No.

STUDY REPORT
ON
THE GRANT AID FOR INFECTIOUS DISEASE

THE PROJECT FOR
INFECTIOUS DISEASES CONTROL
IN
REPUBLIC OF ZAMBIA

July 2003

JAPAN INTERNATIONAL COOPERATION AGENCY

G R 2
CR(1)
03－224

PREFACE

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

JICA sent a study team to the Republic of Zambia in March 2003.

The team held discussions with the officials concerned of the Government of the Republic of Zambia, and conducted a field study at the study area. After returning to Japan, the study team conducted further studies and, as a result, is presenting this final report.

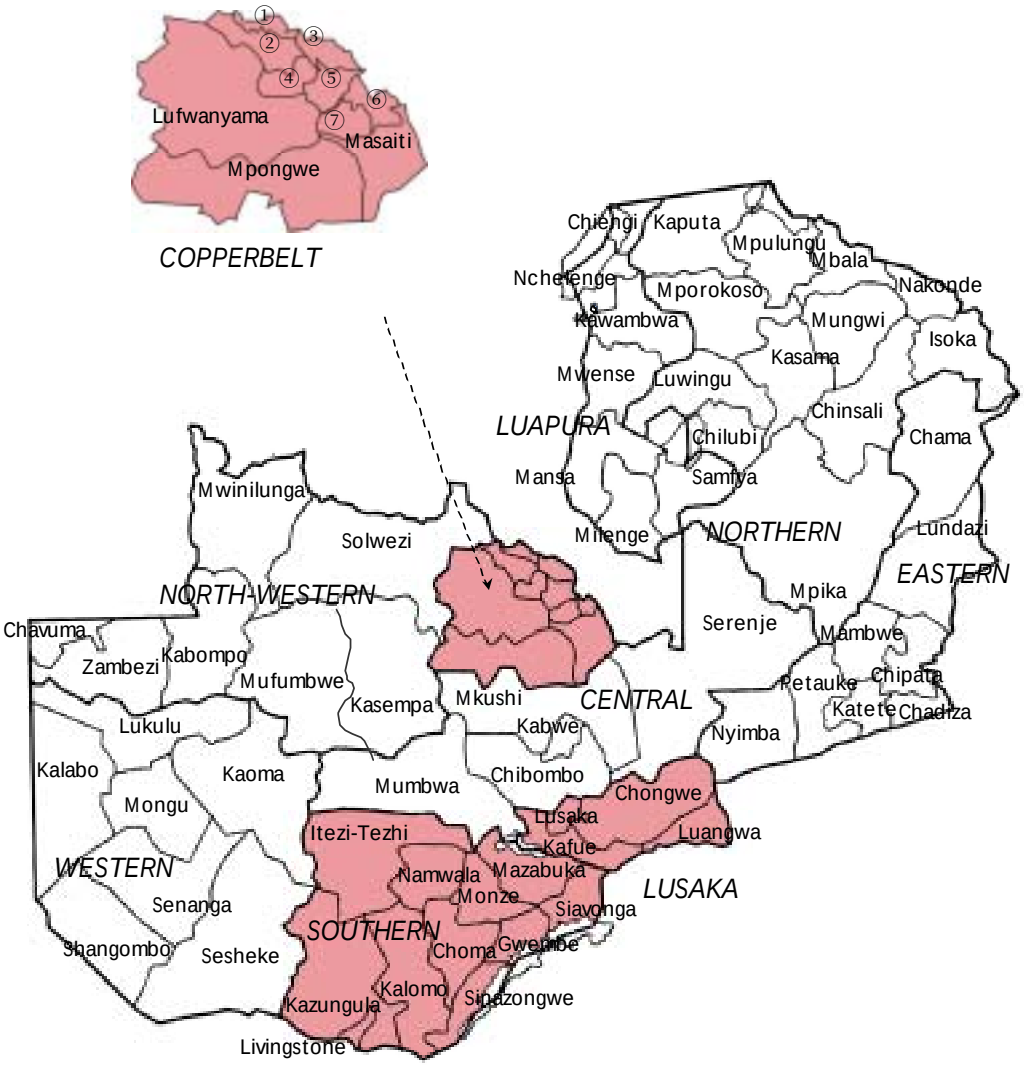
I hope that this report will contribute to the promotion of the project and to the enhancement of friendly relations between our countries.

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

July 2003

Takao KAWAKAMI
President

① Chiliabombwe ⑤ Kitwe
② Chingola ⑥ Ndola
③ Mufulira ⑦ Luansha
④ Kalulushi



Remarks:

1. Anti-TB drugs and laboratory reagents/supplies will be procured for Lusaka, Copperbelt, and Southern Provinces.
2. Health Center Kits will be procured for all Health Centers throughout Zambia

The selection process of the target regions is described under Section 2-2-1-1 Policy on Selecting Equipment.

Location Map

＜Abbreviations＞

AIDS	Acquired Immuno-Deficiency Syndrome
ADB	African Development Bank
CBoH	Central Board of Health
CDC	Federal Centers for Disease Control
CDL	Chest Disease Laboratory
CIDA	Canadian International Development Agency
DAC	Development Assistance Committee
DANIDA	Danish International Development Agency
DALY's	Disability Adjusted Life Years
DFID	Department for International Development
DOTS	Direct Observed Treatment, Short Course
EU	European Union
GDF	Global Drug Facility
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HIV	Human Immunodeficiency Virus
IMF	International Monetary Fund
IUATLD	International Union Against Tuberculosis and Lung Disease
KNCV	Koninklijke Nederlandse Centrale Vereniging tot Bestrijding der Tuberculose
NORAD	Norwegian Agency for Development Cooperation
SIDA	Swedish International Development Authority
TB	Tuberculosis
UNFPA	United Nations Fund for Population Activities
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
YLD	Years of Life Lived with a Disability
YLL	Years of Life Lost
WHO	World Health Organization

Contents

Chapter 1 Background of the Project

Aiming to provide high-quality health services widely and equitably for the nation, the Ministry of Health of Zambia is gradually expanding its infectious disease control campaign that includes the enhancement of health services and measures against TB on a district level as important strategies.

While an uninterrupted supply of anti-TB medicines is vital to the successful implementation of DOTS[1], supplies of such drugs have been unstable since 1996 when the Dutch government discontinued the on-going supply of anti-TB drugs to Zambia. In recent years, Zambia has been resorting to emergency assistance from international donor organizations every time it runs out of medicines. In FY 2002, the country's stock of drugs was barely sustained by the assistance from the governments of Canada and England. Although the needed doses for FY 2003 have been donated by GDF (Global Drug Facility)[2], CIDA, and other organizations, they are temporary provisions, and, according to the projection of CBoH, Zambia will run out of all anti-TB drugs sometime during FY 2004 (See Table-1). For Zambia, which depends on foreign assistance for about 40% of its health/medical finance, provision by other international donors will be imperative for the sustenance and possible expansion of the DOTS program.

Table-1: Current Stock of Anti-TB Drugs in Zambia (at central government level)[3]

Anti-TB medicine	Stock	GDF	CIDA	DFID	Monthly requirement (estimate)	Months remaining	Runs out of stock in (prediction)
Rifampicin + Isoniazid	602,000	9,596,000	9,000,000	4,500,000	1,180,000	20	July 2004
Pyrazinamide	2,859,000	8,317,000	2,000,000	4,000,000	950,000	18	May 2004
Ethambutol	0	3,838,000	4,000,000	2,000,000	480,000	20	July 2004
Ethambutol + Isoniazid	323	14,714,000	0	3,500,000	1,260,000	15	February 2004
Streptomycin	0	213,250	0	85,000	26,000	11	November 2004

Source: CBoH

The Health Centers also suffer from chronic shortages of antibiotics and other drugs against infectious diseases. To strengthen the control of infectious diseases and enhance community-level health services, a

[1] DOTS (Direct Observed Treatment, Short Course):
A TB control strategy recommended by WHO. DOTS has five key components: government commitment to sustained TB control activities; case detection by sputum smear microscopy among symptomatic patients self-reporting to health services; standardized treatment regimen of six to eight months for at least all sputum smear- positive cases, with directly observed therapy (DOT) for at least the initial two months; a regular, uninterrupted supply of all essential anti-TB drugs; and a standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program performance overall.

[2] GDF (Global Drug Facility): A subordinate organization of WHO that assists the procurement of anti-TB medicines. It implements grant aid projects, as well as the brokerage of inexpensive anti-TB drugs for which a certain quality level is assured.

[3] ① The stock levels are as of November 2002.
② GDF and DFID have already donated anti-TB drugs to Zambia, whereas CIDA is planning procurement in the future.
③ Rifampicin+Isoniazid, Pyrazinamide, Ethambutol, and Ethambutol+Isoniazid are in a form of tablet, while streptomycin is supplied in vials.

program was developed in 1990 under the assistance of the Dutch government to distribute a package of several types of medicines and hygiene supplies in specified quantities (Rural Health Center Kit) to the Rural Health Centers.

Generally, the Health Centers in urban areas place monthly orders to replenish necessary items, which have not always fulfilled due to insufficient inventory. Although the introduction of Urban Health Center Kit was called for to ensure more efficient procurement and supply of medical/pharmaceutical supplies, there has been no prospect of providing such kit due to lack of domestic funding and external assistance.

Under these circumstances, the government of Zambia in February 2001 requested the government of Japan to extend grant aid for procuring anti-TB drugs and laboratory reagents necessary for carrying out Zambia's TB control program, in addition to the Health Center Kit to support the health/medical services provided by community-level health facilities in urban areas. The initial request comprised of two-year supplies of anti-TB drugs and reagents for the health facilities throughout the country and two-year supply of Heath Center Kits for the Health Centers in Urban Areas (initially called Urban Health Center Kits) (See Table-2).

The contents of the Rural Health Kit were revised in 2002, and the same Health Center Kit will begin to be distributed to the Health Centers both in rural and urban areas in 2004.

