No.

BASIC DESIGN STUDY REPORT

ON

THE PROJECT

FOR

TUBERCULOSIS CONTROL IN POOR AREAS

(PHASE IV)

IN

THE PEOPLE'S REPUBLIC OF CHINA

March 2004

Japan International Cooperation Agency

GM
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Contents

PREFACE

In response to a request from the Government of the People's Republic of China, the government of Japan decided to conduct a basic design study on the project for Tuberculosis Control in Poor Area (Phase IV), and entrusted the work to the Japan International Cooperation Agency (JICA).

JICA sent a basic design study team to China from February to March 2004.

The study team held discussions with the officials concerned of the Government of the People's Republic of China, and conducted a field survey in the project's target areas. After the study team returned to Japan and further study works were conducted, the present report was finalized.

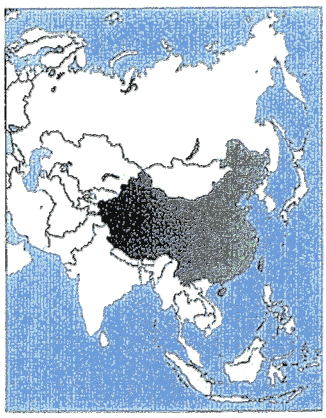
I hope that this report will contribute to the promotion of the project and to the enhancement of friendly relations between our two countries.

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

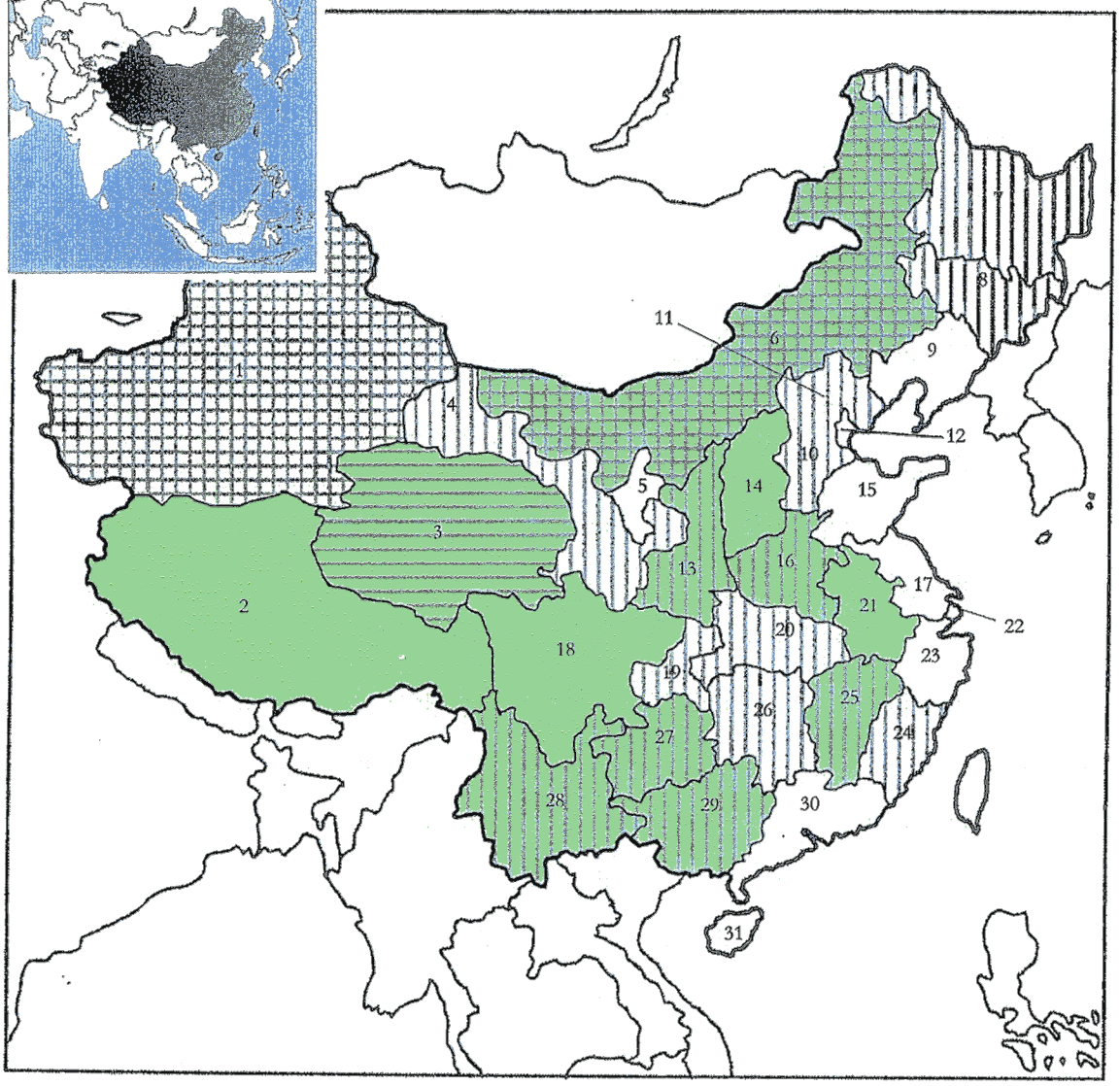
March 2004

Yasuo Matsui,
Vice-President
Japan International Cooperation Agency

Location Map



the nationwide map of China



Japan Project site (under line)　　World Bank/DFID site　　Damian Foundation Belgium site

Province name

1. Xinjiang 新疆ｳｲｸﾞﾙ自治区
2. Xizang チベット自治区
3. Qinghai 青海省
4. Gansu 甘粛省
5. Ningxia 寧夏省
6. Nei Mongol 内ﾓﾝｺﾞﾙ自治区
7. Heliongjiang 黒龍江省
8. Jilin 吉林省
9. Liaoning 遼寧省
10. Hebei 河北省
11. Beijing 北京市
12. Tianjin 天津市
13. Shaanxi 陝西省
14. Shanxi 山西省
15. Shandong 山東省
16. Henan 河南省
17. Jiangsu 江蘇省
18. Sichuan 四川省
19. Chongqing 重慶市
20. Hubei 湖北省
21. Anhui 安徽省
22. Shanghai 上海市
23. Zhejiang 浙江省
24. Fujian 福建省
25. Jiangxi 江西省
26. Hunan 湖南省
27. Guizhou 貴州省
28. Yunnan 雲南省
29. Guangxi 広西自治区
30. Guangdong 広東省
31. Hainan 海南省

LIST OF ABBREVIATIONS

Abbreviation	English
AD	Auto-disable syringe
BHN	Basic Human Needs
CDC	Center for Disease Control and Prevention (an independent entity under the Chinese Department of Health)
CIDA	Canadian International Development Agency
DFB	Damian Foundation Belgium (an NGO supporting tuberculosis and Hansen's disease)
DFID	Department for International Development (United Kingdom)
DOTS	Directly Observed Treatment, Short Course (see Glossary)
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
HIV/ AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
IEC	Information Education Communication
JICA	Japan International Cooperation Agency
NCTB	National Center for TB control and prevention
SARS	Severe Acute Respiratory Syndrome
SFDA	State Food and Drug Administration
TB	Tuberculosis
WB	World Bank
WHO/ WPRO	World Health Organization / Western Pacific Regional Office

Chapter 1 Background of the Project

WHO has assigned 22 countries in the world as high-burden countries that have the high TB incidence. (The top 22 countries in the ranking of the estimated number of TB patients account for 80% of all TB patients in the world.) China is second to India in the list of these high-burden countries (Table 1-1).

Table 1-1 Estimated Number of TB Patients in Top 5 High-burden Countries (2002)

Rank	Country	TB Cases (×1,000)	
		All TB	Smear-Positive TB
1	India	1,761	787
2	China	1,459	656
3	Indonesia	557	250
4	Nigeria	368	159
5	Bangladesh	318	143

Source: WHO Report 2004, Global Tuberculosis Control

Although China has been implementing TB control measures since the end of the 1970s, the lack of appropriate patient management in clinical practice resulted in frequent occurrence of treatment discontinuation and retreatment cases. As a result, development of drug resistance, progression to refractory TB, and expansion of TB emerged as serious problems. To cope with this situation, the DOTS strategy has been promoted since 1992 in 13 provinces and autonomous regions supported by World Bank loans and technical support from WHO. However, due to the vast land areas and large population, the population coverage of the DOTS strategy remains as low as 68% in poor areas, and more than one million patients are unable to receive effective treatment. Because three quarters of TB patients are adolescent or early middle-aged, TB is imposing heavy economic burdens not only on patients themselves but also on their families and society. It is a serious factor hindering the economic and social development of poor areas.

