People's Republic of China
The Project for Tuberculosis Control in Poor Area
(Phase V)
Basic Design Study Report

July, 2005

Japan International Cooperation Agency

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 V) and entrusted the study to the Japan International Cooperation Agency (JICA).

JICA sent to China a study team from February 20 to March 12, 2005.

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

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

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

July 2005
Seiji KOJIMA
Vice-President
Japan International Cooperation Agency

List of Abbreviations

CDC	:	Center for Disease Control and Prevention (an independent entity under the Chinese Department of Health)
CIDA	:	Canadian International Development Agency
DOTS	:	Directly Observed Treatment, Short Course (see Glossary)
GFATM	:	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	:	Good Manufacturing Practice
JICA	:	Japan International Cooperation Agency
SARS	:	Severe Acute Respiratory Syndrome
SFDA	:	State Food and Drug Administration
TB	:	Tuberculosis
WB	:	World Bank
WHO	:	World Health Organization

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Location Map

the nationwide map of China

Province name

1. Xinjiang 新疆ｳｨｸﾞﾙ自治区
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

Chapter 1 Background of the Project

Although the Chinese government has been engaged in TB control measures since the end of 1970s, prior to the DOTS introduction the measures were based on the conventional treatment approach which did not accompany patient management and required a prolonged treatment period. They also imposed a huge financial burden onto the local governments as well as patients and their families, since all medical examinations and treatment used to be paid before these became free of charge in the areas included in the project. All of these factors combined have caused frequent interruption and resumption of treatment and consequently have resulted in developing drug-resistance, making the disease more difficult to cure and spreading it further.

China tentatively implemented TB control measures based on the DOTS strategy in 13 provinces and autonomous regions where the financial conditions were sound in 1992, with loans from the WB and technical assistance from WHO. On the other hand, the Western regions, the poverty areas with a larger number of TB patients, were not able to receive a loan from the WB because they had no means to repay under the financial difficulties. Also, more than 50% of the TB patients in these areas were faced with a problem that their financial conditions would not allow a receipt of effective medical treatment. That being the case, the government of China requested the government of Japan for extending grant aid assistance in procuring anti-TB drugs, microscopes and supplies necessary for expanding the DOTS strategy.

In response to the request, the government of Japan dispatched a study team in 2001 and started assistance in procuring goods and equipment necessary for TB control, including anti-TB drugs, microscopes, posters and others, in the project areas in 2002. As of today, 2005, the goods and equipment procured under phase 4 of the project are being distributed. The initial goal to "achieve the DOTS coverage to 90% by 2006" was already attained during the 2004 project implementation, and the coverage now in the project areas has already reached 100%. However, the improved coverage is not directly reflected in the number of TB patients, and the case detection rate in the country still remains as low as in the 30% range, which is far below the goal set by WHO, 70%. As a result, China still ranks the second in the High-Burden TB Country. In order to make the situation better,

the MOH has set new goals for TB control to improve the case detection rate to 70% by 2005 and 75% by 2006, whereby reducing the numbers of disease and death cases. On the other hand, the target 12 provinces and autonomous regions in this project have financial difficulties to address the TB issue by themselves, and they have requested Japan's grant aid assistance to procure anti-TB drugs needed for TB treatment, posters and brochures to be used in education and training activities, and computers and other tools to gather information, as a means of accomplishing the goal of Phase 5, improvement of the case detection rate. The goods and equipment requested by the Chinese side in Phase 5 include 230,000 doses of anti-TB drugs, 398 computers, 168 sets of laptop PCs and projectors, 2 million posters, 4 million brochures and 1,000 bulletin boards, to be distributed to the all target 1,250 counties of the 9 provinces and 3 autonomous regions in this project. The total cost estimate is approximately 500 million yen.

Chapter 2 Contents of the Project

Chapter 2 Contents of the Project

2-1 Basic Concept of the Project

The MOH has prepared the "Third National Program for the Prevention and Control of Tuberculosis (2001-2010)" for the TB control measures, aiming at strengthening the prevention and treatment of TB during the 10 years by 2010. The Ministry has set its specific goals at increasing the DOTS coverage to 100% by 2005, the detection rate of smear positive patients to 70% and the TB cure rate to 85%.

In order to contribute to the Program, the government of Japan has been providing assistance in procuring goods and equipment, such as anti-TB drugs, microscopes, etc., that are necessary to promote the DOTS strategy in the poor areas within the 9 provinces and 3 autonomous regions since 2002.

Under the original plan, the project intended to improve the DOTS coverage compared to the population in 5 years and set its numeric targets at 30%, 50%, 70%, and 80% for Phase 1 and onwards eventually achieving 90% in Phase 5. This final goal was, however, achieved during Phase 3 owing to the earnest efforts by the Chinese government and the effects of Japan's grant aid assistance. The coverage soon reached 100% during Phase 4.

Unfortunately, however, the improved coverage is not directly reflected in the number of TB patients, and the case detection rate in the country still remains as low as in the 30% range, which is far below the goal set by WHO, 70%. As a result, China still ranks the second in the High-Burden TB Country. In order to improve the situation, the MOH has set new goals for TB control to improve the patient detection rate to 70% by 2005 and 75% by 2006, thereby reducing the numbers of disease and death cases. On the other hand, the target 12 provinces and autonomous regions in this project have financial difficulties to address the TB issue by themselves.

This project aims at improving the case detection rate through procurement of anti-TB drugs and other supplies needed for free medical treatment of 250,000 TB patients that are assumed for 2006 in the project areas.

2-2 Basic Design

2-2-1 Design Policy

The project intends to provide funds to procure goods and equipment necessary for TB control such as anti-TB drugs, microscopes, etc., to contribute to the Chinese government's implementation of TB control measures in poverty areas based on the "National Program for the Prevention and Control of Tuberculosis (2001-2010)" and the specific implementation plan (2001-2005). The project was designed to consist of 5 phases, and this report is on the fifth phase based on the plan drafted at the project design stage.

