BASIC DESIGN STUDY REPORT ON THE PROJECT FOR INFECTIOUS DISEASE CONTROL

IN

THE KINGDOM OF CAMBODIA

June 2004

Japan International Cooperation Agency

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PREFACE

In response to a request from the Royal Government of Cambodia, the Government of Japan decided to conduct a basic design study on the Project for Infectious Disease Control, and entrusted the study to the Japan International Cooperation Agency (JICA).

JICA sent to Cambodia a study team February to March, 2004.

The team held discussions with the officials concerned of the Royal Government of Cambodia, and conducted a field survey at the study area. After the team returned to Japan, further studies were made. Then the present report was finalized.

I hope that this report will contribute to the promotion of the project and to the enhancement of friendly relations between our two countries.

I wish to express my sincere appreciation to the officials concerned of the Royal Government of Cambodia for their close cooperation extended to the team.

June 2004

Yasuo Matsui

Vice-President

Japan International Cooperation Agency

Location Map



Cambodia

Abbreviations

BCG	Bacillus Calmette-Guerine
CENAT	National Center for Tuberculosis and Leprosy Control
CFC	Chloro Fluoro Carbon
CMS	Central Medical Stores
DPT	Diphtheria-Pertussis-Tetanus Combined Vaccine
EPI	Expanded Program on Immunization
GDF	Global Drug Facility
HIV	Human Immunodeficiency Virus
IUATLD	International Union against Tuberculosis and Lung Disease
JICA	Japan International Cooperation Agency
MTEF	Medium Term Expenditure Framework
NIP	National Immunization Program
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WPRO	WHO Western Pacific Region Office

Table of Contents

Preface

Location Map

Abbreviations

Chapter 1	Back	sground of the Project	1
Chapter 2	Cont	tents of the Project	5
	2-1	Basic Concept of the Project	5
	2-2	Basic Design of the Required Japanese Assistance	5
		2-2-1 Design Policy	5
		2-2-2 Basic Design*	11
		2-2-3 Implementation Plan	33
	2-3	Obligations of Recipient Country	37
	2-4	Project Operation Plan	38
	2-5	Cost of Estimation for the Project	39
		2-5-1 Cost of Estimation for the Assistance Projet	39
		2-5-2 Operation and Manintenance Costs	40
Chapter 3	Proj	ect Evaluation and Recommendations	42
	3-1	Project Effect	42
	3-2	Recommendations	43

(Appendices)

- 1. Member List of the Survey Team
- 2. Study Schedule
- 3. List of Parties Concerned in the Recipient Country
- 4. Minutes of Discussions
- 5. References

Chapter 1 Background of the Project

The Cambodian Ministry of Health in an effort to provide quality health services for the entire nation is implementing and gradually expanding nationwide activities by fortifying health services on the Health Center level under the National Strategy on Immunization 5-Year Work Plan 2001-2005, the National Health Strategic Plan for Tuberculosis Control 2001-2005, and other programs against infectious diseases.

The Kingdom of Cambodia (hereinafter to be referenced as "Cambodia") officially launched a National Immunization Program (NIP) in 1986, which expanded to all provinces by the end of 1988. However, under the subsequent political distemper, NIP activities were suspended or cut back considerably, as the procurement or periodic replacement of cold-chain equipment and vehicles, as well as the implementation of immunization campaigns, were seriously affected. In Cambodia, cold rooms, freezers, refrigerators and vehicles that were deployed in the early 1990s through the assistance of UNICEF are still being used. These equipment items are more than ten years old and severely deteriorated. The freezers and refrigerators installed in Provincial Health Offices and Operational District¹ Health Offices are of old kerosene type with limited storage space and improper temperature control. Therefore, some regions are struggling to store sufficient quantities of vaccines to cope with population growth. The wastage² of measles and OPV in Cambodia are as high as 68% and 52% respectively. Improper vaccine storage due to the scarcity of cold-chain equipment is said to be responsible for the high wastage. Since many Health Centers are not equipped with refrigerators, their staffs go to their respective Operational District Health Offices every Monday, carry a cold box to return unused vaccines and receive new ones. This is not a very efficient system and needss to be improved.

¹ Operational Districts are units responsible for managing 10 to 15 Health Centers as designated by the Ministry of Health. Many Operational Districts combine parts of different administrative districts. Operational District Health Office has jurisdiction over Operational Districts. Central Hospitals are positioned as referral hospitals.

² Vaccine wastage is a ratio of vaccine that is discarded because of breakage during transportation or nonuse. For instance, if only one person is to be immunized using a vial containing ten doses, the remaining nine doses go to waste. Thus, the wastage in this case is nine out of ten, or 90%. Vaccine wastage changes considerably depending on the packaging unit (number of doses per vial), the number of people to be vaccinated, improper temperature control of refrigerators, and various other factors.

Immunization services in rural, mountain, and marchland areas that are to be continued and fortified through outreach activities³ are also deadlocked because of the lack of vehicles to transport vaccines and personnel.

Table 1-1 shows the current routine immunization schedule in Cambodia.

Name of vaccine	No. of doses	Timing				
BCG	1	at birth				
OPV	4	at birth and 6, 10, and 14 weeks				
DPT ⁴ -Hepatitis B	3	6, 10, and 14 weeks				
Measles	1	9 months				
Tetanus	2	at the time of confirming pregnancy and 1 month after the 1 st dose				
		Source: Ministry of Health (2001)				

Table 1-1: Vaccination Schedule in Cambodia

Measles vaccination has been given only once to infants at nine months. However, it is estimated that only 80% of children who received an initial dose of vaccine show immunity to measles because of a waning immunity over time or primary vaccine failure.

The 1999 surveillance identified 13,827 measles cases in 1999 and 12,327 cases in 2000, which are estimated to reflect only 40 to 50% of the actual number of cases, indicating the need for more aggressive measures against the disease.

The recent outbreak of measles in some borderland areas and large cities is said to result from the unimminized population who either missed the "catch up" campaign, which was carried out in three phases between December 2000 and April 2003, or vaccinated but did could not generate sufficient amounts of antibodies against measles, as well as the hard-to-decrease susceptible population whose antibodies are declining naturally. Elimination of susceptible population and booster vaccinations are urgently needed in order to eradicate measles from these regions.

In addition, to maintain the polio-free status, additional mass immunization campaign to administer OPV to children under five needs to be conducted in the provinces bordering Thailand and other countries, from which polio virus could enter Cambodia. The sudden increase in demand for vaccines is straining the finances of the Ministry of Health.

³ Outreach activities are part of itinerant medical services, in which health workers are dispatched from Health Center to the residences of patients to vaccinate them.

⁴ Diphtheria-Pertussis-Tetanus Combined Vaccine

As the immunization activities expand, the demand for syringes also increases. Cambodia introduced auto-disable syringes⁵ to immunization campaigns in 1999, began using them on a trial basis in the routine immunizations in Kampong Cham Province in 2001, and would expand the usage thereof in other Provinces starting in November 2002.

Accordingly, the number of auto-disable syringes to be discarded will also increase, which needs to be handled in an environmentally responsible manner.

As part of measures against tuberculosis (hereinafter to be referenced as "TB"), treatment of the disease has been offered free of charge and the drugs were mostly donated by the German government. When German assistance was discontinued in 1997, the Cambodian Ministry of Health took over the procurement of anti-TB drugs and purchased them from one Cambodian company, which led to a sudden rise in national medical expenditures. Even after the forming of the procurement department within the Ministry of Health in 2001, drug price in Cambodia remained as high as three times that of international rate, and poor-quality products continued to circulate in the market. In addition to the unstable supply of drugs, more serious drug shortage is projected because of possible confusion that may be created by international tender to have been introduced in 2003. If that happens, emergency purchase from Global Drug Facility (hereinafter to be referenced as "GDF")⁶ may become necessary to ensure uninterrupted supply of TB drugs, as inconsistent or partial treatment could trigger the development of drug-resistant TB. Reform of the procurement, management, and supply systems to ensure stable procurement and distribution of high-quality drugs that meet the international standards is one of the most pressing tasks for the Cambodian government.

DOTS⁷ in Cambodia has been proceeding favorably, meeting the target cure rates partially owing to external assistance, including the JICA National Tuberculosis Control Project that was initiated in 1999. In addition,

⁵ Auto-disable syringes were developed to prevent the transmitting infectious diseases through inappropriate use of syringes. They become unusable after one injection.

⁶ GDF (Global TB Drug Facility): hosted by WHO and managed by the Stop TB secretariat, established in corporation with Rockefeller Foundation, World Bank, and other organizations to assist the procurement of high-quality anti-TB drugs for DOTS.

⁷ DOTS (Direct Observed Treatment, Short Course): A TB control strategy recommended by WHO. This treatment method tries to prevent the spread of TB infection by having health workers directly observe the swallowing of anti-TB drugs by patients who were detected by sputum smear examination. Strong political commitment by the government, proper storage of patient records, and effective supervision and evaluation of anti-TB activities based on a well established reporting system are all part of a successful DOTS program.

introduction of a new treatment regimen is being planned to reduce the relapse of TB, as the conventional methods have limited efficacy for controlling recurrence and HIV^8 complication. Pilot studies of the new regimen will start in 2003, and if all goes well, it will be used nationwide starting in 2005. Therefore, uninterrupted supply of this drug in consistently high quality will be of vital importance to ensure the effectiveness of DOTS. In order to secure sufficient quantities of high-quality drugs and laboratory reagents before and after the switchover to the new regimen, as well as for restructuring the logistics system within Cambodia during that period, external assistance is necessary.

Under these circumstances, the Cambodian Minstry of Health submitted an official request to the Government of Japan to extend assistance for the procurement of cold-chain equipment, vaccines, auto-disable syringes that are necessary for the implementation of the National Strategy on Immunization, as well as anti-TB drugs that are essential to DOTS.

⁸ Human Immunodeficiency Virus

Chapter 2 Contents of the Project

2-1 Basic Concept of the Project

In 2002, the Royal Government of Cambodia initiated the Medium-Term Expenditure Framework (MTEF 2003-2007) in order to effectively allocate the national budget and foreign assistance funds among necessary projects in different sectors in a comprehensive manner. For the health sector, MTEF plans to improve health and medical services, develop human resources, and reform the health organizations, aiming at lowering the infant and maternal mortality rates, improving maternal-and-child nutrition, decreasing medical expenditures for the poor, reforming the health system, and achieving other objectives.

This Project is designed in line with the National Strategy on Immunization and the National Health Strategic Plan for TB Control that were developed based on MTEF and aims to improve the effectiveness of Cambodia's immunization activities by procuring necessary vaccines and cold-chain equipment to prevent the deterioration of vaccines, as well as to control tuberculosis by improving the case detection rate and supporting the treatment through the provision of anti-TB drugs. This portion of the Project, which was originally implemented in FY 2003, will be installed as the second phase of the Project for the purpose of assisting the Cambodian government in meeting the objectives of its national plans to reduce the morbidity rates of preventable diseases through the procurement of certain equipment and supplies necessary for conducting effective immunization activities.

2-2 Basic Design of the Requested Japanese Assistance

2-2-1 Design Policy

This Grant Aid Project is to assist the Royal Government of Cambodia in the implementation of the National Strategy on Immunization 5-Year Work Plan 2001-2005 and the National Strategic Plan for Tuberculosis Control 2001–2005 by

providing funds to procure syringes and safety boxes necessary for properly discarding used syringes, as well as freezers and refrigerators to install in the Provincial Health Offices, Operational District Health Offices, and immunization sites throughout Cambodia, plus vaccine carrying equipment, temperature monitoring equipment, motorcycles, and anti-TB drugs. This Project was designed based on the following policies and guidelines.

1. Basic Policy (target regions and population)

According to the policy of the Cambodian Ministry of Health for the implementation of the National Strategy on Immunization and the National Strategic Plan for TB Control, this Project targets in all parts of Cambodia, such as at the NIP division of the Ministry of Health, National Center for TB and Leprosy Control (hereinafter to be referenced as "CENAT"), Operational District Health Offices, referral hospitals and Health Centers. OPV will be given in the regions that are exposed to possible invasion of poliovirus from neighboring countries. Such areas consist of the mountainous region along the Thai border (Battambang, Banteay Meanchey, Oddar Meanchey, and Preah Vihear provinces and Pailin city), the northeastern region along the Viet Num border (Kratie, Stung Treng, Ratanakiri, and Mondol Kiri provinces), and Phnom Penh city and Kandal province, where many people live on the water of Mekong River.

The size of the population to be covered in 2005 is estimated based on the FY2001 demographics data of each province and the annual population growth rate of 2.49% as compiled and set by the Cambodian Ministry of Health. The target group consists of infants less than one year of age, the population of which is obtained by multiplying the total population by the ratio of infants or 3.4%. The population to be covered by anti-TB treatment in 2005 is estimated based on the actual number of TB patients and the increase rate in 2003 as recorded and calculated by CENAT.

2. Policy on Natural Environment

The overall climate of Cambodia is tropical monsoon. The average temperature is 27.4° C and could rise to as high as 40° C during the dry season. Therefore, the refrigerators should be able to maintain the inside temperature between +2 and -8° C at 43° C outside temperature, and the freezers should be able to constantly keep the temperature within the

-15 to -30° C range. Cold boxes and vaccine carriers to be used outdoors should be encased in containers made of plastic or other weather-resistant materials. Vaccines, refrigerator monitors⁹, and cold chain monitor cards (CCM)¹⁰ that are susceptible to temperature changes need to be transported and stored within specified temperature ranges.