Table-2: Contents of the Request from Zambian Government

	Item	Unit	For 1st year	For 2nd year	Total
1	Rifampicin + Isoniazid	tablet	29,000,000	21,000,000	50,000,000
2	Pyrazinamide	tablet	22,000,000	18,000,000	40,000,000
3	Ethambutol	tablet	12,000,000	10,000,000	22,000,000
4	Ethambutol + Isoniazid	tablet	33,000,000	26,000,000	59,000,000
5	Streptomycin	vial	475,000	383,000	858,000
6	Microscope slide	sheet	4,600,000		4,600,000
7	Sputum cup	cup	4,600,000		4,600,000
8	Basic fuchsin	gram	70,000		70,000
9	Methylene blue	gram	75,000		75,000
10	Spirit	liter	2,475		2,475
11	Sulfuric acid	liter	2,475		2,475
12	Phenol crystal	kg	1,100		1,100
13	Xylene	liter	4,200		4,200
14	Immersion oil	ml	4,200,000		4,200,000
15	Hydrochloric acid	liter	250		250
16	Methanol	liter	1,125		1,125
17	Health Center Kit (for 10 urban districts)	kit	4,802	5,194	9,996

Source: Request of the Zambian Government, February 2001

Chapter 2 Contents of the Project

2-1 Basic Concept of the Project

This Project will be carried out in line with the "National Health Strategic Plan 2001-2005" currently implemented by the Zambian government, as well as the "TB Implementation Plan 2002-2005," a program formulated based on the national plan. This Project aims to improve the detection of TB cases and treatment thereof to control the spread of TB by procuring anti-TB drugs and laboratory reagents/supplies necessary for sputum smear examinations, and at the same time aims to strengthen the treatment of various infectious diseases and opportunistic infection related to HIV/AIDS by supplying the Health Center Kit, a package of medical/pharmaceutical supplies, for the Health Centers and other healthcare facilities.

This Project will support the achievement of the objectives of the overall developmental plan of the Zambian government by procuring necessary equipment and supplies to improve Zambia's health indices and promote the health of the local residents.

2-2 Basic Design of the Requested Japanese Assistance

2-2-1 Design Policy

This Grant Aid Project is designed to contribute to the TB Implementation Plan that aims to disseminate and promote the implementation of DOTS nationwide to control TB, as well as to support the provision of high-quality health services for the Zambian people as intended by the National Health Strategic Plan of the Zambian government by providing funds necessary for the procurement of five types of anti-TB drugs, laboratory reagents necessary for sputum smear examinations, and Health Center Kit essential for the provision of medical services at the Health Centers.

This Project was formulated based on the guidelines outlined in the following sections.

2-2-1-1 Policy on Selecting Equipment

(1) Anti-TB Drugs and Reagents

Although the district/community-level DOTS campaign is spreading nationwide, there still are 29 districts where the use of DOTS is uncommon. Strict compliance with anti-TB drug regimens is vital to the cure of TB, and the systematic enforcement of DOTS to the reduction of TB incidence afterwards. Unsystematic distribution of anti-TB drugs in the areas where DOTS is not enforced could trigger the development and spread of multiple-drug-resistant tuberculosis (MDR-TB) [4], which could make future TB control extremely difficult. In view of the foregoing, this Project will provide laboratory reagents necessary for sputum smear microscopy to facilitate the detection of TB patients, as well as anti-TB drugs for the treatment of patients, for the three provinces of Lusaka, Copperbelt, and Southern, where the DOTS is practiced in all of their respective districts. According to the 2002 data compiled in March 2003, a total of 33,952 TB patients were registered in these three Provinces (Table-3). This Project will

[4] Tuberculosis bacilli that show resistance to both isoniazid and rifampicin, the two main drugs against TB. Patients infected with MDR-TB are extremely difficult to cure and require more aggressive and expensive treatment.

calculate the necessary quantities of aid supplies based on these figures. Assistance for these three Provinces will cover more than 60% of TB patients in the whole of Zambia.

Table-3: No. of TB Patients in the Three Target Provinces in 2002

Province/District	Population	Sputum smear positive	Sputum smear negative	Extrapul monary	Relapse (sputum smear	Relapse (sputum smear	Failure	Invalid	Total patients
Southern Province	**1,302,660**	**957**	**2,674**	**617**	**98**	**430**	**6**	**17**	**4,799**
Livingstone	158,149	193	725	176	19	125	1	-	1,239
Monze	165,741	195	396	188	12	43	-	-	834
Choma	203,305	241	437	108	17	67	2	-	872
Gwembe	33,391	6	32	6	7	14	2	-	67
Itezhi-tezhi	46,357	12	42	8	1	6	-	-	69
Siavonga	58,932	79	202	24	11	51	1	-	368
Namwala	82,708	6	16	8	1	1	-	-	32
Mazabuka	240,116	145	303	67	11	43	-	1	570
Kalomo	167,446	38	194	14	13	31	-	-	290
Kazungula	66,140	-	-	-	-	-	-	-	-
Sinazongwe	80,375	42	327	18	6	49	-	16	458
Copperbelt Province	**1,657,646**	**3,745**	**5,337**	**951**	**463**	**431**	**74**	**110**	**11,111**
Chililabombwe	84,866	107	140	40	9	6	2	-	304
Kalulushi	72,765	145	142	20	9	6	-	-	322
Luanshya	155,979	119	230	68	7	32	7		463
Chingola	177,445	80	140	28	-	36	-	-	284
Lufwanyama	65,804	218	237	31	30	19	9	6	550
Mufulira	152,664	571	752	89	122	17	3	2	1,556
Masaiti	97,712	44	55	4	-	7			110
Mpongwe	67,972	112	271	117	34	11	8		553
Kitwe	388,646	601	2,396	45	43	100	42	37	3,264
Ndora	393,793	1,748	974	509	209	197	3	65	3,705
Lusaka Province	**1,432,401**	**4,065**	**8,687**	**3,841**	**803**	**578**	**35**	**33**	**18,042**
Luangwa	21,990	11	38	9	4	2			64
Lusaka	1,103,413	3,622	8,461	3,644	734	496	26	30	17,013
Kafue	162,262	68	41	46	5	3	2	-	165
Chongwe	144,736	364	147	142	60	77	7	3	800
Total, Project sites	**4,392,707**	**8,767**	**16,698**	**5,409**	**1,364**	**1,439**	**115**	**160**	**33,952**
Total, nationwide	**10,285,631**	**14,213**	**25,040**	**8,260**	**1,760**	**1,882**	**164**	**240**	**51,559**

Source: CBoH

(2) Health Center Kit

Since the Dutch government used to provide the Rural Health Center Kits on an on-going basis, the Zambian government initially requested the provision of the Urban Health Center Kit that consisted of 62 items. However, the contents of the kits were later revised to include the same 59 items for both the Rural and Urban Health Centers throughout Zambia, while the Dutch government pledged to provide in the quantity equaling to two thirds of the national requirement for 2004. Therefore, this Project, in coordination with the Dutch project, will procure the remaining one third of the annual requirement for the Health Centers nationwide.

2-2-1-2 Policy on Natural Environment

Most of Zambia is situated in a semi-tropical climate that has particularly hot and dry weathers during the months between September and November. Thus, when storing medical/pharmaceutical items in Health Centers that are not installed with air conditioners, special cares need to be taken as to shade the storage space from the sun and secure sufficient ventilation. The average temperature in Lusaka, the capital city of Zambia, is 21.1˚C in January and 16.1˚C in July. Regular storage conditions at Medical Stores Ltd. will be sufficient for keeping the goods to be supplied by this Project.

2-2-1-3 Policy on Social Conditions

Zambia's unique cultural and religious background has been fostering a tradition of numerous volunteer activities based on the spirit of mutual aid. NGOs and volunteers play important roles in the preventive health services on a community level as well. In implementing DOTS, the Central Board of Health (CBoH) is giving specialized training to certain NGO staff and volunteers. This Project will also utilize such NGOs and volunteers as community-level health service providers.

2-2-1-4 Policy on the Operation/Maintenance Capabilities of the Implementing Agency

The Zambian Ministry of Health has its own system to control the distribution and inventory of medical/pharmaceutical supplies. Since the system is functioning effectively to process various tasks from ordering and supplying to inventory control, this Project will also use the existing system for controlling the distribution and inventory of supplies.

2-2-1-5 Policy on Determining the Grade of Equipment

(1) Anti-TB Drugs

Based on the standard TB treatment regimens of Zambia, this Project will consider procuring five kinds of anti-TB drugs, namely, rifampicin+isoniazid, pyrazinamide, ethambutol, ethambutol+isoniazid, and streptomycin, as well as distilled water for diluting streptomycin for injection. The 1000-tablet bottles currently used in Zambia will be used to package the anti-TB drug tablets, which will be procured from pharmaceutical companies that comply with the GMP[5] guidelines published by WHO.

(2) Laboratory Reagents

Laboratory reagents and supplies necessary for the Ziehkl-Neelsen method, a sputum smear examination technique commonly practiced in Zambia and listed in the International Union Against Tuberculosis and Lung Disease (IUATLD) guidelines, will be procured. These items, consisting of

[5] Good Manufacturing Practice: A set of standards for the production and quality control of medical supplies. To comply with the GMP guidelines, a company must control the entire production processes from the acceptance of raw materials to the maintenance of the production facilities, equipment, and environment.

microscope slides, sputum cups, basic fuchsin, methylene blue, sulfuric acid, phenol crystals, hydrochloric acid, immersion oil, methanol, and xylene for cleansing immersion oil, shall meet the applicable JIS standards.

(3) Health Center Kit

The Health Center Kit will be made up of the same contents as those set forth by the Zambian health authority. The medicines in the kit are approved for use at Health Centers according to the Essential Medical Supplies List of Zambia, and their quantities were calculated according to the Patient Morbidity - Standard Treatment Method, a calculation method recommended by WHO, to show the amount necessary to cope with 1,000 people taking examinations based on the typical morbidity trend of Health Centers. Since 1990 when the Dutch government began sending kits to Rural Health Centers, the kit has been reviewed once in every two to three years to readjust the contents and quantities to more appropriate levels.

2-2-1-6 Policy on Procurement Method and Schedule

Although the Zambian government requested the Japanese government to procure a two-year supply of each component, this Project will initially provide one-year supply, as the contents and their quantities may need to be adjusted according to the changes in the relevant health indices and other circumstances, and the procurement plan for the second year, and possibly thereafter, may need to be redesigned according to the subsequent request from the Zambian government.

2-2-2 Basic Plan

Table-4 below shows the description and quantity of each item to be procured by this Project.