This project will be carried out in accordance with the following guidelines, based upon the DOTS strategy that has been implemented since the first phase, the implementing organization at the central and local levels, the continuity from the previous phases, the basic policies of WHO and plans and programs carried out by other donors and international institutions. In addition, all the anti-TB drugs procured under this project will be provided to TB patients without any compensation in the same manner as the preceding four phases.

2-2-2 Basic Plan

1) Areas To Be Covered By This Project

Phase 5 covers the entire 1,250 counties in the 9 provinces and 3 autonomous regions. Table 2-1 below indicates the population in each province and region.

Table 2-1 Target Population in Each Area, 2006

Province/ Autonomous	Target area 2006		
	Population (x 100,000)	New DOTS start	Target County
Sichuan	870.5	0	180
Qinghai	52.3	0	47
Henan	980.2	0	127
Inner Mongolia	234.6	0	101
Jianxi	445.8	0	99
Shaanxi	362.2	0	107
Anhui	649.5	0	84
Guizho	392.7	0	91
Yunnan	415.9	0	129
Shanxi	329.4	0	119
Guanxi	477.9	0	92
Tibet	25.1	0	74
Total	5,236.1	0	1,250

Report of 5th surveillance by MOH of China (Feb, 2005)

2) Patients To Be Covered By This Project

Based on the DOTS strategy of the MOH, the target patients shall be i) new smear positive patients, ii) re-treatment smear positive patients, and iii) new smear negative cases, severe form. The number of patients in each type for 2006 is projected in Table 2-2. This projection was made according to the calculation criteria mentioned in Table 2-3. It should be noted that there is no county to newly introduce the DOTS strategy in the areas covered in the target areas of this project since the DOTS coverage reached 100% therein in Phase 4.

In order to calculate the number of anti-TB drugs to be procured under this project, the number of TB patients was derived by multiplying the number of patients estimated by the WHO and the MOH by 75%, the detection rate targeted for 2006. The government of China conducted national surveys for TB prevalence in 1979, 1984/85, 1990, and 2000. Based on the survey results, the government estimates the latest number of TB patients and the number of new TB patients in the year. Furthermore, the number of patients is also estimated in detail per province or autonomous region by analyzing the past records of the number of patients in each type and other factors.

Table 2-2 Number of Target Patients In This Project

By Provinces/Autonomous Regions

Province/ Autonomous	Estimated number of TB patient detected in 2006			
	New SP(+)	Re-treatment SP(+)	New SN(-)	Total TB patient
Sichuan	34,138	6,025	5,121	45,284
Qinghai	2,738	484	411	3,633
Henan	39,152	6,910	5,873	51,935
Inner Mongolia	10,535	1,860	1,581	10,474
Jianxi	17,592	3,105	2,639	23,336
Shaanxi	7,895	1,394	1,185	10,474
Anhui	28,999	5,118	4,350	38,467
Guizho	10,512	1,856	1,577	13,945
Yunnan	8,374	1,478	1,257	11,109
Shanxi	11,886	2,098	1,783	15,767
Guanxi	13,739	2,425	2,061	18,225
Tibet	2,068	365	311	2,744
Total	187,628	33,118	28,149	248,895

The document of estimated number of TB patients in 2006 by CDC

Table 2-3 below shows the criteria for calculating the number of patients per type.

Table 2-3 Criteria for Calculating the Number of Patients in Phase 5

Type	No. of new smear positive patients	No. of re-treatment smear positive patients	No. of new smear negative cases, severe form
Criteria	The number of new smear positive cases shall be derived by multiplying the total (estimated) number of new smear positive cases by the target case detection rate, 75%.	The number of re-treatment smear positive cases shall be determined by assuming that the new smear positive cases account for 85% of the smear positive patients in total and the remaining 15% are for re-treatment.	The number of smear negative cases, severe form, is assumed as 15% of the new smear positive cases.

3) Major Items To Be Procured

A) Anti-TB drugs (manufactured in GMP-certified factories, compliant with the Chinese Pharmacopoeia)

Anti-TB drugs shall be of the same types and shapes as the ones procured in the second phase and onward. According to the DOTS strategy, a combination of oral tablets or capsules will be packaged in a sheet of blister pack[1] for an easy intake. The shelf life must be more than 22 months at the time of handover.

In China, anti-TB drugs administered in the DOTS therapy are a combination of 600mg

[1] Blister pack: A sheet containing a specific number and combination of tablets and/or capsules. Each tablet/capsule is placed in a pocket on the sheet and the sheet is sealed with aluminum. The patient can take out tablets right before swallowing them by pushing the back of pocket.

of Isoniazid (INH), 600mg of Rifampicin (RFP), 2,000mg of Pyrazinamide (PZA), and 1,250mg of Ethambutol Hydrochloride (EB) for oral tablets or capsules and 750mg of Streptomycin sulfate (SM) for injection. These drugs are administered in combination to three types of TB patients, i) New smear positive cases, ii) Retreatment Smear positive cases, and iii) new smear negative cases, severe form and the combination varies with the types of patients. Furthermore, the combination changes according to the "initial intensive phase", which is beginning of medical treatment, and the "continuation phase", which is the treatment period thereafter. Concretely speaking, the initial intensive phase is set as 2-3 months and the continuation phase 4-6 months. Therefore, the total period of DOTS treatment will be 6 months at the shortest and 9 months at the longest. Table 2-4 below explains the combination of drugs according to the type of patient and the treatment phase.