In 2000, the Ministry of Health requested the Government of Japan for assistance in the introduction of DOTS in poor areas in 9 provinces and 3 autonomous regions (Sichuan Province, Qinghai Province, Henan Province, Inner Mongolia Autonomous Region, Jiangxi Province, Shaanxi Province, Anhui Province, Guizhou Province, Yunnan Province, Shanxi Province, Guangxi Zhuangzu Autonomous Region, and Tibet Autonomous Region) (Phase I). Of these areas, Tibet was excluded from the areas to be covered in the Project, because there was a plan to procure anti-TB drugs for Tibet under the assistance from Damian Foundation Belgium (an NGO supporting Hansen's disease and TB). The Phase I of this Project provided microscopes, anti-TB drugs, and materials for prevention education (posters and pamphlets) for areas covering 35% of the population of 9 provinces and 2 autonomous regions. Because Damian Foundation decided to stop procurement of anti-TB drugs for Tibet and provide only technical

guidance and operation cost support in and after 2003, the Phase II of the Project included Tibet and was expanded to cover 59.0% of the population of 9 provinces and 3 autonomous regions. In Phase III, the population coverage in the same provinces and autonomous regions was expanded to 89.5%. PR boards for counties and PR boards for towns were added to the materials for prevention education. Diagnosis and treatment were provided to patients covered by the DOTS strategy free of charge using the procured microscopes and anti-TB drugs.

Considering that Phase III resulted in the 89.5% population coverage achieving the intended goal, the Ministry of Health requested microscopes, anti-TB drugs, materials for prevention education, and computers for surveillance, aiming to expand the DOTS strategy to all counties in the 9 provinces and 3 autonomous regions (100% population coverage).

Chapter 2 Contents of the Project

2-1 Basic Concept of the Project

The request from the Government of China is concerning the provision of equipment and supplies (anti-TB drugs, microscopes, etc.) needed for the activities to expand the DOTS strategy during 5 years (from 2002 to 2006). The purpose is to treat more TB patients, to prevent transmission to people surrounding patients, and consequently to reduce the number of TB patients by increasing the population coverage of the DOTS strategy. To this end, Japan has been providing assistance since 2002 in the provision of anti-TB drugs, microscopes, etc. needed for starting the DOTS strategy in poor areas in 9 provinces and 3 autonomous regions (9 provinces and 2 autonomous regions in 2002). The equipment and supplies have already been distributed from provinces to county-level facilities, and the DOTS strategy has been launched. The present grant-aid assistance procures anti-TB drugs, microscopes, etc. needed in 2003, which marks the 4th year of the expansion of the DOTS strategy in poor areas. Originally, this project was planned to expand from Phase I to cover 35%, 50%, 70%, 80% and 90% of population over 5 years. However, a 89.6% population coverage has already been achieved in Phase III, the present project aims at a 100% population coverage. The following table shows the plan for expanding the DOTS strategy in each province.

Table 2-1 Plan for Expanding the DOTS Strategy in Each Province

Province/Autonomous Region	Population Coverage of DOTS Strategy (%)			
	2002	2003	2004	2005
Sichuan	3.1	5.2	100*	100
Qinghai	70.4	74.9	95.3	100
Henan	51.6	81.7	89.5	100
Inner Mongolia	42.3	71.7	98.4	100
Jiangxi	13.8	42.5	64.2	100
Shaanxi	19.5	71.3	95.3	100
Anhui	26.1	70.3	80.5	100
Guizhou	39.7	75.1	95.5	100
Yunnan	31.3	56.4	88.8	100
Shanxi	37.3	68.4	77.3	100
Guangxi	35.4	71.1	100	100
Tibet	0.0	76.4	92.1	100
Total	29.6	58.6	89.6	100

Note: The data for 2002 to 2005 are actual results of implementation. Those for 2004 and 2005 reflect finalized implementation plan. (Those for 2006 reflect the plan at the time of study for Phase IV project.) * With respect to Sichuan Province, it has been decided that Phase III and later project include the 134 counties covered by World Bank assistance (the project ends in 2003).

2-2 Basic Design of Assistance Project

2-2-1 Design Policies

The present grant-aid assistance provides fund for procuring anti-TB drugs, microscopes, and equipment and supplies for education and PR purposes to support the implementation of TB control in poor areas based on the National Plan for the Prevention and Control of TB (2001-2010) and specific draft implementation plan (2001-2005). A grand design (specifying target areas, expansion plan, and items to be provided) including 5 phases was developed when Phase I project was designed. The present project is the phase IV (2005) of the monetary support based on this grand design.

Although computer equipment was newly requested in this project, it was excluded from the coverage of this project, because such equipment does not fit in the grand design of this project to provide a minimum set of necessary equipment and supplies for the DOTS strategy that offers TB treatment to the inhabitants of poor areas for free. However, because the socioeconomic situation of China has changed considerably since the grand design was developed in 2001, procurement of computer equipment will be considered in and after the next year. In 2004, GFATM has a plan to provide 904 computers in the target areas of this project. It is considered appropriate to make decisions after evaluating the usage and effectiveness of these computers.

2-2-2 Basic Plan

1) Target Areas (9 Provinces and 3 Autonomous Regions)

The target areas of Phase IV are planned to include all of the 1,250 counties in the 9 provinces and 3 autonomous regions. The number of counties and population in each province are as shown below.

Table 2-2 Target Areas and Population in the 2005 Project

Province	Target Areas in 2005		
	Population (×100,000)	No. of New Target Counties	No. of All Target Counties
Sichuan	896.2	0	180
Qinghai	54.5	5	47
Henan	991.1	13	127
Inner Mongolia	241.0	5	101
Jiangxi	436.2	28	99
Shaanxi	372.0	3	107
Anhui	660.6	17	84
Guizhou	403.4	6	91
Yunnan	427.3	12	129
Shanxi	338.3	24	119
Guangxi	490.9	0	92
Tibet	26.0	12	74
Total	5,337.7	125	1,250

2) Target Patients

Based on the DOTS strategy of the Ministry of Health, the target patients of this Project are (1) new smear-positive pulmonary cases, (2) retreatment smear-positive pulmonary cases, and (3) new smear-negative pulmonary (severe form) cases. The number of target patients (Table 2-3) has been calculated from the actual data in 2002 and 2003 according to the calculation criteria shown in Table 2-4.

Table 2-3 Number of Target Patients

Province	Estimated No. of Patients Detected in 2005			Total No. of Target Patients
	New Smear-positive	Retreatment Smear-positive	New Smear-negative, Severe Form	
Sichuan	21,690	7,346	5,010	34,046
Qinghai	1,622	575	329	2,526
Henan	25,131	6,210	3,755	35,096
Inner Mongolia	5,343	2,271	1,020	8,635
Jiangxi	10,013	3,495	1,944	15,451
Shaanxi	10,482	5,750	2,113	18,346
Anhui	12,985	7,555	2,637	23,178
Guizhou	11,919	4,377	2,202	18,497
Yunnan	13,519	6,429	2,567	22,514
Shanxi	7,848	4,773	930	13,551
Guangxi	13,799	6,868	2,760	23,427
Tibet	1,391	285	224	1,900
Total	135,743	55,935	25,490	217,167

Table 2-4 Calculation Criteria for the Number of Patients in 2005

Number of Target Counties	Estimated Patient Reporting Rate in Each Target Province (per 100,000)	Percentage of Retreatment Cases among Smear-positive Pulmonary Cases	Percentage of Smear-negative Pulmonary (Severe Form) Cases to New Smear-positive Pulmonary Cases
303 counties (starting in 2002)	Actual reporting rate in 2003 + 20%.	If actual rate in 2003 was less than 20%: actual rate in 2003. If actual rate in 2003 was less than 45%: minus 10 points. If actual rate in 2003 was 45% or more: 35%.	If the rate in 2003 was 20% or more: 20%. If the rate in 2003 was less than 20%: the rate in 2003.
421 counties (starting in 2003)	Mean actual reporting rate in 2002/2003 + 20%.	If the mean of actual rates in 2002/2003 was less than 45%: minus 10 points. If the mean of actual rates in 2002/2003 was 45% or more: 35%.	If the mean of the rates in 2002/2003 was 20% or more: 20%. If the mean of the rates in 2002/2003 was less than 20%: mean of the rates in 2002/2003.
401 counties (starting in 2004)	Mean actual reporting rate in 2002/2003 + 10%.	If the mean of actual rates in 2002/2003 was less than 45%: minus 5 points. If the mean of actual rates in 2002/2003 was 45% or more: 40%.	If the mean of the rates in 2002/2003 was 20% or more: 20%. If the mean of the rates in 2002/2003 was less than 20%: mean of the rates in 2002/2003.
125 counties (starting in 2005)	Mean actual reporting rate in 2002/2003.	Mean of actual rate in 2002/2003.	If the mean of the rates in 2002/2003 was 25% or more: 25%. If the mean of the rates in 2002/2003 was less than 25%: mean of the rates in 2002/2003.