Table-4: Contents of this Project

	Item	Specification	Quantity	Application
1	Rifampicin + Isoniazid	150/75mg	16,863,000 tablets	Anti-TB medicine
2	Pyrazinamide	400mg	13,547,000 tablets	Anti-TB medicine
3	Ethambutol	400mg	6,863,000 tablets	Anti-TB medicine
4	Ethambutol + Isoniazid	400/150mg	17,968,000 tablets	Anti-TB medicine
5	Streptomycin	1.0g	381,000 vials	Anti-TB medicine
6	Microscope slide	frost	1,121,000 slides	For making sputum smears
7	Sputum cup	30ml	1,121,000 cups	For taking sputum samples
8	Basic fuchsin	powder	17,000 g	For staining smears (Ziehl carbol fuchsin solution)
9	Methylene blue	powder	17,000 g	For staining smears (Loffler methylene blue solution)
10	Spirit	liquid	578,000 ml	For spirit lamp
11	Sulfuric acid	95%	1,291,000 ml	For discolorizing smears
12	Phenol crystal	crystal	259,000 ml	For staining smears (Ziehl carbol fuchsin solution)
13	Xylene	liquid	1,019,000 ml	For cleansing immersion oil
14	Immersion oil	liquid	102,000 ml	For increasing the resolving power of the objective
15	Hydrochloric acid	35%	51,000 ml	For decolorizing smears (hydrochloric acid alcohol)
16	Methanol	99%	578,000 ml	For decolorizing smears
17	Health Center Kit	59 items	6,540 kits	Medicine kit for Health Centers

(1) Anti-TB Drugs (No. 1 – 5)

In Zambia, TB patients are divided into five categories according to their conditions and treatment regimens. The number of TB patients, based on which the quantities of supplies to be procured by this Project are calculated, is derived by multiplying the total number of TB patients in the three Provinces in 2002 (33,952) by the ratio of each patient type generally used in Zambia (42% for Category I, 10% for Category II, 42% for Category III, 5% for Pediatric I, and 1% for Pediatric II) and rounding fractions (Table-5)[6].

[6] The number of patients in DOTS practicing areas is usually calculated based on the most recent number of detections in each category. However, since DOTS has been introduced only recently to Zambia, the CBoH presumes substantial inaccuracy in the number of patients detected and reported under the underdeveloped examination and reporting system. Therefore, estimated ratio of patients in each category generally used in Zambia was used instead for the calculation.

Table-5: Estimated No. of TB Patients

Type of Patient		Ratio	Estimated no. of patients after adjustment (persons)
A. Category I	New Sputum smear positive Seriously ill smear negative Seriously ill extrapulmonary	42%	14,260
B. Category II	Sputum smear positive relapse Sputum smear positive failure Sputum smear positive treatment after default	10%	3,395
C. Category III	Sputum smear negative not seriously ill Not seriously ill extrapulmonary	42%	14,260
D. Pediatric I	Children under 15, new smear positive	5%	1,698
E. Pediatric II	Children under 15, smear positive relapse	1%	340

Regimens for treating TB are 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 regimens for the continuation phase are designed to eradicate residual bacilli for the prevention of relapse. Descriptions of treatment regimens 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 ethanbutol+isoniazid (EH) is given every day.

In Zambia, the standard dose (X) of each drug per person for each treatment regimen is calculated, with certain adjustment based on the results of actual treatment, as shown in Table-6 below.

Table-6: Standard Dose per Person by Treatment Regimen (X)

Anti-TB Drug	Patient Category	Treatment Regimen	X	Rationale of Calculation
Rifampicin + Isoniazid	A. Category I	2RHZE/6EH	210	(3+4(tablets))÷2×30(days)×2(months)
	B. Category II	2RHZES/1RHZE/5RHE	840	(3+4(tablets))÷2×30(days)×8(months)
	C. Category III	2RHZ/6EH	210	(3+4(tablets))÷2×30(days)×2(months)
	D. Pediatric I	2RHZ/4RH	360	(1+2(tablets))÷2×30(days)×2(months) (1+2(tablets))÷2×30(days)×6(months)
	E. Pediatric II	2RHZS/10RH	540	(1+2(tablets))÷2×30(days)×2(months) (1+2(tablets))÷2×30(days)×10(months)
Pyrazinamide	A. Category I	2RHZE/6EH	210	(3+4(tablets))÷2×30(days)×2(months)
	B. Category II	2RHZES/1RHZE/5RHE	315	(3+4(tablets))÷2×30(days)×3(months)
	C. Category III	2RHZ/6EH	210	(3+4(tablets))÷2×30(days)×2(months)
	D. Pediatric I	2RHZ/4RH	360	(3+4(tablets))÷2×30(days)×2(months)+adjustment
	E. Pediatric II	2RHZS/10RH	210	(3+4(tablets))÷2×30(days)×2(months)
Ethambutol	A. Category I	2RHZE/6EH	150	(3+2(tablets))÷2×30(days)×2(months)
	B. Category II	2RHZES/1RHZE/5RHE	525	(2+3(tablets))÷2×30(days)×3(months) +(2+2(tablets))÷2×30(days)×5(months)

Ethambutol + Isoniazid	A. Category I	2RHZE/6EH	360	(2+2(tablets))×30(days)×6(months)
	C. Category III	2RHZ/6EH	360	(2+2(tablets))×30(days)×6(months)
Streptomycin	B. Category II	2RHZES/1RHZE/5RHE	60	1(vial)×30(days)×2(months)
	E. Pediatric II	2RHZS/10RH	40	0.67(vial) ×30(days)×2(months)

RH: rifampicin + isoniazid, Z; pyrazinamide, E: ethambutol
EH: ethambutol + isoniazid, S: streptomycin

The standard daily dose for adults (Table-7) is calculated based on the assumption that there are an equal number of patients who weigh less than 50kg to those weighing 50kg or more. Since body weight of children vary greatly, certain adjustments were made in reference to the figures in Table-8.

Table-7: Standard Dose for Adults by Drug Type

Name of Drug	Standard Daily Dose for Adults	
	Less than 50kg	50kg or more
Rifampicin + Isoniazid	450mg/300mg (3 tablets)	600mg/300mg (4 tablets)
Pyrazinamide	1.5g (3 tablets)	2g (4 tablets)
Ethambutol	600mg or 800mg (1.5 or 2 tablets)	800mg (2 tablets)
Ethambutol + Isoniazid	600mg/300mg (1.5 tablets)	800mg/300mg (2 tablets)
Streptomycin	1g (1 vial)	1g (1 vial)

Table-8: Standard Dose for Children by Drug Type

Name of Drug	Standard Daily Dose for Children
Rifampicin + Isoniazid	75 - 300mg/50 - 100mg (1 - 2 tablets)
Pyrazinamide	250 - 1,500mg (0.5 - 3.5 tablets)
Streptomycin	250 - 750mg (1 vial)

Table-9 shows the required quantity of each drug that was calculated based on the standard daily dosages per person for each treatment regimen by referring to the calculation table of recommended dosage published by IUATLD. The total quantities are in round numbers and include reserves (6-month supply for the central government level and 3-month supply for the district level) to cope with unforeseeable events during the second year, such as delay in delivery, spread of diseases, and influx of people from neighboring regions.

Table-9: Quantities of Needed Anti-TB Drugs

A			B			C			D			E		
2RHZE/6EH			2RHZES/1RHZE/5RHE			2RHZ/6EH			2RHZ/4RH			2RHZS/10RH		
No. of patients	X	Total	No. of patients	X	Total	No. of patients	X	Total	No. of patients	X	Total	No. of patients	X	Total
14,260	210	2,994,566	3,395	840	2,851,968	14,260	210	2,994,566	1,698	360	611,136	340	540	183,341
14,260	210	2,994,566	3,395	315	1,069,488	14,260	210	2,994,566	1,698	360	611,136	340	210	71,299
14,260	150	2,138,976	3,395	525	1,782,480									
14,260	360	5,133,542				14,260	360	5,133,542						
			3,395	60	203,712							340	40	13,581

A+B+C+D+E = F	(A+B+C+D+E)x0.75 = G	F + G = H	
Annual Requirement	Stockpile(6mos. Central + 3mos. District)	Total requirement (annual)	Total qty. to procure
9,635,578	7,226,683	**16,862,261**	**16,863,000**
7,741,056	5,805,792	**13,546,848**	**13,547,000**
3,921,456	2,941,092	**6,862,548**	**6,863,000**
10,267,085	7,700,314	**17,967,398**	**17,968,000**
217,293	162,970	**380,262**	**381,000**

Each product shall have a shelf life[7] of at least 75% of the total validated period at the time of handover.

The IUATLD guidelines recommend a stockpile of drugs in the same amount as the annual requirement, or three-month supply for the end level (Health Centers), three-month supply for the intermediate level (districts or Provinces), and six-month supply for the central government level. However, as the Zambian government considers the three-month supply at the Health Center level is excessive and the current distribution system can sufficiently cope with emergency situations as long as it operates properly, the quantity of stockpile will consist of six-month supply for the central government and three-month supply for the district level.

(2) Laboratory Reagents and Supplies (No.6 – 16)

In the Ziehl-Neelsen staining method, reagents are prepared according to the formula published by IUATLD as shown in Table-10 below.

Table-10: Formula for Preparing Ziehl-Neelsen Reagents

Application/Name of Reagent	Formula		
Staining/ Ziehl-Neelsen fuchsin solution	①Saturated fuchsin solution 10ml	Basic fuchsin	3g
		95% alcohol	100ml
	②5% phenol solution 90ml	Phenol	5ml
		Distilled water	95ml
Decolorizing/ 25% sulfuric acid	Concentrated acid		10ml
	Distilled water		30ml
Decolorizing/ Hydrochloric acid alcohol	Concentrated (35%) hydrochloric acid		3ml
	95% ethanol or distilled water		97ml
Counterstaining/ Methylene blue solution	Methylene blue		0.3g
	Distilled water		100ml

[7] Although it varies with manufacturers and drugs, a standard shelf life is between two and three years.

Each slide is prepared in the following procedure: i) Take sputa and spread it over the slide, ii) Fix the dried smear by heating it over the flame, iii) Stain the smear with 5ml of Ziehl's carbol fuchsin solution, heat and then rinse the slide with water, iv) Cover the slide with 5-15ml of 25% sulfuric acid solution (or acid-alcohol solution) to decolorize, let it stand for a few minutes, and then wash away the acid solution, v) Counter stain the slide by covering it with 5ml of methylene blue, allow to stand for a minute, drain water off the slides, and allow it to dry. To observe the stained slide, fill the gap between the slide glass and the objective lens by placing a drop (about 0.1ml) of immersion oil for enhanced refraction. After microscopic examination, clean the slide and the microscope with 1ml or so of xylene.

Table-11 shows the amount of each reagent needed to make one slide.