Table 2-4 Types and Combinations of Anti-TB Drugs (Symbols) for Each Treatment Phase

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

Note
H: Isoniazid (INH), 600mg (300mg x 2 tab)/dose
R: Rifampicin (RFP), 600mg (300mg x 2capsules)/dose
Z: Prazinamide (PZA), 2,000mg (500mg x 4 tab)/dose
E: Ethambutol hydrochloride (EB), 1,250mg (250mg x 5 tab)/dose
S: Streptomycin sulfate (SM) 750mg (750mg x 1 vial)/dose
ex)**2**$H_3R_3Z_3E_3$ S_3:INH, RFP, PZA, EB, SM are taken 3/week for two months。

Combination of oral TB drugs, namely HRZE, HR and HRE, are packaged into a blister pack per combination and 15 blister packs/box is provided as at the minimum unit for one patient for one month. As for injection drug, Streptomycin, the minimum unit is 15 vials/box for one patient for one month provided that 1 vial is for one dose. Table 2-5 shows the calculation method for Anti-TB drug procurement.

Table 2-5 Calculation Method for Anti-TB Drugs

Calculation method for q'ty of anti-TB drugs to be procured for 10 TB patients
1. As for HRZE, an anti-TB drug for the initial intensive phase, one sheet of blister pack is for one intake and three sheets for one week (three intakes per week). Therefore, a box will contain 15 sheets of blister packs for one month. i) Of the new smear positive cases, 80% will take HRZE for 2 months and 20% for 3 months. E.g.) For 10 TB patients, HRZE: 8 patients x 2 months = 16 months, 2 patients x 3 months = 6 months therefore HRZE for 16 months + 6 months = 22 months/10 patients will be needed. ii) New smear negative cases, severe form, take HRZE for 2 months. E.g.) For 10 TB patients, HRZE for 10 patients x 2 months = 20 months/10patient will be needed. iii) Re-treatment smear positive cases for, 70% will take HRZE for 2 months and 30% for 3 months. E.g.) For 10 TB patients, 7 patients x 2 months = 14 months and 3 patients x 3 months = 9 months. Therefore, HRZE for 14 months + 9 months = 23 months/10 patients will be needed.
2. As for HR, an anti-TB drug for the continuation phase, one sheet is for one take and three sheets for one week. Therefore, 15 sheets are needed for one month and a box will contain 15 sheets for one month. i) New smear positive cases will take HR for 4 months. E.g.) For 10 TB patients, 10 patients x 4 months = 40 months and HR of 40 boxes/10 patients will be needed. ii) New smear negative cases, severe form, will take HR for 4 months. E.g.) For 10 TB patients, 10 patients x 4 months = 40 months and HR of 40 boxes /10 patients will be needed.
3. As for HRE, an anti-TB drug for re-treatment smear positive cases for the continuation phase, one sheet is for one intake and three sheets for one week. Therefore, 15 sheets are needed for one month and a box contains 15 sheets for one month. i) Re-treatments smear positive cases will take HRE for 6 months. E.g.) For 10 TB patients, 10 patients x 6 months = 60 months and HRE of 60 boxes /10 patients will be needed.
4. As for SM, an anti-TB drug for re-treatment smear positive cases for the continuation phase, 750mg/vial/shot and 3 vials(shots)/week will be administered to a patient. Therefore, 15 vials/box will be needed for one month. i) Of the re-treatment smear positive cases, 70% will take the injection of SM for 2 months and 30% for 3 months. E.g.) For 10 TB patients, 7 patients x 2 months = 14 months and 3 patients x 3 months = 9 months. Therefore, 14 + 9 = 23 months and SM for 23 months x 15 vials = 345 vials/10 patients will be needed in total.

B) Water for injection (manufactured in GMP-certified factories, compliant with the Chinese Pharmacopoeia)

Water for injection will be procured in 5-ml vials to dissolve each vial of freeze-dried Streptomycin sulfate (SM).

C) Disposable syringe (manufactured in ISO9001-certified factories, compliant with the Chinese Standards)

5-ml disposable syringes with 22G needles will be procured for dissolving and intramuscular injection of Streptomycin sulfate.

D) Others

The project will limit the items to be procured to anti-TB drugs, syringes and solution that are minimally required for TB control in the poor areas (in the 9 provinces and 3 autonomous regions) and exclude all the other equipment requested by the Chinese side. All the other goods and equipment requested in the Minutes of Discussions, that is, 875,000 brochures for year 2006, 5 million posters, 482 computers for collecting TB information and 482 printers, will not be procured under this project.

In addition, as for 100 microscopes initially listed in the requested items, although microscopes were 100% in place as of Phase 4, they were requested to replace those that have gone out of order or are not functioning properly. However, these were excluded from the list of items to be procured under this project considering that the Chinese side can take actions such as repair. Bulletin boards were also requested but similarly excluded from the list because they were installed where necessary during the previous phase and do not require annual replacement since they are made of metal and hence durable. Laptop PCs and projectors were requested for use in staff training, which does not correspond to the purpose of this project, “free medical treatment of TB patients in poverty areas.”

4) Scale and Contents of the Project

A) Anti-TB drugs

The quantity of anti-TB drugs to be procured was calculated by adding a 25% buffer, as

recommended by WHO, to the number derived from the estimated number of patients and the target case detection rate (the same way as the calculation made in the previous phases), and adjusting the result in consideration of the inventory in the provinces and autonomous regions left from the 2004 (Phase 3) procurement.

The buffer of anti-TB drugs is defined as three months altogether at the central and local levels in the "Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Program" for year 2004 by WHO. If the administration of anti-TB drugs is ever interrupted for some reason, tubercule bacilli will likely develop drug resistance, which complicates and prolongs the treatment. In order to avoid such a situation, a 3-month inventory, equivalent to 25%, covering from the manufacturing process of the drugs, is planned. As a matter of fact, when China was hit by the outbreak of SARS in March 2003, which spread and threatened not only Southeast Asian countries but also Canada, the distribution of anti-TB drugs was delayed. At that time, people were concerned of a possible interruption of TB control, but the distribution of anti-TB drugs was fortunately secured.