Notes: 1. If the baseline for the registration rate of smear-positive pulmonary cases is 27/100,000 or less, the value 27/100,000 is used in calculation.

2. With respect to Sichuan Province, the data for the 165 target counties covered by the 2003 project (including 31 target counties and the 134 counties covered by the WB project) are used as the baseline, and the estimated patient reporting rate in all target counties in 2005 will be the actual reporting rate in 2003 plus 20%. The percentage of retreatment cases among smear-positive pulmonary cases and the percentage of smear-negative pulmonary (severe form) cases to new smear-positive pulmonary cases are assumed to be equal to the percentages in 2003.

3. With respect to Tibet Autonomous Region, the data for 2003 are used as the baseline. The yearly increase in the registration rate of smear-positive pulmonary cases is assumed to be 10%, and the percentage of retreatment cases among smear-positive pulmonary cases and the percentage of smear-negative pulmonary (severe form) cases to new smear-positive pulmonary cases are assumed to show no changes.

3) Main Items to be Procured

A) Anti-TB Drugs (made by GMP-certified factories, complying with Chinese Pharmacopoeia)

Anti-TB drugs (4 oral types and 1 injection type) having an effective shelf life of 22 months or longer at the time of handover will be procured. Oral drugs (tablets or capsules) will be procured in a form of blister packs, each sheet of which containing a daily dose for easier dosing. Combinations of 5 types of anti-TB drugs will be administered to TB patients that are classified into the three categories shown in Table 2-5 below over a period of six to nine months to treat the patients according to the DOTS strategy.

Table 2-5 Types and Combinations of Anti-TB Drugs (Symbols)

Type of TB Patients	Intensive Phase (2 to 3 months)	Continuation Phase (4 to 6 months)
① New Smear-Positive Pulmonary Case To patients who will not turn negative after 2 months (which is assumed to be 20% of total), the intensive-phase drugs will be given for an additional month.	$2H_3R_3Z_3E_3$ (HRZE) or $3H_3R_3Z_3E_3$ (HRZE)	$4H_3R_3$ (HR)
② Retreatment Smear-Positive Pulmonary Case To patients who will not turn negative after 2 months (which is assumed to be 30% of total), the intensive-phase drugs will be given for an additional month.	$2H_3R_3Z_3E_3S_3$ (HRZE + SM) or $3H_3R_3Z_3E_3S_3$ (HRZE + SM)	$6H_3R_3E_3$ (HRE)
③ New Smear-Negative Pulmonary (Severe Form) Case	$2H_3R_3Z_3E_3$ (HRZE)	$4H_3R_3$ (HR)

Note:
H: Isoniazid (INH), 600mg (300mg x 2 tablets) / dose
R: Rifampicin (RFP): 600mg (300mg x 2 capsules) / dose
Z: Pyrazinamide (PZA) 2,000mg (500mg x 4 tablets) / dose
E: Ethambutol hydrocloride (EB), 1250mg (250mg x 5 tablets) / dose
S: Streptomycin sulfate (SM), 750mg (50mg x 1 vial) / dose
For example,
$2H_3R_3Z_3E_3S_3$ means that INH, RFP, PZA, EB, and SM are taken three times a week (every other day) for two months.

B) Water for Injection (made by GMP-certified factory, complying with Chinese Pharmacopoeia)

Water for injection will be procured in 5-ml vials to dissolve each vial of streptomycin sulfate for injection.

C) Syringes (made by ISO9002-certified factory, complying with Chinese standard)

5-ml disposable syringes with needles that are necessary for dissolving streptomycin sulfate and performing intramuscular injection will be procured.

D) Binocular Microscopes (made by ISO9001 & 14001-certified factory)

Binocular microscopes to determine the presence of TB bacilli (acid fast bacilli) in sputum smears will be procured.

E) Pamphlets, Posters, and PR Boards for Publicity and Educational Purposes

Brochures, posters, and bulletin boards will be procured for publicity and educational purposes. To enable ethnic minority groups to understand the DOTS strategy, Chinese Mongol bilingual versions will be distributed in Inner Mongolia Autonomous Region and Chinese Tibetan bilingual versions in Tibet Autonomous Region.

4) Contents and Quantities

① Contents and Quantities of Main Items to be Procured

Table 2-6 below lists the contents, quantities, and use of main items to be procured by this project.

Table 2-6 Contents and Quantities of Main Items to be Procured

No.	Item	Contents	Use / Calculation	Quantity
1	Anti-TB drug HRZE	15 sheets/box (1-month dose)	For new smear-positive cases, 22 boxes/10 pts For new smear-negative (severe form) cases, 20 boxes/10 pts For retreatment smear-positive cases, 23 boxes/10 pts	567,793 boxes
2	Anti-TB drug HR	15 sheets/box (1-month dose)	For new smear-positive cases, 40 boxes/pts For new smear-negative (severe form) cases, 40 boxes/pts	836,864 boxes
3	Anti-TB drug HRE	15 sheets/box (1-month dose)	For retreatment smear-positive cases, 60 boxes/pts	298,698 boxes
4	Drug for injection	30 vials/box	For retreatment smear-positive cases, 345 vials/10 pts	57,250 boxes
5	Water for injection	5ml/vial 30 vials/box	For dissolving drug for injection, same quantity as drug for injection	57,250 boxes
6	Syringe	5ml with 22G needle, 30 syringes/box	For injecting drug, same quantity as drug for injection	57,250 boxes
7	Micro-scope	Binocular, oil immersion (100x)m mold resistant	For sputum smear examination. Microscope will be procured for the sites at which existing units are out of working order and the sites lacking microscopes. 1)*	310 units
8	Pamphlet	Chinese, Chinese + Mongol, Chinese + Tibetan, 1,000sheets/bundle	For patient education. 20 times the number of TB patients. Distributed to all persons receiving TB examination.	5,187 bundles
9	Poster	Chinese, Chinese + Mongol, Chinese + Tibetan, 1,000sheets/bundle	For inhabitant education. 100 sheets/province, 100 sheets/district, 50 sheets/county, 5 sheets/town, 2 sheets/village.	867 bundles
10	County PR board	Chinese, Chinese + Mongol, Chinese + Tibetan, PVC, water proof, metal frame	PR in counties. One set for each new county in the project. 5 sheets/set.	276 sets
11	Town PR board	Chinese, Chinese + Mongol, Chinese + Tibetan, PVC, water proof, metal frame	PR in towns. One sheet for each new town in the project.	1,839 sheets
12	Inscription plate	65 x 45 cm copper plate	PR of Japanese assistance. One plate for each new city and each new county in the project.	125 plates

1)* One unit per 500,000 population. Replacement of unusable units and addition of new units. (1 unit for a population less than 500,000, 2 units for 500,000-999,999, 3 unit for 1,000,000-1,499,999, 4 units for 1,500,000 or more.) Addition and replacement will be conducted also in the areas covered by Phase I to III projects.

② Quantities to be Distributed to Each Province and Autonomous Region

The quantities of anti-TB drugs have been calculated by applying the calculation criteria in Table 2-4 to the number of patients, starting from the estimated number of patients in 2005 (Table 2-3) and adding a 25% buffer stock and subtracting the stock in each province. However, if the value in Table 2-7 is negative, the quantity to be procured was set at zero. Tables 2-8 and 2-9 shows the quantities of anti-TB drugs, water for injection, syringes, microscopes, educational pamphlets, posters, PR boards, and inscription plates to be distributed to each province.