Table-11: Quantity of Each Reagent Necessary for Preparing 1 Slide

Item	Form	Rationale for Calculating Quantity per Slide
Basic fuchsin	Powder	As 100ml of Ziehl's carbol fuchsin solution contains 10ml of saturated fuchsin solution, the weight of basic fucshin in the 100ml solution is: 10 x $\frac{3}{100}$ = 0.3g. Since 5ml Ziehl's carbol fuchsin solution is used to prepare one slide, the quantity of fuchsin per slide is: 5 x $\frac{0.3}{100}$ = 0.015g.
Methylene blue	Powder	100ml Loffler methylene blue solution contains 0.3g of methylene blue. As 5ml Loffler methylene blue solution is used to make one slide, the amount of methylene blue per slide is: 5 x $\frac{0.3}{100}$ = 0.015g.
Spirit	Liquid	A 150ml spirit lamp can heat and fix about 3000 slides. This translates into 0.5ml of spirit per slide.
Sulfuric acid	Liquid	5ml of 25% sulfuric acid solution to decolorize one slide contains 5 x $\frac{10}{40}$ = 1.25ml of concentrated sulfuric acid.
Phenol crystal	Crystal	As 100ml of Ziehl's carbol fuchsin solution contains 90ml of 5% phenol solution, the weight of phenol in the 100ml solution is: 90 x $\frac{5}{100}$ = 4.5g. Since 5ml Ziehl's carbol fuchsin solution is used to prepare one slide, the quantity of phenol per slide is: 5$\times$ $\frac{4.5}{100}$ = 0.225g.
Xylene	Liquid	About 1ml is used to cleanse one slide.
Immersion oil	Liquid	One drop (or about 0.1ml) is used per slide.
Hydrochloric acid	Liquid	100ml acid-alcohol solution contails 3ml of concentrated hydrochloric acid. In 15ml of acid-alcohol solution to decolourise one slide contains15 x $\frac{0.3}{100}$ = 0.045ml of concentrated hydrochloric acid.
Methanol	Liquid	100ml of Ziehl's carbol fuchsin solution contains 10ml of methanol as alcohol content. Since 5ml Ziehl's carbol fuchsin solution is used to prepare one slide, the quantity of methanol per slide is: 5 x $\frac{10}{100}$ = 0.5ml.

Based on the above and IUATLD's rationale for calculation, the quantity of each reagent to procure under this Project was calculated for the number of TB patients registered in 2002 in the three target Provinces (=33,952 people) and shown in the Table-12 below.

Table-12: Required Quantity of Each Reagent or Material[8]

Item	No. of patients	Qty. per slide	Index of suspicion per patient	Qty. needed per person (after adjustment)	Qty. to procure under this Project (Qty. after adjustment)
	A	B	C	D=(1/C×3+3)×B	E=A×D
Microscope slide	33,952	1	0.10	33 pcs.	1,121,000 pcs.
Sputum cup	33,952	1	0.10	33 pcs.	1,121,000 pcs.
Basic fuchsin	33,952	0.0150	0.10	0.5 g	17,000 g
Methylene blue	33,952	0.0150	0.10	0.5 g	17,000 g
Spirit	33,952	0.5000	0.10	17 ml	578,000 ml
Sulfuric acid	33,952	1.1500	0.10	38 ml	1,291,000 ml
Phenol crystal	33,952	0.2300	0.10	7.6 g	259,000 g
Xylene	33,952	1.0000	0.10	30 ml	1,019,000 ml
Immersion oil	33,952	0.1000	0.10	3 ml	102,000 ml
Hydrochloric acid	33,952	0.0450	0.10	1.5 ml	51,000 ml
Methanol	33,952	0.5000	0.10	17 ml	578,000 ml

Although IUATLD recommends to use the number of sputum smear positive cases for the calculation of needed reagent quantities, the number of TB patients was used instead because the number of smear positive in Zambia does not accurately reflect the actual TB cases, and extra amount was needed to be included to cover the possible increase of patients in the future, as well as for stockpiling.

The grade of each reagent and material shall be equivalent to those currently used for TB treatment in Zambia, and the quality shall comply with the corresponding JIS or similar standards.

(3) Health Center Kit (No. 17)

The procurement quantity of Health Center Kits under this Project (6,540) was derived by subtracting the number of kits to be procured by the Dutch government (12,500) from the number of kits to be distributed to the Health Centers nationwide in 2004 (19,040) (See Table-13). The contents and the grade of each item of the Health Center Kit shall be the same as or equivalent to those from the Dutch government (scheduled to arrive in Zambia in January 2005) (See Table-14).

The nationwide requirement was calculated based on the assumption that one kit per month is distributed to each of the 1,190 Health Centers, including Health Posts (the delivery schedule may vary slightly according to the population size), and a stockpile of 4-month supply is to be included.

[8] The "index of suspicion per patient" in Table-12 refers to the ratio of TB patients in the number of suspected cases of TB living near the TB patient. In Zambia, the index is set at 10%.

Table-13: Nationwide Requirement for Health Center Kits

Medical Facility	No. of facilities (①)	Qty. distributed monthly (②)	Qty. distributed annually (③=②×12 months)	Stockpile (④=②×4 months)	Qty. required (③+④)
Rural Health Center	919	919	11,028	3,676	14,704
Urban Health Center	262	262	3,144	1,048	4,192
Health Post	9	9	108	36	144
Total	1,190	1,190	14,280	4,760	19,040

Source: Draft of Country Health Statistics

Table-14: Components of Health Center Kit

	Component	Dosage form	Specification	Unit	Qty.	Remarks
17	Health Center Kits					
1	Acetylsalicylic acid	Tablet	300mg	1,000 tabs.	2	Antipholgistic/analgesic/antipyretic
2	Erythromycin	Tablet	250mg	500 tabs.	1	Antibiotic
3	Amoxicillin	Tablet/capsule	250mg	1,000 tabs.	2	Antibiotic
4	Benzathine penicillin	Injection	2.4MU	1 vial	20	Antibiotic (anti-syphilis)
5	Distilled water for injection	Injection	10ml	1 amp.	20	For diluting injection
6	Benzyl penicillin G	Injection	5MU (3g)	1 vial	10	Antibiotic
7	Benzyl penicillin G	Injection	1MU (600mg)	1 vial	10	Antibiotic
8	Distilled water for injection	Injection	5ml	1 vial	10	For diluting injection
9	Chlorpheniramin maleate	Injection	4mg	100 tabs.	1	Antihistamin
10	Diazepam	Injection	5mg/ml	10 vial	2	Ataractic/antianxiety
11	Ferrous sulfate	Tablet	200-300mg	1,000 tabs.	2	Nutrient (to prevent anemia)
12	Ferrous sulfate 50mg	Tablet	50mg	1,000 tabs.	1	Nutrient (to prevent anemia)
13	Folic acid	Tablet	5mg	1,000 tabs.	1	Nutrient (to prevent pernicious anen
14	Clotrimazole	Cream	1%	20 g	20	Antifungal
15	Hydrocortisone	Ointment	1%	15 g	5	Adenocorticotropic hormone
16	Hydrocortisone	Cream	1%	15 g	5	Adenocorticotropic hormone
17	Lignocaine hydrochloride	Injection	1%	10 ml	1	Local anesthetic
18	Compound magnesium silicate	Tablet		1,000 tabs.	1	Antiulcer
19	Albendazole	Tablet	400mg	100 tabs.	2	Antiparasitic
20	Methylergometrine maleate	Injection	0.2mg/ml	1 ml	5	Hysterotonic
21	Metronidazole	Tablet	200mg	1,000 pcs.	1	Antiprotozoal
22	Multi-vitamin	Tablet		1,000 tabs.	1	Vitamin supplement
23	Nystatin	Chewable tablet	100,000IU	500 tabs.	1	Antibiotic (anti-candida)
24	Nystatin	Vaginal suppository	100,000IU	500 pess.	1	Antibiotic (anti-candida)
25	Nystatin	Suspension	100,000IU/ml	30 ml	10	Antibiotic (anti-candida)
26	Oral rehydration salt	Powder	27.9g/1L	1 pac.	200	Electrolyte replenisher
27	Paracetamol 500mg	Tablet	500mg	1,000 tabs.	5	Antipholgistic/analgesic/antipyretic
28	Paracetamol 100mg	Tablet	100mg	1,000 tabs.	2	Antipholgistic/analgesic/antipyretic
29	Penicillin V	Tablet	250mg	1,000 tabs.	1	Antibiotic
30	Procaine penicillin	Injection	3MU	10 ml	30	Antibiotic (prolonged)
31	Sulfadoxin/pyrimethamine	Tablet	500mg/25mg	1,000 tabs.	2	Anti-malaria
32	Salbutamol	Tablet	2mg	1,000 tabs.	1	Bronchodilator/antasthmatic
33	Tetracycline	Eye ointment	1%	5 g	75	Antibiotic (for neonates)
34	Doxycycline hydrochloride	Tablet	100mg	1,000 tabs.	1	Antibiotic
35	Quinine sulfate	Tablet	300mg	100 tabs.	2	Anti-malaria
36	Plastic bag for dispensing		min. 64 x 83mm	1,000 pcs.	2	For dispensing drugs
37	Gauze bandage		5cm x 4.5-5m	1 roll	30	Bandage
38	Braided silk suture 3/0		“3/0” 22m	1 reel	1	Surgical suture
39	Braided silk suture 2/0		“2/0” 22m	1 reel	1	Surgical suture
40	Ball-point pen			1 pc.	2	Writing instrument
41	Cetrimide	Powder	10g/1L	1 g	10	Disinfectant
42	Chlorhexidine	Solution	20%	100 ml	1	Disinfectant
43	Condom	Rubber latex, plain type, nipple end, lubricated, electronically	natural color, size 180x20x52mm approx. , single pack in rectangular	1 pc.	1008	FDA approved
44	Absorbent cotton		500g	500 g	1	For surgical procedure
45	Gauze		0.90×5m	1 pc.	1	For surgical procedure
46	Paraffin gauze		10×10cm	36 pcs.	1	For surgical procedure
47	Latex glove M		medium	50 pcs.	1	For medical procedure
48	Latex glove L		large	100 pcs.	1	For medical procedure
49	Disposable injection needle 23G		0.65×32mm	100 pcs.	2	For injection (mostly children)
50	Disposable injection needle 21G		0.80×38mm	100 pcs.	2	For injection (mostly adults)
51	Cutting/suture needle 3/8		1L, 3M, 2S	6 pcs.	1	For suturing
52	Notepad		A5, lined, 100 leaves	1 pc.	1	Foe note taking
53	Surgical tape		7.5cm x 5m	1 pc.	2	For surgical procedure
54	Replacement blade of scalpel		No. 15	10 pcs.	1	For surgical procedure
55	Swab gauze			100 pcs.	1	For surgical procedure
56	Disposable syringe 2ml		2ml	50 pcs.	2	For injecting drug
57	Disposable syringe 5ml		5ml	100 pcs.	2	For injecting drug
58	Hygiene soap		90-100g	1 pc.	5	For washing hands
59	Patient Register			1 pc.	1	For recording data

2-2-3 Implementation Plan

(1) Procurement of Medicines and Supplies (Table-15)

There is one company in Zambia (Pharco Ltd.) that manufactures two kinds of anti-TB drugs (pyrazinamide and ethambutol). The other drugs (rifampicin+isoniazid, ethambuto+isoniazid, and streptomycin) are not produced within the country. Since Japanese-made medicines do not comply with the local specifications, third-country products will be included in the Project. The anti-TB drugs currently used in Zambia are mostly from Europe (England, the Netherlands, Denmark, etc.), as well as India and China. This Project will also procure similar products from those countries.

