary and tertiary prevention of diseases: namely primary prevention against such infectious diseases as malaria and filariasis, secondary prevention by early diagnosis and treatment and tertiary prevention by rehabilitation and aftercare. Drugs form an essential item of supply for activities at all these three stages of prevention. In this connection, at state-established and other public medical facilities the people of Sri Lanka are entitled to health and medical care without cost to them.

2.1.2 Organisation of Medical Administration

The central medical administration of Sri Lanka is under supervision of the Ministry of Health (MOH) in which the Director General of Health Services has jurisdiction over six departments of general administration, medical services, laboratory services, public health services, development and planning, and finance (See Fig. 2.1). In addition, MOH controls the Ministry of Indigenous Medicine which is one of the outer-cabinet ministries.

In Sri Lanka, hospitals attached to universities are under the control of the Ministry of Teaching Hospitals, separately from MOH (See Fig. 2.2). The

Colombo General Hospital boasting a long history and the Sri Jayewardanapura General Hospital constructed recently under the Japanese grant aid are part of these hospitals. Regionally, each of the 24 administrative districts of Sri Lanka is provided with hospitals and other institutions controlled by one Regional Director of Health Services under the MOH's jurisdiction (See Fig. 2.3).

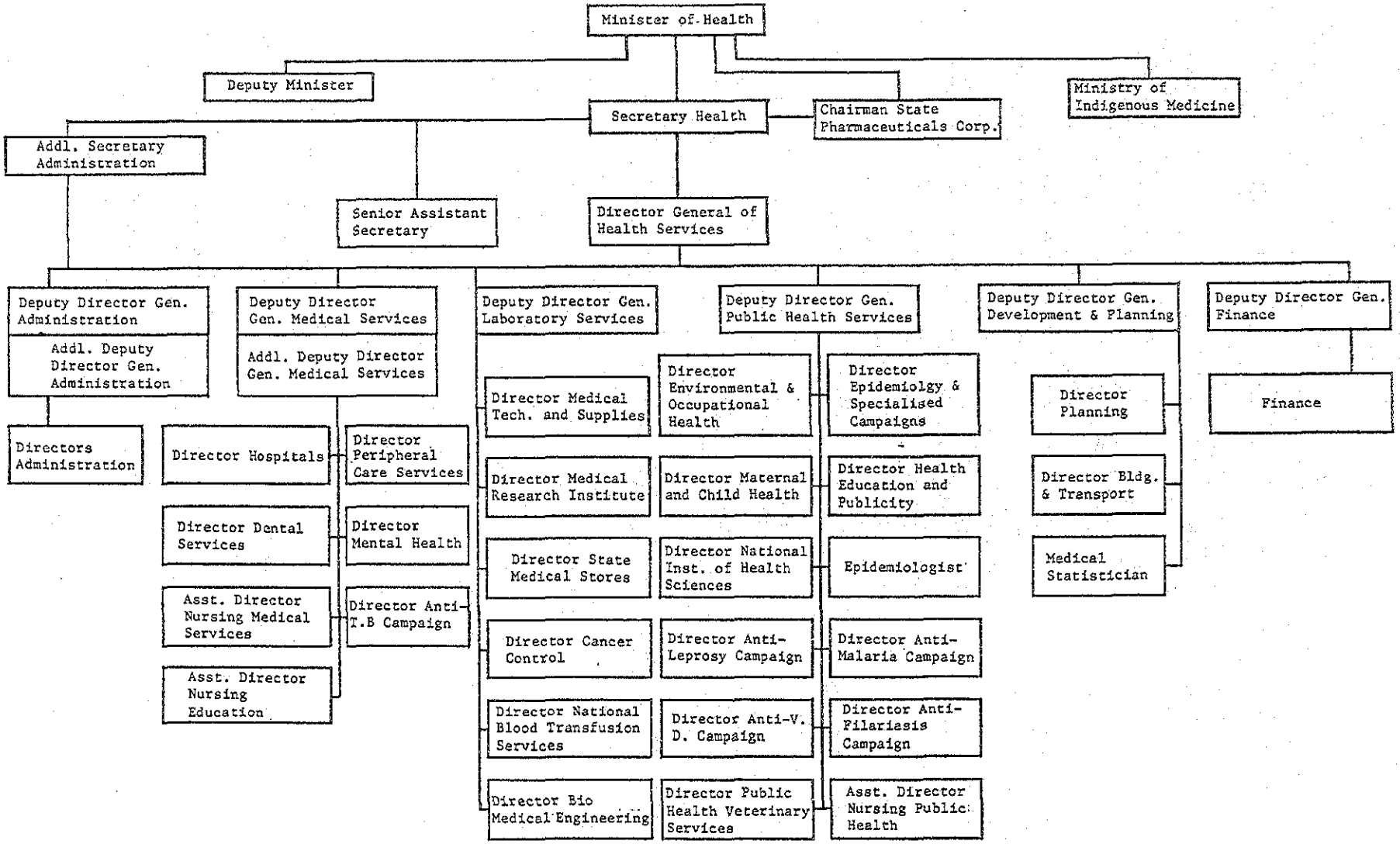


Fig. 2.1 Organisation of the Ministry of Health

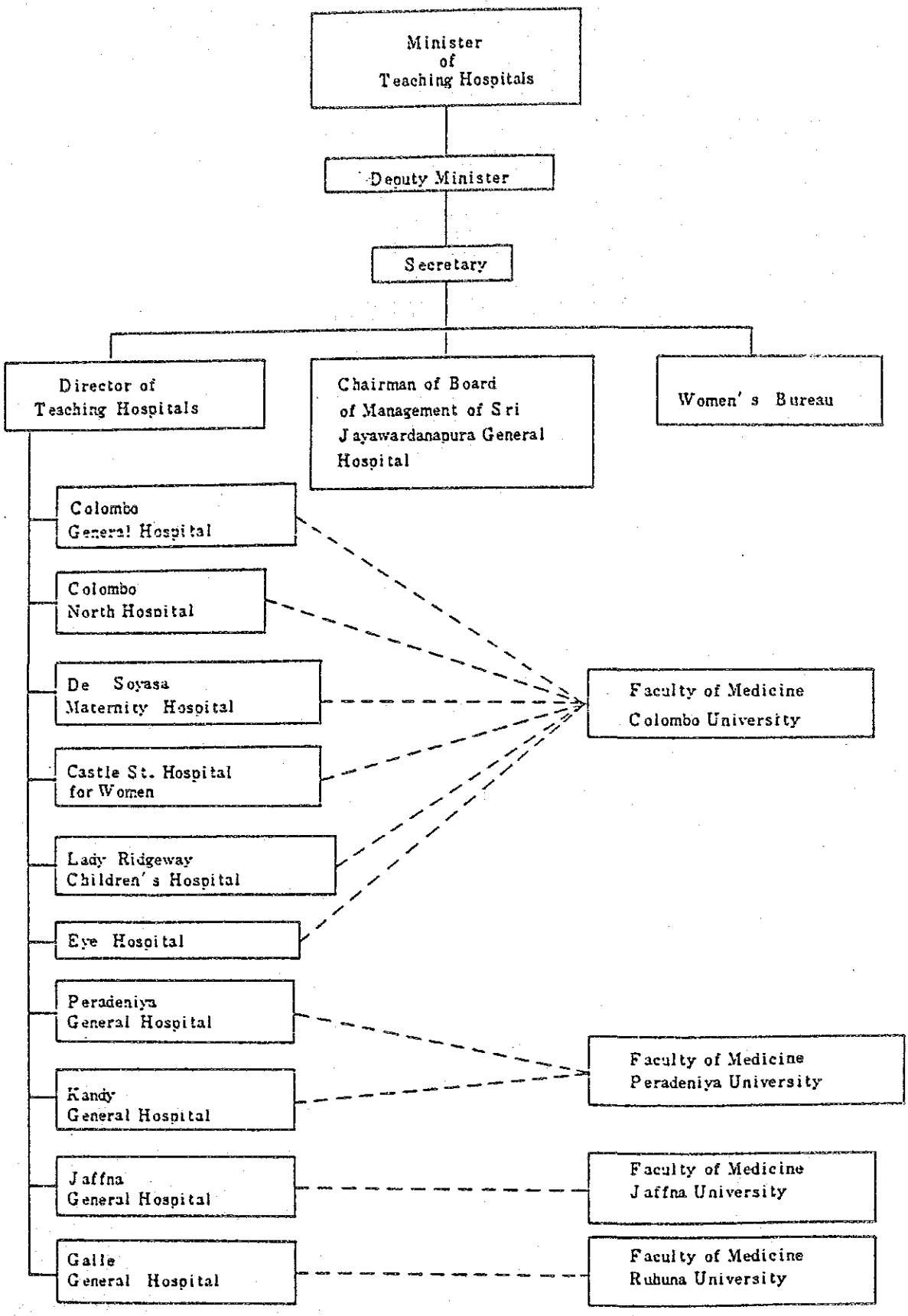


Fig. 2.2 Organisation of the Ministry of Teaching Hospitals

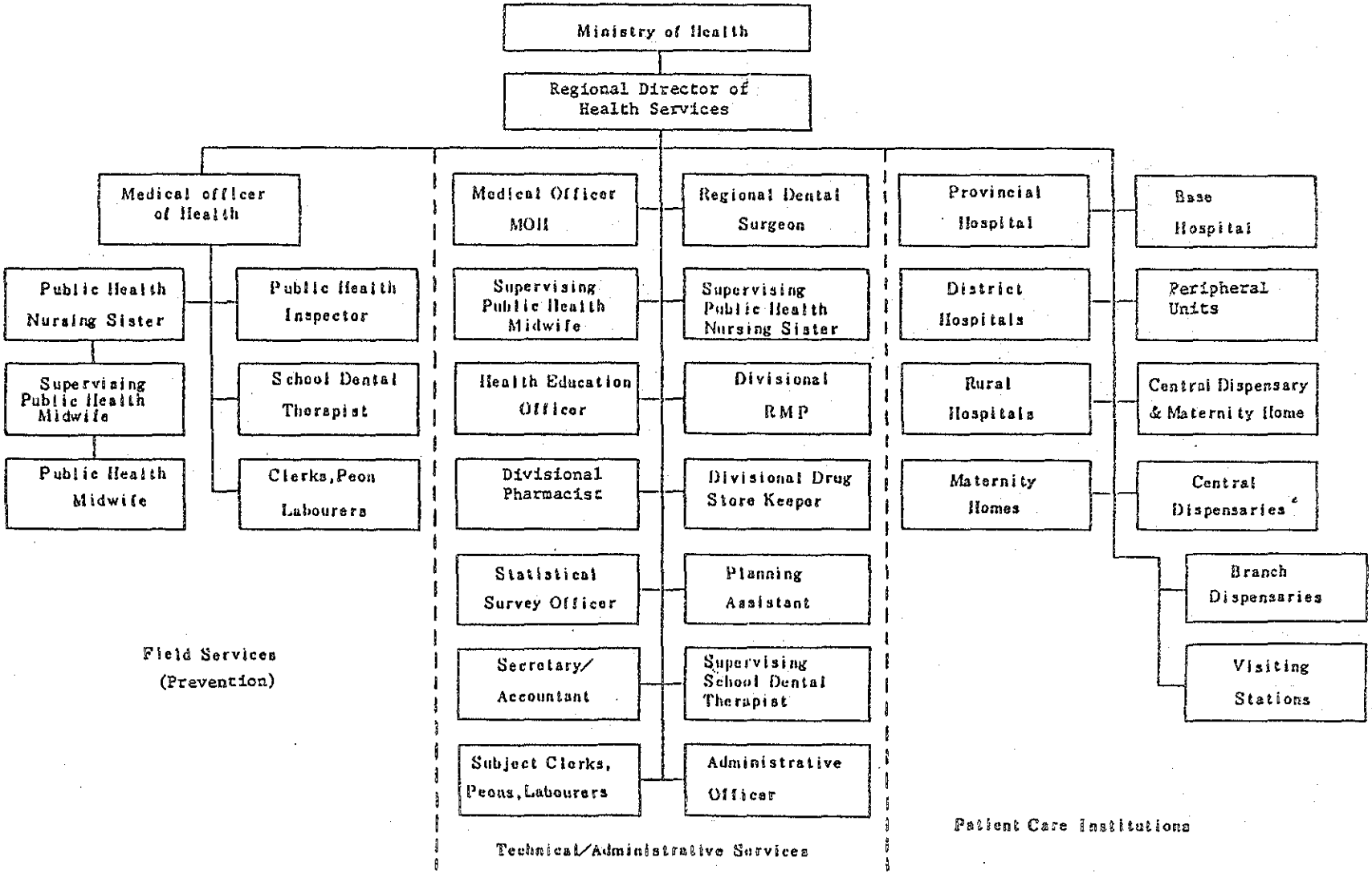


Fig. 2.3 Organisation of Regional Medical Administration

2.1.3 Medical Facilities and Professionals

Presently in Sri Lanka, the improvement programme is in progress to secure more substantial medical care service systems so that the national medical care of a higher level can be provided in the branch of the primary health care, as described in 2.1.1 "Primary Health Care."