In calculating the quantity of anti-TB drugs, if there are stocks, the number of stocks is subtracted from the quantity to be distributed, whereas, in case of a shortage in the stockpile, that shortage is added to the quantity. If the inventory is a negative value, that shortage will be covered up by adding the equivalence to the quantity.

In case of Sichuan Province, the distribution quantity has been determined by subtracting the inventory equivalent to 517 new smear positive cases from 2004 from the number of new smear positive cases (25% included), 42,673. Therefore, the final quantity will be 42,673 – 517 = 42,156.

Following Table 2-6 shows the types and numbers of TB patients that provide the basis for the calculation.

Table 2-6 Number of TB Patients in Each Area for Calculation of the Anti-TB Drugs

No	Province/ Autonomous	Estimated all SP(+) (a)	Estimated New SP (+)		Re-treatment SP(+)		New SN(-)	
			number (b)	+25% (b')	number (c)	+25% (c')	number (d)	+25% (d')
1	Sichuan	45,517	34,138	42,673	6,025	7,531	5,121	6,401
2	Qinghai	3,650	2,738	3,423	484	605	411	514
3	Henan	52,202	39,152	48,940	6,910	8,638	5,873	7,341
4	Inner Mongolia	14,046	10,535	13,169	1,860	2,325	1,581	1,976
5	Jianxi	23,456	17,592	21,990	3,105	3,881	2,639	3,299
6	Shaanxi	10,526	7,895	9,869	1,394	1,743	1,185	1,481
7	Anhui	38,665	28,999	36,249	5,118	6,398	4,350	5,438
8	Guizho	14,015	10,512	13,140	1,856	2,320	1,577	1,971
9	Yunnan	11,165	8,374	10,468	1,478	1,848	1,257	1,571
10	Shanxi	15,847	11,886	14,858	2,098	2,623	1,783	2,229
11	Guanxi	18,318	13,739	17,174	2,425	3,031	2,061	2,576
12	Tibet	2,757	2,068	2,585	365	456	311	389
Total		250,164	187,628	234,535	33,118	41,398	28,149	35,186

The grounds for calculating the numbers of patients in the above table are as follows:

(a) : The estimated number of new smear positive patients (forecast by the MOH and WHO)

(b) : (a) x target detection rate, 75%, (b'): (b) x 1.25

(c) : Assuming the actual number of new smear positive patients (b) as 85% of the total number of smear positive patients, 15% of ; (b) x 15/85, (c'): (c) x 1.25

(d) : The actual number of new smear positive patients (b) x 15%, (d'): (d) x 1.25

Tables 2-7 and 2-8 on the next page indicate the numbers of TB patients and the quantities of anti-TB drugs to be procured according to provinces and autonomous regions respectively.

Table 2-7 Calculated Amount of Anti-TB Drug

Province/ Autonomous	Estimated TB patients 2006 a .			Amount of TB drug with additional buffer (25%) b.			Differential quantity of anti TB drugs compare with 2004 (Differential quantity of drug supplied in Phase III and patient number in 2004) c			**Amount of target patient to be given anti-TB drug in 2006 d**		
	A	B	C	A	B	C	A	B	C	**A**	**B**	**C**
Sichuan	34,138	6,025	5,121	42,673	7,531	6,401	517	-36	-1,564	42,156	7,567	7,965
Qinghai	2,738	484	411	3,423	605	514	-399	434	-263	3,822	171	777
Henan	39,152	6,910	5,873	48,940	8,638	7,341	260	1,904	423	48,680	6,734	6,918
Inner Mongolia	10,535	1,860	1,581	13,169	2,325	1,976	-1,747	514	234	14,916	1,811	1,742
Jianxi	17,592	3,105	2,639	21,990	3,881	3,299	446	120	-90	21,544	3,761	3,389
Shaanxi	7,895	1,394	1,185	9,869	1,743	1,481	-4,433	-1,280	-666	14,302	3,023	2,147
Anhui	28,999	5,118	4,350	36,249	6,398	5,438	-2,631	8	-417	38,880	6,390	5,855
Guizho	10,512	1,856	1,577	13,140	2,320	1,971	-159	1,034	183	13,299	1,286	1,788
Yunnan	8,378	1,478	1,257	10,468	1,848	1,571	-6	2,335	252	10,474	0	1,319
Shanxi	11,836	2,098	1,783	14,858	2,623	2,229	-5,241	-1,061	64	20,099	3,684	2,165
Guanxi	13,739	2,425	2,061	17,174	3,031	2,576	-3,973	960	-971	21,147	2,071	3,547
Tibet	2,068	365	311	2,585	456	389	304	179	145	2,281	277	244
Total	187,628	33,118	28,149	234,535	41,398	35,186	-17,062	5,111	-2,670	**251,597**	**36,774**	**37,856**

A: New SP(+) patient、B: Re-treatment SP(+) patient, C: New SN(-), severe form patient

(Note) The quantities of anti-TB drugs to be procured for 2006 (d) given in Table 207 above already include a buffer of 25% (b) and reflect the actual stockpiles of anti-TB drugs (c) in individual provinces and autonomous regions.

Table 2-8 Amount of Distributed Drugs and Goods in Each Target Area

Province/ Autonomous	HREZ (15sheets/box)	HR (15sheets/box)	HRE (15sheets/box)	SM (30vials/box)	Syringe (with needle, water 30pcs/box)
Sichuan	126,079	200,483	45,404	8,703	8,703
Qinghai	10,356	18,393	1,026	197	197
Henan	136,421	222,393	40,401	7,744	7,744
Inner Mongolia	40,466	66,632	10,866	2,083	2,083
Jianxi	62,826	99,731	22,568	4,326	4,326
Shaanxi	42,711	65,796	18,135	3,476	3,476
Anhui	111,941	178,937	38,337	7,348	7,348
Guizho	35,793	60,349	7,716	1,479	1,479
Yunnan	25,681	47,171	0	0	0
Shanxi	57,020	89,053	22,101	4,237	4,237
Guanxi	58,382	98,776	12,428	2,382	2,382
Tibet	6,145	10,099	1,664	319	319
Total	**713,821**	**1,157,813**	**220,646**	**42,294**	**42,294**

B) Water for injection

An anti-TB drug, Streptomycin sulfate (SM), is freeze-dried and sealed in a vial, and will be dissolved with 5ml of water to be intramuscularly injected. Therefore, the quantity of water to be distributed must equal to that of SM, and the water will be procured in the same quantity as SM.