Microscope slides and sputum cups are not made in Zambia but are available from several Japanese manufacturers, which ensures a sufficient level of competition. As the reagents and other items, except for spirit, are not produced in Zambia and are made only by a limited number of Japanese firms, the procurement sources of these items will include third countries to keep an adequate level of competition.

As for the Health Center Kit, a specialized company that can collect the 59 individual items and package them in a kit will be called upon. Such company should preferably be chosen from organizations that comply with GDP (Good Distribution Practice)[9], a set of standards recognized widely among kit manufacturers and medical product dealers. Since the Dutch government will be procuring two thirds of the required quantity, the Japanese side should make efforts to procure products from the same sources as the Dutch government as much as possible. As Japanese products either do not comply with the same standards as those applicable to the requested items or are not made for export, European or other third-country products are suitable for the Project. The Dutch assistance project plans to hold a public tender by limiting the number of bidders to seven procurement companies from Zambia, the Netherlands, Denmark, and England. Therefore, this Project will procure the Health Center Kits from Zambia or mostly-European third countries to make them consistent with the Dutch-side Health Center Kits as much as possible.

In Zambia, the Pharmacy, Medicines, and Poisons Board is in charge of approving and permitting medical products. Although import of sellable goods generally requires prior registration with the Board, importing generic products under assistance projects do not need such registration. Therefore, Japanese trading companies should be able to send the procured items to Zambia without major difficulties.

[9] Good Distribution Practice of Medical Products: Standards for the storage, shipment, and delivery of medical products to ensure product quality by preventing deterioration, breakage, and contamination in every process. The provisions include the control of location and layout, proper inventory control such first-in-first-out and control of ledgers and other documents, traceability of products, and recall procedures after the distribution of products. GDP accreditation is given by a certification organization in each country. The Japanese version of these standards is the Japanese Good Supplying Practice (JGSP) established by the Federation of Japan Pharmaceutical Wholesalers Association in October 1975.

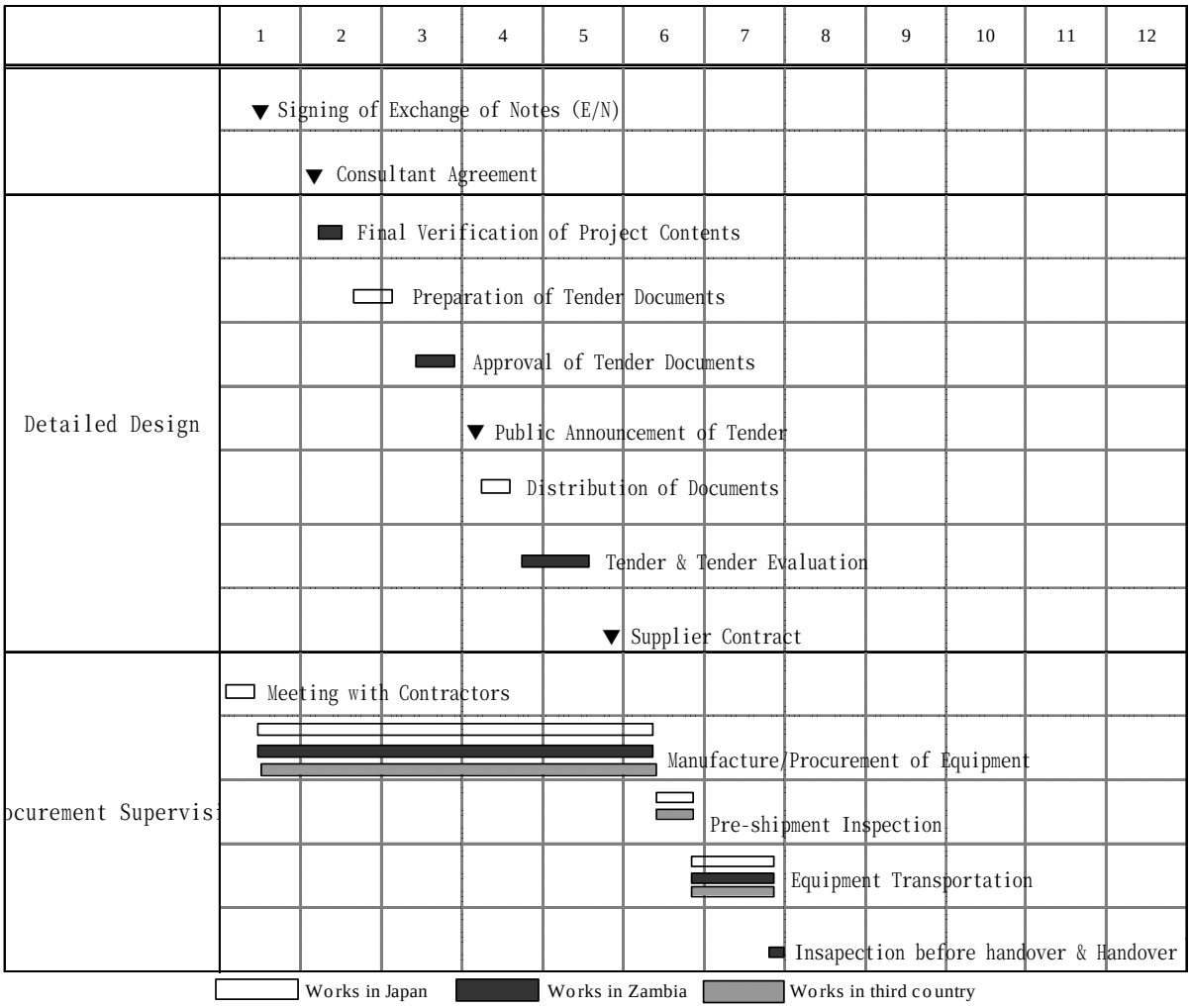
Table-15: Procurement Sources of the Drugs and Supplies

Item	Source			Remarks
	Zambia	Japan	3rd country	
Rifampicin + Isoniazid			○	DAC countries, India, China, etc.
Pyrazinamide	○		○	Same as above
Ethambutol	○		○	Same as above
Ethambutol + Isoniazid			○	Same as above
Streptomycin			○	Same as above
Microscope slide		○		
Sputum cup		○		
Basic fuchsin		○	○	DAC countries
Methylene blue		○	○	Same as above
Spirit	○		○	Same as above
Sulfuric acid		○	○	Same as above
Carbol crystal		○	○	Same as above
Xylene		○	○	Same as above
Immersion oil		○	○	Same as above
Hydrochloric acid		○	○	Same as above
Methanol		○	○	Same as above
Health Center Kit	○		○	Same as above

(2) Implementation Schedule

The entire process of this Project will take a total of 12 months, five months for the detailed design and seven months for procurement supervision (See Table-16). Japanese and third-country products will be disembarked at Durban Port of South Africa and then delivered, along with Zambia products, to Medical Stores Ltd. in Lusaka City under the responsibility of the Japanese side. Distribution of the goods from Medical Stores to the district health agencies and medical facilities will be arranged as needed by the Zambian side.

Table-16: Implementation Schedule



2-3 Obligations of the Recipient Country

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

① To ensure proper and prompt customs clearance procedure for the equipment and supplies to be procured under this Project.

② To secure storage spaces necessary to keep the equipment and supplies to be procured under this Project, taking special precautions for properly maintaining the quality of the anti-TB drugs.

③ To ensure prompt delivery of the equipment and supplies to their final destinations by keeping close communications with the personnel of Medical Stores in charge of storage and transportation, as well as the staff of the district health bureaus and medical institutions.

④ To pay fees associated with the issuance of the Authorization to Pay (A/P) according to the Banking Arrangement (B/A) for the implementation of this Project.

⑤ To make necessary appropriations and employ an adequate number of personnel for the proper operation and maintenance of the equipment and supplies.

2-4 Project Operation Plan

The goods to be procured by this Project will be operated, managed, and applied by utilizing the existing systems of Zambia as much as possible.

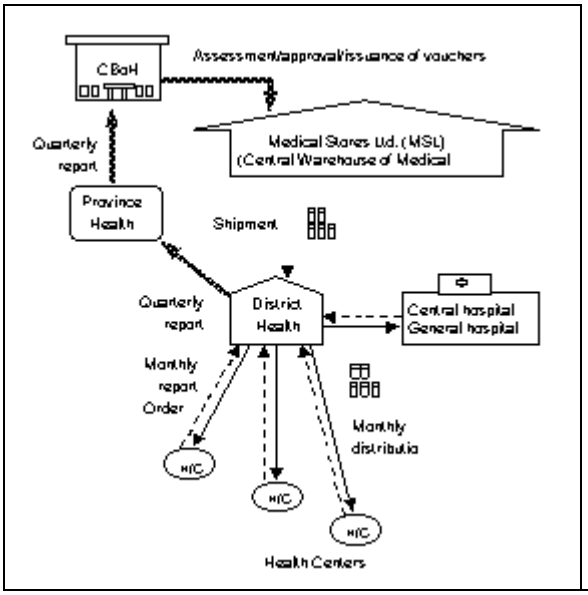
(1) Distribution System of Medical Products

On the state level, medical Stores Ltd. is in charge of the storage, inventory control, and delivery of medical products and reagents to the district health bureaus, which take over the responsibilities for their control and distribution to their respective health facilities. This storage/distribution system is relatively well established and supports the district-level health/medical services, which have been improved since the Health Reform Program in 1992.

Anti-TB drugs and other general medical supplies are distributed through separate channels. To receive a supply of anti-TB drugs, each health facility must submit a quarterly report. Each district health bureau aggregates the data on TB treatment records submitted monthly by their respective health facilities and submits the result to the Provincial Health Bureau along with an anti-TB drug order form. Each Provincial Health Bureau compiles the quarterly reports from the district health bureaus under their jurisdiction and sends the result to the TB Officer of CBoH, who, based on the data submitted, assesses and approves the needed quantity for each district for the coming quarter and notifies thereof to Medical Stores Ltd. Upon receiving the notice, Medical Stores Ltd. prepares and ships quarterly supply of anti-TB drugs for each district along with other medicines and supplies. Each district health bureau sorts out the goods arrived and distributes them, along with other monthly supplies, to the health facilities under its jurisdiction.

No quarterly report to CBoH is required for receiving general medical products and hygiene supplies, which Medical Stores Ltd. distributes according to the monthly request submitted by districts or hospitals. Health Center Kits are distributed in a fixed quantity each month.