Table 2-7 Number of Patients for Calculating the Quantity of Anti-TB Drugs

Province	a. Quantity of Drugs Including Buffer Stock (25%) (Unit: No. of Patients)			b. Quantity of Drugs in Store at the End of December 2003 (Unit: No. of Patients)			c. Quantity of Drugs that must be supplied for 2005 (Unit: No. of Patients) = a.-b.		
	New Smear-positive	Retreatment Smear-positive	New Smear-negative, Severe Form	New Smear-positive	Retreatment Smear-positive	New Smear-negative, Severe Form	New Smear-positive	Retreatment Smear-positive	New Smear-negative, Severe Form
Sichuan	27,112	9,183	6,263	-846	25	-141	27,958	9,158	6,403
Qinghai	2,028	719	411	711	575	-236	1,317	144	646
Henan	31,414	7,762	4,693	-2,659	9,799	282	34,073	-2,037	4,411
Inner Mongolia	6,679	2,839	1,275	565	1,894	73	6,114	945	1,203
Jiangxi	12,516	4,369	2,429	-197	2,089	-293	12,714	2,279	2,723
Shaanxi	13,103	7,187	2,642	-1,631	355	-742	14,734	6,832	3,383
Anhui	16,232	9,444	3,297	344	2,031	-219	15,888	7,413	3,515
Guizhou	14,898	5,471	2,752	-1,488	2,046	-1,173	16,387	3,425	3,925
Yunnan	16,898	8,036	3,209	622	904	-264	16,276	7,132	3,472
Shanxi	9,811	5,966	1,162	-728	-179	367	10,539	6,145	795
Guangxi	17,249	8,585	3,450	125	2,522	-785	17,123	6,063	4,234
Tibet	1,739	356	280	568	114	80	1,171	242	200
Total	169,678	69,918	31,863	-4,615	22,178	-3,048	174,293	47,740	34,911

Table 2-8 Quantities of Equipment and Supplies to be Distributed to Each Province and Autonomous Region: Anti-TB Drugs

Province	Anti-TB Drug			Injection		
	HRZE 15 Sheets/box	HR 15 Sheets/box	HRE 15 Sheets/box	SM 30 Vials/box	Solution 30 Vials/box	Syringe 30 Vials/box
Sichuan	95,381	137,452	54,948	10,532	10,532	10,532
Qinghai	4,523	7,856	864	166	166	166
Henan	83,785	153,940	0	0	0	0
Inner Mongolia	18,030	29,268	5,670	1,087	1,087	1,087
Jiangxi	38,661	61,748	13,680	2,622	2,622	2,622
Shaanxi	54,901	72,476	40,998	7,858	7,858	7,858
Anhui	59,038	77,616	44,484	8,526	8,526	8,526
Guizhou	51,781	81,248	20,556	3,940	3,940	3,940
Yunnan	59,157	78,996	42,792	8,202	8,202	8,202
Shanxi	38,912	45,336	36,876	7,068	7,068	7,068
Guangxi	60,088	85,436	36,378	6,972	6,972	6,972
Tibet	3,537	5,492	1,452	278	278	278
Total	567,793	836,864	298,698	57,250	57,250	57,250

Table 2-9 Quantities of Equipment and Supplies to be Distributed to Each Province and Autonomous Region: Microscopes, Pamphlets, and Posters

Province	Microscope	Pamphlets	Poster	PR Board		Inscription Plate
	Unit	1,000 Sheets/pack	1,000 Sheets/pack	For Counties and Higher Levels 5 Boards/set	For Towns Boards	Plates
Sichuan	48	871	155	8	0	0
Qinghai	5	43	24	14	14	5
Henan	47	770	125	32	35	13
Inner Mongolia	5	166	56	18	244	5
Jiangxi	47	355	58	40	492	28
Shaanxi	5	500	87	14	32	3
Anhui	56	537	78	34	340	17
Guizhou	11	475	66	16	78	6
Yunnan	18	538	60	29	160	12
Shanxi	29	350	76	36	281	24
Guangxi	9	549	47	15	0	0
Tibet	30	33	35	20	163	12
Total	310	5,187	867	276	1,839	125

2-2-3 Procurement Plan

1) Procurement Policies

Item	Procured from			Reason
	Japan	China	3rd country	
4 oral anti-TB drugs: (isoniazid, rifampicin, pyrazinamide, ethambutol hydrocloride)	○	○		These items are manufactured both in China and Japan.
Streptomycin sulfate for injection	○	○		
Water for injection	○	○		
Syringe	○	○		
Microscope	○	○		

2) Remarks Concerning Procurement

Chinese products will be shipped directly from the manufacturing plants to the warehouse of the Health Bureau (within the TB Center or Laboratory) situated in the capital of each province via railway, but trucks or air transport may be used for shipping items destined for Tibet Autonomous Region. Some Chinese-made microscopes may be shipped out of Japanese inspection facilities. The Chinese side is responsible for transporting the items from the provincial capitals to the health units of each target city or county.

Pharmaceutical supplies will be delivered in three installments by taking into account their effective shelf lives as follows:

1st shipment: 40% of all drugs and syringes and 100% of other items by the end of March 2005

2nd shipment: 40% of all drugs and syringes by the end of July 2005

3rd shipment: 20% of all drugs and syringes by the end of December 2005

The effective shelf life of the drugs and syringes is two years. Usually, pharmaceutical products with a remaining shelf life of 75% (18 months) or longer are eligible for shipment. However, to avoid delivering products from the same production lot in two consecutive shipments that are four months apart, the required remaining shelf life shall be set at 22 months.

Responsibility of the Japanese Side	Responsibility of the Chinese Side
To the warehouse of the Health Bureau of each Province	From the warehouse of each Provincial Health Bureau to municipal/county sites

3) Scope of Works

Works to be undertaken respectively by the Japanese and Chinese sides with regard to the procurement and delivery of the equipment and supplies are divided as follows:

Division of Work	Japan	China
Procurement	All equipment and supplies	None
Transportation	To the Health Bureau's warehouse in each Provincial capital	From each Provincial capital to county sites
Assembly of Microscopes	Assembly instruction in each Provincial capital	Transportation to and assembly at each county site

While most items will be transported by rail, truck or airfreight may be used for shipping goods to Tibet Autonomous Region. Foreign-made products will be transported from the port (or airport) of import to the storage facility of the Health Bureau of each province. Although no installation work is needed for this Project, some assembly is required for setting up microscopes, for which a Japanese engineer (from the microscope manufacturer) will be dispatched to China to instruct the assembly procedure of microscopes.

4) Procurement Supervision Plan

A chief consultant, procurement planning supervisor-1, and procurement planning supervisor-2 will be assigned to the Project to provide consultation services.

5) Quality Control Plan

① Sampling inspection of pharmaceutical items

Pharmaceutical items manufactured in China will be checked by SFDA inspection (central) at the time of shipment from factory.

② GMP (Good Manufacturing Practice)

Pharmaceutical items shall be procured only from manufacturers that have obtained GMP certification.

③ Mold resistance

Microscopes shall be mold resistant, as molds tend to grow on them in high humidity.

④ ISO (International Standardization Organization)

Syringes and microscopes shall comply with applicable ISO standards for quality and environmental issues.