3. Policy on Social Conditions

The electric power distribution network in Cambodia is not fully developed, and power outages occur frequently. Since many local Health Centers are not connected to power supply lines, selection of cold-chain should take these factors into account. Electric refrigerators will be icelined, meaning that the walls are engirdled with frozen tubes to maintain the proper inside temperature during power outage. Freezers and refrigerators to be deployed in areas without power supply, gas-type equipment will be chosen, as LP gas is available in almost any part of Cambodia.

4. Policy on Environmental Protection

In order to protect the ozone layer to prevent global warming, CFC-free refrigerators and freezers should be selected.

5. Policy on Operation and Maintenance

Cambodia is in the process of standardizing cold-chain equipment and has established ten standard types (Table 2-1).

⁹ Refrigerator monitor is a card to monitor whether or not the vaccine is kept within a proper temperature range (2 – 8°C). When the vial is exposed to improper temperatures (below 0°C or above 10°C or 34°C), the marking on the card changes its color, indicating that the vaccine cannot be used and must be discarded. Once the color has changed, the card cannot be reused.

¹⁰ Cold chain monitor card (CCM) is an indicator that monitors exposure to improper temperatures (above 10°C and 34°C) throughout the entire journey of vaccine. The indicator shows whether or not the vaccine is usable and under what conditions by changing its color. Once the color has changed, the card cannot be reused.

	Central	Provincial	Operation	Operational District Health Office			Health Center			
	Medical Stores	Health Office	Electrified areas	Unelectrified areas	Transport of vaccine	Electrified areas	Unelectrified areas	Vaccination site		
Vaccines to be refrigerated	Cold room (refrigeration)	Icelined refrigerator (medium)	Icelined Refrigerator (small)	Gas/electric	ic	Icelined Refrigerator (small)	Gas/electric			
Vaccines to be frozen	Cold room (freezer)	Chest freezer			Chest freezer	refrigerator & freezer	20-litre cold box	Chest freezer (small) (for selected	refrigerator & freezer	1.6-liter vaccine carrier
Production of icepacks		(large or medium)	(small)	(large)		Health Centers only)	alth			

Table 2-1: List of Standard Cold-Chain Equipment

Standardization of equipment is favorable to Cambodia where financial and human resources are scarce and maintenance services and spare parts are available only from a limited number of suppliers. Therefore, this Project will select cold-chain equipment that corresponds to the Cambodian standardization.

6. Policy on Model Types and Grades

1) Equipment Related to Vaccination Activities

This Project will procure auto-disable syringes, safety boxes, cold-chain equipment, and temperature monitoring devices that meet the standards for performance and testing defined by WHO. Such models are designed for use in developing countries. They are highly durable and heat resistant and have other design features to ensure proper storage of vaccines. Other advantages include the availability and longer stock periods of spare parts, as they undergo fewer model changes than other standard models.

2) Vaccine / Disposable Syringe

WHO has examined and selected certain manufacturers that could produce vaccines to satisfy certain quality requirements in large enough quantities at reasonable prices, and qualified them as suppliers for UNICEF and other UN organizations. This Project will procure vaccines from these manufacturers also.

Since no standards are set by WHO for disposable syringes, this Project will procure the product from manufacturers that have obtained ISO9001 or 9002 certifications to ensure the quality.

3) Motorcycle

This Project will select 100-110cc motorcycles that can be driven by small-figured female immunization staff and

procure them from the manufactures that can provide spare parts and repair services on a local level.

4) Anti-TB Drug

The following anti-TB drugs will be procured, as they are currently used in Cambodia (Table 2-2, 2-3).

Name of Drug	Pharmaceutical form	Abbreviation
Rifampicin 150 mg+ Isoniazid 75 mg	Tablet	RH150/75
Pyrazinamide 400 mg	Tablet	Z400
Ethambutol 400 mg	Tablet	E400
Streptomycin 750 mg	Injection	S750

Table 2-2: Anti-TB Drugs Currently Used in Cambodia (for adults)

Table 2-3: Anti-TB Drugs Currently Used in Cambodia (for infants and children)

Name of Drug	Pharmaceutical form	Abbreviation
Rifampicin 60 mg + Isoniazid 30 mg + Pyrazinamide 150 mg	Tablet	RHZ60/30/150
Rifampicin 60 mg + Isoniazid 30 mg	Tablet	RH60/30

Drug manufacturers will be chosen from those recommended by GDF to international donor organizations and developing countries as a result of their joint investigation to identify companies that could manufacture drugs to consistently meet a certain quality level and supply them at a relatively low price. As for packaging of tablets, the Ministry of Health has chosen the blister package¹¹ to minimize mix-ups by the medical staff and errors in dispensing work. To make the observation of drug intake easier, each sheet will contain 1-week doses for an adults (=28 tablets), 10 tablets for infants and children.

7. Policy on Procurement Method and Timeframe

This portion of the Project, which consists of three phases, will be installed as Phase II in line with the 2001-2005 of Immunization 5-Year Work Plan and the National Health Strategic Plan for Tuberculosis Control 2001–2005 of the Cambodian government. However, the contents may need to be adjusted according to the revisions to these national

¹¹ Contains a specific number of tablets on a sheet of blisters, by pushing which the patient can take out a needed number of tablets right before swallowing them. This type of packaging is hygienic, damp-proof, and easy to see the contents.

plans that are likely to be made, an expected increase in the number of newly detected TB patients because of expanded DOTS programs, and especially the result of the pilot study¹², which started in 2004 to test the effectiveness of new treatment regimens, as it could significantly alter the quantities and contents of needed equipment. Therefore, it would be desirable to conduct another survey before designing Phase III to assess the latest situations to estimate more accurately the actual demand for equipment.

¹² In order to establish guidelines for introducing the new regimen (=6-month treatment regimen), CENAT is planning to test the regimen on an estimated number of 400 newly detected TB cases from 2-3 Operational District Health Offices and part of Phnom Penh to compare the efficacies of the new and conventional regimens, identify possible side effects and other problems, precautions to be taken, and observe the changes in the detection and recurrence rates.

2-2-2 Basic Design

1. Equipment Plan

The table below shows the equipment items that are deemed necessary, their descriptions, applications, and quantities

(Table 2-4).

Item		Description	Phase I Oty. procured	Phase II Qty. to be procured			
1	Autocombustion Incinerator	For incinerating used safety boxes and auto-disable syringes in 26 Operational Districts.	26 units	-			
2	Safety Box, Large	18,000 pcs.	10,000 pcs.				
3	Safety Box, Medium	other medical facilities. ety Box, Medium For discarding used syringes in outreach programs.					
4	Autodisable Syringe	atodisable Syringe For injecting measles, DTP-Hep B, tetanus, and hepatitis B vaccines					
5	Cold Room, Refrigeration	16?, prefabricated walk-in type For storing DTP, tetanus, and other vaccines.	1 unit	-			
6	Cold Room, Freezer	32? prefabricated walk-in type For storing measles, polio, BCG, and other vaccines.	1 unit	-			
7	Generator	Backup system for keeping power supply to cold rooms during outages	1 unit	-			
8	Icelined Refrigerator, Large	For storing vaccines at Provincial Health Offices and Operational District Health Offices (200L class)	10 units	10 units			
9	Icelined Refrigerator, Small	For storing vaccines at suburban Health Centers in electrified areas (40-50Lclass)	2 units	74 units			
	Type, Large	For storing vaccines at Operational District Health Offices in un-electrified remote areas (170L class)	6 units	-			
11	Refrigerator and Freezer, Gas and Electric Type, Small	For storing vaccines at Health Centers in un-electrified remote areas (70L class)	500 units	45 units			
12	Chest Freezer, Small	For storing vaccines and making icepacks at Provincial Health Offices (110L class)	22 units	8 units			
13	Chest Freezer, Large	For storing vaccines and making icepacks at Provincial Health Offices (320L class)	10 units	5 units			
14	Cold Box	For transporting vaccines. To be provided for each Operational District Health Office and Health Center	600 units	300 units			
15	Vaccine Carrier	For transporting vaccines in outreach programs. To be provided for each Operational District Health Office and Health Center.	1,000 units	1,000 units			
16	Vaccine Thermometer	For monitoring temperatures of freezers and refrigerators.	1,000 pcs.	500 pcs.			
17	Temperature Data Logger	For monitoring temperatures of freezers and refrigerators to properly store vaccines at Provincial Health Offices (periodic observations and data analysis).	20 units	24 units			
18	Freeze Watch Indicator	Irreversible temperature indicator to monitor exposure to sub-freezing temperatures when transporting DTP-Hep B, tetanus, and hepatitis-B vaccines.	500 pcs.	500 pcs.			
19	Refrigerator Monitor	Dual irreversible temperature indicator Monitor mark at +10 - +34°C and Freeze watch	1,000 pcs	3,000 pcs			
20	Cold Chain Monitor Card	Irreversible temperature indicator with monitor mark at +10 - +34	2,000 pcs	2,000 pcs			
21	Measles Vaccine	Dry attenuated vaccine to prevent measles infection.	1,410,000 doses	1,440,000 doses			
22	Disposable Syringe	For injecting measles vaccine (freeze dried) dilution	141,000 pcs.	144,000 pcs.			
23	Oral Polio Vaccine	Attenuated live virus Oral polio vaccine (OPV) to prevent polio	790,000 doses	790,000 doses			
24	Hepatitis B Vaccine	Recombinant DNA Hepatitis B vaccine to prevent neonates from becoming a hepatitis B carrier ¹³ .	-	580,000 doses			

Table 2-4: Equipment List

¹³ Hepatitis B carrier is a person who is infected with the virus but not showing any symptoms.

	Item	Description	Phase I	Phase II
			Qty. procured	Qty. to be procured
25	Desktop Computer System		4 sets	-
26	Desktop Printer	For storing, managing, and distributing data for immunization and	2 sets	-
27	Lap Top Computer	surveillance activities, as well as cold chain monitoring	2 sets	-
28	Portable Printer		2 sets	-
29	Station Wagon	For surveillance, supervision, immunization activities, and staff training	3 units	-
30	4WD Pick-up Truck, Double Cabin	To be used by Operational Districts for transporting vaccines	6 units	-
31	Motorcycle	To be used by Health Centers' staff in outreach programs	50 units	50 units
32	Rifampicin 150 mg+ Isoniazid 75 mg		26,537 boxes	27,828 boxes
33	Pyrazinamide 400 mg	Anti-tuberculosis drugs for adults recommended by GDF/WHO to be used	15,050 boxes	6,187 boxes
34	Ethambutol 400 mg + Isoniazid 150mg	throughout Cambodia.	9,123 boxes	-
35	Ethambutol 400 mg		16,827 boxes	3,810 boxes
36	Streptomycin 750 mg		204,000 units	103,000 units
37	Rifampicin 60 mg + Isoniazid 30 mg + Pyrazinamide 150 mg	Anti-tuberculosis drugs for infants to be used throughout Cambodia.	-	345,000 tablets
38	Rifampicin 60 mg + Isoniazid 30 mg		-	689,000 tablets
39	Fuchsin		2 kg	-
40	Methylene Blue	For sputum smear examinations at CENAT	2 kg	-
41	Phenol Crystal	r or sputum sinear examinations at CENAN	30 kg	-
42	Hydrochloric Acid		25 L	-

Quantities and contents of equipment to be procured in Phases II and III were determined at the time of the survey of Phase I and modified in this survey for Phase II in order to better reflect the present conditions. The modifications include the following:

- · Switch to different types of refrigerators due to an increase of electrified areas
- · Adjustment in the needed quantities of refrigerators and freezers as a result of recent purchase of similar equipment by

the Cambodian government.

- Procurement of hepatitis B vaccines in response to an additional request by the Cambodian government.
- · Adjustment to the needed quantities of autodisable syringes and safety boxes due to the addition of hepatitis B
- vaccines.

· Adjustment to the needed quantities of anti-TB drugs according to the estimated number of patients calculated based

on the latest data.

- Procurement of anti-TB drugs for infants in response to an additional request by the Cambodian government.
- Exclusion of reagents for sputum smear examination due to withdrawal of the request by the Cambodian government.

How we calculated the needed quantity of each equipment item is described later in this document under "2. Rational

for Calculation." During this survey, the Cambodian government made an additional request for hepatitis- B vaccines and anti-TB drugs for infants. BCG vaccines were also requested but later withdrawn, as the government decided to procure them at its own account. We have examined the viability of the additional request for hepatitis B vaccines and infant anti-TB drugs, the details of which are described below.

(1) Hepatitis B Vaccine

It is estimated that about 350 million people worldwide, or about 6% of the world population, are persistently infected¹⁴ with hepatitis-B virus. Most of the people with persistent infection reside in Asia and Africa, three fourths of which are the residents of China and Southeast Asia. In these countries, 8 - 10% of the people are persistently infected with hepatitis B and carry a large number of viruses in their blood streams. Most of them are infected during childhood, and 60% of their populations get infected at least once in their lifetime, 1/4 to 1/3 of which becomes persistently infected. In Cambodia, 8.2% of the blood donors in 1999 were tested HBs antigen positive¹⁵.