Distribution of Anti-TB Drugs



Distribution of General Medical Products and Reagents (including Health Center Kits)

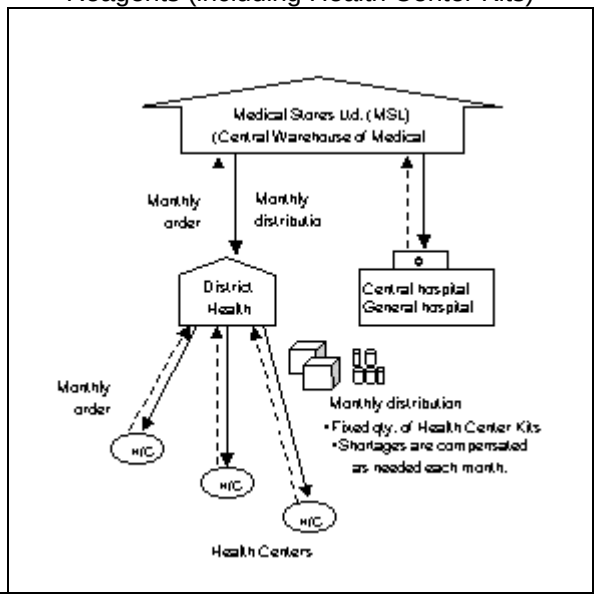


Figure-1: Distribution System of Medical Supplies and Reagents in Zambia

Medical Stores Ltd. has developed a computer system that manages the storage of goods at the central level and tracks the status of transportation vehicles delivering the supplies to the district health bureaus. Using radio communications or sending typed messages, the system directs the trucks to their destinations accurately and swiftly.

No one but the designated personnel at each Health Center is allowed to open the Health Center Kit after packed and sealed by the manufacturers. This prevents steeling or sales to black markets during transportation thereby ensuring the integrity of the contents.

(2) Control System of Medical Products

Anti-TB drugs, reagents, and Health Center Kits are stored at the central, district, and medical institution levels and transferred to the lower level (central→ district → medical facility) as needed (See Table-17).

Expired medical products are collected by Medical Stores Ltd. and incinerated under the supervision of the Ministry of Health.

Table-17: Storage System of Medical Supplies and Reagents in Zambia

Central Level (Medical Stores Ltd.)	(1) Operation & Personnel Land and buildings are owned by MOH. A private company (GMR) signed a 5-year commissioned operation contract with MOH in 1998. In 2000, the management right of GMR was transferred to Sunrise. 75 personnel, including 2 supervising pharmacists and 1 laboratory technician (2) Warehouse Management Ventilation by wall and ceiling fans Efficient placing/picking of goods by using hand lift Generally, goods are controlled for each program/project Storage capacity: approx. 6,000 ㎡ Warehouse entry is restricted to those having appropriate ID cards. Locking system, security guards (3) Inventory Control Entry/exit of each item is recorded in Inventory Control Card. Computer inventory control is used concurrently. INVEC II System, software specially developed by Management Science for Health for the inventory control at the central warehouse of developing countries. Stock is taken every month to check the actual stock against the record. Stock status is distributed to all districts every month. (4) Distribution System 7 10-ton class trucks are operating. Covers all 72 districts via 9 routes from Lusaka. Cargos are attached with color-coded stickers indicating different routes. Delivery is made once a month per route. Uses a tracking system that combines radio communication and GPS to identify and track the present location and delivery route of the truck.
District Level (District Health Bureau's Medical Warehouse)	(1) Administration/Personnel Annexed to district health bureaus or hospitals. Constantly supervised by at least one pharmacist, pharmaceutical technician, or nurse. (2) Warehouse Management Use of pallets, securing of sufficient ventilation, use of air-conditioner, shading Antibiotics are stored in lockable cupboard. Locks and grills (3) Inventory Control Entry/exit of each item is recorded in the Inventory Control Card. Entry/exit of goods is entered in ledger. Periodic (quarterly) stocktaking to check the actual stock against the records. (4) Distribution System Month delivery to each Health Center by trucks owned by the district.
Medical Institution Level (Health Center's Medical Warehouse)	(1) Personnel in charge of controlling the supplies Clinical officer or nurse (2) Warehouse Management Securing of sufficient ventilation, shading, locks and grills Organized shelf layout by application or efficacy, labeling (3) Inventory Control Entry/exit of each item is recorded in the Inventory Control Card.

(3) Implementation System of DOTS

Each Health Center has a medicine taking room, in which the patients swallow the prescribed drugs in front of full-time TB personnel (usually a nurse) who keeps the record of drug intake. For those who cannot come to Health Centers, TB supporters visit their homes every morning to give drugs. Each supporter

covers 15 or so patients on the average. These services are offered free of charge.

Basic information, results of follow-up and other examinations, and assessment record of each patient are entered in the TB Register of each health facility. Details of daily drug intake are recorded in the Patient Register (=drug history chart), as well as in the Patient Card with an ID number that each TB patient is required to carry. Each TB supporter and health worker is given a special notebook to enter the records of drug intake, side effects, and other pertinent information of patients they visited, and report to the personnel in charge of TB control upon returning to the Health Center (See Table-18).

Table-18: Information Management in the Implementation of DOTS

①TB Register	A list of TB patients for whom treatment was deemed necessary. An ID number is assigned to each patient, which is used for cross-reference with the Patient Register and Patient Card. Information contained includes examination results, progress of treatment, and assessment.
②Patient Register	A substitute for drug history or clinical record, containing the basic information, drug intake record, progress, and other detailed information of each patient.
③Patient Card	Each patient is required to carry the card, in which the record of daily drug intake is entered.
④TB Laboratory Register	A special register to enter the records related to sputum smear examinations, including the data of each patient examined and result of the initial and follow-up examinations.
⑤Report Form	Superior agencies are provided with a new report form that has been revised to comply with the WHO format. Submission of a quarterly report is mandatory.

Each district has an average of two to three Health Centers, some of which have a TB Laboratory within their premises that conducts sputum smear microscopy. Health Centers without examination facilities periodically send the collected samples to the nearest Examination Centers, which send back the results several days later. Follow-up examinations are done three times: two months after the start of the initial phase (or the completion thereof), five months thereafter, and eight months thereafter (or at the completion of the treatment regimen).

These activities are monitored and evaluated by the TB officers and personnel of each Province and district. On the district level, the TB personnel visit each Health Center every month to supervise their operations and give guidance. District TB personnel attend the quarterly report forum organized by the Province, and the TB officers of nine Provinces attend the national conference hosted by the central government.

The above facts indicate that the target regions of this Project have the distribution and storage systems on the central, district, and health facility levels that are well established to ensure the movement and storage of medical supplies in good condition, as well as a system to enforce DOTS. Therefore, this Project can utilize these existing systems for the proper management of procured items.

Since the drugs and supplies to be procured under this Project can be kept under normal temperature, no additional facilities need to be constructed for their storage. Administrative systems on all levels are also in place under the supervision of CBoH that manages all medical equipment and supplies to be used for health services by public institutions. As this Project will utilize these existing systems, the Zambian side will not incur additional expenses for the operation and maintenance of the Project.

Chapter 3 Project Evaluation and Recommendations

3-1 Project Effect

3-1-1 Direct Effect

(1) Procurement of anti-TB drugs and laboratory reagents and supplies will provide those suspected of TB infection with opportunities to take sputum smear examinations and receive proper treatment.

(2) Ensuring of uninterrupted supplies of anti-TB drugs to local health facilities will contribute to the expansion and enforcement of DOTS and reduction of TB patients as intended by the Zambian government as part of its TB control campaign.

(3) The Health Center Kits to be procured under this Project, combined with 12,500 kits to be donated by the Dutch government, will satisfy the quantity that needs to be distributed to the Health Centers throughout Zambia during 2004 (19,040 kits). This will cover 80 to 90% of typical infectious diseases in Zambia by treating an estimated number of 19 million patients who visit healthcare facilities on the annual average. About 6.54 million patients will be treated with the procured supplies by this Project alone.

3-1-2 Indirect Effect

(1) Reduction of patients will contribute to the socio-economic development and the alleviation of poverty in Zambia.

(2) Qualitative improvement of community-level health services and the reduction of morbidity rates of major diseases will decrease medical expenditures of the Zambian government.

3-2 Cost of Estimation for the Project

3-2-1 Cost to be borne by the Japanese side

The total cost for implementing the Project is estimated at about 510 million yen, as shown in the Table-19 below.

Table-19 Estimated Total Project Cost

Description		Estimated Cost（million yen）	
Equipment	Anti-TB Drugs and reagents	175.5	489.8
	Health Center Kit	314.3	
Implementation Design / Procurement Supervision			20.8
Total Cost			510.6

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

3-2-2 Cost of Operation and Maintenance of the Project

Since the goods to be procured in this Project can be stored at a normal temperature, particular facilities for project operation are not necessary.

As mentioned in 2-4, the distribution system of medical products has been already established in Zambia and CBoH has the responsibility to control all medical products necessary for the health/medical services. By utilizing this system, the Zambian government shall not bear further cost.

3-3 Recommendations

To maximize the effects of this Project, the following agendas need to be addressed and solved.

3-3-1 Promotion and Expansion of DOTS

This Project will assist the procurement of anti-TB drugs and laboratory reagents for the three Provinces where DOTS is commonly practiced. However, the degree to which DOTS is used as standard treatment regimen varies from region to region in the whole of Zambia or from community to community within the same district. Although an officer in charge of TB control has been assigned to each district, there are still 29 districts as of today that have yet to start DOTS. In addition, while some districts regularly submit reports to CBoH on the number of patients and the progress of their treatment, others tend to be delinquent in the submission of such reports due to underdeveloped infrastructure, etc.

Therefore, to enhance the effects of TB control measures in Zambia, it is desirable that other Provinces will start DOTS as soon as possible so that it will be practiced as standardized procedures throughout the country. Also, those districts that are already adopting DOTS are encouraged to rectify the disparities in the quality of health services among the communities or medical facilities to further improve the overall medical services.

3-3-2 Continuance of the Project

Treatment of TB, even the presently most-common short course, will take six to twelve months. Therefore, visible effects of this Project will not be confirmed until at least a year later after the commencement of the Project. To sustain and expand the Project effects, on-going practice of DOTS, as well as additional supply of drugs to support it, will be necessary. Moreover, improper treatment using drugs of poor or inconsistent quality or suspension of treatment due to a shortage of drugs could not only increase the number of new patients but also trigger the emergence of MDR-TB. Therefore, ensuring the uninterrupted supply of anti-TB drugs is of vital importance for TB control in Zambia.