As for the medical facilities available in Sri Lanka, there are various kinds of hospitals as indicated in Table 2.1 with the Sri Jayewardanapura General Hospital and the Colombo General Hospital at the top of the list of all medical facilities. In addition to these, there are such specialised hospitals as maternity hospitals, chest hospitals, eye hospitals, mental hospitals, cancer hospitals, children's hospitals, dental hospitals, etc.

A patient is as a rule sent from lower facilities to higher ones depending on his condition; however, he can receive necessary treatment at any of the facilities at his option. According to the latest available data, the total number of beds in all the hospitals and other medical facilities amounts to 44,016, and this means that one bed is available for every 285 people. For reference, the availability of beds is every 65 people in Japan (in 1982), 823 people in Thailand (in 1976) and 597 people in the Philippines (in 1978).

Although the bed availability in Sri Lanka is thus comparatively high in Asia, most of the hospitals and other medical facilities with the exception of the Sri Jayewardanapura General Hospital have become too old for use. Even the Colombo General Hospital does not maintain hygiene in general sickrooms.

The Government of Sri Lanka has the programme to improve medical facilities in the primary health care on the basis of the following concepts (See Fig. 2.4).

(1) To arrange the cooperative relations among teaching hospitals and other medical facilities.

(2) To give weight to local health administration.

(3) To establish Primary Health Care Complexes in regions for substantiating (1) and (2).

As for medical and paramedical professionals, Sri Lanka has, according to the 1983 statistics, a total of 2,070 medical doctors (i.e., one doctor for every 7,246 people) of whom 1,762 are actually engaged in medical

activities, 306 dentists, 7,112 nurses and 211 X-ray technicians. In these recent years, however, outflow of doctors and nurses to the Middle and Near Eastern countries, etc. mainly for earning larger incomes has been continuing, and this has made it extremely difficult for some medical facilities in Sri Lanka to exhibit their functions fully because of shortage of medical and paramedical experts, thereby creating a serious problem.

In order to cover such shortage of doctors, Sri Lanka has qualified such new types of medical professionals as Registered Medical Practitioners (RMP) and Assistant Medical Practitioners (AMP), and they are actually engaged in medical services much in the same manner as doctors do. According to the recent data, there are 933 such practitioners in total.

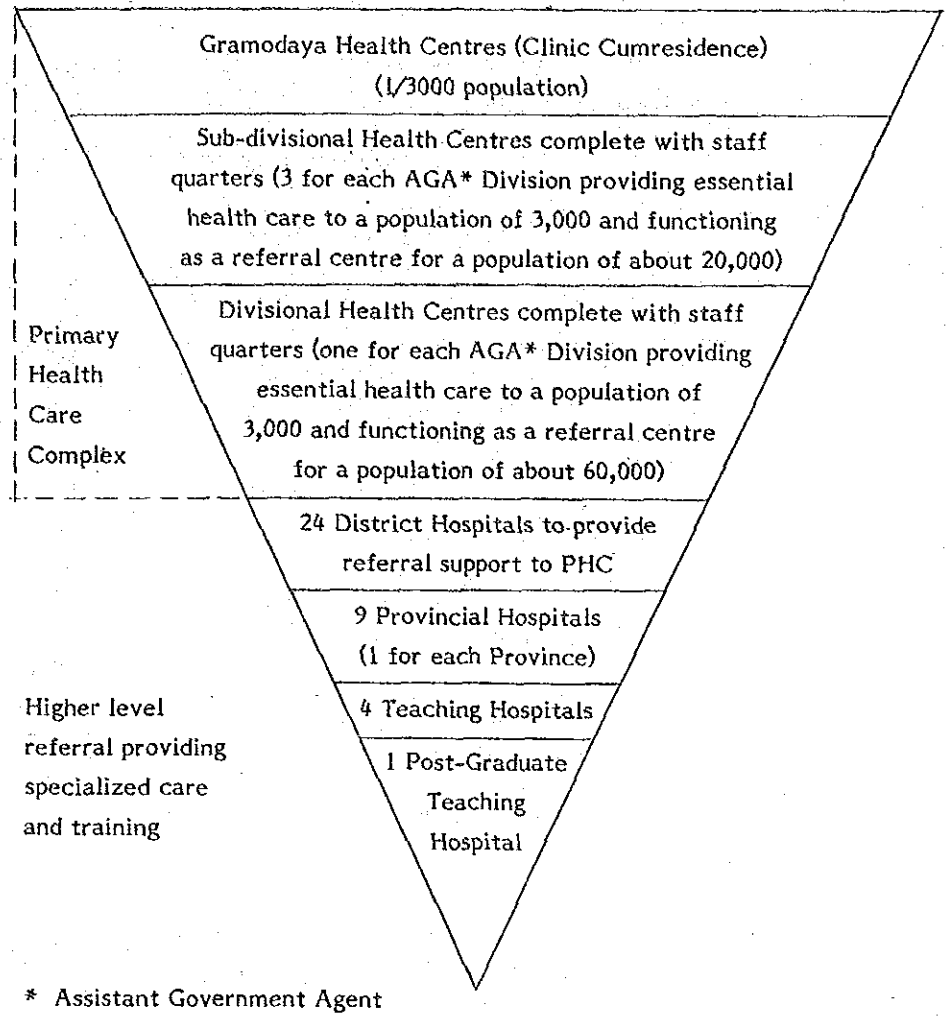
Table 2.1 Various Types of Medical Facilities existing in Sri Lanka

Types of Medical Facilities	No. of Facilities	Features of Facilities
Teaching Hospitals	11	These are large provincial hospitals where medical education is given to students at undergraduate and graduate schools. The Sri Jayewardanapura General Hospital and other hospitals shown in Fig. 2.2 are classified in this type. As a rule, each hospital of this kind is capable of offering medical services in a number of specialised disciplines and has not less than 600 beds.
Provincial Hospitals	12	These hospitals are generally located in the provincial capitals and each has not less than 500 beds. Branches of medical services covered by them are at variance depending on individual facilities, and some of them have darmatological, ophthalmological departments, etc. Seven of the teaching hospitals are classified also as a provincial hospital.
Base Hospitals	18	These hospitals have generally 150 or more beds each and are located in large cities. They usually have departments of internal medicine, surgery, pediatrics, obstetrics and gynecology. Almost all of them have one or two Medical Officers of Health (MOH's) and many of them are provided with an examination room attended by a Medical Laboratory Technologist (MLT).

(to be continued)

(continued)

Types of Medical Facilities	No. of Facilities	Features of Facilities
District Hospitals	112	These hospitals generally have one or two doctors each and like base hospitals are provided with an examination room attended by an MLT.
Peripheral Hospitals	114	In these hospitals, patients suffering from various kinds of diseases are taken care of by an RMP. They each have 30 beds more or less and are also provided with a maternity room.
Rural Hospitals	118	These hospitals generally have no maternity rooms (some of newer hospitals have them) and in many of them medical care is given at RMP's or AMP's responsibility. Also, some of them have a plan to add maternity rooms to the existing facilities.
Central Dispensaries and Maternity Homes	83	In addition to giving medical care to out-patients, these facilities admit women in pregnancy as in-patients. Medical care is given at RMP's or AMP's responsibility.
Maternity Homes	19	In these homes, only pregnant women are admitted as in-patients and taken care of by midwives.
Central Dispensaries	338	These are the medical facilities of the smallest scale where out-patients are taken care of at AMP's responsibility.
Branch Dispensaries and Visiting Stations	650	These facilities are provided in rural communities where it is difficult for their inhabitants to visit hospitals in large towns because of a long distance. Medical care is given by RMP's who visit such facilities from the nearest medical institutions at specific time on predetermined days.



Note: This service system which was drawn out as the future plan has facilities named differently from the current ones given in Table 2.1. The District Hospitals and the Divisional Health Centres in this figure are equivalent to the Base Hospitals and the District Hospitals in Table 2.1 respectively.

Fig. 2.4 Hierarchical Service Systems planned for the Primary Health Care

2.1.4 Morbidity Structure

The cases of in-hospital death account for 30 % of the total mortality in Sri Lanka. According to the official data of 1982, the mortalities of major diseases causing in-hospial death are as given below in the descending order.

(1)	Diseases of the circulatory system	38.9 %
(2)	Accidents	22.1 %
(3)	Diseases of the respiratory system	20.9 %
(4)	Infant perinatal disorders	16.8 %
(5)	Ill-defined signs and symptons	12.0 %
(6)	Gastroenteritis	11.7 %
(7)	Diseases of the gastrointestinal tract	8.4 %
(8)	Malignancies	7.2 %
(9)	Infectious diseases (excl. gastroenteritis, tuberculosis and helminithiasis)	7.2 %
(10)	Diseases of the nervous system and sense organs	7.0 %

These are followed by tuberculosis, urogenital diseases, anemias, endocrine disorders, congenital abnormalities, avitaminoses and other nutritional deficiencies, abnormal delivery and complications of pregnancy, etc. Adding out-of-hospital death to the above, however, it is pointed out that such diarrheal and infectious diseases as enteritis, cholera, dysentery, salmonellosis and typhoid fever account for about a half of the total mortality. Mortality due to such causes can be considerably reduced by stable supply of drugs as well as improvement of medical facilities, education of medical professionals and measures for public hygiene.

2.2 Present Situation of Pharmaceuticals

2.2.1 Pharmaceutical Administration

(1) Administration and State Budget

Like the medical administration mentioned previously, the pharmaceutical administration in Sri Lanka is also supervised by MOH. As shown in Fig. 2.1, SPC which is to become the implementing agency of this project when it is implemented is under direct command of the Minister of Health.

With a policy of free-of-charge medical care for all citizens, medicines are supplied to patients without cost to them at all state and other public medical facilities, and the costs incurred thereby are expended from the MOH's budget. Table 2.2 indicates the budgetary situation in this respect.

Table 2.2 Financial Aspects of Supply of Pharmaceuticals in Sri Lanka

	1982	1983	1984	1985
Total Budget of the State	38,605	51,120	51,210	59,900
Total Budget for Health Care	1,150	1,369	1,792	2,336
Percentage of Health Care Budget in the Total State Budget	2.98 %	2.73 %	3.50 %	3.90 %
Cost of Pharmaceuticals needed by the Government-established Hospitals	-	195	215	265
Percentage of the Cost of Pharmaceuticals needed by the Government-established Hospitals in the Health Care Budget	-	14.2 %	12.0 %	11.3 %
Total cost required for Pharmaceuticals in Sri Lanka	440	450	573	675
Cost of Pharmaceuticals used by one citizen (US$)	1.49	1.37	1.57	1.58

Note: Unit is million rupees unless otherwise noted.