Hepatitis B is largely transmitted by direct contact with the blood or other bodily fluids of an infected person. The main route of infection is through vertical transmission from mother to child. According to Japanese data, about 40 - 50% of children whose mothers are HBs antigen positive become infected, and about 90% of children whose mothers are HBs antigen positive become infected, and about 90% of children whose mothers are HBs antigen positive become infected, and about 90% of children whose mothers are HBs antigen positive become infected, and about 90% of children whose mothers are HBs antigen positive become infected with the virus. In Taiwan, it is reported that about 25% of the siblings of HBe antigen positive become infected with the virus. People who are infected at young ages become hepatitis-B carriers at a very high percentage. Carriers have a high risk of infecting others, as well as developing chronic hepatitis, liver cirrhosis, and hepatocellular carcinoma in themselves. Therefore, controlling infection during the neonate to infant stage by vaccination and other measures could work very effectively

¹⁴ Persistent infection is a state where a person remains infected for a prolonged period of time without developing clinical symptoms.

¹⁵ Hepatitis B surface (HBs) antigen: A hepatitis-B virus is made up of distinct shell and core layers. HBs antigens exist on the surface of virus particles, which can be detected in a blood sample, and therefore are used as one of the markers of hepatitis. When a person is tested HBs antigen positive, it indicates an active infection with hepatitis B viruses.

¹⁶ Hepatitis B e (HBe) antigens exist within the HBc antigens in the core layer of a hepatitis-B virus. When a person is tested HBe antigen positive, it indicates that the person is infected with highly-infectious viruses and has a risk of aggravating hepatitis.

for preventing liver diseases.

In 1992, WHO recommended that hepatitis B vaccine be integrated into the national immunization programs of all countries by 1997. As of May 2003, 151 (or 79%) of 192 WHO member states have adopted hepatitis B vaccination in the infant stage. According to the immunization data submitted by 137 of these countries, 76 (or 55%) are administering the first hepatitis B shot right after birth.

64 (or 72%) of 89 WHO member states, whose rates of persistent hepatitis-B infection have been traditionally high, are also adopting the infant-stage hepatitis-B vaccination program, and 34 countries (or 53%) are giving vaccination immediately after birth.

In September 2003, the 54th Session of the WHO Regional Committee for the Western Pacific took place in the Philippines, in which eradication of measles and the control of hepatitis-B were established as two core strategies for strengthening EPI (Expanded Programme on Immunization) activities.

The Cambodian government listed the reduction of hepatitis-B infection rate as one of the objectives of the National Immunization 5-Year Plan (2001 - 2005). In 2001, it began introducing DPT-Hep B vaccines to gradually spread the program nationwide, which is to cover 38 (or 50%) in 2004 and 100% of the entire Health Districts in 2005. In parallel to this, the Cambodian Ministry of Health began giving hepatitis B vaccines to babies immediately after birth at the hospitals in Phnom Penh City and the Health Centers in Takeo, Kandal, and Kampong Chhnang Provinces and is making a significant progress in the reduction of hepatitis B infection from 2003, as this kind of vaccination can prevent birth-canal infection quite effectively.

The Ministry of Health plans to disseminate the neonate vaccination throughout the country as part of its routine immunization program. The Ministry of Health's total budget related to vaccines and vaccination activities in 2003 was 5.19 million dollars, of which the Ministry appropriated 1.84 million dollars from its own funds. This would be enough to purchase basic vaccines to be used in routine immunization but would barely cover the cost of additional types of vaccines. Nevertheless, the Cambodian government has been increasing the annual budget of the Ministry of Health every year to enforce EPI activities. Therefore, we have determined that procurement of hepatitis B vaccines through this Grant Aid Project was appropriate in terms of assisting the Cambodian government for the next two years until it can appropriate sufficient funds for successfully integrating neonate hepatitis B vaccination into its routine immunization program nationwide.

(2) Anti-TB Drugs for Infants

Infant and elderly TB patients are at higher risk of progression, as their immune systems are compromised or not fully developed. As with adults, first infection tends to go unnoticed without symptoms until the TB viruses that were lying dormant in their lungs become active to develop secondary TB as the hosts' body resistance deteriorates with age or other reasons. On the other hands, small children are more susceptible to primary TB (developing TB immediately after first infection), which tends to spread to the entire body through the lymphatic system and blood vessels to cause serious conditions. The younger the patient, the faster the primary infection tends to progress into such grave diseases as miliary TB (= disseminated TB)¹⁷ and tuberculous meningitis¹⁸ that are extremely serious to infants often resulting in death or severe sequela.

Infant TB is mostly caused by infection within the family. According to a study report, the infection and incidence rates of children aged between 0 and 14 who have made contact with smear-positive cases are 39 - 65% and 37.7% respectively.

Japanese technical assistance, National Tuberculosis Control Project in Cambodia, have helped the dissemination of TB treatment among Cambodian people. In the past, there was a tendency among TB patients and their family members to conceal the illness from others. However, as a result of education and guidance under anti-TB projects, more and more people now recognize the importance of early detection and treatment of TB. When parents develop TB, they are more willing to have their children tested for infection, which is raising the detection rate of infant TB.

Phase I of this Project, during which the number of infant patients were not fully identified, attended the situation by giving each infant patient a portion of adult anti-TB drugs made by breaking up tablets. However, this method left a number of problems, such as inaccurate doses and hard-to-swallow tablets for children because of large size and

¹⁷ Miliary TB is a life-threatening condition that occurs when large numbers of TB bacilli get into the blood stream and spread throughout the body. It is defined as millet-like seeding or similar-sized nodules of TB bacilli in at least two organs.

¹⁸ Tubeculous meningitis is caused by hematogenic dissemination of TB bacilli to the meninges or by secondary progress of tuberculous nodules in the brain base to the meninges.

bitterness. Prescription of chewable-type anti-TB drugs for infants would solve these problems, which would lead to improved compliance¹⁹ and more cases of successful completion of treatment regimens.

The detection rate of infant TB has been rising since the last survey 1.5 years ago. Consequently, control of infant TB has become one of the priority agendas of JICA's anti-TB projects, under which an emergency budget was appropriated in March 2003 for procuring infant anti-TB drugs for 500 patients, an estimated number of infants who would need treatment in 2004. Although the Cambodian government has decided to procure such drugs on its own account, it will take nearly two years between the time of budget application and the actual delivery of drugs, during which the Cambodian government needs assistance in sustaining its infant TB control program and requested the Japanese government to procure such drugs under this Grant Aid Project.

2. Rationale for Calculation

1) Vaccine (Item No. 16, 18 & 19)

Outbreaks of measles are still occurring in Cambodia despite the introduction of routine vaccination and the catch-up campaign (blanket operation) that took place between December 2000 and April 2003. Therefore, this Project will procure measles vaccines in a quantity needed to cover the second opportunity vaccination of infants less than one year of age in FY 2005.

Oral polio vaccines (OPV) will be procured to cover the target population comprised of infants less than one year of age in the mountainous regions along the Thai border, the northeastern regions along the Vietnam border, and the Provinces where a large number of boat people live in the Mekong River. It is being planned that Phase III, which to be implemented in 2006, will select high risk areas to conduct an anti-polio campaign for young children less than five years of age.

Hepatitis-B vaccines will be procured to cover the entire country to immunize newborns immediately (within 24 hours) after birth.

The needed quantity of each vaccine was calculated based on the projected size of each target population in 2005 in

¹⁹ Compliance means that a patient takes prescribed medicines exactly as instructed by the physician.

the formulas shown below, which took into account deactivation of vaccines²⁰ due to inadequate cold-chain equipment, as well as other wastage caused by breakage or loss during transportation and discarding of unused vaccines. In addition, a certain percentage of reserve stock was included in case of possible delay in vaccine delivery, population influx into the target regions from neighboring areas, and other contingencies.

Needed doses of vaccine = (target population \times coverage \times no. of doses \times wastage coefficient) + reserve stock

Variables used in the calculation were as follows:

Target population

Target population in FY 2005 was estimated by multiplying the population in FY 2001 as published in Ministry of Health's "National Health Statistics" by the population growth rate (2.49) and the ratio of infants (3.4%).

Target regions

Measles vaccines will be given nationwide. In Phase II, as was the case in Phase I, OPV will be administered in the mountainous regions along the Thai border (Battambang, Banteay Meanchey, Oddar Meanchey, and Preah Vihear Provinces and Pailin City), the northeastern regions along the Viet Num border (Kratie, Stung Treng, Ratanakiri, and Mondol Kiri Provinces), and Phnom Penh City and Kandal Province, where many people live on the water of Mekong River. Hepatitis B vaccines will also be given nationwide.

Coverage

The coverage of each vaccine as set by the Ministry of Health is as follows:

Measles: 80%, OPV: 90%, Hepatitis B: 50%

No. of doses

The number of doses required for each target individual by vaccine type is as follows:

Measles: 1 (for second opportunity), OPV: 2, Hepatitis B: 1

Wastage coefficient

Wastage is a ratio of vaccine that was opened but not used within the same day and therefore needs to be discarded,

²⁰ Deactivation in this case means a loss of potency of vaccines.

to the total volume procured. The Cambodian Ministry of Health has set the wastage for each vaccine. Considering the underdeveloped cold-chain system of the country, these figures are deemed appropriate at this moment²¹. The wastage coefficient is obtained using the formula below:

Wastage Coefficient = $\frac{100}{(100 - Wastage)}$

Wastage = Measles: 68%, OPV: 52%, Hepatitis B: 50%

Reserve stock

Reserve stock is kept in case of interrupted supply. In developing countries, reserve stock rates are set somewhere between 20 and 30% while Cambodia sets it at 25%, which was used to calculate the volume of reserve stock in the following formula:

Reserve stock = (target population \times coverage \times no. of doses \times wastage coefficient) \times reserve stock rate (25%)

Based on the above, the quantity of vaccines is calculated and adjusted by rounding up the figures to units of 10,000 as shown in the table below (Table 2-5).

	Vaccine	Target population A	Coverage B%	Dose C	Needed doses D=AxBxC	0	Qty. taking into account (F) G=DxF	Reserve stock rate H	Reserve stock I=GxH	Total J=G+I	Adjusted to unit of 10,000
FY 2005 (Phase II)	Measles	459,748	80%	1	367,798	3.13	1,151,209	25%	287,802	1,439,011	1,440,000
	OPV	167,387	90%	2	301,297	2.08	626,698	25%	156,675	783,373	790,000
	Hepatitis B	459,748	50%	1	229,874	2.00	459,748	25%	114,937	574,658	580,000

Table 2-5: Needed Quantities of Vaccines

2) Auto-Disable Syringe (Item No. 3)

Size of the auto-disable syringe will be 0.5 ml to hold one dose for one person. This Project will procure

²¹ The Cambodian Ministry of Health is concerned about the high wastage ratios and making efforts to reduce them. In February 2003, the Ministry established the Open Vial Policy, which permitted Health Centers that were equipped with refrigerators to use vaccines left in opened vials for up to 4 weeks after the opening of vials as long as certain conditions are met. As a result, the wastage rates will likely decrease as more and more Health Centers will be installed with properly working refrigerators.

auto-disable syringes in the quantity necessary for giving four types of vaccines, namely, measles, DPT-Hep B, tetanus, and hepatitis B (for shots immediately after birth). OPV and BCG are not included in the calculation, as OPV will be given in a special dispenser, and BCG uses a disposable syringe of 0.05 ml

. Wastage coefficient was included in the calculation by taking into account the breakage and loss during transportation and by misuse during the vaccination activity. A certain amount of reserve stock was also added, as was the case with vaccines:

Qty. to procure = (target population \times coverage \times no. of doses \times wastage coefficient) + reserve stock

Variables used in the calculation were as follows:

Target population

Target population in FY 2005 was estimated by multiplying the population in FY 2001 as published in Ministry of

Health's "National Health Statistics" by the population growth rate (2.49) and the ratio of infants (3.4%).

Coverage

The vaccine coverage of each vaccine as set by the Ministry of Health is as follows:

Measles: 80%, DPT-Hepatitis-B: 80%, Tetanus: 85%, Hepatitis-B: 50%

No. of doses

According to the national immunization schedule, the number of doses required for each target individual by vaccine

type is as follows:

Measles: 2,²² DPT-Hepatitis-B: 3, Tetanus: 2, Hepatitis-B: 1

Wastage coefficient

Wastage is a ratio of broken or misused syringes that need to be discarded to the total number of syringes procured.

We used 10% wastage as calculated by WHO:

Wastage coefficient = $\frac{100}{(100 - \text{Wastage})}$

²² Includes first- opportunity vaccination as part of routine immunization in addition to second-opportunity vaccination, which is to be covered by this Project.

Reserve stock

Reserve stock is kept in case of interrupted supply. In Cambodia, the reserve stock rate is set at 25% as calculated using the formula below:

Reserve stock = (target population \times coverage \times no. of doses \times wastage coefficient) \times reserve stock rate (25%)

Based on the above, the quantity of auto-disable syringes for each project phase is calculated as follows (Table 2-6):

	Vaccine	Target population (A)	Coverage (B%)		Needed doses (D=A x B x C)	Wastage coefficient (F)	Qty. taking into account (F) (G=DxF)	Reserve stock rate (H)	Reserve stock (I=GxH)	Total (G+I)	Adjusted to units of 10,000
	Measles	459,748	80%	2	735,597	1.11	816,513	25%	204,129	1,020,642	1,020,000
FY 2005	DPT-HepB	459,748	80%	3	1,103,396	1.11	1,224,770	25%	306,193	1,530,963	1,530,000
(Phase II)	Tetanus	459,748	85%	2	781,572	1.11	867,545	25%	216,887	1,084,432	1,090,000
	Hepatitis B	459,748	50%	1	229,874	1.11	255,161	25%	63,791	318,952	320,000
									Quantity (to procure	3,960,000

Table 2-6: Needed Quantity of Auto-Disable Syringes

3) Disposable Syringe (Item No. 17)

Measles vaccine is freeze-dried and needs to be diluted with 'water for injection' at the time of vaccination. As one vial of measles vaccine will require 5ml of solution, the needed quantity of 5ml disposable syringes per vial (10 doses) is calculated as follows:

Qty. to procure = qty. of measles vaccine in doses $\div 10$

4) Safety Box (Item No. 1 & 2)

Safety boxes will be procured in the quantity to sufficiently hold the four types of syringes to be used in immunization activities as listed in the table below. They will be in two different sizes: large 10-liter type that can store 200 syringes for health facilities and 5-liter boxes that can hold 100 syringes for outreach activities. The needed quantity of safety boxes is calculated in the following formula based on the number of syringes used annually (Table 2-7).