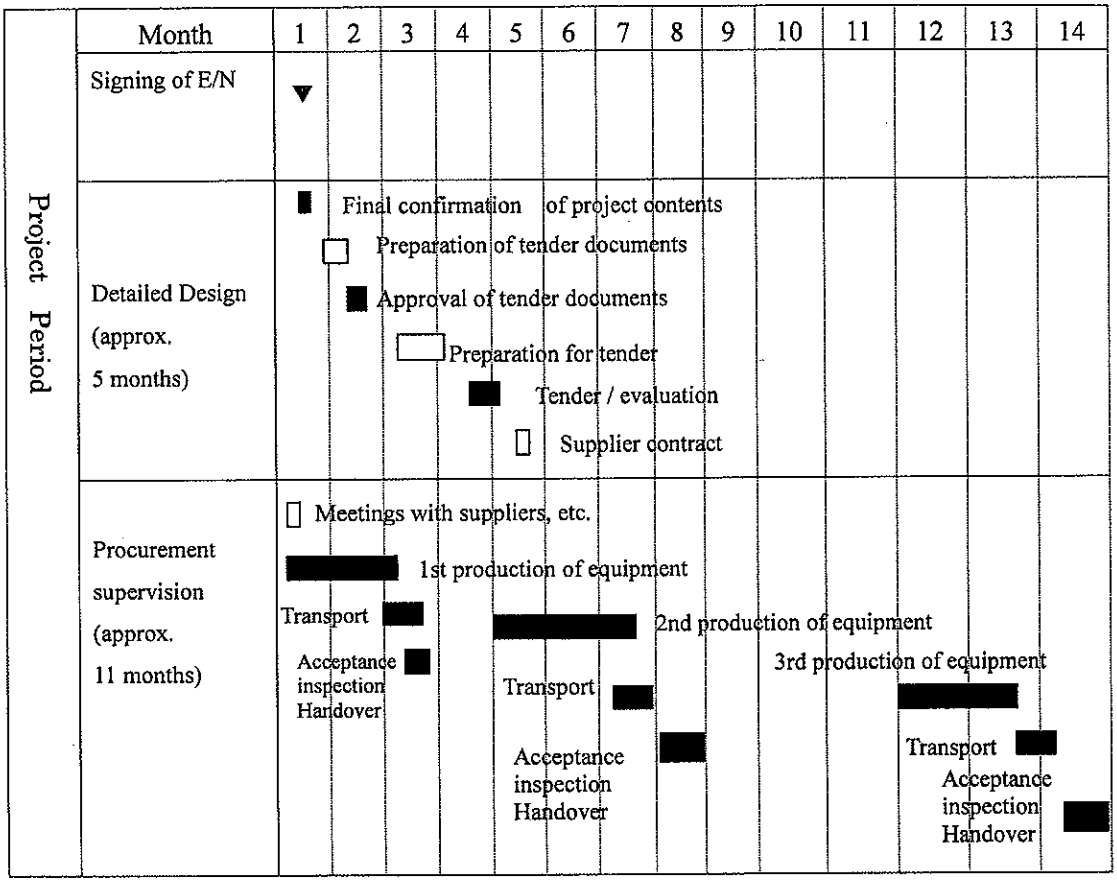
6)Procurement Plan

Item	Procured from			Route
	Japan	China	3rd country	
4 oral anti-TB drugs: (isoniazid, rifampicin, pyrazinamide, ethambutol hydrocloride)		○		Chinese products will be shipped directly from their factories to the storage house of each Provincial Health Bureau by rail. However, truck or airfreight may be used for transporting goods to Tibet Autonomous Region.
Streptomycin sulfate for injection		○		
Water for injection		○		
Syringe		○		
Microscope		○		

* Although these items are produced in Japan, Chinese products will be procured because of superiority in standards, permission/approval requirements, and price.

7) Implementation Schedule

Total project period (from E/N to handover): 18 months
From E/N to supplier contract: 4 months
Delivery (from supplier contract to handover): 14 months



Works at project site Works in Japan

2-3 Obligations of the Recipient Country

In implementing this Project, the Chinese side shall be responsible for:

① Ensuring proper and prompt customs clearance procedures for the equipment and supplies to be procured and imported into China for this Project,

② Securing sufficient storage spaces to keep the equipment and supplies,

③ Transporting and distributing the equipment and supplies from the official warehouses of the target provinces and autonomous regions to their final destinations,

④ Assigning experts of the central government to teach the operation and maintenance of microscopes to their actual users in lower-level organizations,

⑤ Appropriating a sufficient fund for the implementation of DOTS,

⑥ Ensuring the proper operation, use, and maintenance of the equipment and supplies,

⑦ Paying service fees for the issuance of the Authorization to Pay (A/P) and banking charges associated with the payment according to A/P, and

⑧ Evaluating the usage and stocktaking (quarterly) of anti-TB drugs and reporting the result to the Japanese side.

2-4 Project Operation and Maintenance Plan

The equipment and supplies to be procured by this Project will be delivered directly to the warehouse of the Health Bureau of each target Province/Autonomous Region, which will distribute needed quantities of the equipment and supplies to lower-level organizations according to the TB control system. Medical supplies are usually stored in the TB Prevention Clinic of each county. The county-level storage is well controlled and documented. If a person is diagnosed with TB at a county clinic, the patient himself or herself will directly receive a one-month supply of anti-TB drugs from the county clinic and bring them back to the health dispensary of the village, in which he/she lives. The patient will have to swallow the drugs in front of a village doctor working at the dispensary that the patient is to visit every other day. In case of retreatment, the village doctor injects streptomycin sulfate into the patient. TB patients are required to visit the county hospital once in every month or two months for checkup or medication until the treatment regimen is completed.

Through the technical guidance to be provided by the Ministry of Health and WHO (education, training, and supervision), certain skills and techniques will be passed down to the health workers in the target areas of this Project. As for the operation and maintenance of microscopes, experts will be assigned to train the local technicians, and the manufacturers' Chinese agents will be providing spare parts, repair work, and other after-the-sales services. In view of the foregoing in addition to the fact that all items to be procured by this Project will be of a basic kind, major problems are unlikely to occur with regard to their operation and maintenance.

2-5 Estimated Project Cost

2-5-1 Estimated Cost of Assistance Project

1) Cost to be borne by the Japanese Side

If this Project is to be implemented under Japan's Grant Aid scheme, it would incur an estimated cost of about 405 million yen. The itemized cost to be borne by the Japanese and Chinese sides respectively based on the scope of works as defined above, as well as the parameters of estimation as described in the subsequent paragraph, is estimated as shown in Table 2-10 below.

Note that this estimated project cost does not directly indicate the limit amount of assistance on the exchange of notes.

Table 2-10 Estimated Project Cost

Division of Work	Amount (million yen)
Equipment Procurement Cost	384.4
Equipment Cost	375.9
On-site Procurement Supervision Cost	8.5
Equipment Design Supervision Cost	32.9
Implementation Design Cost	17.3
Procurement Supervision Cost	15.6
Total	41.7

Note: Exchange Rates : Yen/US$ 1 US$=110.17 yen
: Yen/Local Currency Local Currency = 13.17 yen

2) Cost to be borne by the Chinese Side

The Chinese side will pay for the cost of transporting the equipment and supplies from the warehouse of the Health Bureau in each provincial capital to county TB prevention clinics.

3) Parameters for Calculation

① Time of calculation:

March 2004

② Exchange rate:

1US$ = 108.07 yen 1 yuan = 13.05 yen

③ Implementation period:

This project will be implemented as a single fiscal-year project. The time period required for each implementation process is outlined in the implementation schedule.

④ Miscellaneous:

This project will be implemented according the framework of Japan's Grant Aid scheme.

2-5-2 Operation and Maintenance Cost

At the central level, the annual budget of the Ministry of Health for disease control is about 190 million yuan (about 2.57 billion yen), including 48 million yuan (about 650 million yen) allocated to TB control. On the other hand, the 2004 budgets of each province allocated for the DOTS strategy are as listed in the table below. A 10% increase is expected in 2005. (Budget of the central government is not included in Table 2-11.)

Table 2-11 2004 Budgets for TB Control (10 million yen)

Province	WB/DFID	GFATM	DFB	Local Government	Central Government
Sichuan	0.00	55.66	0.00	12.18	7.32
Qinghai	0.00	1.76	0.00	2.40	0.00
Henan	14.57	2.34	0.00	14.43	0.00
Inner Mongolia	6.17	1.86	2.46	5.72	0.00
Jiangxi	2.52	4.14	0.00	35.41	0.00
Shaanxi	30.55	2.51	0.00	15.89	0.00
Anhui	0.00	13.82	0.00	6.91	0.00
Guizhou	11.08	2.01	0.00	1.16	0.00
Yunnan	25.69	2.35	0.00	12.66	0.00
Shanxi	0.00	9.48	0.00	9.91	0.00
Guangxi	36.03	1.55	0.00	4.85	0.00
Tibet	0.00	9.49	0.76	1.63	0.00
Total	126.62	106.97	3.21	123.16	7.32

1 yuan = 13.50 yen

2-6 Points to be Noted Concerning Implementation of Assistance Project

1) Timing of Procurement of Equipment and Supplies

In new target areas, equipment and supplies must be delivered without delay so that the DOTS strategy can be started promptly after medical personnel complete training in sputum smear examination and in the methods for recording and reporting test results in new target areas, as well as the activities in existing target areas can be continued without suffering from shortage of drugs.

2) Confirmation of Effective Utilization of Anti-TB Drugs

As confirmed in the minutes of discussion, proper distribution of anti-TB drugs to the patients in the target areas must be confirmed based on the quarterly reports obtained from the Government of China. The beneficial effects of the project must be verified based on annual reports, so that the findings may be reflected in future support plans.

3) Coordination with Other Donors

This project is based on the technical guidance and support from the WHO and also supported by the involvement of the UK Department for International Development, Damian Foundation Belgium, CIDA, GFATM and other donors. Close coordination among these donors, such as regular meetings for adequate information exchange and participation in joint evaluation by donors, is essential to the enhancement of the effectiveness of Japanese grant aid assistance.

4) Value-added Tax (VAT)

In September 2001, the Government of China decided to exempt the items procured under Japanese grant aid assistance from VAT on Chinese products. The Ministry of Health and the supplier must jointly submit application for VAT exemption to the Ministry of Commerce and the State Administration of Taxation after conclusion of supplier contract.

5) Disposal of Syringes

Syringes for TB treatment are used in small quantities, and on-site personnel (village physicians) usually use about one syringe a day. Thus, the project does not increase the burden of medical waste treatment. However, syringes must be disposed of by incineration after use to avoid the risk of medical accidents such as secondary infection of HIV and hepatitis B virus.

Chapter 3 Project Evaluation and Recommendations

3-1 Project Effects

(1) Direct Effects

① Persons suspected to have TB (10 to 20 times as many as the approximately 217,000 TB patients) are examined properly.