As found in Table 2.2, the total cost required for pharmaceuticals in Sri Lanka has been showing a tendency to increase at a rate of about 20 % per annum in these few years, while the percentage of the cost of pharmaceuticals needed by the government-established hospitals in the health care budget has been in the downward trend. The reason for this seemingly paradoxical phenomenon is that the Government of Sri Lanka has been increasing the budget for improvement of the primary health care with stress on preventive rather than curative health care and, consequently, that constructional, administrative and other costs for preventive aspects has increased at a higher rate than costs of pharmaceutical requirements.

(2) Law

There is a law concerning the pharmaceutical administration. This law entitled "Cosmetics, Devices and Drugs" was promulgated as Act No. 27 in 1980 and then partly amended as Act No. 38 in 1984. The law is composed of four parts as outlined below:

Part I Prohibition in Respect of Cosmetics, Devices and Drugs

- Licensing for manufacturing, importing, storing and selling drugs, etc.
- Prohibition of manufacture, importation, storage, sale and distribution under insanitary conditions
- Conformity with the formulation standards contained in the pharmacopoeia in Sri Lanka, U.K., U.S.A., India, Japan, etc.
- Prohibition on sale of certain drugs

Part II Administration

- Organising the Cosmetics, Devices and Drugs Technical Advisory Committee (CDDTAC) for administering this act as an advisory body of MOH
- The Committee consisting of the Chairman, the Secretary Health and 13 other members (including the Professor of Pharmacology of the University of Colombo and the Chairman of SPC)
- Duties of the Committee

Part III Legal Proceedings

- Offences

Part IV General

- Definitions, etc.

This law, however, includes neither specific descriptions nor GMP (Good Manufacturing Practice) standard, applicable to pharmaceutical manufacturing facilities such as a drug formulation centre to be constructed in this project. As described later, the approval of pharmaceutical manufacturing and products of the projected Formulation Centre is made by CDDTAC.

(3) Education and Research

Any of the universities in Sri Lanka has no pharmacological department; the University of Colombo, etc. have pharmacological lectures in the medical department. The qualified pharmacists consist of the Internal Pharmacist working in the state and other public medical facilities and the External Pharmacist in the private pharmacies. Citizens having completed the high school can take a state licensing examination for the External Pharmacist after one-year attendance at lectures of the medical department of a university and one-year intern period or that for the Internal Pharmacist after two-year apprenticeship under a licensed pharmacist. As already seen for doctors and nurses, the pharmacists thus licensed also are liable to drain into foreign countries for earning larger incomes. The number of licensed pharmacists who are actually at work in Sri Lanka is at present 480.

(4) Approval of Manufacturing and Importation

The approval of pharmaceutical manufacturing and products including imports had been previously made by the National Formulary Committee (NFC) under supervision of MOH. With the enactment of the drug regulations under the aforesaid act of "Cosmetics, Devices and Drugs," NFC ceased to exist and CDDTAC was newly formed to take the place of NFC. Actual work for the approval is being made by the Drugs Sub-committee of CDDTAC.

(5) Quality Control

The quality of pharmaceuticals to be supplied is analysed by the Drug Quality Control Laboratory (DQCL) which is under the supervision of the Deputy Director General of Laboratory Service Division of MOH. DQCL has a physicochemical laboratory (about 130 m^2) and an analytical room (about 100 m^2), both sited in the Colombo General Hospital. Biological assays and testing are carried out by the Medical Research Institute (MRI) which is another subordinate organisation of MOH, because DQCL does not have instruments for such testing.

The basic design study team visited the facilities of DQCL and MRI. It was the first impression that both the facilities were very old. For example, MRI was conducting various kinds of bacteriological examinations in an environment not protected from biohazards at all.

In this connection, a new national quality control laboratory is being set up under the grant aid of Norway. The National Quality Control Laboratory (NQCL) will replace DQCL and carry out the work being done by the analytical section of DQCL. The physicochemical section of DQCL will be transferred to the MRI.

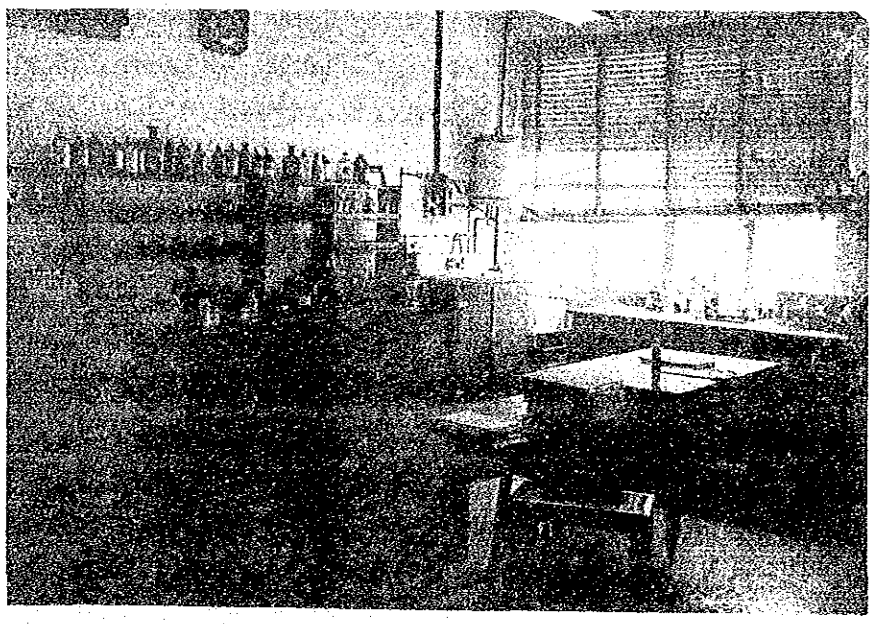


Fig. 2.5 Physicochemical Laboratory of DQCL

2.2.2 Demand for Pharmaceuticals

The consumption per capita of pharmaceuticals in Sri Lanka is at a very low level compared with that in other Asian countries as indicated in the following Table.

Table 2.3 Consumption per Capita of Pharmaceuticals (From WHO's data for 1976)

Countries	Consumption per Capita (US$)
Japan	147
Singapore	9
Korea	6.1
Malaysia	4.27
The Philippines	4.25
Thailand	3.2
Indonesia	1.8
Sri Lanka	**0.9**
India	0.75
Nepal	0.54
Burma	0.52

The value given for Sri Lanka in the above list has increased to US$ 1.58 per capita as of now, i.e., 1985; however, if the cost escalation in these past years is taken into account, it must be admitted that the consumption of pharmaceuticals in the country is still virtually at a very low level. This low consumption level may be accounted for by the fact that although the free-of-charge national medical care system is enforced in Sri Lanka, sufficient pharmaceutical supply is not being secured at the state and other public medical facilities because of the Government's budgetary limits. Further, when the fact that heavy dependence of pharmaceutical supply on the import makes it difficult to supply a necessary amount of drugs at a necessary time is taken into consideration, it may be concluded that the demand for pharmaceuticals in the country is forcefully supressed by the budget for drug procurement and suppliable volume of drugs.

When the basic design study team visited the Colombo General Hospital at Phase I, it was observed that kinds and quantities of pharmaceuticals in the dispensary were seemingly in short supply (See Fig. 2.6). The above conside-

rations may be justified by this observation.

Fig. 2.6 Dispensary in the Colombo General Hospital

2.2.3 Pharmaceutical Distribution Pattern and Supply System

One of the pronounced features of the medical care and drug distribution in Sri Lanka is the fact that there are two distribution routes of drugs: one is the free-of-charge drug supply accompanying the free-of-charge medical care at the state and other public medical facilities; and the other is the charged supply of drugs to those patients who wish to receive medical care of a higher level and drugs of higher quality at medical facilities and pharmacies in the private sector.

Of the above two drug distribution routes, drugs needed by the public sector are procured solely by SPC. Drugs of which purchase is handled by SPC are then supplied to Medical Supplies Division (MSD) which is a subordinate organisation of MOH, and MSD in turn forwards them to its three Central Drug Stores (in Deans Road, Francis Road and Old Railway Yard) in Colombo for the classification and stock, from where they are distributed to 20 relay centres which supply them to the medical facilities.

When the basic design study team visited the aforesaid three Central Drug Stores, the following observations were made. All the facilities are old; one of them has the building history dating back not less than 100 years. Although drugs are classified in stores, they are only stacked without shelves. Consequently, part of corrugated cartons at the bottom are so damp as to cause their collapse and declination. Further, cartons and packages covered with mould or drugs of which the efficacy period expired are left indoors and outdoors. Thus, it may be concluded that drugs are stored in an unfavourable environment. This means that, even if production of high quality essential drugs is realised by completion of the proposed project, such unfavourableness of the drug storage may cause deterioration in the quality of drugs before they are finally taken by patients. Therefore, it is considered necessary to make the present storing environment good at the earliest time.

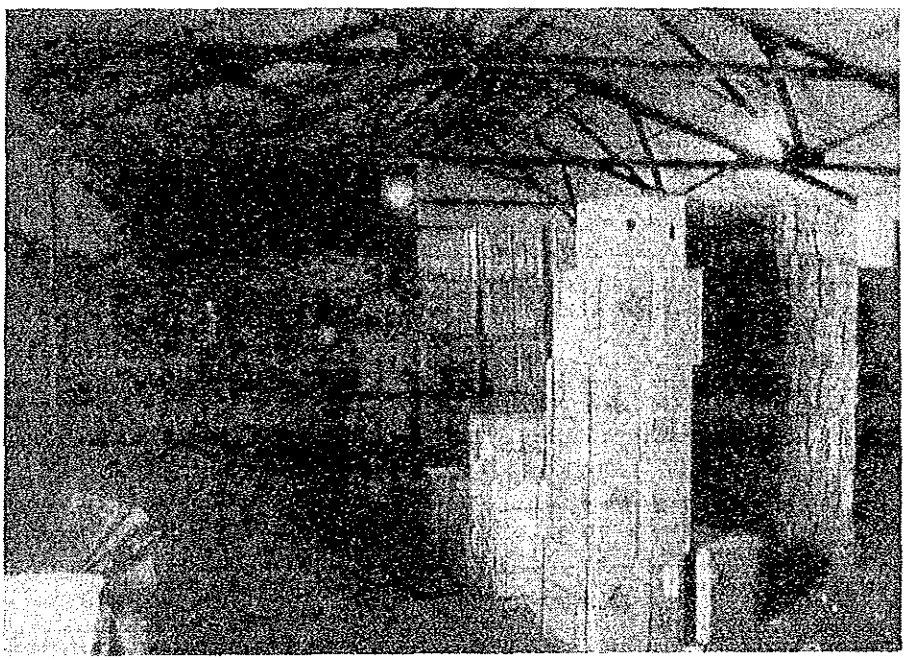


Fig. 2.7 Central Drug Stores of MSD

On the other hand, drugs required by medical facilities in the private sector are supplied not only by SPC but by private importers and private pharmaceutical manufacturers. The pharmaceutical distribution pattern in Sri Lanka is as shown in Fig. 2.8. Further, SPC itself has its own retail shops known as Osu Sala in four locations in the country. The existence in Sri Lanka of these free-of-charge and charged distribution routes creates a

problem which will be discussed in 2.4 "Problems of Essential Drugs."

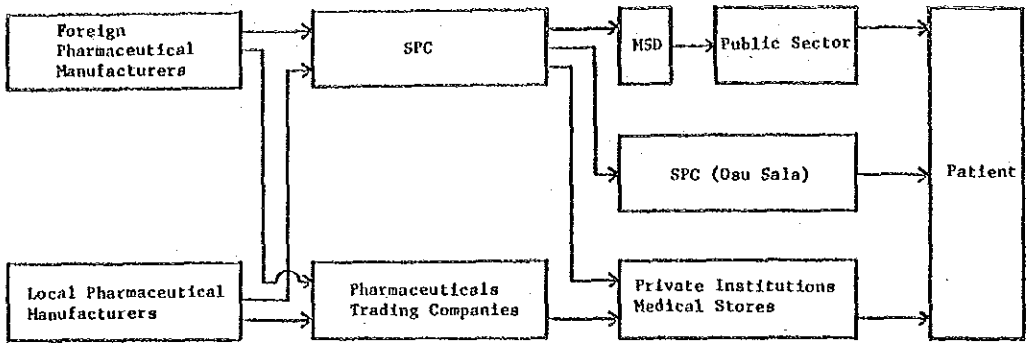


Fig. 2.8 Pharmaceutical Distribution Pattern in Sri Lanka

The annual supplies of drugs by SPC to the public sector and to the private sector, those imported by the private import firms and those manufactured by local manufacturers are, in terms of rupees, as given in Table 2.4.