Table 2-7: Quantity of Syringes to be Used Annually

Auto-disable syringe ^{*1}		Syringe for diluting measles vaccine ^{*2}	Syringe for BCG ^{*3}	Syringe for diluting BCG ^{*3}	Total
FY 2005 (Phase II)	3,960,000	288,000	511,000	144,000	4,903,000

*1: See paragraphs 2) for the details of calculation.

*2: The quantity includes the number of syringes to be used in first-opportunity vaccination as part of the routine immunization program, in addition to the144,000 syringes for second-opportunity vaccination, which are to be covered by this Project.

*3: Same method as that for counting auto-disable syringes and measles-vaccine diluting syringes is used.

(BCG immunization rate - 80%, No. of doses - 1, Wastage - 84%)

The total needed quantity of safety boxes converted into 5-liter type can be calculated by using the following formula. The divisor (100) indicates that one 5-liter box can hold approximately 100 syringes. A certain amount of reserve stock is included in the needed quantity in case of disrupted supply. Here, we used 2 as the coefficient of reserve stock

as set by the Cambodian authority.

Needed quantity (in 5-liter boxes) = (no. of syringes \div 100) × reserve stock coefficient

Records of past activities indicate that the number of 10-liter safety boxes used in Health Centers is about 20% of that of 5-liter boxes used in outreach activities. Based on this ratio, the total quantity of 5-liter boxes was divided between the two types of boxes and adjusted as shown in Table 2-8 below.

	Total no. of 5-liter safety boxes derived from the formula		own by capacity ter adjustment)	Adjusted to units of 1,000
FY 2005	08.060	10-liter	9,806	10,000
(Phase II)	98,060	5-liter	78,448	79,000

Table 2-8: Quantity of Syringes to be Used Annually

5) Cold-Chain Equipment

• Icelined Refrigerator (Item No. 4 & 5)

Large refrigerators will be procured to replace deteriorated ones in the Provincial Health Offices and Operational District Health Offices in electrified regions. Small ones will be installed in Health Centers in electrified areas. The Phase II survey identified 88 Health Centers situated in electrified areas, of which 12 will be supplied with

refrigerators through donations from PATH (Program for Appropriate Technology in Health), an US-based NGO. Therefore, this Project will procure 74 refrigerators as a result of subtracting 12 and 2 (procured in Phase I) from 88.

· Small Refrigerator and Freezer, Gas / Electric-Type (Item No. 6)

Each of the Health Centers without electric power supply throughout Cambodia will be provided with one unit. 855 of the total of 943 Health Centers (including National Rubber Plant Clinic²³) are situated in unelectrified areas, of which 500 have already been provided by Phase I, 200 by the Cambodian government, 10 by CPV (Children's Vaccine Program), and 100 by PATH. Thus, Phase II will procure 45 units to cover the remaining 45 Health Centers.

According to the initial plan, six large gas/electric-type freezers/refrigerators were also to be procured by Phase II for replacing antiquated or broken units of Operational District Health Offices in unelectrified areas. However, they were later excluded as it was found out that another donor was planning to cover these offices.

Chest Freezer (Item No. 7 & 8)

Severely aged or broken freezers of Provincial Health Offices will be renewed. As a result of reviewing the initial distribution plan in the Phase II survey, It was decided that Phase II would procure five large freezers as initially planned, and eight small freezers instead of five to provide additional three Health Offices that were to be covered by Phase III because of the high necessity for the equipment in those offices.

• Cold Box (Item No. 9)

Old cold boxes with deteriorating cooling function that they have been used for five or more years in the Operational District Health Offices and Health Centers nationwide are to be replaced. There are a total of 1,089 of such health facilities throughout Cambodia, each of which needs one properly functioning cold box. 189 of them are using relatively new cold boxes that were procured about three years ago, and 600 facilities have already been provided with new boxes by Phase I. Therefore, Phase II will procure 300 cold boxes to cover the remaining 300 facilities.

• Vaccine Carrier (Item No. 10)

Each Operational District Health Office and Health Center needs at least one vaccine carrier for on-site vaccination

²³ A health facility established within a state-owned rubber plant that has the same status as Health Center.

and at least another one for outreach programs. Since vaccine carriers tend to wear out quickly in Cambodia due to frequent use, WHO recommends that the Cambodian government to replace vaccine carriers every two years to maintain sufficient cooling capacities. In consideration of the above, Phase II will procure 1,000 carriers to provide one unit for each of the 1,089 facilities minus 89, which the Cambodian Ministry of Health can obtain using its own budget.

•Vaccine Thermometer (Item No. 11)

Vaccine thermometers are used in all freezers and refrigerators to monitor temperatures. A total of 1,486 units consisting of 1,416 refrigerators (1,143 units that were installed in or after 2003 plus 273 units procured before 2003) and 70 freezers (installed in or after 2003) will be operating upon the completion of Phase II. Since 1,000 thermometers have already been procured by Phase I, Phase II will cover the remainder by procuring 500 thermometers (rounded up to the nearest packing unit) and store the excessive 14 in the central storehouse as replacements for broken ones.

'Temperature Data Logger (Item No. 12)

Each of the 24 Provincial Health Offices needs to have one data logger. In Phase I, 20 units were procured to cover all Health Offices except four for which the Ministry of Health had already procured. As the operating life of the logger is about two years, Phase II will procure 24 units to renew previously procured units.

•Freeze Watch Indicator (Item No. 13)

Freeze Watch indicator is inserted in each vaccine package when transporting certain types of vaccines (DTP-Hep B, tetanus, and hepatitis B) that are susceptible to subfreezing temperatures. These vaccines are transported from the central storehouse to each of 24 Provinces four times a year, and each transportation uses an average of five indicators. Phase II will procure 500 indicators by rounding up the needed quantity to the nearest packing unit.

•Refrigerator Monitor (Item No. 14)

Refrigerator monitor cards are needed to control the temperatures of refrigerators used in all parts of Cambodia. As these cards cannot be reused once a sign indicating exposure to abnormal temperatures appears on the card, each refrigerator will need two cards annually. There will be 1,416 refrigerators operating nationwide upon the completion of Phase II. Therefore, Phase II will procure 3,000 monitor cards by rounding up the needed quantity to the nearest packing unit.

Cold Chain Monitor Card (Item No. 15)

CCM cards are used to monitor the temperatures of vaccines during transportation. Vaccines are transported from the central to 24 Provincial storehouses four times per year, each using an average of 10 cards. Transporation from Province to their respective Operational Districts takes place once a month, each using one card. Based on the foregoing, Phase II will procure 2,000 cards by rounding up the needed quantity to the nearest packing unit.

6) Motorcycle (Item No. 20)

The Cambodian Ministry of Health is currently allotting a total of 160 motorcycles exclusively for immunization activities, of which 25 were procured by WHO in 1997, 50 by UNICEF for Operational District Health Offices between 1988 and 1989, and 85 by a Japanese Grant Aid Project in 1995. Most of these motorcycles, however, are broken primarily due to normal wear and tear and irreparable because of discontinuation of spare parts. Insufficient motorcycles are presently supplemented by borrowing motorcycles assigned for other programs or personally-owned ones, which are not enough to properly carry out the immunization activities as scheduled. The Ministry of Health plans to procure at least two motorcycles for each of 24 Provincial Health Offices for supervision and monitoring of cold chain equipment, as well as at least one motorcycle for each of 76²⁴ Operational District Health Offices. This Project plans to replace one motorcycle of each Provincial and Operational District Health Office. Since 50 have already been procured by Phase I, Phase II will procure remaining 50.

7) Anti-TB Drugs (Item No. 21, 22, 23, 24, 25 & 26)

Target population

We divided adult TB patients into three categories according to the type of treatment (Table 2-9) and estimated the number of patients in 2005 for each category (Table 2-10). The number of infant TB patients in 2005, when the equipment procured under Phase II are scheduled to arrive in Cambodia, were estimated based on the record of

²⁴ There are 75 offices as of March 2004, and an additional office is scheduled to open in August 2004.

CENAT, National Pediatric Hospital, and Angkor Children Hospital, the three major institutions that had been playing a central role in the diagnosis and treatment of infant TB until 2003. We also included additional patients on the average of 20 for each of 34 referral hospitals that will begin accepting infant TB cases in 2005 (Table 2-11).

Classification	Type of Patient
Category I:	 new smear positive smear-negative pulmonary TB extra-pulmonary TB, severe form ··· about 1/3 of total extra-pulmonary cases
Category II:	 relapse cases failure cases return after default cases
Category III:	 smear-negative pulmonary TB, non severe form extra-pulmonary TB, non-severe form ··· about 2/3 of total extra-pulmonary cases

Table 2-9: Classification of Adult TB Patients

Table 2-10: Estimated Number of Adult TB Patients by Category

Year	New smear positive (A)	Retreatment (B)	Smear- negative (C)	Extra- pulmonary (D)	Category I (A)+(D)×1/3	Category II (B)	Category III (C)+(D)×2/3
2003	18,391	1,201	3,486	3,214	19,462	1,201	5,629
2004	19,678	1,225	4,532	3,696	20,910	1,225	6,996
2005	21,056	1,250	5,891	4,251	22,473	1,250	8,725
Anuual increase	7%	2%	30%	15%			

Table 2-11: Estimated Number of Infant TB Patients

Year	CENAT	Referral hospitals	National Pediatric Hospital	Angkor Children Hospital	Total
2004	60	-	130	220	410
2005	60	680	143	242	1,125
		(20 patients ×34 Referral hospitals)	(Annual increase: 10%)	(Annual increase: 10%)	

Treatment regimen

Treatment regimen is comprised of the initial phase and the continuation phase. During the initial phase, drugs are given to make the patients smear negative and alleviate clinical symptoms, whereas the treatment regimen for the continuation phase is designed to eradicate residual bacilli for the prevention of relapse. Descriptions of treatment regimen are expressed by placing the number of months indicating the duration of treatment in front of the acronym for each drug or drug combination.

Example: 2RHZE/6EH (in case of Category I)

In the initial phase of two months, Rifampicin+Isoniazid (RH), Pyrazinamide (Z), and Ethambutol (E) are administered daily, followed by the six-month continuation phase, during which Ethambutol+Isoniazid (EH) is given every day.

The Cambodian Health Ministry plans a complete switch to new treatment regimens by January 2005, and four

Operational Districts have already begun giving new prescriptions, two main features of which are:

- Change in the combination of drugs for the continuation phase from Ethambutol+Isoniazid to Rifampicin+Isoniazid.
- Shortening of the duration of each treatment course from eight months to six months.

The above changes are expected to improve compliance and reduce relapses.

	Old treatment regimen (8-month regimen)	New treatment regimen (6-month regimen)
	until December 2004	from January 2005
Category - a	2RHZE/6EH or	2RHZE/ <u>4RH</u> or
- b ²⁵	3RHZE/5EH	3RHZE/ <u>3RH</u>
Category II	2RHZES/1RHZE/5RHE	2RHZES/1RHZE/5RHE (no change)
Category III	2RHZ/6EH	2RHZ/ <u>4RH</u>

Table 2-12: Treatment Regimen

Based on the above, the needed quantity of each drug in Phase II is estimated in the following procedure:

(a) Calculate the quantity of each drug to be consumed by each patient under the new and old treatment regiments

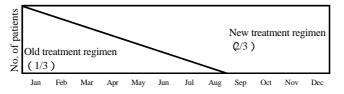
(Table 2-13).

(b) Estimate the total consumption of each drug in 2005 based on the size of the target population as determined under Section and the quantities of drugs as derived under Paragraph (a) above. Then calculate the projected monthly consumption by dividing the yearly consumption volume by 12 (Table 2-14).

Although new treatment regimens will start in January 2005, patients who were registered during 2004 will continue with their old treatment. This means that patients undergoing old regimens will remain until the end of August 2005, while the number of patients undergoing new treatment will gradually increase after January 2005 until

²⁵ 10% of treated patients do not turn sputum smear negative after two months of treatment in initial phase. For such patients, additional 1-month treatment is given.

September 2005 when all patients will be treated under the new prescriptions. For the purpose of convenience, we have set the ratio of old to new treatment patients at one to two as shown in the figure below. Based on this ratio, we estimated the annual consumption of drugs under the old regimen by multiplying the total consumption by 1/3 and the annual consumption under the new regimen by multiplying the total by 2/3.