C) Disposable syringe

Similar to the water explained above, syringes are indispensable for SM injection, therefore they will be procured in the same quantity as SM. The syringes shall be a 5-ml disposable type with 22G needles and aseptized. The syringes will be used for dissolving the freeze-dried medicine and intramuscular injection of Streptomycin.

2-2-2 Implementation Plan

2-2-3-1 Implementation Policy

Table 2-9 Countries to Procure Drugs and Goods

Item	Procured from			Reason
	Japan	China	The 3rd country	
Anti-TB drugs 4 kind (Isoniazid, Rifampycin, Pyrazinamid, Ethambutol)	○	○		These items are manufactured in Japan and China.
Streptomycin sulfate for injection	○	○		
Water for injection	○	○		
Disposable syringe with needle	○	○		

All the goods to be supplied can be procured in both China and Japan, and in fact are procurable in China. Thus they will be procured in China.

2-2-3-2 Implementation Condition

Products manufactured in China will be shipped directly from the factories to the warehouses of the MOH (at TB Prevention and Control Institute or CDC) in the individual provinces and autonomous regions. The delivery will be via land transportation in principle, with an exception of occasional use of air to Tibet Autonomous Region. Japan will be responsible for transportation between the manufacturers and the project provinces

and autonomous regions, whereas China will be responsible from the provinces and autonomous regions to cities and counties and beyond.

As described so far, the project only procures anti-TB drugs and associated supplies. These will be distributed to the project provinces and autonomous regions in three times during the project year, in light of the shelf life of the drugs, the inventory of each project site, and so forth.

1st Lot: 40% of the total supplies by March 2006

2nd Lot: 40% of the total supplies by July 2006

3rd Lot: 20% of the total supplies by December 2006

However, the above split is a brief plan, and the exact quantity per distribution must be adjusted in consideration of the number of new TB patients, the period of treatment required, the inventory status of drugs, etc. Therefore, the quantity to be distributed will vary from project site to project site. Phase 4 took the same approach. The Chinese side is responsible for reporting to the Japanese side on the changed or adjusted distribution quantities. Table 2-10 below defines the demarcation of responsibilities on both sides.

Table 2-10 Responsibility of Japan and China

Responsibility of Japan	Responsibility of China
To the warehouse of Health Bureau of each Province and Autonomous Region	Transportation from each capital to county sites

2-2-3-3 Scope of Work

Table 2-11 below clarifies the scopes of work of both countries concerning the goods to be supplied under this project.

Table 2-11 Scope of Works

Work	Japan side	China side
Procurement	All items	None
Transportation	To Health Bureau's warehouse in each area	From each capital's warehouse to county site

2-2-3-4 Consultant Supervision

A team leader and a procurement supervisor will be dispatched as consultants.

2-2-3-5 Quality Control Plan

i) Sampling test for medical/pharmaceutical supplies

As for medical/pharmaceutical supplies manufactured in China, SFDA[2] tests must be performed prior to shipping from the factories.

ii) Medicine-related GMP (guideline for manufacturing pharmaceuticals and quality control)

Manufactures shall be limited to GMP-certified pharmaceutical factories.

2-2-3-6 Procurement Plan

The project requires no installation or maintenance work since it targets only drugs and drug-related goods (syringes). It requires no trade works such as customs clearance because all the items are to be procured within China.

2) Implementation Schedule

Overall Project (from E/N to Handover)	: 16 months
From E/N to Contract with Suppliers	: 4 months
Delivery (From Contract with Suppliers to Handover)	: 12 months

[2] SFDA: A compulsory registration system in China in which all medicine-related goods (including medical electronic devices, medical apparatus, drugs, etc.) should be registered to the State Food and Drug Administration (SFDA). SFDA is an organization under direct jurisdiction of the State Council and supervises safety control systems for food, health food, cosmetics and various other products. For it also serves as an authorization agency for regulations regarding medicines, any medical equipment to be sold and used in China ought to be registered to the SFDA.