Table 2.4 Annual Supplies of Drugs in Sri Lanka (In million rupees)

Years	To Public Sector	To Private Sector			Total
	Supply by SPC	Supply by SPC	Supply by Private Importers	Supply by Local Drug Manufacturers	
1978	113.3	127.5	19.5	62.0	320.3
1979	116.7	78.45	30.1	63.0	288.25
1980	119.1	79.06	64.5	76.0	338.66
1981	162.7	63.6	84.6	90.0	400.9
1982	130.2	90.2	129.3	100.0	449.7
1983	113.3	89.24	153.7	120.0	474.24
1984	145.43	104.68	192.41	125.0	567.52

Note: The supply of drugs by local drug manufacturers includes that for the public sector purchased by SPC. But the amount of such supply is so small that it can be disregarded.

In Sri Lanka, seven private pharmaceutical manufacturers are engaged in regular manufacture of tablets and capsules in their own ways. Presently, however, none of these local manufacturers are producing such essential drugs as are considered in this project because these drugs have only small added values and low profitability. Hence, it is believed that the commencement of production by SPC of such essential drugs will not arouse competition with the existing local private drug manufacturers.

2.2.4 Observations on Private Pharmaceutical Manufacturers

Of the private pharmaceutical manufacturers, the basic design study team visited three factories of MacWoods Winthrop Ltd., Warner Lambert (Lanka) Ltd. and Glaxo Ceylon Ltd. so as to ascertain the general technological level of pharmaceutical manufacturing in Sri Lanka and obtain useful information for setting up the grade of facilities and installations of the projected Formulation Centre.

The production area of MacWoods Winthrop Ltd. is provided in a remodelled warehouse. Therefore, the receiving process of liquid bottles, etc. do not have so rational layout plan. The concept of partitioning each process meets the GMP requirements and wear change is strictly controlled.

Warner Lambert (Lanka) Ltd. has a relatively new factory consisting of a production building, a welfare building (canteen and wear change room) and an administration building. The total floor area is about 1,900 m^2. The production building has a plain plan with due consideration given to personal and goods circulation and the formulating and packaging area is equipped with centralised air-conditioning system.

The Glaxo Ceylon factory is at present the most advanced and excellent in Sri Lanka. Principal functions are housed in one building. Production area is on the ground floor and packaging area and quality control area are on the first floor. The production area is planned with due consideration for the GMP requirements and circulation of persons and goods. Constructionally, special care is exercised for example in sealing the connection of mechanical and electrical installations with wall and ceiling surfaces.

The seven private pharmaceutical manufacturers in Sri Lanka are outlined in Appendix 2. In addition to them, hundreds of pharmaceutical manufacturers are engaged in manufacture of ointments, crude drugs or the like. The

manufacturers doing regular manufacture of tablets and capsules are limited to the seven indicated in Appendix 2.

2.3 Brief Description of SPC

SPC was established by the Government to be a sole original source of supplying drugs to the medical facilities in the public and private sectors. Since 1977 when the foreign trade was liberalised by the Government and import of drugs by private trading firms for supply to the medical facilities in the private sector was approved, SPC has ceased to be a monopoly for the supply of drugs to the private medical facilities but it still displays its functions to stabilse the price of drugs in the private market. As for the supply of drugs to the public sector, SPC is still functioning as a sole supplier. Because of this public nature of SPC, it is placed under direction and control of MOH. To be more specific, as shown in Fig. 2.1 the Minister of Health exercises direct control over SPC and the Secretary Health takes part in the management of SPC as one of the directors. The following table indicates the outline of SPC.

Table 2.5 Outline of SPC (As of July 1985)

Formal Name	The State Pharmaceuticals Corporation of Sri Lanka	
Address of the Head Office	75 Sir Baron Jayatillaka Mawatha, Colmbo 1	
Capital	Rs. 39,842,000 (fully invested by MOH)	
Chairman	Dr. (Mrs.) L. G. Jayewardene	
No. of Employees	439	
Major Facilities	Warehouse cum Distribution Centre for supply to the Private Sector	One facility located in Ratmalana
	Pharmaceutical Manufacturing Plant	One oral rehydration salt (ORS) mfg. plant located adjacent to the above-mentioned facility
	Retail Shop (Osu Sala)	Three in Colombo and one in Kandy
Annual Business Volume	Handling about 700 kinds of drugs, etc. amounting to Rs. 380-million approx.	

SPC's balance sheet was in deficit in 1979 and 1980 because drugs were sold below their costs by the Government directions. However, since 1983 when MOH began to pay SPC 10 % of C & F prices of drugs as service charges for import handling on behalf of MOH, it has maintained a stabilised financial condition as indicated in the following table.

Table 2.6 SPC's Financial State

Years	Net Profit before Tax (In Rs. 1,000)
1979	- 1,069
1980	- 2,850
1981	2,426
1982	4,765
1983	1,639
1984	20,430
1985	25,000 (Estiamted)

SPC is headed by the chairman who is the chief executive and has 439 staff members and workers who are engaged in the work within the frame of the organisation shown in Fig. 2.10. The organisation chart shown in this figure includes the proposed organisation of the Formulation Centre to be implemented under this project. Particulars of this proposal will be described in 3.3.1 "Implementing Organisation."

Further, Tables 2.7, 2.8 and 2.9 indicate the outline of the warehouse/distribution centre (the Store Complex), ORS formulation plant and Osu Sala which are held and operated by SPC.

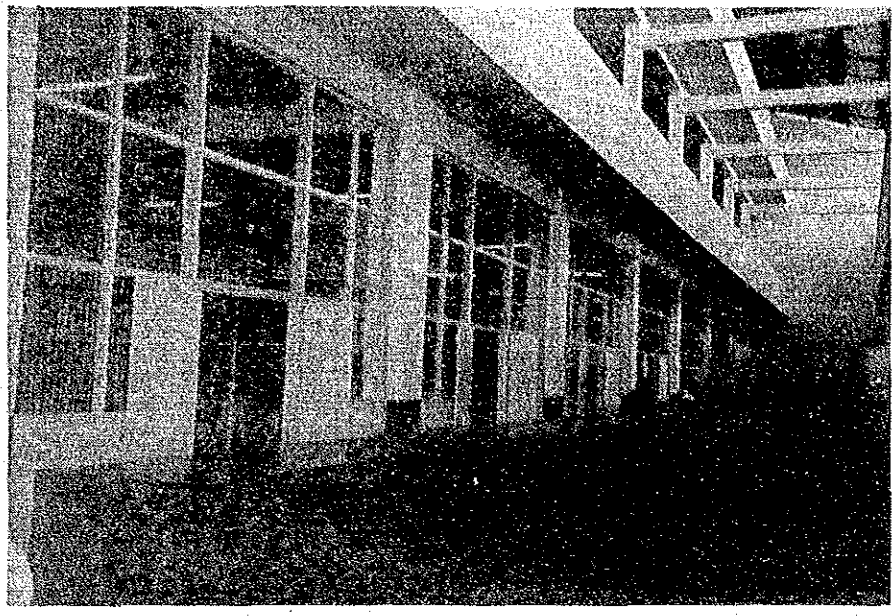


Fig. 2.9 The SPC Store Complex

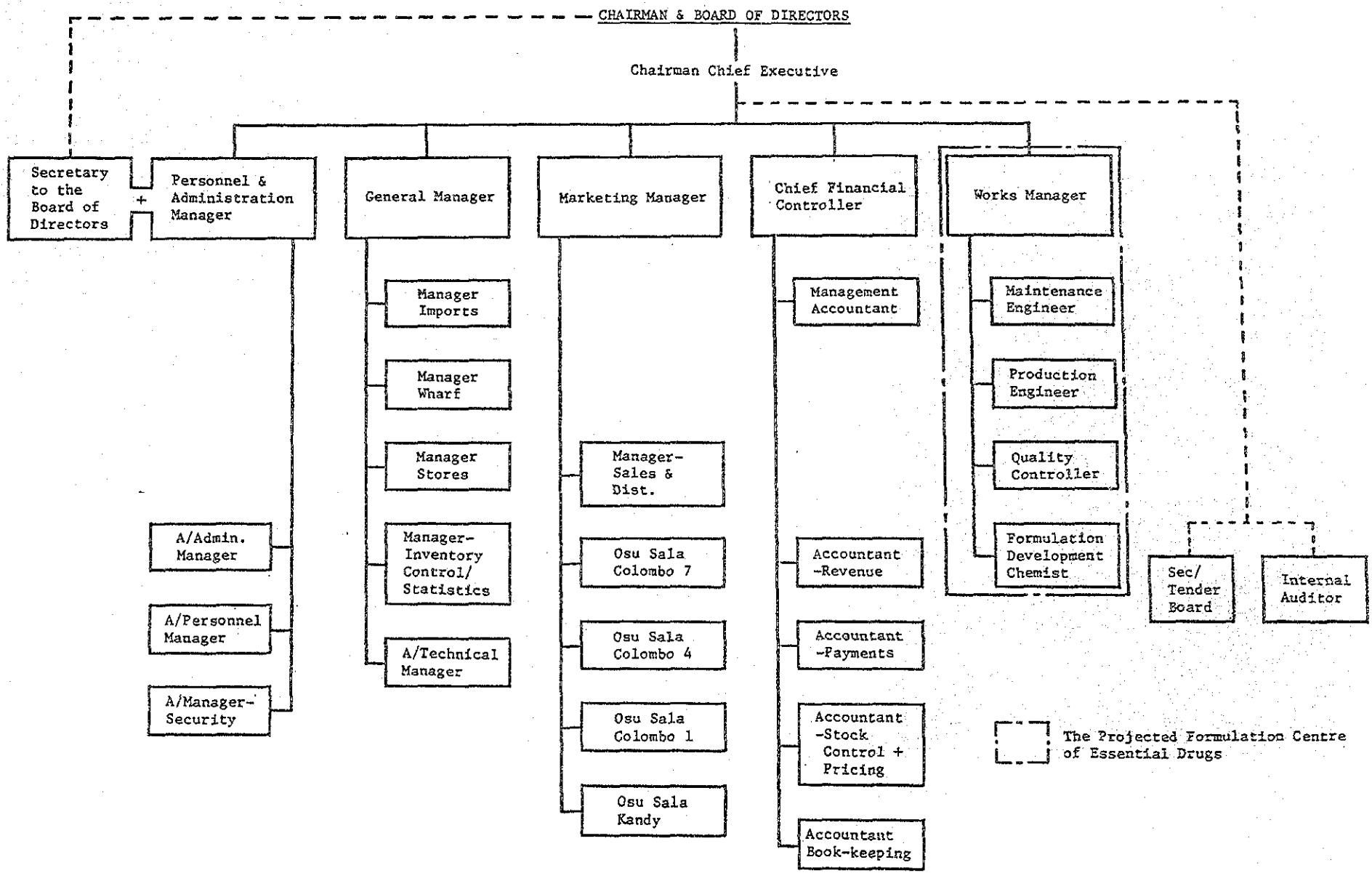


Fig. 2.10 Organisation of SPC

Table 2.7 Outline of the SPC Store Complex

Name	The SPC Store Complex
Location	No. 2 Kandawala Estate, Sir John Kotalawala, Mawatha, Ratmalana, Dehiwala-Mt. Lavinia
Principal Functions	Centre of storage and distribution of drugs for use in the private sector
Start of Operation	July 1984
Scale of the Building	Three-storeyed building with a total floor area of 3,470 m^2 approx.
Description of Structure	Reinforced concrete structure with roof trusses of structural steel
Cladding and Roofing	Cladding : Brick walls coated with cement mortar and paint finished Roofing : Asbestos cement sheets
Interior Finishes	Walls : Cement mortar, paint finished Floors and Baseboards : Painted Ceilings : Asbestos calcium silicate boards, paint finished (in office portion) Slabs of a floor above or asbestos cement sheets, paint finished (in warehouse portion)
Intra-building Transport System	Lifts, dollies and skids
Facilities	Ground Floor : Unloading berth, loading platform, and predistribution storages (six booths) First Floor : General warehouse, prefabricated cool storage, office and canteen Second Floor : Warehouse Outdoors : Substation, water supply system, septic tank and guardhouse
Storage Capacity	Area of Warehouse/Storage : 2,643.6 m^2
No. of Workers	A total of 97 (58 for warehouse, 30 for clerical/sales, and 9 guards)