(c) To cope with an unexpected increase of patients, a reserve stock, consisting of a six-month supply of anti-TB drugs for adults as recommended by IUATLD (International Union Against Tuberculosis and Lung Disease) and a three-month supply of anti-TB drugs for infants, was included in the estimation of the quantity of each drug that needs to be procured in Phase II, which also took into account the monthly consumption of each drug as estimated under Paragraph (b) and the current stock volumes on the premise that anti-TB drugs for adults and infants would go out of stock 18 months and 15 months respectively after their arrival in Cambodia (Table 2-15).
(d) The quantity of each drug was adjusted by rounding up the estimated figure to the nearest packing unit (Table

2-16).

Since streptomycin is produced in powder form, diluent (water for injection) to dissolve the powder right before injection needs to be procured along with the drug. Syringes necessary for diluting powdered drugs are available in Cambodia and therefore not included in the Project.

Old treatment		Categ	gory I		Cate	egory II	Category III	
regimen	I-a (90	%)	Ib (10	Ib (10%)		RHZE/5RHE	ADUZ/CEU	
(8M regimen)	2RHZE/6EH		3RHZE/5EH		2KHZES/1	KHZE/JKHE	2RHZ/6EH	
RH 150/100	$3 \text{ tabs} \times 2M =$	180 tabs	$3 \text{ tabs} \times 3\text{M} =$	270 tabs	3 tabs×8M =	720 tabs	$3 \text{ tabs} \times 2M =$	180 tabs
Z 500	$2 \text{ tabs} \times 2M =$	120 tabs	$2 \text{ tabs} \times 3M =$	180 tabs	$2 \text{ tabs} \times 3M =$	180 tabs	$2 \text{ tabs} \times 2M =$	120 tabs
E 400	$2 \text{ tabs} \times 2M =$	120 tabs	$2 \text{ tabs} \times 3M =$	180 tabs	$2 \text{ tabs} \times 8M =$	480 tabs	-	
EH 400/150	2 tabs×6M =	360 tabs	2 tabs \times 5M =	300 tabs		-	2 tabs×6M =	360 tabs
S1000	-		-		1 vial×2M =	60 vials	-	

Table 2-13: Consumption of Drugs per Patient by Category

New treatment		Categ	gory I		Catego	ory II	Category III		
regimen	I-a (90	I-a (90%)		Ib (10%)		2RHZES/1RHZE/5RHE		2RHZ/4RH	
(6M regimen)	2RHZE/4	4RH	3RHZE	/3RH	2KHZES/IKHZE/JKHE		2ΚΠΖ/4ΚΠ		
RH 150/75	3 tabs×6M =	540 tabs	3 tabs×6M =	540 tabs	3 tabs×8M =	720 tabs	3 tab×6M =	540 tabs	
Z 400	$3 \text{ tabs} \times 2M =$	180 tabs	$3 \text{ tabs} \times 3\text{M} =$	270 tabs	$3 \text{ tabs} \times 3\text{M} =$	270 tabs	3 tab×2M =	180 tabs	
E 400	$2 \text{ tabs} \times 2M =$	120 tabs	$2 \text{ tabs} \times 3M =$	180 tabs	$2 \text{ tabs} \times 8\text{M} =$	480 tabs	-		
S 750	-		-		1 vial×2M =	60 vials	-		

	Children						
RHZ 60/30/150	$3 \text{ tabs} \times 2M =$	180 tabs					
RH 60/30	3 tabs×4M	360 tabs					

RH 150/75	Category I-a	(180 tabs \times 22,473 patients \times 1/3 + 540 tabs \times 22,473 patients \times 2/3) \times 90% =	8,494,794 tabs
	I-b	Q70 tabs \times 22,473 patients \times 1/3 + 540 tabs \times 22,473 patients \times 2/3) \times 10% =	1,011,285 tabs
	Category II	720 tabs \times 1,250 patients =	900,000 tabs
	Category III	180 tabs \times 8,725 patients \times 1/3 + 540 tabs \times 8,725 patients \times 2/3 =	3,664,500 tabs
Total			14,070,579 tabs
Monthly con	sumption		1,172,548 tabs
Z 400	Category I-a	(120 tabs \times 1.25 \times 22,473 patients \times 1/3 + 180 tabs \times 22,473 patients \times 2/3) \times 90% =	3,438,369 tabs
	I-b	(180 tabs \times 1.25 \times 22,473 patients \times 1/3 + 270 tabs \times 22,473 patients \times 2/3) \times 10% =	573,062 tabs
	Category II	180 tabs \times 1.25 \times 1,250 patients \times 1/3 + 270 tabs \times 1,250 patients \times 2/3 =	318,750 tabs
	Category III	120 tabs \times 1.25 \times 8,725 patients \times 1/3 + 180 tabs \times 8,725 patients \times 2/3 =	1,483,250 tabs
Total			5,813,431 tabs
Monthly con	sumption		484,453 tabs
E 400	Category I-a	120 tabs \times 22,473 patients \times 90% =	2,427,084 tabs
	I-b	180 tabs \times 22,473 patients \times 10% =	404,514 tabs
	Category II	$480 \text{ tabs} \times 1,250 \text{ patients} =$	600,000 tabs
Total			3,431,598 tabs
Monthly con	sumption		285,967 tabs
S 750	Category II	$60 \text{ vials} \times 1,250 \text{ patients} =$	75,000 vials
Monthly con	sumption		6,250 vials
RHZ 60/30/1	150	$180 \text{ tabs} \times 1,125 \text{ patients} =$	202,500 tabs
Monthly con	sumption		16,875 tabs
RH 60/30		$360 \text{ tabs} \times 1,125 \text{ patients} =$	405,000 tabs
Monthly consumption			33,750 tabs

Note: The old treatment guidelines instructed the use of RH150/100, Z500, and S1000, which were replaced by RH150/75, Z400, and S750 by the new policy. In estimating the monthly and annual consumption of each drug in 2005, CENAT converted the quantity of each drug to be used under old regimen into the amount used under new regimen by replacing RH150/100 (old) and

S1000 (old) with RH150/75 (new) and S750 (new) and applying the "Z500 = Z400 x 1.25) equivalent formula in the calculation of Z (pyrazinamide).

		Apr-04	May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04	Jan-05	Feb-05	Mar-05
		2002 national budget			Japan's Grant Aid I								
		budget			Grant Ald I								
RH 150/75	Receipt				17,832,864								
	Consumption	507,773	507,773	507,773	507,773	507,773	507,773	507,773	507,773	507,773	1,172,548	1,172,548	1,172,548
	Balance	3,322,681	2,814,908	2,307,135	19,632,226	19,124,453	18,616,680	18,108,907	17,601,134	17,093,361	15,920,813	14,748,265	13,575,717
Z 400	Receipt				10,113,600								
	Consumption	307,890	307,890	307,890	307,890	307,890	307,890	307,890	307,890	307,890	484,453	484,453	484,453
	Balance	1,525,330	1,217,440	909,550	10,715,260	10,407,370	10,099,480	9,791,590	9,483,700	9,175,810	8,691,357	8,206,904	7,722,451
E400	Receipt	4,000,000			2,130,912								
	Consumption	268,555	268,555	268,555	268,555	268,555	268,555	268,555	268,555	268,555	285,967	285,967	285,967
	Balance	4,870,335	4,601,780	4,333,225	6,195,582	5,927,027	5,658,472	5,389,917	5,121,362	4,852,807	4,566,840	4,280,873	3,994,906
S1000	Receipt				97,000								
	Consumption	6,125	6,125	6,125	6,125	6,125	6,125	6,125	6,125	6,125	6,250	6,250	
	Balance	7,666	1,541	-4,584	86,291	80,166	74,041	67,916	61,791	55,666	49,416	43,166	36,916
RHZ 60/30/150	Receipt												
	Consumption	0 90,000	0	0 90,000	0 90.000	0 90.000	0 90.000	0 90,000	0	6,150	16,875	16,875	
DH (0/20	Balance	90,000	90,000	90,000	90,000	90,000	90,000	90,000	90,000	83,850	66,975	50,100	33,225
RH 60/30	Receipt				0	0	0	~		12,300	33,750	33,750	33,750
	Consumption Balance	180.000	180.000	180.000	180.000	180.000	180.000	180.000	180.000	12,300	133,950	33,750 100,200	55,750 66,450
	Datatice	2005年4月	May-05	Jun-05	Jul-05	Aug-05	Sep-05	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	Mar-06
		2003-1-1/3	191ay-03	Jun-05	Japan's	Aug-05	3cp-03	0000	1107-05	Det-05	Jan-00	100-00	W141-00
					Grant Aid II								
					18M	17M	16M	15M	14M	13M	12M	11M	10JM
RH150/75	Receipt				18,700,080								
	Consumption	1,172,548	1,172,548	1,172,548	1,172,548	1,172,548	1,172,548	1,172,548	1,172,548	1,172,548	1,654,920	1,654,920	
	Balance	12,403,169	11,230,621	10,058,073	27,585,605	26,413,057	25,240,509	24,067,961	22,895,413	21,722,865	20,067,945	18,413,025	16,758,105
Z400	Receipt				4,157,013								
	Consumption	484,453	484,453	484,453	484,453	484,453	484,453	484,453	484,453	484,453	572,948	572,948	
	Balance	7,237,998	6,753,545	6,269,092	9,941,652	9,457,199	8,972,746	8,488,293	8,003,840	7,519,387	6,946,439	6,373,491	5,800,543
E400	Receipt				2,559,758								
	Consumption	285,967	285,967	285,967	285,967	285,967	285,967	285,967	285,967	285,967	304,680	304,680	
	Balance	3,708,939	3,422,972	3,137,005	5,410,796	5,124,829	4,838,862	4,552,895	4,266,928	3,980,961	3,676,281	3,371,601	3,066,921
S750	Receipt				102,334								
	Consumption	6,250	6,250	6,250	6,250	6,250	6,250	6,250	6,250	6,250	6,375	6,375	
DH/2 (0/20/150	Balance	30,666	24,416	18,166	114,250 344,250	108,000	101,750	95,500	89,250	83,000	76,625	70,250	63,875
RHZ 60/30/150	Receipt	16.075	16.975	16 975		16.075	16.975	16.975	16.975	16 975	22.570	22.570	22.570
	Consumption Balance	16,875 16,350	16,875 -525	16,875 -17,400	16,875 309,975	16,875 293,100	16,875 276,225	16,875 259,350	16,875 242,475	16,875 225,600	22,560 203,040	22,560 180,480	22,560 157,920
RH 60/30		10,550	-323	-17,400	688,500	295,100	270,223	239,330	242,473	225,000	205,040	180,480	157,920
KH 00/30	Receipt Consumption	33,750	33,750	33,750	33,750	33,750	33,750	33,750	33,750	33,750	45,120	45,120	45,120
	Balance	32,700	-1.050	-34,800	619,950	586,200	552,450	518,700	484,950	451.200	406,080	360,960	315,840
	Balance	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06	Jan-07	Feb-07	Mar-07
		Apr-00	May-00	3uii-00	341-00	Aug-00	5cp-00	001-00	1107-00	Dec-00	Jan-07	105-07	1111-07
		9M	8M	7M	6M	5M	4M	3M	2M	1M	0M		
RH150/75	Receipt												
	Consumption	1,654,920	1,654,920	1,654,920	1,654,920	1,654,920	1,654,920	1,654,920	1,654,920	1,654,920	1,863,825	1,863,825	1,863,825
	Balance	15,103,185	13,448,265	11,793,345	10,138,425	8,483,505	6,828,585	5,173,665	3,518,745	1,863,825	0	-1,863,825	-3,727,650
Z400	Receipt												
	Consumption	572,948	572,948	572,948	572,948	572,948	572,948	572,948	572,948	572,948	644,011	644,011	644,011
	Balance	5,227,595	4,654,647	4,081,699	3,508,751	2,935,803	2,362,855	1,789,907	1,216,959	644,011	0	-644,011	-1,288,022
E400	Receipt												
	Consumption	304,680	304,680	304,680	304,680	304,680	304,680	304,680	304,680	304,680	324,801	324,801	324,801
	Balance	2,762,241	2,457,561	2,152,881	1,848,201	1,543,521	1,238,841	934,161	629,481	324,801	0	-324,801	-649,602
S750	Receipt												
	Consumption	6,375	6,375	6,375	6,375	6,375	6,375	6,375	6,375	6,375	6,500	6,500	
	Balance	57,500	51,125	44,750	38,375	32,000	25,625	19,250	12,875	6,500	0	-6,500	-13,000
RHZ 60/30/150	Receipt												
	Consumption	22,560	22,560	22,560	22,560	22,560	22,560	22,560	22,560	22,560	28,290	28,290	28,290
	Balance	135,360	112,800	90,240	67,680	45,120	22,560	0	-22,560	-45,120	-73,410	-101,700	-129,990
RH 60/30	Receipt	15 100	10.000	10.000	15 100	45 100	10 100	15 100	10.000	10.000			
	Consumption	45,120	45,120		45,120	45,120	45,120	45,120	45,120	45,120	56,580	56,580	
	Balance	270,720	225,600	180,480	135,360	90,240	45,120	0	-45,120	-90,240	-146,820	-203,400	-259,980

Table 2-15: Needed Drug Quantity

Item	Needed Quantity	Adjusted Quantity to be Supplied	Packing Unit
Rifampicin 150 mg+ Isoniazid 75 mg	18,700,080 tablets	27,828 boxes	672 tablets (28 tablets × 24 sheets) per box
Pyrazinamide 400 mg	4,157,013 tablets	6,187 boxes	672 tablets (28 tablets × 24 sheets) per box
Ethambutol 400 mg	2,559,758 tablets	3,810 boxes	672 tablets (28 tablets × 24 sheets) per box
Streptomycin 750 mg	102,334 vials	103,000 vials	1,000 vials
Rifampicin 60 mg + Isoniazid 30 mg + Pyrazinamide 150 mg	344,250 tablets	345,000 tablets	1,000 tablets
Rifampicin 60 mg + Isoniazid 30 mg	688,500 tablets	689,000 tablets	1,000 tablets

Table 2-16: Adjusted Quantity to be Supplied (Phase II)

3. Distribution Plan

Table 2-14 shows the distribution plan of cold chain (freezers, refrigerators, motorcycles). Vaccines (Measles, OPV and Hepatitis B), syringes, safety boxes, and temperature monitoring devices will be delivered from Central Medical Stores (hereinafter to be referenced as "CMS") according to the size of target population and the quantity consumed as reported by each Operational District.