② TB patients in the poor areas covered by the project receive appropriate treatment with anti-TB drugs free of charge.

③ More than 85% of the 217,000 TB patients are cured completely.

(2) Indirect Effects

① By properly treating patients discharging TB bacilli, the risk of infection to their families and neighbors will be reduced.

② TB patients, after successful treatment, will be facilitated to become productive members of society again.

③ Procurement of microscopes will enhance the pathogen testing systems of local governments.

3-2 Issues and Recommendations

To maximize the effect of this Project, the following agenda need to be examined.

(1) Continuation of Grant Aid

Japan has been providing grant-aid assistance to support microscopic sputum smear examination and the regular supply of anti-TB drugs, which are two of the five key components of the DOTS strategy. Considering the vital importance of not interrupting DOTS programs, as well as the financial conditions of the local governments in poor areas, Japan's assistance should be continued for five years (2005 being the 4th year) as originally requested by the Government of China.

(2) Partnerships and Coordination with Other Donors

WHO is conducting joint missions consisting of TB specialists from various donors every year. Japan should continue to participate in these missions and carry on the monitoring and evaluation of this Project. It is important to ensure coordination and sharing of plans and objectives related to TB control with other donors and the Chinese side through information exchange at donor meetings that are held regularly.

(3) Contribution to Human Resource Development

Japan has been adopting various methods to educate and train Chinese experts and technicians engaged in TB control. Future expansion of the DOTS strategy will require further improvement of the capabilities of on-site leaders and personnel. Training sessions for supervisors of provincial TB prevention clinics will be held in April of this year as a part of the soft component plan in Phase III. In addition to such efforts, appropriate technical cooperation should be conducted as necessary, such as the dispatch of Japanese specialists and acceptance of trainees.

(4) Elongation of the Shelf Life of Anti-TB Drugs

The State Food and Drug Administration of China defines the expiration period of all drugs in the country to be two years. While the quantities of anti-TB drugs provided by this project have been calculated based on the estimated number of patients in 2005, accurate prediction of the number of patient is extremely difficult. Because the shortage of drugs directly leads to the interruption of the treatment of patients, a buffer stock of drugs must also be provided, and this may result in generation of surplus drugs. Unless utilized cleverly by coordination among provinces, some of the surplus drugs are discarded due to expiration of shelf life. A way to minimize such waste of drugs is the elongation of the expiration period from two to three years, which is widely accepted in the world. The Japanese side has proposed that the Ministry of Health may consider such measures.

(5) Appropriate Allocation of Microscopes

The study by the WHO joint evaluation mission in 2003 confirmed that two microscopes provided by this project were located at the same county TB prevention clinic. Because dispersed allocation is desirable for the sake of more effective detection of patients, the Japanese side requested the Ministry of Health to develop guidelines for appropriate allocation of microscopic examination rooms in this project.

(6) Monitoring and Evaluation

WHO, donors, and the Ministry of Health are conducting joint evaluation of assistance projects in China every year, and TB specialists from Japan are participating in this evaluation. Japan should continue this participation for continued monitoring and evaluation of this project.

〔Annex〕

Annex 1 Member List of the Study Team

1. Study Team Members; Names and Affiliations

	Name	Responsibility	Affiliation
(1)	Satoshi Iwakiri	Chief	Deputy Manager, JICA China Office
(2)	Masashi Suchi	Technical Councilor	Manager, Department of International Cooperation, The Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association
(3)	Hitomitsu Ohashi	Equipment Procurement Planning	General Grant Aid Management Division, Grant Aid Management Department, Japan International Cooperation System
(4)	Yoko Ishikawa	Analysis and Evaluation of Effects	General Grant Aid Management Division, Grant Aid Management Department, Japan International Cooperation System
(5)	Naoko Iimura	Interpreter	Training and Supervision Department Japan International Cooperation Center

Annex 2 Study Schedule

	Day		Itinerary	Of/JICS	Lodging
1	2.29	Sun	10:35 Narita (NH905) to 13:35 Beijing		Beijing
2	3. 1	Mon	JICA Office, meeting 10:30 Ministry of Health, greeting & discussion 14:00		Beijing
3	3. 2	Tue	Maker survey (pharmaceutical factory in Hebei) 11:00		Beijing
4	3. 3	Wed	Maker survey (travel day) 10:00 Beijing (CA1519) to 12:00 Shanghai		Shanghai
5	3. 4	Thu	Maker survey (Shanghai Meilang Screen Printing Factory) 16:30 Shanghai (CA1518) to 18:30 Beijng		Beijing
6	3. 5	Fri	CDC, discussion 10:00 SFDA, discussion 14:00 Maker survey (Zhongde Printing) 16:00		Beijing
7	3. 6	Sat	Data filing		Beijing
8	3. 7	Sun	10:35 Narita (NH905) to 13:35 Beijing		Beijing
9	3. 8	Mon	WHO, discussion 9:00 JICA Office, Meeting 13:00 Ministry of Commerce, greeting & discussion 15:00 Japanese Embassy, greeting & discussion 16:30		Beijing
10	3. 9	Tue	Donor meeting 9:00, JICA Office CDC, discussion 14:00		Beijing
11	3.10	Wed	CDC, discussion		Beijing
12	3.11	Thu	A.M. CDC, discussion P.M. Minutes discussion		Beijing
13	3.12	Fri	Minutes discussion, signing, exchange Report to Ministry of Commerce 14:00 Report to Japanese Embassy 16:00 Report to JICA Office 17:30		Beijing
14	3.13	Sat	8:30 Beijing (NH956) to 12:40 Narita		

Annex 3 List of Parties Concerned in the Recipient Country

Embassy of Japan in China	Airo Komiyama	First Secretary (Health Care)
	Kazuaki Omori	First Secretary (Chief of Economic Cooperation Section)
	Umitaro Nonomura	Second Secretary
JICA China Office	Satoshi Iwakiri (Chief)	Supervising Vice Manager
	Satoshi Nakamura	Staff
	Wang Xin	Local Staff
Ministry of Commerce	Kang Bingjian	Ministry of Commerce (Vice Manager)
Ministry of Health, International Cooperation	Yin Li (Signing Person)	Director
	Dai Wei	Interpreter
Ministry of Health, Disease Conrol	Wan Liya	Manager-Level Researcher, in Charge of TB Control
Ministry of Health, Disease Conrol	Cheng Shiming	Vice Superviser of TB Prevention and Control Center
Ministry of Health, Disease Conrol	Wang Lin (in Charge of the Project)	Supervisor of Health Improvement Division, TB Prevention and Control Center
Ministry of Health, Disease Conrol	Lai Yuji	TB Prevention and Control Center
Ministry of Health, Disease Conrol	Fang Gun	Manager of General Affairs Section, TB Prevention and Control Center
State Food and Drug Administration	Zhu Jiong	Pharmaceuticals Department
(SFDA)	Wang Jiawei	International Department
WHO China Office	Daniel Chin	Infection Control Project
	Wang Li Xia	TB Control Project
DFID	Peter Shelley	China Office
Damian Foundation Belgium	Jaucot Alex	Representative of China Office
Zhongyi International Tendering Co., Ltd.	Tao Xiangrong	Vice General Manager (Customs Clearance Services, Ministry of Health)
Shijiazhuang Pharmaceutical Group Co., Ltd.	Zhao Guolin	Vice General Manager
	Liu Weizhuo	International Department
	Dong Qingjie	International Department
Shanghai Meilang Screen Printing	Yang Hanping	General Manager
Beijing Meilang Screen Printing	Liu Jinying	Business Department
Zhongde Printing	Qin Yu	
Empire Printing	Chai Yong	Sales Department
Kinko's	Zhang Xuefei	Sales Department

中华人民共和国
第四期贫困地区结核病控制计划简易器材调查
会谈纪要

根据中华人民共和国的申请，日本政府决定对“中华人民共和国第四期贫困地区结核病控制计划”（以下称计划）进行简易器材调查，并委托给独立行政法人国际协力机构（以下称 JICA）。

JICA 自 2004 年 2 月 29 日至 3 月 13 日向中华人民共和国派遣以 JICA 中国事务所副所长岩切敏为团长的简易器材调查团（以下称调查团），在与中华人民共和国政府有关方面（以下称中方）进行协商，并进行了实地调查。