(to be continued)

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Working Hours	Five days a week. 8:30 - 17:00 hours (with 45 minutes lunch time intermission)
No. of Products Handled	700 kinds of products (of which 28 kinds are local products)
Annual Volume of Business	Rs. 150-million approx.
Basic Plan	Provided by SPC
Design	By Director, Urban Development Authority
Construction	By Edward and Christie, Civil Engineering Contractor

Table 2.8 Outline of SPC's ORS Formulation Unit

Location	Located to the west of and adjoining to the warehouse described in Table 2.7
Principal Functions	Formulation of ORS
Establishment	Under the UNESCO grant aid programme
Start of Operation	March 1984
Size of Building	One-storeyed building with a floor area of about 100 m^2
Description of Building	Walls : Mortar, paint finished Floors and Baseboards : Paint finished Ceilings : Asbestos calcium silicate boards, paint finished
No. of Workers	14 in total
Volume of Production	650,000 sachets of ORS per annum
Major Equipment for ORS Formulation	On-floor scale, drum type mixer, auger type unit-dose packaging machine, heat-sealing machine, etc.

Table 2.9 Outline of SPC's Own Retail Stores (Osu Sala)

	Colombo 1	Colombo 4	Colombo 7	Kandy
Daily Business Hours	9 hours	12 hours	24 hours	11 hours
No. of Workers	9	12	25	8
Average Number of Customers per Day	400	450	850	300

2.4 Problems of Essential Drugs

In Sri Lanka, a number of private pharmaceutical manufacturers many of whom are under financial and technical control of foreign enterprises are presently carrying out manufacture of considerable kinds of drugs as shown in Appendix 2 "Brief Description of Private Pharmaceutical Manufacturers in Sri Lanka." As for 40-plus kinds of drugs which are considered essential for the first stage of manufacture in view of the morbidity structure and the national policy of primary helath care closely related with such morbidity structure, they used to be partly manufactured by these private manufacturers upon the Government's request. However, because of low added values and low profitability which result from the nature of these essential drugs, all the manufacturers backed out one after another from the manufacture of such drugs and they are now engaged in production of more profitable pharmaceutical products. In consequence, SPC which is responsible for supply of these essential drugs has been compelled to depend fully on import for supply of all these drugs except ORS. This heavy dependence on import in securing the essential drugs has created the following problems with respect to quality, supply, etc. of the essential drugs.

(1) These essential drugs by their nature cannot be good profit-making products, and they are more often than not are manufactured by small manufacturers in exporting countries with poor quality control. Thus, qualitative problems cannot be avoided in many cases.

(2) SPC, being a public organisation, procures most drugs by tendering. Because of the need of tender preparation and the fact that exporters are residents of remote countries, a lead time of at least 10 months is needed for confirmation of pharmacopoea, check of samples, etc.

(3) Since drugs are supplied by successful tenderers who are different from time to time, drugs of the exactly same properties may be different in size, shape and colour, and conversely, the drugs which are different in size, shape and colour may have exactly the same properties. This eventually creates confusion, illusion and psycological anxiety on the part of doctors and patients.

(4) Drugs imported from some of the foreign manufacturers are very poorly packaged, and loss and waste due to this cause sometimes amount to as high as 0.5 %. Cooperation to improve this situation has not been obtained despite inclusion of more strict packaging requirements in SPC's procurement specifications.

(5) A considerable amount of essential drugs supplied to patients free-of-charge at the national and other public medical facilities are distributed to private medical facilities through illegal routes. This illicit practice can be prevented to some extent by placing a special marking on each tablet supplied to the state and other public medical facilities. Since it is practically impossible to expect that any foreign pharmaceutical manufacturers will place such marking on their products, this solution is practicable only when tablets are manufactured in Sri Lanka.

(6) Each foreign drug manufacturer produces a specific drug in accordance with the pharmacopoeia (BP, USP, etc.) as specified in SPC's procurement specification. However, drugs made to the same pharmacopoeia are often at variance with respect to bioavailability depending on manufacturers, and patients generally shows different physiological reaction to them.

(7) Purchase prices of essential drugs are governed by market fluctuations and large price variations are caused by market conditions. This makes it difficult to maintain sound pre-planned financial management.

(8) If small orders are placed, unit prices of drugs will tend to become high. Thus, SPC is compelled to purchase a considerable amount of drugs at a time instead of placing small orders from time to time. In consequence, drugs are at present kept in stock for 4 to 6 months on average. This often causes expiration of the available period and imposes high interest on SPC's procurement fund.

(9) Most of foreign pharmaceutical manufacturers from whom SPC imports the essential drugs for primary health care are small enterprises who are incapable of meeting Sri Lanka's unexpected need of import in case of emergency. Even under normal circumstances, these foreign suppliers delay their product delivery making up such reasons as port workers' strikes and raw material shortage whereas a real reason for delay of shipment is their financial deficiency. (If these essential drugs come to be manufactured by SPC, it will import raw materials from large foreign firms; therefore, the problem as described above is not liable to occur.)

2.5 Setting the Request for Grant Aid

The WHO conference on drug policies and management was held in Colombo in 1978 following the previously described international conference on primary health care held in Alma-Ata, USSR in the same year. At the former conference, it was resolved that developing countries should manufacture certain essential drugs for primary health care in their own countries.

In Sri Lanka, too, it was considered indispensable for the success of the intended primary health care services that essential drugs of uniform quality should be supplied at reasonable costs. Thus, MOH directed SPC to implement domestic manufacture of certain essential drugs in lieu of importing them from foreign countries.

Pursuant to this MOH's directive, SPC prepared the Project Proposal in May 1982. This proposal suggested that the following two kinds of drug manufacturing plant projects should be implemented.

Project A : Sterile Products Manufacturing Unit

Project B : Tablets & Capsules Manufacturing Unit

The Government of Sri Lanka, however, gave consideration to the present level of pharmaceutical production technology in the country and other factors, and gave priority to Project B. Thus, after working out the project implementation plan for Project B, the Government of Sri Lanka requested the Government of Japan to extend a grant aid for the implementation of the construction project for Pharmaceutical Formulation Centre of Essential Drugs for Primary Health Care.

The request can be summarised to provision of facilities and installations capable of producing 47 items of essential drugs of which respective kinds and outputs are indicated in Annex 1 of Appendix 1.3 "Minutes of Discussion (Phase II)." The proposed site is located at No. 2 Kandawala Estate, Sir John Katalawa, Mawatha, Ratmalana, Dehiwala-Mt. Lavinia south of Colombo, and is held by SPC under lease for 99 years from the Urban Development Authority (UDA) which is a subordinate organisation of the Ministry of Local Government, Housing and Construction.

CHAPTER 3 DESCRIPTION OF THE PROJECT

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3.1 Objective

It is the objective of this project to stabilise the supply, to solve a number of qualitative problems and to supply domestic products in lieu of imported products in connection with the essential drugs which play a highly important role in the primary health care. The intent of this project is to achieve the aforesaid objective by estabilishing a formulation centre for essential drugs for primary health care at the industrial estate in Ratmalana with SPC as the implementing agency.

3.2 Review and Evaluation of the Request

3.2.1 Effects and Application of Essential Drugs

The names of diseases described in 2.1.4 "Morbidity Structure" are not so concrete as to specify the items of drugs effective in treatment. However, if effects and application of the 47 items of essential drugs requested for this project are studied as shown in Table 3.1, it may be concluded that all the requested items are highly needed for direct and indirect treatment of the major diseases showing high mortality in Sri Lanka (e.g., diseases of circulary system, respiratory system and digestive system, gastroenteritis, infectious diseases) and so have been chosen in good agreemnet with the morbidity structure of Sri Lanka.

Table 3.1 Effects and Application of the Proposed Essential Drugs

Item No.	Drug	Effect	Application	Remarks
1	Aluminium Hydroxide Tablets BP 500 mg	Gastric antacid	Hyperacidity, Gastritis, Lienteric diarrhea	Aluminium hydroxide
2	Aluminium Hydroxide and Magnesium Hydroxide Tablets			Aluminium hydroxide plus Magnesium hydroxide
3	Ascorbic Acid Tablets BP 100 mg	Vitamin C	Avitaminosis	Vitamin C
4	Ascorbic Acid Tablets BP 500 mg			
5	Aspirin Tablets 300 mg	Antifebrile, Analgesic	Fever, Headache, Toothache	
6	Co-trimoxazole Tablets BP 480 mg	Antibacterial agent	Infection	Trimethoprim plus Sulphamethoxazole
7	Co-trimoxazole Tablets BP 480 mg (Paediatric)			
8	Diethylcarbamazine Citrate Tablets BP 50 mg	Antifilarial agent	Filariasis (TPE), Tropical pulmonary, Eosinophilia	
9	Frusemide Tablets	Diuretic drug	Nephrotic syndrome, Chronic renal failure, Cardiac failure	
10	Griseofulvin Tablets BP 125 mg	Antibiotic	Fungal infections	
11	Hydrochlorothiazide Tablets BP 50 mg	Diuretic, Antihypertensive	Heart failure, Hypertension, etc.	
12	Isosorbide Dinitrate Tablets 10 mg	Coronary vasodilator	Angina	
13	Magnesium Hydroxide Tablets	Laxative, Antacid	Constipation, Hyperacidity	

(to be continued)

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Item No.	Drug	Effect	Application	Remarks
14	Metronidazole Tablets 200 mg	Antiprotozoal	Trichomonas vaginalis, Amoebiasis	
15	Multivitamin Tablets	Vitamin complex or multiple vitamin	Avitaminosis	Vitamins A, D, B_1, B_2 and C; Niacin
16	Phenoxymethyl Penicillin Tablets 125 mg	Antibiotic	Infection	
17	Phenoxymethyl Penicillin Tablets 250 mg			
18	Ibuprofen Tablets BP 200 mg	Non steroid Anti-inflammatory agent, Antipyretic analgesic agent	Chronic articular rheumatism, Arthralgia, Arthritis, Neuralgia, Neuritis,	
19	Ibuprofen Tablets BP 400 mg			
20	Prednisolone Tablets 5 mg	Synthetic steroid	Anti-inflammatory, anti-allergic	
21	Promethazine HCl Tablets BP 25 mg	Antihistamic agent, Sedative, Antitussive	Allergic disease (asthma, rhinitis, urticaria, etc.), Abirritant	
22	Propranolol Tablets BP 10 mg	Antihypertensive, Antiarrhythmic agent	Angina, Arrhythmia, Hypertension	
23	Propranolol Tablets BP 40 mg			
24	Trifluoperazine HCl Tablets BP 5 mg	Tranquilizer	Psychosis	
25	Vitamin B Complex Tablets	Vitamin	Avitaminosis, Beriberi	
26	Spironolactone Tablets 25 mg	Diuretic drug	Nephrotic syndrome, Hyperaldosteronism	

(to be continued)