Table 2-17: Distribution Plan

No	Province and Operational District	No. of health center	Icelined Refrigerator, Large	Icelined Refrigerator, Small	Refrigerator and Freezer, Gas and Electric Type, Small		Chest Freezer, Large	Motorcycle
Ι	B.M.CHEY		1					1
1	MONKUL BOREY	19		5	0			
2	O CHROV	10		0	0			
3	THMOR PUOK	12		0	0			
4	PREAH NETH PREAH	12		0	0			
	TOTAL	53	1	5	0	0	0	1
п	BATTAMBANG							1
5	BATTAMBANG	22		5	0			
6	SANG KE	15		1	0			
7	THMOR KOL	17		1	0			
8	MONG RUSSEY	13		1	0			
9	SAMPOV LOUN	7		1	0			
	TOTAL	74	0	9	0	0	0	1

No	Province and Operational District	No. of health center	Icelined Refrigerator, Large	Icelined Refrigerator, Small	Refrigerator and Freezer, Gas and Electric Type, Small	Chest Freezer, Small	Chest Freezer, Large	Motorcycle
ш	KG. CHAM		2					1
10	KAMPONG SIEM	23		3	0			1
11	CHAMKAR LEU	13	1	1	1			
12	CHOEUNG PREY	13		1	1			
13	KRAUCH CHHMAR	9		0	0			
14	MEMOT	8		2	0			
15	O RAING OV	8		1	0			
16	PONHEAKREK	14		2	0			
17	PREY CHHOR	15		1	0			
18	SREY SANTHOR	13	1	1	0			
19	TBONG KHMUM	13		2	0			1
	TOTAL	129	4	14	2	0	0	3
	KG.CHHNANG		1				1	1
	KG.CHHNANG	23		2	2			
21	KG.TRALACH	11		1	2			
				-				
	TOTAL	34	1	3	4	0	1	1
	KG.SPEU	22		-				1
	KG. SPEU	22		1	1			1
	KONG PISSEY	19		0	0			1
24	OU DONG	9		1	0			
	TOTAL	50	0	2	1	0	0	3
	IOTAL	50	0		1	0	0	3
VI	KG .THOM						1	1
	KG.THOM KG.THOM	21		2	1		1	1
_	BARAY	19		2	0			
	STAUNG	10		1	1			
21	STACING	10		1	1			
	TOTAL	50	0	5	2	0	1	1
VП	КАМ РОТ						1	1
	КАМРОТ	10	1	1	1			1
-	ANKORCHEY	10		0	1			
	СННОИК	15		0	1			
_	KG.TRACH	12		1	0			1
	TOTAL	47	1	2	3	0	1	3
VIII	KANDAL						1	1
32	ТАКНМАО	14		1	0			1
33	KEAN SVAY	17		4	0			1
34	KHSACH KANDAL	9		0	1			1
35	КОН ТНОМ	12		0	1			1
36	MUK KAMPOUL	6		0	1			1
37	ANG SNUOL	8		1	0			1
38	PONHEA LOEU	10		0	1			1
	SAANG	12	1	1	0			
	TOTAL	88	1	7	4	0	1	8

No	Province and Operational District	No. of health center	Icelined Refrigerator, Large	Icelined Refrigerator, Small	Refrigerator and Freezer, Gas and Electric Type, Small	Chest Freezer, Small	Chest Freezer, Large	Motorcycle
IX	KOH KONG							1
40	SRE AMBIL	6		1	0			1
41	SMACH MEAN CHEY	6		1	0			1
	TOTAL	12	0	2	0	0	0	3
	KRATIE							1
-	CHHLONG	10		0				
43	KRATIE	12		1	0			
	TOTAL	22	0	1	1	0	0	1
						-		
	MONDUL KIRI		1		_	2		1
44	SEN MONORUM	6		1	0			1
<u> </u>	(+ 6 Health posts) TOTAL	6	1	1	A		0	
	IUIAL	0	1		0	2	0	2
VII	PHNOM PENH					1		1
_		10			2	1		1
	CHAMKAR MORN (kandal)	10		0				1
-	TUOL KORK (lech)							1
	MEAN CHEY (thong)	9		0				1
48	DAUN PPENH (choeung)	8		1	0			1
		37	0	1	8	1	0	5
	HI	57	0		0	1		5
XIII	PREAH VIHEAR		1			2		1
	PREAH VIHEAR	12	1	1	1	2		1
49	FREAD VIDEAR	12		1	1			1
	TOTAL	12	1	1	1	2	0	2
XIV	PREY VENG					0	1	1
50	KAMCHAY MEAR	11		0	1			
51	KG.TRABEK	11		0	1			
52	MESANG	10		0	0			
53	NEAKLOEUNG	17		1	1			
54	PEA RAING	15		0	1			
55	PREAH SDACH	9		0	1			
56	PREY VENG	17		1	1			
	TOTAL	90	0	2	6	0	1	1
	PURSAT							1
	SAMPOV MEAS	21		2				
58	BAKAN	10		0	1			
	TOTAL	31	0	2	2	0	0	1
<u> </u>		<u> </u>						
	RATTANAKIRI							
59	RATTANAKIRI	10		2	3			1
	(+17 health posts)	4.0	^	· .	-			
	TOTAL	10	0	2	3	0	0	1
	PAILIN	-		-		1		
60	PAILIN	3		2	0			
	TOTAL	3	0	2	0	1	0	0
L	IVIAL	3	U	4	U	1	U	U

No	Province and Operational District	No. of health center	Icelined Refrigerator, Large	Icelined Refrigerator, Small	Refrigerator and Freezer, Gas and Electric Type, Small		Chest Freezer, Large	Motorcycle
XVIII	SIEMREAP							
61	SIEMREAP	29		2	0			1
62	KRAR LANH	7		1	0			1
63	SOTHR NIKUM	17		1	0			1
	TOTAL	53	0	4	0	0	0	3
XIX	SIHANOUK VILLE							
64	SIHANOUK VILLE	11		4	0			2
	TOTAL	11	0	4	0	0	0	2
XX	STUNG TRENG							
65	STUNG TRENG	10		1	0			1
	TOTAL	10	0	1	0		0	1
XXI	SVAY RIENG					1		2
	SVAY RIENG	20		1	1			
67	CHI PHOU	8		0	1			1
68	ROMEAS HEK	9		0	0			1
	TOTAL	37	0	1	2	1	0	4
XXII	ТАКЕО					1		
69	DAUNKEO	15		1	1			
70	ANGROKA	9		0	2			
71	BATI	13		0	1			1
72	KIRIVONG	20		0	1			1
73	PREY KABASS	13		0	1			1
	TOTAL	70	0	1	6	1	0	3
XXIII	КЕР							
74	KEP	4		1	0			
	TOTAL	4	0	1	0	0	0	0
	ODAR MEAN CHEY							
75	SAMRONG	10		1	0			
	TOTAL	10	0	1	0	0	0	0
	National Hospitals and NIP, MOH Grand Total	943	10	74	45	8	5	50

2-2-3 Implementation Plan

2-2-3-1 Implementation Policy

Equipment for this Project will be procured from the manufacturers in Japan, Cambodia, and third countries, among whom public tenders will be held. Eligible tenderers will be Japanese trading firms incorporated and registered under the law of Japan. Pre-shipment inspection for third-country products will be conducted by independent inspection agency assigned by the consultant. As for vaccines, pharmaceutical products, and other items that need strict quality control, the procurement supervisor will inspect them before shipment and at the time of delivery to each project site.

The NIP of the Ministry of Health and CENAT will be in charge of supervising the distribution, operation, and

maintenance of the equipment, while CMS will be directly responsible for the actual transportation of the equipment.

2-2-3-2 Implementation Conditions

Certain difficulties are expected in procuring large volumes of vaccines²⁶. Delays in delivery could occur for a number of reasons. For example, the vaccine manufacturer may need the maintenance work on the production lines, etc. Therefore, the production status of the manufacturer should be closely monitored, and if necessary, prompt measures should be taken, such as shipping vaccines from the reserve stock (in this case, make sure to check the expiration date) and switching to different manufacturers.

Vaccines will be transported by air to Phnom Penh International Airport. Other items will be delivered via ocean to and discharged at Sihanouk Ville Port, and transported by land to the handover site (CMS in Phnom Penh). Transportation of the equipment from CMS to their final destinations is the responsibility of the Cambodian side.

Those items requiring temperature control should be properly packaged and promptly transported and inspected so as not to affect their qualities. The Cambodian side is encouraged to ensure prompt customs clearance procedures and handover to CMS.

2-2-3-3 Scope of Works

Table 2-18 below shows the division of work between Japan and Cambodia.

Country	Scope of Works
Japan	Procurement of equipment Transportation of equipment to handover site (CMS in Phnom Penh)
Cambodia	Distribution of equipment from handover site (CMS in Phnom Penh) to target facilities

²⁶ Problems in vaccine procurement: This Project will procure vaccines from the manufactures whose product qualities have been pre-qualified by WHO. However, sources of reliable vaccines are becoming scarce recently, as some large European vaccine makers decided not to participate in ODA projects due to irregular orders and restrictions on procurement timeframe. Therefore, the procurement plan should be carefully worked out by taking into these factors.

2-2-3-4 Consultant Supervision

One representative from the Supplier will be dispatched as the procurement supervisor to oversee the acceptance inspection, sorting out, and handover of the procured equipment in Cambodia.

2-2-3-5 Procurement Plan

The table below shows the sources from which major equipment items for this Project will be procured.

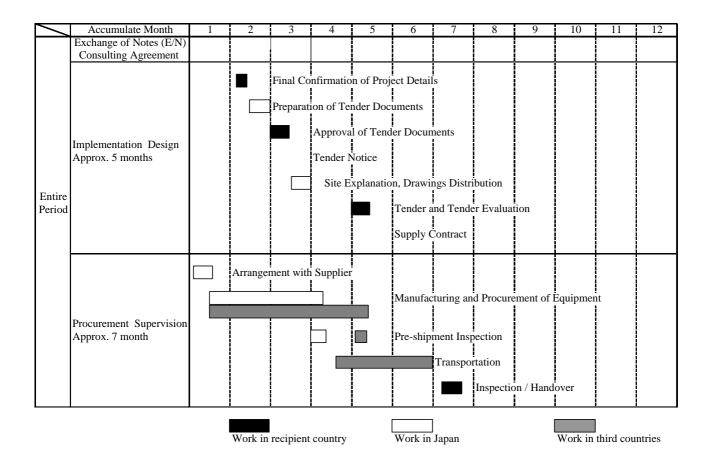
Equipment	Cambodia	Japan	3 rd country	Reason
Safety box				WHO quality standards products are not manufactured in Cambodia or Japan.
Auto-disable syringe				WHO quality standards products are manufactured in several European countries but not in Cambodia or Japan.
Cold-chain equipment •Icelined refrigerator •Gas/electric type refrigerator & freezer • Chest freezer • Cold box • Vaccine carrier • Temperature monitoring equipment				WHO quality standards products are not manufactured in Japan or Cambodia. They will probably be procured from Europe or other third countries.
Vaccine				Shall be sourced from manufactures that have been pre-qualified by WHO. Although one Japanese manufacture has been qualified to produce measles vaccine, it is limited to supplying for UNIICEF.
Disposable syringe				Produced by more than one Japanese manufacturer but not in Cambodia.
Motorcycle				Produced by more than one Cambodian manufacturer.
Anti-TB drug				Since TB drugs officially recommended by GDF are not manufactured in Japan or Cambodia, they will be procured from India, China, South Africa or other third countries.

Table 2-19: Sources of Equipment and Supplies

2-2-3-6 Implementation Schedule

Work schedule

Total period of work (from E/N to delivery)	:	12 months
From E/N to supply contract	:	5 months
Time of delivery (from supply contract to delivery)	:	7 months



2-3 Obligation of Recipient Country

The undertakings of the Cambodian side in implementing this Project consist of the following:

To ensure proper and prompt customs clearance procedure for the equipment to be procured under this Project.

To secure storage spaces necessary to keep the equipment to be procured under this Project, taking special precautions for properly maintaining the quality of the anti-TB drugs.

To ensure prompt distribution the equipment to their final destinations by keeping close communications with the CMS personnel in charge, as well as the staff of the target facilities.

To make necessary appropriations and employ an adequate number of personnel for the proper operation and maintenance of the equipment.

To check the status of the distribution and use of the equipment.

These tasks have already been undertaken by the Cambodian Ministry of Health in implementing the 2001-2005 of Immunization 5-Year Work Plan and the National Health Strategic Plan for Tuberculosis Control 2001–2005 and are currently being carried out under the assistance of WHO and UNICEF. Therefore, the Cambodian side is deemed capable of continuing these activities without major difficulties.