经协商及实地调查结果，双方确认了附属文件所示的主要事项。日方调查团将继续进行调查，将汇总为简易器材调查报告书。

本会谈纪要由正文和附属文件构成，用中文和日文各制三份，两种文本具有同等效力，各有关机构在同意的基础上署名，各执一套。

2004 年 3 月 12 日　于北京

中华人民共和国
卫生部
国际合作司 司长
尹 力

日本国
独立行政法人国际协力机构
简易器材调查团长
岩切　敏

见证人
世界卫生组织
驻华代表处
代表
Henk　Bekedam

附属文件

1．本计划的目的

为了在2010年以前治愈400万结核病患者，中国政府在全国推进直接面视下短程督导化疗（DOTS）结核病对策，向日本国政府提出在经济较困难的九个省和三个自治区为采购DOTS策略实施时必要的抗结核药品及显微镜等提供无偿资金援助的申请。本无偿资金援助项目的目的是：以通过采购中方推进的2005年计划必要的物资和器材，进行援助。

2．对象地区

本计划的对象地区是九个省、三个自治区（河南、云南、贵州、广西、山西、陕西、青海、内蒙古、四川、安徽、江西、西藏）。各省、自治区的项目对象县数如附件1所示。

3．负责单位和实施单位

本计划的负责单位是中华人民共和国商务部，实施单位是中华人民共和国卫生部。

4．申请内容

通过与本调查团的磋商，中方最后申请的物资和器材如附件2所示。

5．援助的基本方针

JICA通过今后实地调查和日本国内分析，验证其申请内容的妥当性，判断适合于无偿资金援助时，向日本政府建议批准本项目。但是本项目物资器材的品种、规格及数量，需在日本经过分析并考虑日本政府有关本项目的预算金额作出最后决定。

6．日本无偿资金援助的制度

本调查团就附件3所示的日本国无偿资金援助制度再次作了说明，中国方面对此表示充分的理解。同时中方理解了附件4所示的在实施本项目无偿资金援助时为顺利落实本项目中方应采取的必要措施，表示将来实施该措施。

7．今后的调查

JICA将编写简易器材调查报告书，于2004年7月份左右向中方发送。

8．其他协商事项

8-1 本计划的药品量测算标准

中国方面基于 2002 年及 2003 年结核病对策的实际实施情况以及今后实施可行性，向日方说明本测算标准。日方确认了本标准是中国国家结核病对策的标准，而不是只限于本计划的测算标准。

8-2 DOTS 快速扩大

日方对中方强烈要求 DOTS 快速扩大的省份也要确保结核病对策的质量而恰当实施 DOTS。中方同意在 WHO 的合作下恰当地进行督导，出现预料不到的情况时进行妥善处理并迅速向日方联系。

8-3 采购器材的使用

通过本计划的实施所采购的抗结核药品等，双方确认了按照 DOTS 策略免费供于使用，并采取防止转卖的措施。另外，中方确认，对药品和显微镜做好适当的管理，每个季度汇总结核病对策报告，向日本国驻华使馆和 JICA 中国事务所提交。

8-4 药品的库存管理

为了做到按照结核病对策的记录和报告的恰当的药品供给，日方建议在省级保管通过本计划采购的一定量抗结核药品，根据对象地区实际患者数合理实施药品供给，中方表示同意。

中方确认，每季度汇总本计划所采购药品在各省区的库存量，一年一次向日本国驻华使馆和 JICA 中国事务所提交。

8-5 结核病对策实施情况的评估和指导

中方说明，关于结核病对策实施情况，准备中方有关人员以及外部专家实施定期性的评价和指导。双方确认在本计划的实施和督导上继续与 WHO 密切配合。中方与 WHO 合作而实施活动，进行评价，将结果向日本国驻华使馆和 JICA 中国事务所通报。

另外，日方希望，根据中国疾病预防控制中心的工作计划尽早增加结核病预防控制中心的人员并加强机构。

8-6 确保实施体制

中方保证，尽快完善为有效使用通过本计划采购的药品、显微镜等所必要的实施体系，并确保为完善设施、确保人员、人员培训、检查费、管理费、督导费、维护管理费等的实施结核病对策时必要的经费，以顺利地实施本计划。另外，中方保证，在确保经费方面，利用其它援助机构的贷款以及全球艾滋病、结核和疟疾基金的资金援助等。

8-7 技术合作

为了适当地利用所采购的药品和显微镜等，并在项目对象地区依照 DOTS 策略有效实施结核病控制措施，中方要求继续实施中国国内培训以及派遣赴日进修员。中方说明，希望日本专家参加今后进行的世界卫生组织等外部专家进

行的联合评估。日方理解联合评估的有效性。

8-8 对中国国民的宣传

中方保证，就结核病知识、DOTS 策略、免费治疗等结核病对策向居民进一步开展启发宣传活动。另外中方要求，为了进一步开展面向少数民族的启发宣传活动，制作写有藏语和汉语的、以及写有汉语和蒙语的宣传册、宣传画及宣传板，双方达成一致意见。

8-9 理解日本的援助

日方要求，本计划是通过日本无偿资金援助实施的，为了使当地居民对此有更加广泛地了解，在本计划采购的抗结核药品等的包装上应标明日本援助的字样，并在项目对象单位挂牌匾，同时由中方进行必要的宣传活动，中方对此表示同意。中方保证，将在中国国内通过报纸、电视等新闻媒体等广泛地宣传本无偿资金援助项目的日本援助，努力取得中国国民的理解。

8-10 抗结核药品质量的保证

日方指出进一步提高抗结核药品质量的必要性，中方也表示同意。

8-11 适当布置显微镜

中方要求，就人口 100 万以上的县补充提供显微镜。日方表示，为进一步提高患者发现率，需要中方做出有关显微镜检验室适当布置的指南，在中方同意的前提下，在可能的范围内同意追加。

8-12 信息系统的改善

这次中方提出要求提供计算机，对此要求日本方面说明，本计划的总体规划内没有包括该设备，计算机的提供是很困难的。对此，中国方面说明了项目的实施体制以及该设备在本项目内的利用方针等，再一次要求本期项目包含计算机。

最后双方达成一致意见，即：根据今后全球基金的计算机供应状况及其利用情况，研究下期以后是否加在提供器材之内。

8-13 免税措施

于 2002 年 1 月中国政府决定：通过日本无偿资金援助在中国国内采购中国产品的时候，免征对其发生的增值税(VAT)。该措施可适用于本计划。另外，中方为免征除此以外的各种税金，对有关部门采取必要的措施。

附件 1 省别对象县数

附件 2 申请物资和器材清单

附件 3 日本无偿资金援助制度

附件 4 日中两国政府的主要分担事项

附件 1

省别对象县数

	省名	2002 年	2003 年	2004 年	2005 年	总计
1	四川	10	21	149	0	180
2	青海	23	7	12	5	47
3	河南	65	38	11	13	127
4	内蒙古自治区	30	30	36	5	101
5	江西	11	30	30	28	99
6	陕西	18	59	27	3	107
7	安徽	24	33	10	17	84
8	贵州	32	32	21	6	91
9	云南	30	41	46	12	129
10	山西	40	40	15	24	119
11	广西壮族自治区	20	40	32	0	92
12	西藏自治区	0	50	12	12	74
总计		303	421	401	125	1250

数据来自中方提出的项目县数

附件 2

申请物资和器材清单

	品种
1	口服抗结核药物（异烟肼、利福平、吡嗪酰胺、乙胺丁醇）
2	注射用抗结核药物（链霉素）
3	注射用水
4	注射器
5	双目显微镜
6	宣传册(汉语、汉语和蒙语、汉语和藏语)
7	宣传画(汉语、汉语和蒙语、汉语和藏语)
8	宣传板（省、地区、县）(汉语、汉语和蒙语、汉语和藏语)
9	宣传板（乡）(汉语、汉语和蒙语、汉语和藏语)
10	牌匾

注：汉语和蒙语的宣传材料向内蒙古自治区发放，汉语和藏语的宣传材料向西藏自治区和青海省发放。

测算标准

	品种	
1	口服抗结核药物	参阅下表
2	注射用抗结核药物	
3	注射用水	
4	注射器	
5	双目显微镜	按人口 50 万为 1 台的比率，对不能使用的显微镜进行更新和补充。（人口未满 50 万=1 台，50 万以上未满 100 万=2 台，100 万以上未满 150 万=3 台，150 万以上=4 台） 对第一期到第三期计划的实施单位，按同样标准进行补充、更新。
6	宣传册	患者数乘 20 张
7	宣传画	100 张/省，100 张/地区，50 张/县，5 张/乡，2 张/村
8	宣传板（省、地区、县）	1 套/省、地区、新启动县
9	宣传板（乡）	1 张/新启动乡
10	牌匾	1 张/新启动县