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Item No.	Drug	Effect	Application	Remarks
27	Furazolidone Tablets 100 mg	Chemotherapeutic agent (antibacterial)	Bacterial disease	
28	Mebendazole Tablets 100 mg	Anthelmintic drug	Helminthiasis	
29	Primaquine Tablets BP	Antimalarial agent	Malaria	
30	Ethambutol Tablets BP 400 mg	Antitubercular agent	Tuberculosis	
31	Diloxanide Furoate Tablets 500 mg	Amebacide	Infection	
32	Paracetamol Tablets 500 mg	Antipyretic, Analgesic	Cold, Inflammatory disease, Headache, Toothache, Menorrhalgia, Lumbago, Myalgia, etc.	
33	Salbutamol Tablets BP 2 mg	Bronchodilator	Bronchial asthma	
34	Salbutanol Tablets BP 4 mg			
35	Choline Theophyllinate Tablets BP 100 mg	Bronchodilator, Antitussive, Sedative	Bronchial asthma	
36	Choline Theophyllinate Tablets BP 200 mg			
37	Phenobarbitone Tablets BP 60 mg	Anticonvulsant		
38	Ampicillin Tablets 125 mg (Paediatric)	Antibiotic	Infection, Dysentery, Diarrhea, Urinary-tract infection	
39	Chloramphenicol Capsules BP 250 mg	Antibiotic	Typhoid, Paratyphoid, Meningitis	

(to be continued)

(continued)

Item No.	Drug	Effect	Application	Remarks
40	Indomethacin Capsules BP 25 mg	Analgesic, Anti-inflammatory	Chronic articular rheumatism, Spondylosis deformans, Arthrosis deformans, Lumbago, Gout	
41	Rifampicin Capsules BP 150 mg	Antituberculous agent	Tuberculosis	
42	Rifampicin Capsules BP 300 mg			
43	Ampicillin Capsules BP 250 mg	Antibiotic	Infection, Dysentery, Diarrhea, Urinary-tract infection	
44	Cloxacillin Capsules BP 250 mg		Resistant to destruction by staphylococcal penicillinase	
45	Ampicillin Mixture BPC 125 mg/5 ml 60 ml		Infection, Dysentery, Diarrhea, Urinary-tract infection	
46	Cloxacillin Mixture BPC 60 ml		Resistant to destruction by staphylococcal penicillinase	
47	Oral Rehydration Salts	Saline	Diarrhea, Dehydration	

3.2.2 Justification for Construction of the Formulation Centre

When the major problems concerning supply of the essential drugs for the primary health care in Sri Lanka as mentioned in 2.4 "Problems of Essential Drugs" are considered one by one, it is found that almost all of these problems are essentially derived from the fact that all the essential drugs except ORS are not manufactured in Sri Lanka but imported from foreign countries. Such heavy dependence on import in securing the essential drugs has directly created the following problems.

(1) A long preparatory time is needed to obtain necessary essential drugs.

(2) Since SPC is a public organisation managed within its limited budget, any drugs are procured by tendering. This means that successful tenderers are different from time to time and so that drugs of the same properties are different in bioavailability as well as size, shape and colour.

(3) To make a purchase as low-priced as possible, a considerable amount of drugs is ordered at a time. In consequence, drugs are kept in stock for a long period and this often causes expiration of the available period and imposes high interest on the procurement fund.

Further, import of the essential drugs from foreign pharmaceutical manufacturers has indirectly caused the following problems beyond the control of the Government of Sri Lanka.

(1) Drugs imported are problematic in quality and poorly packaged.

(2) Purchase prices and time of the essential durgs are not stable.

(3) It is practically impossible to expect any foreign pharmaceutical manufacturers will admit procurement specifications such as additional marking on their products for supply to the public sector.

In view of the above, it is considered that the problems cannot be solved unless the present heavy dependence on import to maintain supply of essential drugs is discontinued and they are manufactured under strict quality control and management programmed to the demand in Sri Lanka. Because of the small profit margins of the essential drugs, it is most

unlikely that private pharmaceutical industries in Sri Lanka that are bent upon benefit by their nature will undertake the manufacture of such drugs.

Taking into account the circumstances so far described and the necessity of essential drugs in the primary health care, it is reasonable to conclude that the essential drugs should be manufactured in Sri Lanka under the control and direction of the Government; therefore, the need and justification for constructing a pharmaceutical formulation centre for essential drugs in Sri Lanka can be emphatically asserted.

3.2.3 Study for Items of Drugs to be Manufactured, Manufacturing Capacity and Scale of the Project

The Government of Sri Lanka conducted studies to select the kinds of essential drugs to be covered by this project and at the outset decided that 47 items as already described should be manufactured. Later, the Sri Lankan side agreed that the existing ORS manufacturing plant would not be moved to the new centre contemplated by this project because the current production fills the demand and has facilities and installations meeting the GMP (Good Manufacturing Practice) requirements. And, the same side requested that the remaining 46 items of drugs should be manufactured within the country in such quantities as would meet the predicted demand in 1990 by which time the contemplated Formulation Centre would be in almost stabilised operation.

This original request by the Government of Sri Lanka, however, involved extremely large volume of drugs as indicated in Table 3.2 and it was believed that such a request would very probably necessitate a project of an excessively large scale. Hence, the Sri Lankan side was requested to show the order of priority in converting the items of drugs to be supplied in large quantities from import to domestic manufacture in order to set the contemplated project at a reasonable scale. The priority thus presented by the Sri Lankan side was studied bearing in mind its effects on the project scale on one hand and considering possible problems that might arise if the import of certain items of drugs was continued by Sri Lanka. In consequence, the necessity of domestic manufacture was confirmed with respect to 43 items, or to be more specific about the aforesaid 46 items from which three items (aspirins, prednisolones and vitamin B complex tablets) were excepted.

These studies were made using the reliable data on:

- Government-planned purchase volume for 1986, and
- Predicted demand for 1990 (from the demand increase so far of 6 % on annual average)

based on the actual demand for 1984 and the determined supply volume for 1985. On the basis of such data, effects on the scale of the facilities was studied. Table 3.2 indicates what has been discussed in this subparagraph in terms of numerical values to facilitate comparison.

Table 3.2 Case Studies on Scale of Drug Formulation

		Case A (Original Request)	Case B	Case C
Contemplated No. of Items and Quantities to be Manufactured		Predicted Demand in 1990 (for 46 items of drugs)	Predicted Demand in 1990 (for 43 items selected according to priority)	Predicted Demand in 1986 (for 43 items selected according to priority)
General Drugs	Tablets	1,065.31 (35)	527.81 (32)	427.56 (32)
	Capsules	42.95 (4)	42.95 (4)	25.36 (4)
Penicillins	Tablets	68.00 (3)	68.00 (3)	54.40 (3)
	Capsules	64.25 (2)	64.25 (2)	51.40 (2)
	Powder (in thousand litres)	11.25 (2)	11.25 (2)	9.00 (2)
Total numbers of items		(46)	(43)	(43)

Notes: 1. Figures in parentheses indicate the numbers of items of drugs.

2. Unit is million pieces unless otherwise indicated.

Based on the foregoing case studies, the following judgement may be made.

(1) Supply of one and the same item of drugs by both import and domestic manufacture should be avoided because this will not ensure a uniform and stabilised quality nor does it eliminate complicated tender and import procedures.

(2) Because of the nature of the Formulation Centre, it is ideal to construct a centre which is capable of manufacturing enough drugs to meet the predicted demand in 1990 when the centre will have reached a stabilised operating stage. On the other hand, however, Sri Lankan attempt to construct drug formulation plants by its own efforts should naturally be expected.

(3) Three low priority items proposed by SPC require manufacturing in such large quantities as would greatly influence the project scale. When a judgement is made with consideration for securing them in sufficient quantities and at a stabilised qualitative level, it may be concluded that the supply of these three items may as well depend on import as at present.

For the reasons stated in the immediately preceding paragraphs, it is considered reasonable and justifiable to set the scale of this project on the basis of Case C, namely to meet the predicted demand for 43 items in the year 1986. It goes without saying that, if the entire predicted demand is to be met by the drugs manufactured in the proposed Formulation Centre, the time will come before long when the centre's production capacity will be outrun by the demand. Problems arising in such cases, however, can be overcome by adopting an overtime or two-shift operation.

3.3 Project in Briet

3.3.1 Implementing Organisation

(1) SPC as the Implementing Agency

This project is to be implemented by SPC of which the brief description is already given in 2.3 "Brief Description of SPC." As shown in Fig. 2.10, in the framework of the whole SPC this Formulation Centre is to be immediately controlled by the chairman, together with the personnel & administration, general, marketing and financial departments of SPC.

As a result of the studies, it is considered reasonable and justifiable to predict that the projected Formulation Centre will have five divisions organised by about 74 persons including the Works Manager. The predicted organisation of the Formulation Centre is shown in Fig. 3.1.

The five divisions will have the following functions and duties.

Administrative Division	:	General, financial and personnel affairs
Maintenance Division	:	Maintenance of process, quality control and utility equipment and operation of utility equipment
Quality Control Division	:	Quality control fo raw materials, in-process goods and products
Formulation Development Division	:	Development and improvement of protocols and establishment of production techniques
Production Division	:	Production

Of them, the 30 workers in production division will be assigned as shown in Table 3.3. The numbers of persons given in this table, however, are subject to some changes after the level of skills of persons availale for various types of work and the working custom in Sri Lanka are more well taken into account.

SPC is carrying out such preparatory works as studies for employment conditions, qualifications, etc. so that the staff necessary for operation of the Formulation Centre can be employed in time. In this connection, SPC informed the basic design study team that Japan was expected to assist SPC in training of key personnel in Japan before the test run and

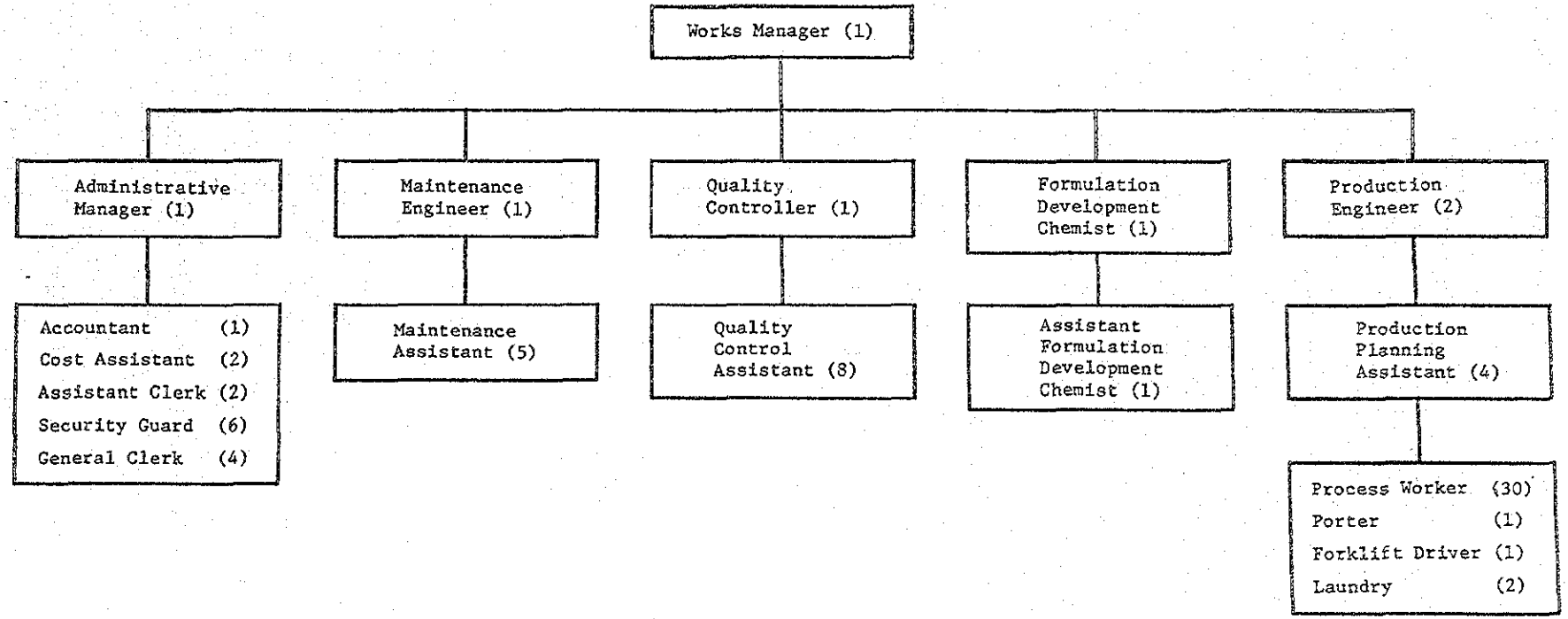
to extend a technical cooperation for local training by Japanese experts during the initial run.