2-4 Project Operation Plan

The cold chain equipment to be procured by Phase II for immunization activities will be installed in the Provincial Health Offices, Operational District Health Offices, and Health Centers throughout Cambodia. At present, each health facility is properly storing vaccines by assigning personnel to periodically monitor the refrigerators and freezers by measuring and recording inside temperatures daily. Each Provincial Health Office employs at least one trained engineer, and each Provincial Health Office or Operational District Health Office has an assigned staff that can perform basic maintenance work. Complicated repair works are done at the repair shop of the equipment manufacturer in Phnom Penh. Spare parts are usually supplied by Operational District Health Offices, or are available for purchase in each Operational District in case the Health Offices are out of stock. In addition, UNICEF and other donor organizations are extending assistance in the procurement of spare parts.

Each project site can perform simple maintenance work and inspection on motorcycles. Repair works, depending on the degree of technical difficulty, are entrusted to private repair shops within the Province or the repair shop of the motorcycle manufacture or its local agent in Phnom Penh.

Distribution and injection of the vaccines to be procured by Phase II will be carried out using the existing systems. Currently, vaccines are transported from the central storehouse to the Provincial Health Offices by CMS on the average of once in every three months. Each Provincial Health Office delivers vaccines once a month by their pickup truck to the Operational District Health Offices, wherefrom each Health Center equipped with a refrigerator receives a monthly supply. In preparation for the installation of a small gas/electric-type freezer/refrigerator in each target Health Center under this Project, the Cambodian government, in cooperation with WHO, has established specific guidelines pertaining to the proper procurement, storage, and transportation of vaccines and begun giving training to the health workers concerned under newly formulated education/training strategies.

After each immunization activity, a large quantity of auto-disable syringes needs to be discarded. Cambodia began using incinerators in 1998 under the guidance of WHO Western Pacific Region Office (WPRO), has already developed operational manuals of incinerators, and is conducting staff training. Therefore, collection and incineration of used syringes should be carried out without major difficulties under the current system.

The tubercilosis control activities will also utilize the current systems in Cambodia as much as possible. CENAT is the implementation agency of the National Health Strategic Plan on TB Control that plans to expand DOTS. TB control activities, including free diagnosis and treatment, are carried out by CENAT in close coordination with Provincial Health Offices, Operational District Health Offices, referral hospitals, and Health Centers. Since the implementation and administration systems of DOTS programs are adequately in place on the central, provincial, and Operational District levels, the tubercilosis control activities should be managed and maintained properly.

2-5 Cost of Estimation for the Project

2-5-1 Cost Estimation for the Assistance Project

The total implementation cost of this assistance project is estimated at 232 million yen. The expenses to be borne by the Japanese and the Cambodian side according to the division of work defined above and based on the parameters listed below are estimated as follows.

This cost estimate is provisional and would be further examined by the Government of Japan for the approval of the Grant.

1. Expenses to be Borne by the Japanese Side

	Estima	ated Total Project Cost A	Approx. 232 million yen
	Item	Estimated Project C	Cost (in million yen)
D • •	NIP	162	217
Equipment	TB Control	55	217
Detail design, procurement supervision, technical guidance			15
Total			232

2. Expenses to be Borne by the Cambodian Side

None (No additional cost will be incurred for transporting the equipment and supplies, as they will be delivered along with other medical supplies and equipment using the regular distribution routes of the Ministry of Health.)

3. Parameters of Cost Estimation

Time of calculation	: March 2004
Exchange rate	: 1 US dollar = 108.21 yen

US dollar was used in the cost estimation, as the currency is widely used in Cambodia.

2-5-2 Operation and Manintenance Costs

Of the cold-chain equipment to be procured by this Project, ice-lined refrigerators, gas/electric-type refrigerators, chest freezers, and motorcycles will incur maintenance cost.

Utility and repair costs of the Health Centers, where the freezer/refrigerator will be newly installed, will be covered by the operation/maintenance budget of the Provincial Health Offices. In some Provinces, where beneficiary charges are applied, about 1% of profits of each Health Center is appropriated for partial payment of fuel and repair costs.

The annual fuel cost of the gas-type freezer/refrigerator to be used in unelectrified areas is estimated between US\$84.00 and US\$116.00.

In the budget of the Ministry of Health for immunization programs, fuel cost for motorcycles is included in the

"transportation cost" and the operation/maintenance cost of freezers and refrigerators in the "operation and maintenance cost," which are distributed among the Provinces. The Cambodian government plans to secure the Health Ministry's budget by projecting about 20% annual increase in the transportation cost and about 5% annual increase in the operation and maintenance cost, which should sufficiently ensure the sustainability of the operation and maintenance of the equipment to be procured under this Project.

	2003	2004	2005
Vaccines (for routine vaccinations)	1,354,600	1,545,012	2,098,304
Syringes, etc.	232,076	236,198	240,843
Labor	962,374	1,046,824	1,119,710
Transportation	101,568	122,747	144,418
Operation and maintenance	288,750	303,188	318,347
Short-term training	140,760	147,794	155,188
Public relations	410,000	395,500	453,250
Monitoring / epidemiological surveillance	122,049	128,152	134,559
Vehicles	441,667	390,849	410,392
Cold chain equipment	948,320	510,091	535,880
Additional campaign expenses	0	598,941	684,814
Other	196,980	3,859	0
Total	5,199,144	5,429,155	6,295,705

Table 2-20: Budget of the Ministry of Health (itemized)

(in US\$)

Chapter 3 Project Evaluation and Recommendations

3-1 Project Effect

1) Direct Effect

About 140,000 infants and 3.17 million women in reproductive ages (childbearing ages between 19 and 49) will be given vaccines that have been properly stored to ensure the effectiveness of vaccinations (acquisition of immunity). Renewing the unusable or antiquated refrigerators by distributing new refrigerators to Health Centers that have been using cold boxes will enable the Health Centers to keep vaccines at proper temperatures and thereby maintain their efficacy.

Procurement of auto-disable syringes for preventing reuse, as well as safety boxes for properly discarding used syringes, will lead to the establishment of a comprehensive and safe immunization system, thereby preventing the spread of HIV and Hepatitis-B infections.

Provision of motorcycles will enable the health workers to travel to remote areas to give injections and education to the residents who have been deprived of such services, thereby expanding immunization coverage.

Procuring the needed quantity of anti-TB drugs for adults will enable the treatment of about 32,000 TB patients.

Procurement of drugs more suitable for treating infant TB will provide more effective treatment.

2) Indirect Effect

Establishment of a safe immunization system against all major infectious diseases, as well as proper enforcement of routine vaccinations, will contribute to lowering Cambodia's morbidity rate.

Expanded and upgraded cold chain system will reduce the wastage of vaccines thereby cutting the vaccine purchase cost of the Cambodian Health Ministry.

Collection of all used syringes and their proper disposal by incineration in accordance with the rules and regulations set by the Ministry of Health will actualize environmentally-sensitive immunization activities.

Improved medical service quality on community levels will lower the morbidity of major diseases, leading to the reduction of medical expenditures.

3-2 Recommendations

Although the Ministry of Health is deemed highly capable of properly implementing this Project, its success will be further ensured if conscious efforts are made on the following points:

- Currently, CMS has old and new warehouses that are situated apart from each other. Large quantities of medical supplies to be procured by this Project will be stored in the new CMS, where managing staffs are scarce. Therefore, proper maintenance of the medical goods at the new CMS and their prompt delivery to each Operational District Health Office should be closely monitored and ensured.
- The treatment default rate of TB should be minimized to prevent the generation of drug-resistant TB bacillus strains.
- All used auto-disable syringes must be collected from the vaccination sites and properly incinerated to prevent secondary infection.

(Appendices)

[Appendix]-1 Member List of the Study Team

Leader Mr. Tsuyoshi YUSA Assistant Resident Representative, Japan International Cooperation Agency Cambodia Office

Equipment Planner Mr. Tetsuo KODAMA Japan International Cooperation System

Procurement Planner Ms. Tomoko NIKAI Japan International Cooperation System

[Appendix]-2 Study Schedule

No.	Date	e	Itinerary	Accomm.
1	2/22	Sun	Tokyo 10:45? 15:45 Bangkok (TG647) Bangkok 17:30? 18:45 Phnom Penh (TG698) Internal Meeting	Phnom Penh
2	2/23	Mon	Meeting, JICA, WHO Courtesy call on Ministry of Health Meeting, CENAT	Phnom Penh
3	2/24	Tue	Meeting, NIP Site Survey (\$amrong Krom Health Center in Phnom Penh) Meeting, JICA	Phnom Penh
4	2/25	Wed	Meeting, NIP	Phnom Penh
5	2/26	Thu	Market Research Meeting, EPI	Phnom Penh
6	2/27	Fri	Meeting, NIP, Visit Old CMS Phnom Penh Battambang Banteay Meanchey Site Survey (Hospital Mongkul Borei, Banteay Meanchey)	Poi Pet
7	2/28	Sat	Site Survey (Poi Pet Health Center, Banteay Meanchey, Measles immunization campaign, CARE) Banteay Meanchey Siem Reap	Siem Reap
8	2/29	Sun	Siem Reap Phnom Penh Internal Meeting	Phnom Penh
9	3/1	Mon	ICSC meeting Meeting, CENAT	Phnom Penh
10	3/2	Tue	Site Survey (Sandech Euv Hospital, Km 9 Health Center, Phnom Penh) Report, Embassy of Japan Meeting, CENAT	Phnom Penh
11	3/3	Wed	Meeting, CENAT, NIP	Phnom Penh
12	3/4	Thu	Meeting, Ministry of Health Discussion on M/D (NIP, CENAT)	Phnom Penh
13	3/5	Fri	Site surbey (New CMS) Signing of M/D Phnom Penh 20:25 21:30 Bangkok (TG699) Bangkok 23:40	In flight
14	3/6	Sat	? 7:30 Tokyo (TG642)	

[Appendix]-3 List of Parties Concerned in the Recipient Country

1. Embassy of Japan

Mr. Kazumi JIGAMI	Counselor
Ms. Chinami HANAZONO	Special Advisor

2. JICA Cambodia Office

Mr. Hiroto MITSUGI	Deputy Resident Representative
	Deputy Resident Representative

3. Ministry of Health

Prof. Eng Hout	Secretary of State for Health	
Dr. Sann Chan Soeung	Manager, MIP	
Dr. Chea Kim Ly	Deputy Manager, NIP	
Ms. Ly Nareth	Deputy Manager, NIP	
Dr. Svay Sarath	Deputy Manager, NIP	
Dr. Mao Tang Eang	Director, CENAT	
Dr. Tieng Sivanna	Deputy Chief of Technical Bureau, CENAT	
Mr. Chay Sokun	Technical Bureau officer, CENAT	
Mr. Kou Soum Mardy	Technical Bureau officer, CENAT	
Dr. Saint Saly	International Reserch Coordinator, CENAT	
Mr. Chea Chhiv Srong	Director, CMS	
Dr. Ma Sophann	Deputy Chief of Technical Bureau, CMS	
Mr. Keo Srun	Chief of vaccine storage, CMS	
Mr. Bun Saren	Deputy Chief of drug program	
Dr. Chi Mean Hea	Deputy Director of Hospital Services Department	
Dr. Sok Chann	Bio-Medical Engineering Unit, Hospital Services Department	

4. JICA National Tuberculosis Control Project

Dr. Kosuke OKADA	Chief Advisor
Dr. Yuta UCHIYAMA	Drug Management Advisor
Dr. Takashi MIURA	Medical Technologist
Mr. Masaru IIZUKA	Project Coordinator

5. Samronf Krom Health Center, Phnom Penh

Dr. Hing Surhorn	Vice Director
Dr. Ouk Narith	Protection Maternal Infantil
Dr. Paou Linar	MCH Programer

6. Hospital Mongkul Borei, Banteay Meanchey

Dr. Chumm Vanarith	Provincial Health Director
Mr. Kun Navuth	Provincial EPI Manager
Dr. Youk Vanndy	Labo

Dr. Rat So Phanet	Labo
Dr. Oeun Hea	Labo
Dr. Preap Sangvan	Labo
Dr. Kuy Thy	Labo
Dr. Has Mamchandara	Labo

7. CARE

Mr. Sok Serey	HIV/AIDS Project Manager
Mr. Serey Rith	Assistant Project Manager

8. Km 9 Health Center, Phnom Penh

Dr. San Sarin	Chef
Dr. Meas San	TB Supervisor

9. WHO/WPRO

Dr. Yoshikuni SATO	EPI Medical Officer, WPRO
Mr. Hisakazu HIRAOKA	EPI Technical Officer, WPRO

10. WHO Representative Office

Dr. Kohei TODA WHO/EPI Technical Officer
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[Appendix]-4 Minutes of Discussion

MINUTES OF DISCUSSIONS ON THE BASIC DESIGN STUDY ON THE PROJECT FOR INFECTIOUS DISEASES CONTROL IN THE KINGDOM OF CAMBODIA

In response to a request from the Government of The Kingdom of Cambodia (hereinafter referred to as "the Cambodia), the Government of Japan decided to conduct a Basic Design Study on the Project for Infectious Diseases Control (hereinafter referred to as "the Project") and entrusted the study to the Japan International Cooperation Agency (hereinafter referred to as "JICA").