However, no foreign assistance, including from Japan, is being planned after the completion of this

Project. Considering the fact that Zambia relies on external assistance for nearly 40% of its health/medical budget, it is unlikely that the Zambian government can make sufficient appropriations in the near future.

Since the effects of TB control efforts are ensured by the continuous provision of necessary medical/pharmaceutical supplies, the Japanese government is encouraged to positively consider additional assistance in case no other donors will take over this Project and the Zambian government submits an official request for the continuation of the Project.

Appendix

Member List of the Study Team

(1) Ms. MUTO Ako	Leader	Director, Second Project Management Division, Grant Aid Management Department, Japan International Cooperation Agency
(2) Mr. KODAMA Tetsuo	Equipment Planner	General Grant Division, Grant Aid Management Department, Japan International Cooperation System
(3) Mr. MIYASHITA Hiromichi	Procurement Planner	General Grant Division, Grant Aid Management Department, Japan International Cooperation System

Study Schedule

No.	Date		Activities		Stay
			Officials	Consultant	
1	3/2	Sun		Tokyo 12:00→18:20 Singapore (SQ997)	
2	3/3	Mon		Singapore 01:35→06:05 Johannesburg (SQ406) Johannesburg 09:05→11:10 Lusaka (SA062) Visit JICA, Courtesy call on Embassy of Japan	Lusaka
3	3/4	Tue		Ministry of Health, Ministry of Finance Meeting with WHO, CDC/USAID, Embassy of the Netherlands	Lusaka
4	3/5	Wed		Site Visit (CDC DOTS Project in Lusaka)	"
5	3/6	Thu		Site Visit (DOTS Trainig District)	"
6	3/7	Fri		Site Visit (Health Centres)	"
7	3/8	Sat	London 18:55 → (BA255)		"
8	3/9	Sun	→ Lusaka 06:25 Meeting	Data Analysis Meeting	Lusaka
9	3/10	Mon	Meeting with MOH Discussion of M/D		Lusaka
10	3/11	Tue	Signing of Minutes Report JICA, Report Embassy of Japan		Lusaka
11	3/12	Wed	Lusaka 12:45 → 14:45 Johannesburg(BA6250) Johannesburg 17:20 → (SA286)	Market Research	Lusaka
12	3/13	Thu	→ 12:30 Hong Kong Hong Kong 15:50 → 20:35 Tokyo (JL734)	Meeting with MOH (H/C Kits & Drug Registration System)	Lusaka
13	3/14	Fri		Visit Medical Stores Limited Visit Central Laboratory (for Quality Control)	Lusaka
14	3/15	Sat		Market Research	Lusaka
15	3/16	Sun		Internal Meeting	Lusaka
16	3/17	Mon		Site Visit (District Hospital, Urban Health Centre)	Lusaka
17	3/18	Tue		Visit Pharmaceutical Company Collect Pro-forma Invoice	Lusaka
18	3/19	Wed		Meeting with MOH (Project detail, Specifications)	Lusaka
19	3/20	Thu		Report JICA, Report Embassy of Japan Lusaka 14:00 → 16:10 Johannesburg (SA065)	Johannesburg
20	3/21	Fri		Johannesburg 14:15 → (SQ405)	on board
21	3/22	Sat		→ 06:35 Singapore Singapore 09:45 → 17:05 Tokyo (SQ012)	

List of Parties Concerned in the Recipient Country

1. Ministry of Health

(1) Dr. S. K. Miti	Permanent Secretary
(2) Mr. Bornface Chaabila Nalishiwa	Director, Human Resources & Administration

2. Central Board of Health

(1) Dr. B. U. Chirwa	Director General
(2) Dr. Lyndon M. Kafwabulula	TB / Leprosy Specialist
(3) Mr. Grace Kahenya FIBMS MSC	Laboratory Specialist
(4) Mr. A Lupupa	Purchasing & Supplier Specialist (Pharmaceuticals)
(5) Mrs. Felicia C. Mwele	Chief Policy Analyst (Paramedical)
(6) Dr. M. R. Sunkutu	Director Public Health & Research
(7) Mr. Nyirenda F.	Assistant Director Public Health & Research
(8) Mr. Hidehiro Otake	JICA expert

3. Lusaka District Health Management Board

(1) Dr. Moses Sinkala	Director of Health - LDHMB
(2) Mr. Graham Samungole	District TB/LEP, AISE, STI Coordinator
(3) Mr. Maxwell Kasonde	District Pharmacy Coordinator

4. Ndola District Health Management Board

(1) Mr. Watson Mulubwa	Pharmacy Technologist
(2) Mr. George Kaluba	Ag. Provincial TB / Leprosy Specialist

5. Kafue District Health Management Board

(1) Dr. Charles Yekha Msiska	Director of Health – Kafue DHMB

6. Ministry of Finance and National Planning

(1) Ms. Monde F. Sitwala	Chief Economist, Multilateral Unit
(2) Mr. Tsuneo Tsurusaki	JICA expert

7. Royal Netherlands Embassy

(1) Mr. Marco Gerritsen	First Secretary
(2) Ms. Marlie Gommans	Program Officer

8. Department for International Development (DFID)

(1) Mr. Anthony Dalay	Health Advisor

9. Centers for Disease Control and Prevention (CDC Global AIDS Program, Zambia)

(1) Mr. David B. Nelson	Director
(2) Dr. Alwyn Mwinga, Mmed	Medical Epidemiologist

10. World Health Organization (WHO)

(1) Dr. Eddie M. Limbambala	Medical Officer, Disease Prevention and Control

11. Community based TB Organization (NGO)

(1) Mr. Webby Mwape	Executive Director
(2) Ms. Rachael Kaluta	Project Manager
(3) Mr. Charles Mfura	Administrator

12. Medical Stores Limited

(1) Mr. Johan Richter	Warehouse Manager

13. Pharco Limited

(1) Ms. Norma H. Diaz	General Manager

14. International Chemical Limited

(1) Mr. G. M. Simpungwe	Chairman
(2) Mr. Samuel Chingambu	Product Manager

15. JICA Zambia Office

(1) Mr. Katsuhiro Sasaki	Resident Representative
(2) Mr. Shiro Kitazawa	Assistant Resident Representative
(3) Ms. Tomoko Zama Sichone	Programme Officer
(4) Mr. Kotaro Oizumi, M.D. Ph.D	JICA expert (HIV/AIDS TB Control Project Leader)

16. Embassy of Japan

(1) Mr. Takashi Kimura	Second Secretary(Economic cooperation)

MINUTES OF DISCUSSIONS
ON
THE STUDY
ON
THE PROJECT
FOR
INFECTIOUS DISEASE CONTROL IN ZAMBIA

In response to the request from the Government of the Republic of Zambia (hereinafter referred to as Zambia), the Government of Japan decided to conduct a Study on the Project for Infectious Disease Control in Zambia (hereinafter referred to as the Project) and entrusted the study to Japan International Cooperation Agency (hereinafter referred to as JICA).

JICA sent the Study Team (hereinafter referred to as the Team) headed by Ms. Ako MUTO, Second Project Management Division, Grant Aid Management Department, JICA to Zambia from March 3 to 20, 2003.

The Team had series of discussions with the officials concerned of Zambia and conducted a field survey.

In the course of discussions and field studies, both parties confirmed the main items described in the attached sheets. The team will proceed to further works and prepare the Study Report.

Lusaka, March 11, 2003

Ms. Ako MUTO
Leader
The Study Team
Japan International Cooperation Agency
Japan

Dr. S. K. MITI
Permanent Secretary
Ministry of Health
The Republic of Zambia

ATTACHMENT

1. Objectives

The Objectives of the Project is to improve the infectious disease control service through procurement of medicines.

2. Project Sites

TB drugs and reagents: the maximum project sites are 22 districts of Zambia, i.e. Kabwe, Kasama, Ndola, Mansa, Mongu, Chipata, Solwezi, Lusaka, Livingstone, Lundazi, Lukulu, Kapiri-Mposhi, Mumbwa, Luanshya, Masaiti, Petauke, Nakonde, Nchelenge, Kafue, Choma, Mufumbwe, Kasempa.

Health Center Kit : the Project sites are 10 districts of Zambia, i.e. Chingola, Chililabombwe, Luanshya, Kalulushi, Kitwe, Mufulira, Ndola, Kabwe, Lusaka, Livingstone

3. Responsible and Executing Agency

Responsible Agency is Ministry of Health

Executing Agency is Central Board of Health.

4. Items Requested by the Government of Zambia

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

However, the final components of the Project will be decided after further studies.

5. Japan s Grant Aid System

5-1. The Zambian side understands the Japan s Grant Aid Scheme explained by the Team, as described in Annex-2.

5-2. The Zambian side will take necessary measures as described in Annex-3 for the smooth implementation of the Project on the condition that the Grant Aid is extended to the Project by the Government of Japan.

6. Schedule of the Study

6-1. The consultants will proceed to further studies in Zambia until March 20.

6-2. Based on the Minutes of Discussions and technical examination of the study results, JICA will prepare a study report on the Project and send it to Zambia around August 2003 provided that the Government of Japan approves the report.

7. Other relevant issues

7-1 Both sides agreed that the components of the Project would include the amount covering only one year. Both sides also understood that this was because appropriate quantity of TB drugs and Health Centre Kits should be calculated year by year based on the achievement of DOTS

strategy and record of using Health Centre Kits.

7-2 The Zambian side promised to submit to the consultant before 20 March, the answers of the questionnaire and detailed information about DOTS implemented 22 districts, such as;

1) Population, number of health facilities (hospitals, health centres), number of diagnostic centres in each district
2) Number of TB cases registered during the last year by treatment status: new smear-positive (or Cat 1), relapse (or Cat 2), new smear-negative and extra-pulmonary (Cat 3) and Total cases
3) Sputum conversion rate at 2 month in smear-positive patients enrolled on short course chemotherapy during the last year
4) Number of cured, treatment completed, died, failure, defaulted, transferred to another district, and total number of evaluated pulmonary TB patient in new cases and re-treatment during the last year

The Team explained and the Zambian side accepted that without the abovementioned answers and detailed information, TB drugs and reagents would not be the components of the Project.

7-3 Both side confirmed that at the implementation stage, the procured amount of the Project should be distributed to the targeted districts directly. The Zambian side promised to allocate necessary budget at the implementation stage of the Project, such as;

1) Commissions to the Japanese bank for banking services based upon the B/A and A/P.
2) Expenses that cover the transportation of the medicines
3) Tax exemption and custom clearance of the medicines at the port of disembarkation

The total amount will appear at the time of approval by Japanese government.

7-4 The Zambian side agreed to submit the confirmation letter to Embassy of Japan and JICA Zambia Office that the medicine arrived at each district.

7-5 The Zambian side agreed to submit quarterly distribution report to Embassy of Japan and JICA Zambia Office.