(2) Budgetary Preparation by Sri Lanka

The Government of Sri Lanka must bear costs of filling at the site, extension of power and telephone lines and water supply pipeline to the site, etc. MOH has already secured on behalf of SPC the budget of about Rs. 5-million for the fiscal 1985. The fund provided by this budgetary measures will be expended for the purposes which will be more specifically described in 4.7 "Approximate Project Cost on the Part of Sri Lanka." It is understood that arrangement has already been made to continue similar budgetary provision in 1986 and onward.

Table 3.3 Proposed Personnel Assignment in Production Division

Processing Work	General Drug Dept.		Penicillin Dept.	
	Male	Female	Male	Female
Weighing	2	-	2	-
Granulating, Drying, Mixing	7	-		
Tabletting	4	-	1	-
Sugar Coating, Paste & Syrup Preparation	3	-	-	-
Capsule Filling	-	1	-	1
In-process Control	-	1	-	-
Store Control	2	-	-	-
Mixture	-	-	-	1
Packaging	-	5	-	
Total	18	7	3	2
	25		5	



Note: Figures in bracket show the number of persons.

Fig. 3.1 Predicted Organisation (Tentative) of the Essential Drug Formulation Centre

3.3.2 Capacity and Scale of the Project

(1) Drugs to be Manufactured and Manufacturing Capacity

As the result of study in 3.2.3 "Study for Items of Drugs to be Manufactured, Manufacturing Capacity and Scale of the Project," the items of drugs to be manufactured in the Formulation Centre and manufacturing capacity of each item are as listed in Table 3.4. The listed 43 items are classified as follows:

General Drugs	Tablets	: 32 items	427.5 million tablets per yr
	Capsules	: 4 items	25.3 million tablets per yr
Penicillins	Tablets	: 3 items	54.4 million tablets per yr
	Capsules	: 2 items	51.4 million capsules per yr
	Bottled Powder	: 2 items	9,000 litres per year

43 items in total

(2) Protocols

For implementation of any pharmaceutical production plants, it is essential that what is known as a protocol should be secured. Protocols are in essence documents which stipulate such basic matters as preparation for raw material proportioning, requirements for equipment to be used and quality control techniques. Since protocols are always prepared by persons who have actually engaged in pharmaceutical production on the basis of their own experience, it is generally difficult for persons inexperienced in this specific discipline to obtain them. SPC, however, has already in its possession the protocols on all the proposed 43 items. The production equipment to be installed in the Formulation Centre will be chosen by studying and, if necessary, modifying these protocols.

(3) Operating Conditions

The operating conditions are set as follows taking into account the working custom in Sri Lanka, machine maintenance and operation, etc.

No. of Working Days	:	240 days per year
No. of Days for Maintenance Services	:	10 days per year
No. of Actual Operating Days	:	230 days per year
Working Hours	:	8 hours/day
Machine Working Hours	:	6 hours/day*

* The remaining two hours in the working hours will be used for warmup and cleanup, except for tabletting machines which will be operated 8 hours/day.

Table 3.4 Items of Essential Drugs to be Manufactured and their Manufacturing Capacity
(Items No. 5, No. 20 and No. 25 are voided.)

No.	Item	Description of items to be formulated: Wt.per Tablet/Capsule in mg	Diameter in mm	Split Line	Colour	Coating	Penicillin Yes ···· O	Packaging size Tablets/capsules	Technical Know How (protocol) complete ···O incomplete···×	Quantity Projected for 1986 In Millions
	TABLETS									
1	Aluminium Hydroxide Tabs BP 500mg	1.018	16.0	Quarter Scored	White	uncoated		1.000	O	30.6
2	Aluminium Hydroxide and Magnesium Hydroxide Tabs	800	16.0	Scored	Pink	uncoated		500	O	3.0
3	Ascorbic Acid Tabs BP 100mg	300	9.5	Half Scored	White	uncoated		1.000	O	31.0
4	- do - BP 500mg	810	14.0	Half Scored	White	uncoated		1.000	O	3.0
6	Co-trimoxazole Tabs BP 480mg	600	12.5	Half Scored	White	uncoated		500	O	9.0
7	- do - Paediatric	200	8.0	Half Scored	White	uncoated		1.000	O	1.32
8	Diethylcarbamazine Citrate Tabs BP.50mg	217	8.0	—	White	uncoated		1.000	O	22.3
9	Frusemide Tabs BP 40mg	180	8.0	Half Scored	White	uncoated		500	O	10.7
10	Griseofulvin Tabs BP 125mg	151	8.0	Half Scored	White	uncoated		100	O	2.1
11	Hidrochlorothiazide Tabs BP 50mg	200	8.0	Half Scored	White	uncoated		1.000	O	12.0
12	Isosorbide Dinitrate Tabs 10mg	220	9.0	Half Scored	White	uncoated		100	O	9.6
13	Magnesium Hydroxide Tabs 300mg	583	11.0	Half Scored	White	uncoated		100	O	0.8
14	Metronidazole Tabs 200mg	380	12.5	Half Scored	Yellow	uncoated		100	O	14.5
15	Multivitamin Tabs	103	—	—	Brown	sugar-coated		5.000	O	75.0
16	Phenoxymethyl Peni. Tabs 125mg	162	8.0	Scored	White	uncoated	O	1.000	O	49.0
17	- do - 250mg	324	10.0	Scored	White	uncoated	O	500	O	3.6
18	Ibuprofen Tabs BP 200mg.	290	10.0	—	Magenta	film-coated		100	O	0.6
19	- do - BP 400mg	530	12.0	—	Dark-Magenta	film-coated		100	O	—
21	Promethazine HCL Tabs BP 25mg	130	7.0 (core)	—	Red	sugar-coated		1.000	O	16.1
22	Propranolol Tabs BP 10mg	120	6.5	—	White	uncoated		250	O	1.0
23	Propranolol Tabs BP 40mg	240	8.5	Half Scored	Dark-Pink	uncoated		250	O	10.2
24	Trifluoperazine HCL Tabs BP 5mg	152	7.5	Half Scored	White	uncoated		1.000	O	20.1
26	Spironolactone Tabs 25mg	262	9.0	Half Scored	Light tan	uncoated		1.000	O	1.42
27	Furazolidone Tabs 100mg	244	9.0	Half Scored	Yellow	uncoated		500	O	13.6
28	Mebendazole Tabs 100mg	300	10.0	—	Orange	uncoated		250	O	1.1
29	Primaquine Tabs BP	165	8.0	—	White	uncoated		1.000	O	12.4
30	Ethambutol Tabs BP 400mg	593	13.0	—	White	uncoated		100	O	9.0
31	Diloxanide Furoate Tabs 500mg	620	12.5	Half Scored	White	uncoated		500	O	0.115
32	Paracetamol Tabs 500mg	602	12.5	Half Scored	White	uncoated		1.000	O	94.0
33	Salbutamol Tabs BP 2mg	144	6.5	Half Scored	White	uncoated		1.000	O	3.2
34	Salbutamol Tabs BP 4mg	217	8.5	Half Scored	White	uncoated		1.000	O	2.0
35	Choline Theophyllinate Tabs BP 100mg	225	8.0	—	White	sugar-coated		100	O	1.0
36	- do - BP 200mg	400	10.0	—	White	film-coated		100	O	1.5
37	Phenobarbitone Tabs BP 60mg	100	6.3	—	White	uncoated		1.000	O	15.3
38	Ampicillin Tabs 125mg (Paed)	225	8.0	Half Scored	White	uncoated	O	100	O	1.8
								TABLETS TOTAL		481.955
	CAPSULES									
39	Chloramphenicol Caps BP 250mg	277	No 2	—	White /White			1.000	O	11.4
40	Indomethacin Caps BP 25mg	184	No 4	—	Ivory /Ivory			500	O	11.0
41	Rifampicin Caps BP 150mg	260	No 2	—	Red /Blue			100	O	2.16
42	- do - BP 300mg	400	No 1	—	Chocorate Brown /Chocorate Brown			100	O	0.8
43	Ampicillin Caps BP 250mg	293	No 1	—	Scarlet /Black		O	1.000	O	42.0
44	Cloxacillin Caps BP 250mg	290	No 1	—	Black /Orange		O	500	O	9.4
								CAPSULES TOTAL		76.76
	MIXTURE									
45	Ampicillin Mixture BPC 125mg /5ml 60ml	23.61	4 oz (60ml)				O		O	7.600
46	Cloxacillin Mixture BPC 60ml	30	4 oz (60ml)				O		O	1.400
								MIXTURE TOTAL		9.000

3.3.3 Location and State of the Project Site

(1) General

The site prepared for this Formulation Centre by SPC is located in Dehiwala-Mt. Lavinia about 13 km south of Colombo. This municipality forming part of the Colombo Metropolitan Region contains the second largest population (177,000 as of 1982) in Sri Lanka. In the Colombo Regional Structure Plan drawn up by UDA, Dehiwala-Mt. Lavinia, particularly Ratmalana, is expected to serve as an industrialised zone (See Fig. 3.2).

They can go from Colombo to the site by taking Route 2 "The Galle Road" toward the south and then following the Ratmalana Airport approach road about 1.6 km to the east. The site is in the Ratmalana Industrial Estate developed by UDA. In the vicinity, the Textile Training Centre, the Food (Fruits Juice) Storage and the Powder Milk Plant are being constructed and the Cement Factory Headquarters is waiting for construction. The Ratmalana Airport (the Air Force Base) is on the north of the site with a road between them.

The site has an area of about 2.4 hectares (6 acres), of which about 0.8 hectares (2 acres) is already occupied by the Store Complex functioning as a storage and distribution centre mainly for drugs for the private sector. In addition, ORS is being manufactured in part of the Store Complex. The site is held by SPC under lease for 99 years from UDA. This means that roads, gutters, etc. around the site are maintained by UDA. Therefore, it was made certain that the faults of the southern stormwater gutter found during the Phase II survey were to be repaired by UDA.

In this connection, UDA is in charge of urbanisation in Sri Lanka, and the present industrial estate is one of the various industrial estates developed by UDA for the purpose of industrialisation of Sri Lanka.