JICA sent to Cambodia the Basic Design Study Team (hereinafter referred to as "the Team"), which is headed by Tsuyoshi Yusa, staff, JICA Cambodia Office, and is scheduled to conduct the study from February 22nd to March 5th 2004.

The Team held discussions with the officials concerned of the Government Cambodia and conducted a field survey at the study area.

In the course of discussions and field survey, both parties confirmed the main items described on the attached sheets. The Team will proceed to further works and prepare the Basic Design Study Report.

Phnom Penh, March 5, 2004

Tsuyoshi Yusa Leader)Basic Design Study Team Japan International Cooperation Agency (Japan)

Prof. Dr. Eng Huot Director General for Health Ministry of Health (The Kingdom of Cambodia)

(Witnessed by)

Dr. Jim Tulloch Resident Representative World Health Organization

ATTACHMENT

1.Objective of the Project

The objective of the Project is to accelerate the Expanded Programme on Immunization (EPI) and National Tuberculosis Programme (NTP) implemented by the Government of Cambodia and to reduce the morbidity and mortality due to vaccine preventable diseases, and Tuberculosis in the Project sites.

2.Project sites

The sites of the Project are all areas in Cambodía where the EPI and NTP are being implemented.

3.Responsible and Implementing Agency

3-1. The Ministry of Health is both the responsible and implementing agency.

4. Items requested by the Government of Cambodia

After discussions with the Team, the items described in Annex-1 were finally requested by Cambodia side. JICA will assess the appropriateness of the request and will recommend to the Government of Japan for its approval.

5. Japan's Grant Aid Scheme

5-1. Cambodia side understands the Japan's Grant Aid Scheme explained by the Team, as described in ANNEX-3.

5-2. Cambodia side will take the necessary measures, as described in Annex-2, for smooth implementation of the Project, as a condition for the Japanese Grant Aid to be implemented.

6.Schedule of the Study

6-1. Based on the Minutes of Discussions and technical examination of the study results, JICA will complete the final report and send it to the Government of Cambodia by July 2004.

7.Other relevant issues

7-1. The Government of Cambodia shall allocate the necessary budget and personnel for implementation of the Project.

7-2. The Government of Cambodia shall properly distribute and utilize the equipment, pharmaceuticals, and other items which will be procured under the Grant in collaboration with JICA Tuberculosis Control Project, WHO and UNICEF. In this regard, the Government of Cambodia is required to ensure proper stock management at Central Medical Store(CMS) and distribution of items to the Project sites.

7-3. Both sides understand that the Project shall be implemented with the collaboration and technical support from CENAT/JICA Tuberculosis Control Project, WHO, and UNICEF, especially activities related to EPI activities, especially Hepatitis B Control, Measles Elimination, safe disposal of used syringes, and proper use of cold chain equipment.

ANNEX1

No.	Item	Quantity	Priority
 l	Safety Box, Large	10,000 pcs.	A
2	Safety Box, Medium	79,000 pcs.	A
3	Autodisable Syringe	3,960,000 pcs.	А
4	Icelined Refrigerator, Largé	10 units	A
5	Icelined Refrigerator, Small	74 units	A
6	Refrigerator and Freezer, Gas and Electric Type, Small	45 units	A
	Chest Freezer, Small	8 units	A
8	Chest Freezer, Large	5 [°] units	A
9	Cold Box	300 units	A
10	Vaccine Carrier	1,000 [;] units	A
11	Vaccine Thermometer	500;pcs.	A
12	Temperature Data Logger	24 units	A
13	Freeze Watch Indicator	500 pcs.	· A
14	Refrigerator Monitor	3,000 pcs.	A
15	Cold Chain Monitor Card	2,000 pcs.	A
16	Measles Vaccine	1,440,000 doses	A
17	Disposable Syringe	144,000 pcs.	A
18	Oral Polio Vaccine	790,000 doses	A
19	Hepatitis B Vaccine	580,000 doses	A
20	Motorcycle	50 [°] units	A
21	Rifampicin 150mg + Isoniazid 75mg	18,700,080 tablets	A
22	Рутаzinamide 400mg	4,157,013 tablets	A
23	Ethambutol 400mg	2,559,758 tablets	A
24	Streptomycin 750mg	102,334 vials	A
25	Rifampicin 60mg + Isoniazid 30mg + Pyrazinamide 150mg	344,250 tablets	A
26	Rifampicin 60mg + Isoniazid 30mg	688,500 [:] tablets	A

11

Major Undertakings to be taken by Each Government

NO	Items	To be covered by	To be covered by
	· · · · · · · · · · · · · · · · · · ·	Grant Aid	Recipient side
1	To bear the following commissions to a bank of Japan for the banking services based upon the B/A		
1) A	livising commission of A/P		٠
2) Pa	yment commission		¢
2	To ensure prompt unloading and customs clearance at the port of disembarkation in recipient country		
1) M	arine(Air) transportation of the products from Japan to the recipient country	•	
	ax exemption and custom clearance of the products at the port of nbarkation		•
3) In	ternal transportation from the port of disembarkation to the project site	(•)	(•)
3	To accord Japanese nationals whose services may be required in connection with the supply of the products and the services under the verified contract such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work		•
4	To exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contract		¢
5,	To maintain and use properly and effectively the facilities constructed and equipment provided under the Grant Aid		•
6	To bear all the expenses, other than those to be borne by the Grant Aid, necessary for the transportation and installation of the equipment		• .

JAPAN'S GRANT AID SCHEME

Anniex-3

1. Grant Aid Procedure

 Japan's Grant Aid Program is executed through the following procedures. Application (Request made by a recipient country) Study (Basic Design Study conducted by JICA) Appraisal & Approval (Appraisal by the Government of Japan and Approval by Cabinet) Determination of (The Notes exchanged between the Governments of Japan Implementation and the recipient country)

2) Firstly, the application or request for a Grant Aid project submitted by a recipient country is examined by the Government of Japan (the Ministry of Foreign Affairs) to determine whether or not it is eligible for Grant Aid. If the request is deemed appropriate, the Government of Japan assigns JICA to conduct a study on the request. If necessary, JICA send a Preliminary Study Team to the recipient country to confirm the contents of the request.

Secondly, JICA conducts the study (Basic Design Study), using Japanese consulting firms.

Thirdly, the Government of Japan appraises the project to see whether or not it is suitable for Japan's Grant Aid Programme, based on the Basic Design Study report prepared by JICA, and the results are then submitted to the Cabinet for approval.

Fourthly, the project, once approved by the Cabinet, becomes official with the Exchange of Notes signed by the Governments of Japan and the recipient country.

Finally, for the implementation of the project, JICA assists the recipient country in such matters as preparing tenders, contracts and so on.

- 2. Basic Design Study
- 1) Contents of the Study

The aim of the Basic Design Study (hereinafter referred to as "the Study"), conducted by JICA on a requested project (hereinafter referred to as "the Project"), is to provide a basic document necessary for the appraisal of the Project by the Government of Japan. The contents of the Study are as follows:

- a) confirmation of the background, objectives and benefits of the Project and also institutional capacity of agencies concerned of the recipient country necessary for the Project's implementation:
- b) evaluation of the appropriateness of the Project to be implemented under the Grant Aid Scheme from the technical, social and economic points of view;
- c) confirmation of items agreed on by both parties concerning the basic concept of the Project;
- d) preparation of a basic design of the Project; and
- e) estimation of costs of the Project.

The contents of the original request are not necessarily approved in their initial form as the contents of the Grant Aid project. The Basic Design of the Project is confirmed considering the guidelines of Japan's Grant Aid Scheme.

The Government of Japan requests the Government of the recipient country to take whatever measures are necessary to ensure its self-reliance in the implementation of the Project. Such measures must be guaranteed even through they may fall outside of the jurisdiction of the organization in the recipient country actually implementing the Project. Therefore, the implementation of the Project is confirmed by all relevant organizations of the recipient country through the Minutes of Discussions.

Selection of Consultants

For the smooth implementation of the Study, JICA uses a consulting firm selected through its own procedure (competitive proposal). The selected firm participates the Study and prepares a report based upon the terms of reference set by JICA.

At the beginning of implementation after the Exchange of Notes, for the services of the Detailed Design and Construction Supervision of the Project, JICA recommends the same consulting firm which participated in the Study to the recipient country, in order to maintain the technical consistency between the Basic Design and Detailed Design as well as to avoid any undue delay caused by the selection of a new consulting firm.

3. Japan's Grant Aid Scheme

Grant Aid

2)

1)

The Grant Aid Program provides a recipient country with non-reimbursable funds to procure the facilities, equipment and services (engineering services and transportation of the products, etc.) for economic and social development of the country under principles in accordance with the relevant laws and regulations of Japan. Grant Aid is not supplied through the donation of materials as such.

2) Exchange of Notes (E/N)

Japan's Grant Aid is extended in accordance with the Notes exchanged by the two Governments concerned, in which the objectives of the project, period of execution, conditions and amount of the Grant Aid, etc., are confirmed.

3) "The period of the Grant" means the one fiscal year which the Cabinet approves the project for. Within the fiscal year, all procedure such as exchanging of the Notes, concluding contracts with consulting firms and contractors and final payment to them must be completed.

However, in case of delays in delivery, installation or construction due to unforeseen factors such as weather, the period of the Grant Aid can be further extended for a maximum of one fiscal year at most by mutual agreement between the two Governments.

4) Under the Grant, in principle, Japanese products and services including transport or those of the recipient country are to be purchased.

When the two Governments deem it necessary, the Grant Aid may be used for the purchase of the products or services of a third country.

However, the prime contractors, namely consulting, contracting and procurement firms, are limited to "Japanese nationals". (The term "Japanese nationals" means persons of Japanese nationality or Japanese corporations controlled by persons of Japanese nationality.)

5) Necessity of "Verification"

The Government of the recipient country or its designated authority will conclude contracts

denominated in Japanese yen with Japanese nationals. Those contracts shall be verified by the Government of Japan. This "Verification" is deemed necessary to secure accountability of Japanese taxpayers.

- 6) Undertakings required to the Government of the recipient country
- a) to secure a lot of land necessary for the construction of the Project and to clear the site;
- b) to provide facilities for distribution of electricity, water supply and drainage and other incidental facilities outside the site;
- c) to ensure prompt unloading and customs clearance at ports of disembarkation in the recipient country and internal transportation therein of the products purchased under the Grant Aid;
- d) to exempt Japanese nationals from customs duties, internal taxes and fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contracts;
- e) to accord Japanese nationals whose services may be required in connection with the supply of the products and services under the verified contracts such as facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work;
- f) to ensure that the facilities constructed and products purchased under the Grant Aid be maintained and used properly and effectively for the Project; and
- g) to bear all the expenses, other than those covered by the Grant Aid, necessary for the Project.

7) "Proper Use"

The recipient country is required to maintain and use the facilities constructed and equipment purchased under the Grant Aid properly and effectively and to assign the necessary staff for operation and maintenance of them as well as to bear all the expenses other than those covered by the Grant Aid.

8) "Re-export"

The products purchased under the Grant Aid shall not be re-exported from the recipient country.

9) Banking Arrangement (B/A)

a) The Government of the recipient country or its designated authority should open an account in the name of the Government of the recipient country in an authorized foreign exchange bank in Japan (hereinafter referred to as "the Bank"). The Government of Japan will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by the Government of the recipient country or its designated authority under the verified contracts.

b) The payments will be made when payment requests are presented by the Bank to the Government of Japan under an Authorization to Pay (A/P) issued by the Government of recipient country or its designated authority.

ANNEX : UNDERTAKINGS BY THE GOVERNMENT OF THE RECIPIENT COUNTRY

- 1. To secure a lot of land necessary for the Project;
- 2. To clear and level the site for the Project prior to the commencement of the construction;
- 3. To provide a proper access road to the Project site;
- 4. To provide facilities for distribution of electricity, water supply, telephone trunk line and drainage and other incidental facilities outside the site;
- 5. To undertake incidental outdoor works, such as gardening, fencing, exterior lighting, and other incidental facilities in and around the Project site, if necessary;
- 6. To ensure prompt unloading and customs clearance of the products purchased under the Japan's Grant Aid at ports of disembarkation in the Recipient Country;
- 7. To exempt Japanese nationals from customs duties, internal taxes and fiscal levies which may be imposed in THE RECIPIENT COUNTRY with respect to the supply of the products and services under the verified contracts;
- 8. To accord Japanese nationals whose services may be required in connection with the supply of the products and services under the verified contracts such facilities as may be necessary for their entry into THE RECIPIENT COUNTRY and stay therein for the performance of their work;
- 9. To bear commissions, namely advising commissions of an Authorization to Pay (A/P) and payment commissions, to the Japanese foreign exchange bank for the banking services based upon the Banking Arrangement (B/A);
- 10. To provide necessary permissions, licenses, and other authorization for implementing the Project, if necessary;
- 11. To ensure that the facilities constructed and equipment purchased under the Japan's Grant Aid be maintained and used properly and effectively for the Project; and
- 12. To bear all the expenses, other than those covered by the Japan's Grant Aid, necessary for the Project.

Annex-3

[Appendix]-5 References

No.	References	Issued by	Year	original/ copy
1	National Immunization Program Plan 2004-2006	Ministry of Health	2002	сору
2	Financial Sustainability Planning Immunization Services in Cambodia Update 2003	Ministry of Health	2003	original
3	Guideline on Cold Chain	Ministry of Health	2003	original
4	Tuberculosis Standard Treatment Regimens	Ministry of Health	2001	original