7-6 The Team emphasized the importance of appropriate implementation and expansion of DOTS strategy and necessary budgetary allocation to control TB effectively.

7-7 The Zambian side agreed to allocate sufficient budgets to operate the Project including the improvement of technical skills and arrangement of laboratory equipment and supplies in diagnostic centers.

No.	Item
1	Rifampicin + Isoniazid
2	Pyrazinamide
3	Ethambutol
4	Ethambutol + Isoniazid
5	Streptomycin
6	Microscope slides
7	Sputum cups
8	Basic fuchsin
9	Methlene blue
10	Methylated spirit
11	Sulphuric acid
12	Phenol crystals
13	Xylene
14	Immersion oil
15	Hydrochloric acid
16	Methanol
17	Health Centre Kit (contents as per attached)

17 Health Centre Kit

No.	Item	Dosage form	Specifications	Unit	Quantity
1	Acetylsalicylic acid (Aspirin BP)	tablet	300mg	1000 tabs.	2
2	Erythromycin (as stearate BP)	tablet	250mg	500 tabs.	1
3	Amoxycillin USP	tablet / cap	250mg	1000 tabs.	2
4	Benzathine penicillin BP vials	injection	2.4MU	1 vial	20
5	Water for injection, sterile vials	injection	10ml	1 amp.	20
6	Benzyl penicillin G BP, vials	injection	5MU (3g)	1 vial	10
7	Benzyl penicillin G BP, vials	injection	1MU (600mg)	1 vial	10
8	Water for injection, sterile vials	injection	5ml	1 vial	10
9	Chlorpheniramine maleate BP	tablet	4mg	100 tabs.	1
10	Diazapam BP	injection	5mg/ml	10 vial	2
11	Ferrous sulphate BP, sugarcoated, red coloured	tablet	200mg	1000 tabs.	2
12	Ferrous sulphate BP, sugarcoated	tablet	50mg	1000 tabs.	1
13	Folic acid BP	tablet	5mg	1000 tabs.	1
14	Clotrimazole 20g BP	cream	1%	20 g	20
15	Hydrocortisone, tube	ointment	1%	15 g	5
16	Hydrocortisone, tube	cream	1%	15 g	5
17	Lignocaine HCl, vial	injection	1%	10 ml	1
18	Magnesium trisillicate co, BPC	tablet		1000 tabs.	1
19	Albendazole tablets	tablet	400mg	100 tabs.	2
20	Methylergometrine maleate BP, amp	injection	0.2mg/ml	1 ml	5
21	Metronidazole BP (scored)	tablet	200mg	1000 pcs.	1
22	Multivitamin BPC, formula	tablet		1000 tabs.	1
23	Nyastatin (uncoated tab for oral thrush)	loz / tablet	100,000IU	500 tabs.	1
24	Nyastatin	pessary	100,000IU	500 pess.	1
25	Nyastatin	suspension	100,000IU/ml	30 ml	10
26	ORS (WHO-formula), citrate BP	powder	27.9g/1L	1 pac.	200
27	Paracetamol BP, (scored)	tablet	500mg	1000 tabs.	5
28	Paracetamol BP	tablet	100mg	1000 tabs.	2
29	Penicillin V potassium BP (scored)	tablet	250mg	1000 tabs.	1
30	Procaine penicillin BP/USP, vials	injection	3MU	10 ml	30
31	Sulphadoxine/pyrimethamine BP film coated (scored)	tablet	500mg/25mg	1000 tabs.	2
32	Salbutamol (scored)	tablet	2mg	1000 tabs.	1
33	Tetracycline USP, with 1.1 wide nozzle	eye ointment	1%	5 g	75
34	Doxycycline Hydrate USP	tablet	100mg	1000 tabs.	1
35	Quinine Sulphate BP/USP	tablet	300mg	100 tabs.	2
36	Bag, Plastic, self-sealing, with white textfield		min. 64×83mm	1000 pcs.	2
37	Bandage, cotton WOW size 5 cm×5m		5cm×5m	1 roll	30
38	Braided silk suture, hospital reels "3/0" 22m		"3/0" 22m	1 reel	1
39	Knotless non-capillary wax finish "2/0" 22m		"2/0" 22m	1 reel	1
40	Ball pen			1 pc.	2
41	Cetrimide BP, sachets	powder	10g/1L	1 g	10
42	Chlorhexidine gluconate 20%, solution	solution	20%	100 ml	1
43	Condoms, lubricated			1 pc.	1008
44	Cotton wool absorbent BP		500g	500 g	1
45	Gauze absorbent, non-sterile, 4 fold 0.90×5m		0.90×5m	1 pc.	1
46	Gauze, paraffin, dressing, sterile		10×10cm	36 pcs.	1
47	Gloves, exam, latex, disposable – non sterile M		medium	50 pcs.	1
48	Gloves, exam, latex, disposable – non sterile L		large	100 pcs.	1
49	Needles, disposable 23G		0.65×32mm	100 pcs.	2
50	Needles, disposable 21G		0.80×38mm	100 pcs.	2
51	Needles, suture, curved 3/8, cutting		1L, 3M, 2S	6 pcs.	1
52	Note book pad		A5, lined, 100	1 pc.	1
53	Strapping tape adhesive, zinc oxide BP		7.5cm×5m	1 pc.	2
54	Scalpel surgical blade, carbon steel, sterile		No. 15	10 pcs.	1
55	Swabs, gauze, non-sterile, 12ply			100 pcs.	1
56	Syringe, luer, disposable 2ml (2 way)		2ml	50 pcs.	2
57	Syringe, luer, disposable 5ml (2 way)		5ml	100 pcs.	2
58	Toilet soap		90-100g	1 pc.	5
59	Out patients register (laying A4), print soft cover, 100pp		90-100g	1 pc.	1

JAPAN'S GRANT AID SCHEME

1. Grant Aid Procedures

(1) 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 Implementation	(The Notes exchanged between the Governments of Japan 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 (Japan International Cooperation Agency) to conduct a study on the request.

Secondly, JICA conducts the study (Basic Design Study), using (a) Japanese consulting firm(s).

Thirdly, the Government of Japan appraises the project to see whether or not it is suitable for Japan's Grant Aid Program, 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 Japanese Government. The contents of the Study are as follows:

1) Confirmation of the background, objectives, and benefits of the requested project and also institutional capacity of agencies concerned of the recipient country necessary for the Project's implementation.

2) Evaluation of the appropriateness of the Project to be implemented under the Grant Aid Scheme from a technical, social and economical point of view.

3) Confirmation of items agreed on by both parties concerning the basic concept of the Project.

4) Preparation of a basic design of the Project.

5) 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 though 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.

(2) Selection of Consultants

For smooth implementation of the Study, JICA uses (a) registered consultant firm(s). JICA selects (a) firm(s) based on proposals submitted by interested firms. The firm(s) selected carry(ies) out a Basic Design Study and write(s) a report, based upon terms of reference set by JICA.

The consulting firm(s) used for the Study is (are) recommended by JICA to the recipient country to also work in the Project's implementation after the Exchange of Notes, in order to maintain technical consistency.

3. Japan's Grant Aid Scheme

(1) Grant Aid

The Grant Aid Program provides a recipient country with non-reimbursable funds to procure 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 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 Aid" means the one fiscal year which the Cabinet

approves the Project for. Within the fiscal year, all procedures such as exchanging of the Notes, concluding contracts with (a) consultant firm(s) and (a) contractor(s) and a 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 by mutual agreement between the two Governments.

(4) Under the Grant Aid, 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 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 to Japanese taxpayers.

(6) Undertakings required of the Government of the Recipient Country

In the implementation of the Grant Aid project, the recipient country is required to undertake such necessary measures as the following:

1) To secure land necessary for the sites of the Project, and to clear, level and reclaim the land prior to commencement of the construction.

2) To provide facilities for the distribution of electricity, water supply and drainage and other incidental facilities in and around the sites.

3) To secure buildings prior to the procurement in case the installation of the equipment.

4) To ensure all the expenses and prompt execution for unloading, customs clearance at the port of disembarkation and internal transportation of the products purchased under the Grant Aid.

5) To exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which will be imposed in the recipient country with respect to the supply of the products and services under the Verified Contracts.

6) 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.

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 staff necessary for this operation and maintenance 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 should 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 a 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 issued by the Government of the recipient country or its designated authority.

Major Undertakings to be taken by Each Government

Annex-3

NO	Items	To be covered by Grant Aid	To be covered by Recipient side
1	To bear the following commissions to a bank of Japan for the banking services based upon the B/A		
	1) Advising commission of A/P		●
	2) Payment commission		●
2	To ensure prompt unloading and customs clearance at the port of disembarkation in recipient country		
	1) Marine(Air) transportation of the products from Japan to the recipient country	●	
	2) Tax exemption and custom clearance of the products at the port of disembarkation		●
	3) Internal 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		●

References

No.	References	Sources
1	The Study on Japan's Official Development Assistance to Southern African Countries Volume Ⅳ; Zambia (main reports)	JICA
2	Rapid Assessment of Progress on Revitalization of the NTP and Accessibility to Anti TB Drugs, 15th to 19th October 2001	KNCV/WHO
3	Report of the Visit to the Central Board of Health Tuberculosis Control Program of Zambia from10-21November 2002, CIDA-KNCV Support to Zambia Report No 2, November 2002	KNCV
4	National Health Strategic Plan 2001-2005, December 2000	Ministry of Health
5	Public Health and Research Directorate, Draft Country Health Statistics, Library, July 2002	Central Board of Heath
6	National Health Strategic Plan 1998-2000	Ministry of Health
7	TB Implementation Plan 2002-2005	Central Board of Health
8	Approved New Structure of the Central Board of Health, May 2000	Republic of Zambia
9	National TB Review, 2-18 August 2000, Final Report	Central Board of Health
10	National Budget Book 2001	Republic of Zambia
11	National Budget Book 2002	Republic of Zambia
12	HIV/AIDS in Zambia, Background Projections Impacts Interventions, September 1999	Ministry of Health, Central Board of Health
13	. Zambia National Tender Board, Government of the Republic of Zambia, Tender Document, Selective Tender for the Procurement of Rural Health Center Kits, Funded by the Royal Netherlands Embassy, May 2002	The Royal Netherlands Embassy
14	Tuberculosis Manual, The National AIDS/STD/Tuberculosis and Programme, Second Edition, May 2001(Draft)	Central Board of Health/WHO
15	Management of Tuberculosis, A Guide for Low Income Countries, Fifth edition, 2000	International Union Against Tuberculosis and Lung Disease
16	Sector Wide Approach to Health Zambia, Project Memorandum, 20 August 2001	Republic of Zambia