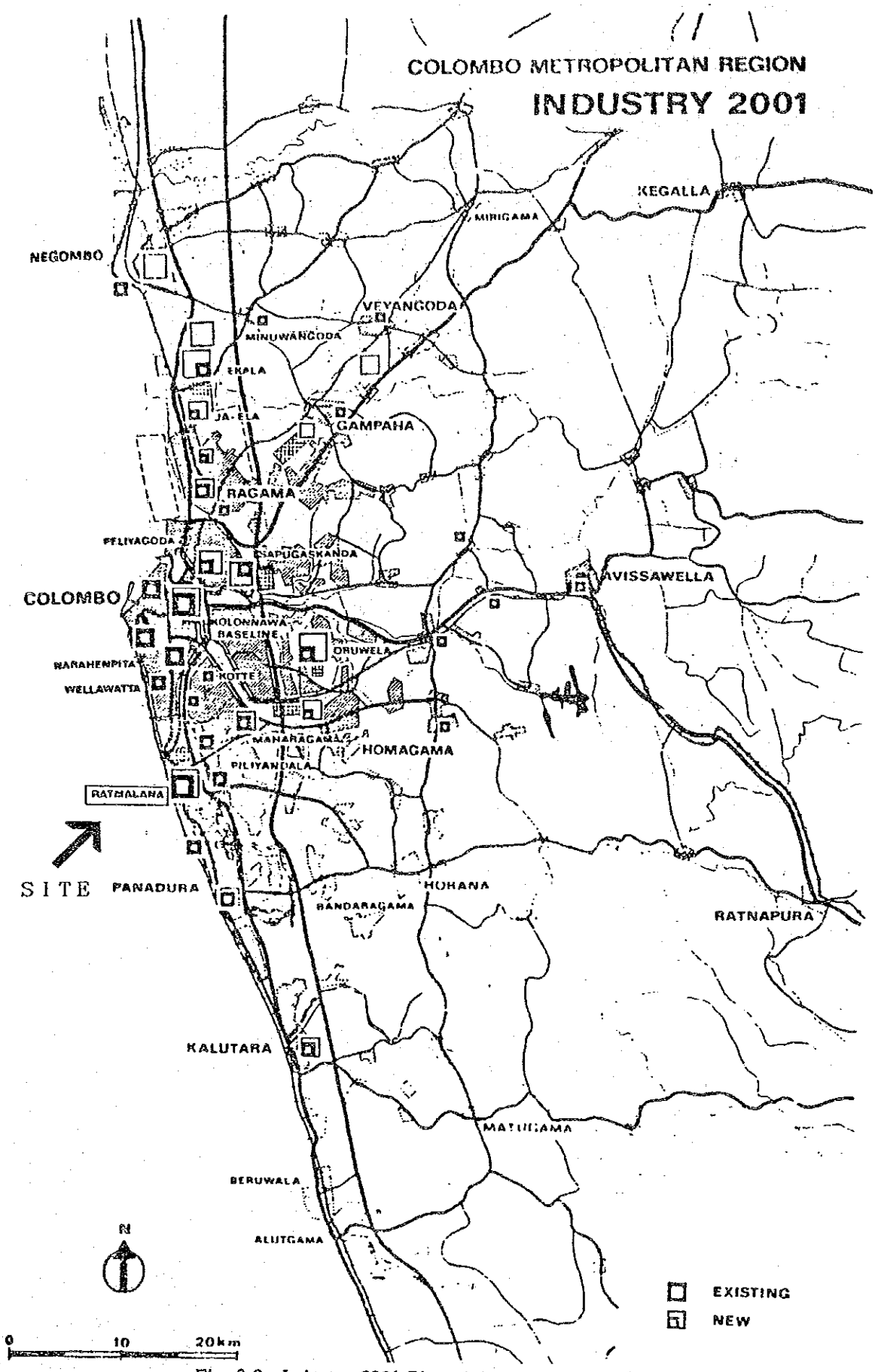


Fig. 3.2 Industry 2001 Plan of Colombo Metropolitan Region

Galle Road

The Junction of the Galle Road and
the Ratmalana Airport Approach

Fig. 3.3 Photos of the Vicinity of the Ratmalana Industrial Estate

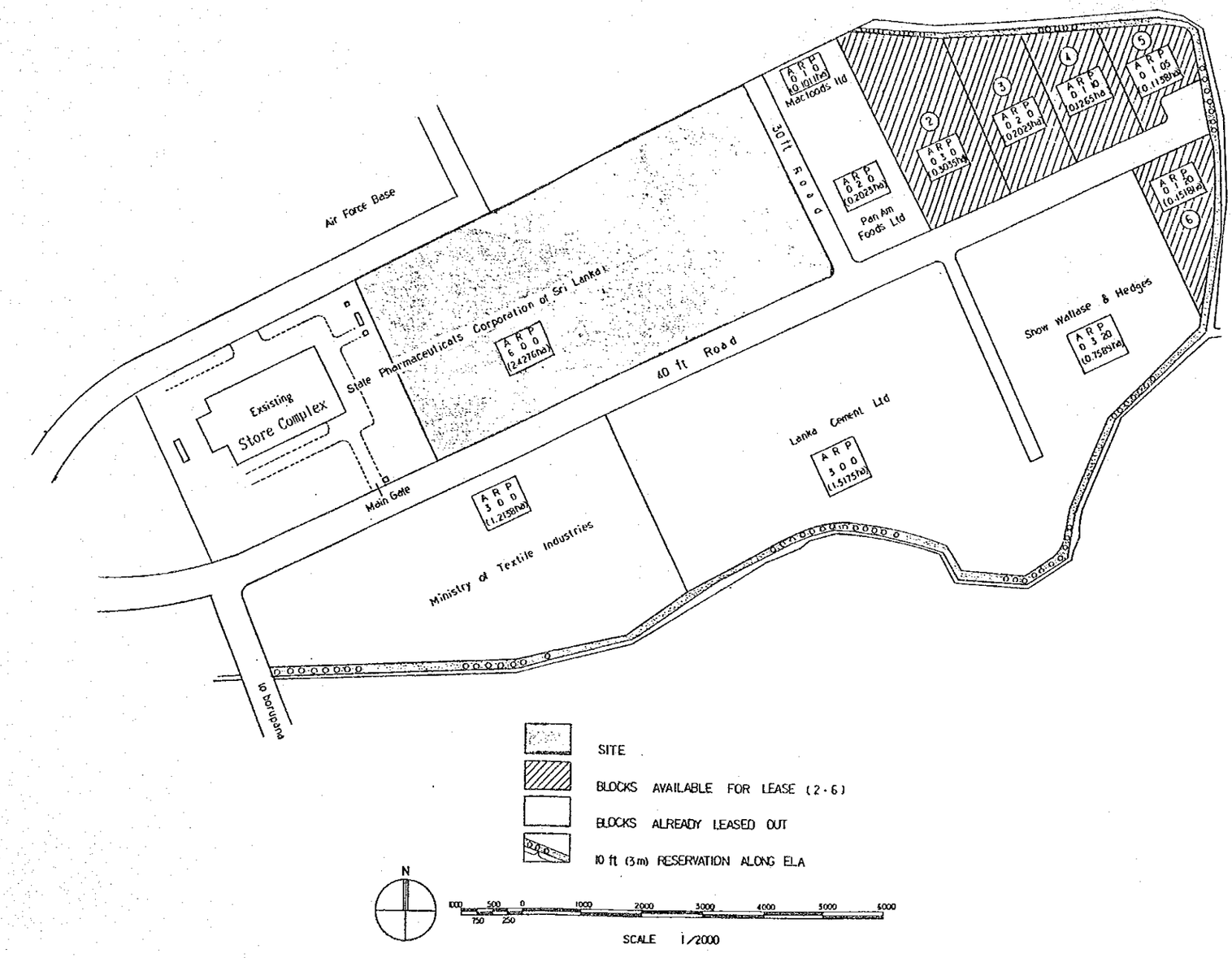


Fig. 3.4 Vicinity Map

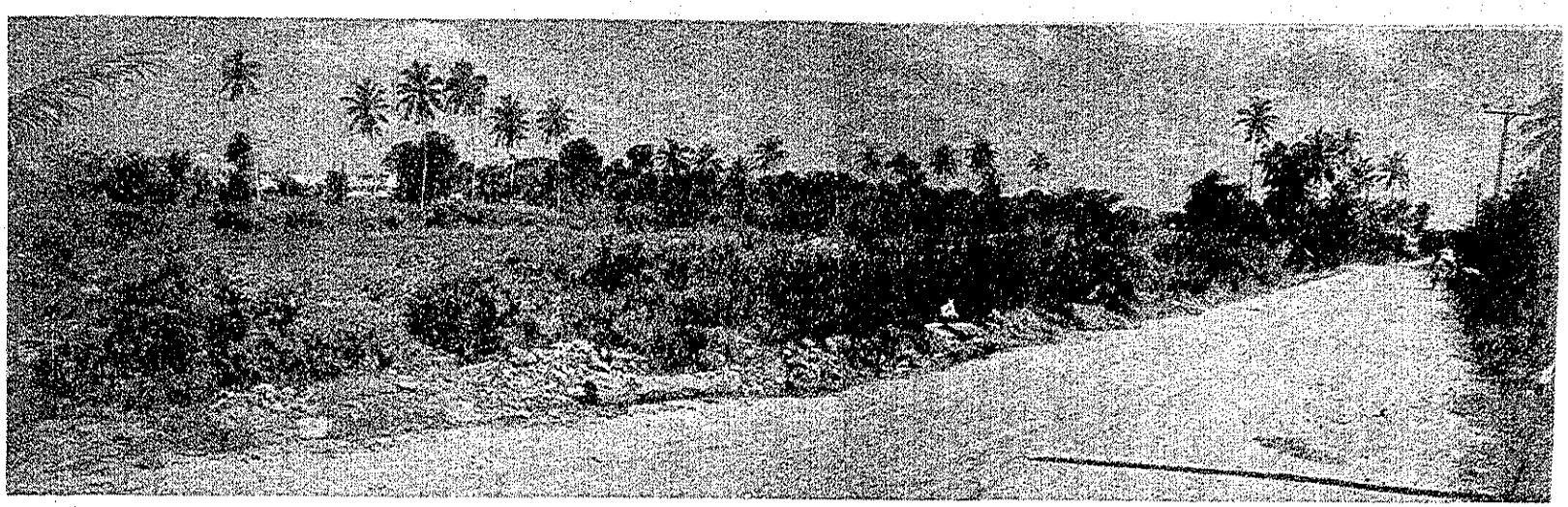


Fig. 3.5 Photos of the Surrounding Area of the Site

(2) Geographical and Geological Features

The project site is of a rectangular shape, measuring about 185 m from east to west and about 87 m from north to south. The ground surface is almost flat through the whole area and its lowest part is about 1 m below the surrounding roads. The site is covered by 10-odd coconut trees and shrubs and in part densely by shrubs and weeds. The surrounding roads apparently show flood traces. SPC workers of the Store Complex say that the roads are inundated about 15 cm deep at the time of heavy rainfall. The water table of the well in the site is normally about 1 m below the ground level and, in rainy seasons, may rise to the ground level at the lower points. Thus, it is considered that the site is prone to be flooded with water in rainy seasons. As for climatological conditions of the vicinity, it is high in both temperature and humidity. The mean annual maximum temperature is about 30 °C. The annual rainfall concentrates in April to June and September to November. Appendix 3 shows the climatological data for Ratmalana obtained from the Department of Meteorology.

Viewed from the above, it is deemed necessary to provide about 1 m high fill for the construction of the Formulation Centre. As for soil conditions, the boring data obtained from SPC show that hard sandy soil exists 6 m or deeper below the ground level, underlying comparatively soft clayey and sandy soil (See Appendix 5). Therefore, it is a suitable solution to place foundations after compaction of these upper soft layers by preloading of good soil.

(3) Infrastructures

Pavement of the roads near the site is not so good, but is maintained to such a degree that transportation for construction and after completion would not be adversely affected. At present, therefore, it may be concluded that Route 2 "The Galle Road" running from Colombo to Ratmalana and roads in Ratmalana including the industrial estate have no considerable problems. However, since the traffic volume in the area in question has a tendency to increase, it is considered that these roads including subgrades should be made better as necessary in the future.

A municipal water main 100 mm in diameter is laid under the south

road and so water can be easily received from that main.

Gutters are provided along the east road and the south road to lead stormwater from the site to them. However, they are in part broken or filled with soil and not terminated at the nearest river, the Weras Ganga. As a result of the discussion with the Phase II study team, UDA stated that the gutters would be restored and extended without delay.

For sanitary sewage and process waste, UDA stated that they might be discharged into the aforesaid gutters after treatment. The Central Environment Authority (CEA) provided the permissible limits of discharged effluent in May 1984. The CEA standard values of waste water discharged into inland surface waters is shown in Appendix 4.

Electricity can be received from the 33 kV overhead line running along the south road. The other overhead line striding across the middle of the site from north to south will have to be relocated to the east road. SPC and UDA have already asked the Ceylon Electricity Board (CEB) for this relocation in writing.

For telephone system, three direct lines are at present provided to the Store Complex. When it applied for extension of these lines, SPC paid the cost sharing for service of 10 loops in total. SPC has requested the Regional Telecommunication Engineer's Office to provide the lines to be required during the periods of construction and production of the Formulation Centre, including use of the pending lines.