2005 年计算病人的标准

项目县的日援计划启动期	病人报告率(/100,000)	在涂阳病人中复治病人所占的比率(%)	重症涂阴病人占初治涂阳的比率(%)
2002	2003 年实际报告率+20%	2003 年的实际比率≤20%：2003 年的实际比率 2003 年的实际比率＜45%：减 10 个百分点 2003 年的实际比率≥45%:35%	2003 年的实际比率≥20%:20%; 2002/2003 年的实际比率＜20%:2003 年的实际比率
2003	2002/2003 年的平均报告率+20%	2002/2003 年的平均比率＜45%：减 10 个百分点 2002/2003 年的平均比率≥45%:35%	2002/2003 年的平均比率≥20%:20%; 2002/2003 年的平均比率＜20%:2002/2003 年的平均比率
2004	2002/2003 年的平均报告率+10%	2002/2003 年的平均比率＜45%：减 5 个百分点 2002/2003 年的平均比率≥45%:40%	2002/2003 年的平均比率≥20%:20%; 2002/2003 年的平均比率＜20%:2002/2003 年的平均比率
2005	2002/2003 年的平均报告率	2002/2003 年的平均比率	2002/2003 年的平均比率≥25%:25%; 2002/2003 年的平均比率＜25%:2002/2003 年的平均比率

注：1、涂阳病人登记率的基线低于 27/10 万时，以 27/10 万计算。

2、四川省以 2003 年 165 个项目县（包括 31 个日本项目县和 134 个世行项目县）的数据为基线，2005 年所有项目县的病人报告率：2003 年实际报告率+20%，在涂阳病人中复治病人所占的比率和初治重症涂阴病人的比率：2003 年的实际比率。

3、西藏以 2003 年的数据为基线，涂阳病人登记率年增长 10%，在涂阳病人中复治病人所占的比率和初治重症涂阴病人的比率保持不变

附件 3

日本无偿资金援助的制度

1. 无偿资金援助的实施程序

我国的无偿资金援助按照如下程序进行。

第一阶段的“申请”，日本国政府（外务省）根据受援国提出的申请书，研究其做为无偿资金援助的适当性，当确认其作为项目的优先度高时，指示 JICA 进行调查。

第二阶段的调查（基本设计调查）由 JICA 实施，不过 JICA 原则上采取与我国咨询公司签订合同的方法进行该调查。

第三阶段的审查和批准，根据第二阶段 JICA 编写的基本设计调查报告书，日本政府审查该项目作为无偿资金援助是否适当，然后提交内阁会议审议。

内阁会议批准的项目在第四阶段由两国政府签署换文后正式决定，无偿资金援助开始实施。

实施无偿资金援助时，JICA 就招标、签约手续及其他事项，对受援国政府给予协助。

2. 调查的定位

（1）调查的内容

JICA 实施的调查（基本设计调查）是调查申请的背景、目的、效果及实施时所必要的维护管理能力等，从技术方面和社会经济方面验证其适当性，在与受援国政府协商的基础上，双方确认计划的基本构想，同时进行基本设计并概算事业经费，其目的在于为日本政府提供作为无偿援助批准本计划所需的基础材料（判断材料）。

当然，申请的内容并不全部成为援助的对象，而是考虑我国无偿援助的方式等，确认计划的基本设想。

另外，作为无偿援助实施本项目时，我国从寻求受援国自主努力的立场出发，要求受援国采取必要的措施，即使该措施超过主管实施机构所管辖的范围，也向该机构要求保证实施该措施，最后以会谈纪要与对方政府相关的所有机构进行确认。

（2）咨询公司的选定

关于签署换文决定实施调查后的咨询公司签约，为了保证基本设计调查和详细设计业务在技术上的连贯性，JICA 向受援国政府推荐从事基本设计的咨询公司。

3. 无偿资金援助的方式

（1）什么是无偿资金援助

无偿资金援助是不要求受援国有偿还义务而向其提供资金援助，根据我国的有关法规，按照以下原则提供为采购有利于受援国自身经济社会发展计划的设施、材料器材及服务（技术和运输等）所必要的资金，我国不采取直接采购材料、器材、设备等以实物提供的方式。

（2）签署换文

实施无偿援助时需要政府之间达成协议、签署换文（E/N）。在 E/N 中确认该项目的目的、援助期限、实施条件、援助限额等。

（3）援助期限

“援助期限”在我国内阁会议决定的该会计年度内。在此期间必须完成从签署换文到与咨询单位及承包单位签约，直至最终付款的全部工作。

但是，如因气象等不可抗力的原因造成运输、安装、施工等的延误时，根据两国间的协议可延长一年（一个财政年度）。

（4）利用无偿援助所采购的产品及服务，原则上应合理地且专门地购买日本国及受援国的产品以及日本国民的服务。这里所说的“日本国民”是指日本国的自然人或其支配的日本国的法人。

此外，两国政府认为有必要时，无偿资金援助也可用于购买第三国（日本国和受援国以外的国家）的产品或运输等服务。但是，本着无偿援助的原则，实施无偿援助时所需的主要承包单位，即咨询单位、施工单位及采购单位仅限于“日本国民”。

（5）“认证”的必要性

受援国政府或政府指定的当局与“日本国民”之间应签订以日元支付的合同。并且有必要由日本政府“认证”。“认证”是因为无偿援助的资金来源是日本国民的税金。

（6）要求受援国采取的措施

实施无偿援助时要求受援国政府采取下列措施。

1）实施建设设施的项目时，落实建设设施所需的土地，并平整用地。

2）平整用地时，应进行至用地的供电、供水、排水及其他附带设施的装备、施工等。

3）对于提供材料器材的项目，应确保必要的建筑物等。

4）原则上应负担无偿援助资金所购入产品的港口卸货、报关及国内运输等所产生的经费，并确保迅速实施。

5）根据已认证的合同所采购的产品及服务中，应免除向日本国民征收的关税、国内税及其他财政税捐。

6）对根据已认证的合同而提供的日本国民的服务，为其履行工作而入境及逗留提供必要的便利。

7）合理使用

为实施该计划应合理且有效地维护并使用利用无偿援助所建设的设施和所购买的器材，并确保为此所需的人员等。并且，除了无偿援助所负担的经费以外，还应负担实施计划所需的维护管理费等所有经费。

8）再出口

利用无偿援助购买的产品不得从受援国再出口。

9）银行协定

（a）受援国政府或“受指定的当局”必须在日本国内的外汇认定银行开设受援国政府

名义的账户。日本国政府根据被认证的合同，将受援国政府或受指定的当局用于偿还所承担债务的资金，用“日元”汇入上述账户，以此实施无偿资金援助。

（b）“银行”根据受援国政府或受指定的当局发行的“支付授权书”，向日本国政府提交付款通知单时，日本国政府实施缴付。

10）支付授权书

受援国政府应负担向签订银行协定的银行付出的支付授权书通知手续费及支付手续费。

附件 4

日中两国政府的主要分担事项

	负担事项	日本	中国
1	根据银行协定（B/A）的手续费 ①支付授权书（A/P）发行手续费 ②支付手续费		 ● ●
2	到中国港口卸货业务和报关业务相关的经费 ①用无偿资金援助采购的产品自日本到中国的运输 ②用无偿资金援助采购的产品的免税、报关手续 ③用无偿资金援助采购的产品到计划对象省会的国内运输	 ● ●	 ●
3	根据合同采购的产品和劳务中，免除对日本国民征收的关税、国内税款及其它财政税捐		●
4	对根据已核定的合同而提供的日本国民的劳务，为其履行工作而入境和逗留提供必要的便利		●
5	为了实施本计划，通过无偿资金援助所购买的器材得到合理且有效的使用，做好所需维护管理工作		●
6	无偿资金援助没有包括的器材安装费等其它所需经费		●

Annex 6 List of References

No.	Title	Type
1	Reference Material for Phase IV Study of Japanese Assistance Project in TB Control, March 9, 2004 Version	Brochure
2	China Health Statistical Annual 2003	Book
3	China Health Yearbook 2003 (Chinese)	Book
4	China Health Yearbook 2003 (English)	Book
5	Material Concerning Japanese Assistance (2001-2002)	Brochure
6	TB Prevention and Treatment Plan, 2004 Operation Plan	Photocopy
7	Introduction of TB Control Project	Photocopy
8	2005 Japanese Assistance Project Plan (Presentation Material)	Powerpoint file
9	Progress of Japanese Assistance Projects (Presentation Material)	Powerpoint file
10	Fourth Call for Proposal of TB (Presentation Material)	Phbotocopy
11	China News, TB Special Issue	Brochure
12	Brochure of Meilang Printing	Brochure
13	Brochure of Shijiazhuang Pharmaceutical Group Co., Ltd.	Brochure

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