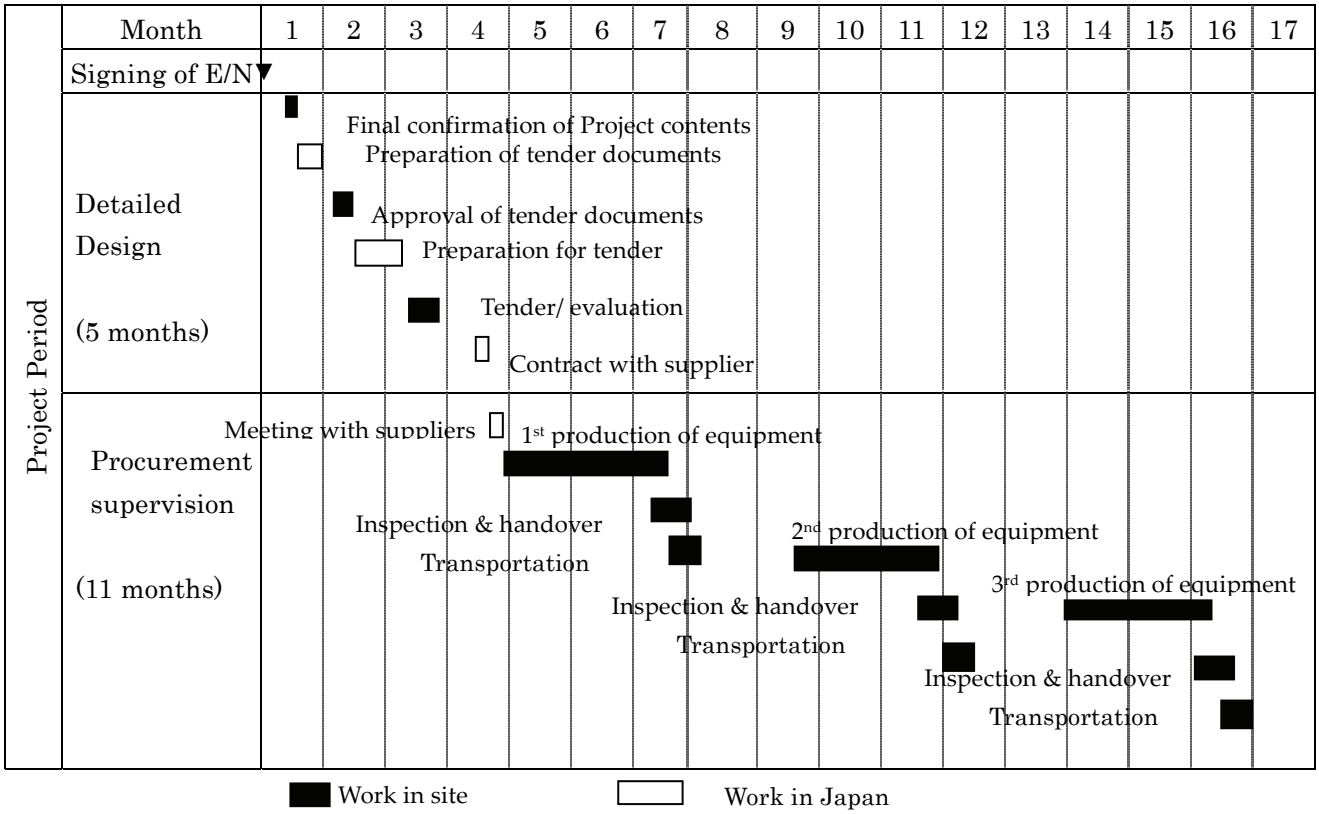

Figure 2-1 Implementation Schedule

2-3 Obligations of the Recipient Country

In the project implementation, the Chinese side shall be responsible for the following.

i) To secure necessary space in warehouses for storage of the goods to be supplied.

ii) To distribute the goods supplied from the warehouses in the project provinces and autonomous regions to the final destinations within the jurisdictional areas.

iii) To provide instruction on the management of the goods to be distributed by the central government experts to local government users

iv) To secure necessary appropriations to implement the DOTS strategy.

v) To carry out adequate operation, use and maintenance of the procured goods.

vi) To bear the charges associated with issuance of the Authorization to Pay (A/P).

vii) To report on quarterly evaluation surveys regarding the use and inventory of anti-TB drugs to the Japanese side (through JICA local office).

2-4 Project Operation Plan

The goods procured under this project will undergo pre-shipment inspection and be distributed to the warehouses of the Health Bureau in the project provinces and autonomous regions. The Bureau in each province/autonomous region will then distribute the goods in the necessary quantity to the counties in accordance with the system of TB control.

The field surveys in the project have confirmed the adequate management and storage of goods supplied at the provincial, city and county levels, by surveying on the inventory records, patient cards, chart of treatment progress, etc.

At the front line of TB treatment, anti-TB drugs and other goods stored in TB Prevention and Control Institute in individual counties are provided to patients at the said Institute, and the patients will bring the rest of medication to the dispensaries in the villages they reside in. The medicine is provided for one month at a time, therefore the patient needs to visit the center every month. In order to receive the medicine, the patient has to bring the empty blister pack from the previous month. The TB patient visits the dispensary in the village every other day, and the village physician or nurse watches the patient take in the anti-TB drug. As for patients for re-treatment, the physician is responsible for injecting Streptomycin to them. What is more, the patient needs to visit the county hospital or TB center every 3 months to receive smear examination until the DOTS therapy is completed.

All the data collected regarding TB, including medical records of patients, intake records, medication, progress of treatment, cure, registration of new patients, etc. will be reported from dispensaries in the villages and towns to TB Prevention and Control Institute of the counties, and there forwarded to cities or provinces/autonomous regions. All the data will ultimately concentrate to the central organ of the system, CDC/MOH, via the Internet.

2-5 Estimation of Cost for the Project

2-5-1 Estimation of Cost for the Project

The cost for implementing this Project is approximately estimated 628 million yen. Details of the cost are shown below. It should be noted that this cost estimate is provisional and would be further examined by the Government of Japan for the approval of the Grant.

(1) Estimated Cost to be borne by Japan

Estimated project cost: approx. 627.8 million yen

Item	Cost (in million yen)
Equipment (Anti-TB drugs)	609.0
Working design / Procurement supervision / technical support	18.8
Total	627.8

(2) Estimated Cost to be borne by Chinese side

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

(3) Parameters of Estimation

① Time of estimation March 2005

② Exchange rate 1USD=105.25yen, 1 yuan = 12.75 yen

③ Work 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 Other This Project will be implemented in accordance with the framework of the Grant Aid System of the Government of Japan

2-5-2 Operation and Maintenance Costs

The goods procured under this Project are anti-TB drugs and solution as well as syringes only. Under the normal storing condition, there will be no problem, however, it is necessary to avoid storing above 30 centigrade. Because of this, the cost of storing and maintaining would not arise.

2-5-3 Points to be noted in implementing the Project

1) Timing of Procurement of Goods and Equipment

At present anti-TB drugs have already been distributed to each target area. Thus, anti-TB drugs under this Project (Phase V) will have to be procured without delay in order to implement DOTS strategy continuously.

2) Confirmation of Effective Use of Anti-TB Drugs

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. In the distribution plan, anti- TB drugs will be distributed 3 times per year, to say 40%, 40% and 20% respectively. However, ratio of distribution would be adjusted based on the stock at each county and region. 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 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

Chapter 3 Project Evaluation and Recommendations

3-1 Project Effect

(1) Direct Effect

i) 85% (252,500) or more TB patients will be cured.

ii) Anti-TB drugs procured will enable free and adequate TB treatment in the project sites.

iii) The target case detection rate, 75%, will be achieved or exceeded, contributing to the reduction of TB patients, which is one of the priority goals of the MOH.

(2) Indirect Effect

i) Effects resulting from the TB control will lead to prevention of infection from spreading to the patients' families and close relatives.

ii) The project will encourage prompt return of the patients to the society, hence contributing to the socioeconomic development of the country.

3-2 Recommendations

1) Continued Procurement and Distribution of Anti-TB Drugs

Japan's assistance in TB control in China has taken place for the past five years since 2001, and there is no request from the government of China for continued cooperation in TB control after the completion of the current project. On the other hand, treatment of TB becomes more difficult once it is interrupted at one point, due to the nature of disease that the TB bacteria will develop drug resistance during the pause. For this reason, the government of China is expected to continue the implementation of free TB treatment in the areas covered in this project by any means such as assistance from other donors.

2) Coordination with Other Donors

The MOH and WHO conduct an annual evaluation of TB-related activities led by a joint mission consisting of TB experts dispatched from various donors. Even after

the implementation of this project, Japan will continue to participate in this mission, in order to constantly monitor and evaluate this project as well as verifying the effects of Japan's assistance in TB control in China through the entire five phases.

[Appendices]

1. Member List of the Study Team
2. Study Schedule
3. Minutes of Discussions
4. List of References

1. Member List of Study Team

Mr. Hiroshi FUJIYA	Team Leader	JICA China Office
Dr. Toru MORI	Technical Councilor	The Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association
Mr. Daizo ARAI	Equipment Procurement Planning	Japan International Cooperation System
Ms. Miki OKAMOTO	Analysis and Evaluation of Effects	Japan International Cooperation System

2. Study Schedule

No	Date		Technical Councilor	Consultant	Lodging
1	Feb/20	Sun	Narita → Beijing		Beijing
2	Feb/21	Mon	JICA China Office, Embassy of Japan, Ministry of Health, Courtesy call and discussion		Beijing
3	Feb/22	Tue	Explanation of present TB situation from TB Officer from Sichuan and Guizhou Provinces		Beijing
4	Feb/23	Wed	Ministry of Health, discussion		Beijing
5	Feb/24	Thu	Ministry of Health, discussion of minutes (draft)		Beijing
6	Feb/25	Fri	Signing the Minutes		Beijing
			Beijing→Narita	Maker survey	Beijing
7	Feb/26	Sat		Maker survey, Data filing	Beijing
8	Fen/27	Sun		Internal meeting	Beijing
9	Feb/28	Mon		Beijing→Xian(Shaanxi)	Xian
10	March/1	Tue		Review in Yenan	Yenan
11	March/2	Wed		Review in Yenan	Yenan
12	March/3	Thu		Review in Yenan Xian→Kunming	Kunming
13	Marhc/4	Fri		Review in Kunming	Kunming
14	March/5	Sat		Kunming→Beijing	Beijing
15	March/6	Sun		Beijing→Shenyang	Shenyang
16	March/7	Mon		TB drug maker, discussion Shenyang→Beijing	Beijing
17	March/8	Tue		Beijing→Shijiazhuang TB drug maker, discussion	Shijiazhuang
18	March/9	Wed		TB drug maker discussion Shijiazhuang→Beijing	Beijing
19	March/10	Thu		Ministry of Health, discussion	Beijing
20	March/11	Fri		Ministry of Health, discussion, JICA China Office, report	Beijing
21	March/12	Sat		Beijing→Tokyo	-

3. Minutes of Discussions

中华人民共和国
第五期贫困地区结核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「中华人民共和国第五期贫困地区结核控制计划」(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 2005 年 2 月 20 日至 3 月 12 日向中华人民共和国派遣了以 JICA 中国事务所藤谷副所长为团长的简易器材调查团（以下称调查团），与中华人民共和国政府有关人员（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，预计汇总形成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 3 份，中日双方在同意的基础上署名，各有关部门各执 1 份，两种文本具有同等效力。

2005 年 2 月 25 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
简易器材调查团团长

藤谷　浩至

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年前治愈400万结核患者，中国政府在全国范围内推进直接面视下短程督导化疗（DOTS)的结核对策，并向日本国政府提出了无偿资金援助的申请，即为经济较困难的九个省和三个自治区提供实施DOTS策略时所必需的抗结核药品。本无偿资金援助项目是以采购中方开展2006年计划所必要的物资以及进行相应的支援为目的。

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）全部的1252个县（区）。

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

通过与本调查团的协商，中方最后申请的物资和器材如附件1所示。

5．援助的基本方针

JICA通过今后实施的实地调查和国内分析来验证中方申请的内容是否妥当，当判断其符合无偿资金援助时，向日本国政府建议批准本项目。但本计划的物资、器材的种类、规格及数量等，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等后才能做出最后的决定。

6．日本无偿资金援助的制度

本调查团就附件2所示的日本国无偿资金援助制度重新作了说明，中方对此表示理解。同时中方也理解了附件3所示的在实施本项无偿资金援助时，为顺利地实施本项目中方应采取的必要措施，并表示要落实这些措施。

7．今后的调查

JICA将编写简易器材调查报告书，于2005年7月左右寄给中方。

8．其他的协商事项

8－1　结核对策的进展情况

日方在确认中国国家的结核对策及接受日本援助地区的结核对策的进展情况时，中方重申了需将结核作为三大传染病对策之一来对待，要扩大结核对策的预算、注重人员培训等，全国各级部门也要加强结核病控制工作。在接受日本的援助地区，DOTS覆盖率达到了100%，在中央政府的领导下，更加完善的结核病防治体系在快速地发展。然而，一部分省份距国家

规划目标还存在一定的差距，为实现项目最初设定的目标，日方希望中方进一步加强中央政府和省级政府对结核防治工作的干预。

8－2　本计划的药品量测算标准

中方以 2006 年结核病控制的规划目标（患者发现率 75%）为基础，测算出 1 2 个省・自治区的初治涂阳患者的标准数量，就复治患者和重症涂阴患者的比例，基于各省从 2002 年到 2004 年的实际情况和 WHO 专家的意见等提出了适用的测算标准。2006 年的患者推算数量和规划目标是中国国家结核病防治规划的目标，不仅仅限于本计划，日方承认了中方提议的合理性。双方达成了以下共识：按照第三期计划提供的药品人份数与病人发现数之间的差额，进行调整后再决定本期药品的供应量。

8－3　DOTS 快速扩大

日方对中方强烈要求：即使在 DOTS 快速扩大的省份也要确保结核防治工作的质量而恰当地实施。中方同意在 WHO 的合作下进行适当的督导，出现预想不到的情况时将进行妥善处理并迅速与日方取得联系。

8－4　关于采购器材的使用

对于通过本计划的实施采购的抗结核药品等，双方同意按照 DOTS 策略免费供患者使用，同时采取了防止转卖该药品的有关措施，另外，中方表示对药品、显微镜等要做好管理。

8－5　药品的库存管理

为满足结核病防治工作在记录、报告的需求提供恰当的药品，日方建议在省级单位保管通过本计划采购的一定数量的抗结核药品，并要根据对象地区实际发现的患者数量合理地分配药品，中方对此表示同意。

8－6　结核病防治工作实施情况的评估、指导及向日方进行通告

中方说明：关于结核病防治工作的实施情况，将请中方有关人员及外部专家实施定期的评价和指导。双方确认在本计划的实施和督导上，继续与 WHO 密切配合。中方在与 WHO 合作的基础上，开展结核防治工作和相关的评估工作，并将其结果向日本国驻华使馆和 JICA 中国事务所通报。另外，日方希望中方就器材的使用情况、药品在各省的库存管理情况、患者的发现情况以及治疗效果等每季度汇总一次向日本国驻华使馆和 JICA 中国事务所通报。

此外，日方还希望根据中国疾病预防控制中心的工作计划，今后继续加强结核病控制组织的建设和队伍建设等工作。

8－7　确保实施体制

中方为有效地使用因实施本计划而筹措的药品，加强了必要的实施体制，确保了设施、

工作人员、人员培训以及检查费、管理费、督导费、运营管理费等开展结核防治工作所必需的经费，同时保证顺利地实施本计划。另外，中方承诺：在确保经费方面上将活用来自其他合作机构的贷款及来自全球艾滋病、结核、疟疾对策基金的资金援助等。

8－8　技术合作

中方为妥善使用筹措的药品以及有效地在项目对象地区实施 DOTS 结核防治对策，向日方申请在中国国内进行人员培训时给以援助。

中方说明：希望日本专家继续参加今后由 WHO 等外部专家进行的联合评估，日方理解联合评估的有效性。

8－9　对中国民众的启蒙及宣传活动

中方保证对本国民众在结核病预防知识、DOTS 策略、免费治疗等结核病对策上进一步推行启蒙及宣传活动。并请求日方制作面向少数民族启蒙和宣传的、设计出任何人都可一目了然、由藏语和蒙古语及用中文记述的宣传手册、海报等，双方对此达成共识。

8－10　对日本援助的理解

本计划是通过日本无偿援助资金实施的，为了使当地居民对此项目有更广泛的了解，日方要求在本计划采购的抗结核药品等的包装上应标明日本的字样，此外还要求中方进行必要的启蒙和宣传活动，中方对此表示理解。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该日本无偿资金援助项目，并努力取得中国人民的理解。

8－11　抗结核病药品质量保证

日方指出进一步保证抗结核药品高质量的必要性，中方对此表示同意。

8－12　信息系统的改善

中国从 2004 年开始，以及时获取重大传染病信息为目的，建立了通过网络系统将患者发病时的有关信息及时向上级机构通报的系统。特别是对于结核病，以管理结核病患者为目的，在县级水平将每名患者的信息进行电子化管理，引进了与省、中央连接的网络系统，从 2005 年开始对全国的主要工作人员进行培训。该系统也用于抗结核病药品的库存管理。

根据该项政策，2004 年在本计划实施的一部分地区，通过全球艾滋病、结核、疟疾基金等配备了电脑，但实施对象只局限于一部分地区，中方强烈要求在未配备地区的县级水平上由日方援助提供电脑，日方决定予以讨论。但各省・地区用的手提电脑和多媒体投影仪等从本计划的基本方针中排出而不予考虑。

8－13　免税措施

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）。该项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，对有关部门采取了必要的措施。

8－14　项目的继续扩展要求

该项目将于2006年结束，鉴于目前已经取得了较好的效果，中方希望中日双方能够继续巩固项目已经取得的成绩，在更广泛的范围内开展结核病控制工作方面的援助与合作。

日方说明：5年项目结束后如果中方希望继续得到援助，需重新明确说明其必要性等，无论日方是否进行援助，均希望中方政府能确实保证项目结束后的药品等供应。

附件 1　申请器材一览表
附件 2　日本无偿援助资金制度
附件 3　日中两国政府的主要分担事项

附件 1

2006 年度申请物质清单和测算标准

	品种	数量
1	口服抗结核组合包装药物（异胭肼、利福平、吡嗪酰胺、乙胺丁醇）	24.8 万人份
2	注射用抗结核药物（链霉素）	
3	注射用水	
4	注射器	
5	台式计算机	482 台
6	宣传画（汉语、汉语和蒙语、汉语和藏语）	500 万张
7	宣传册（汉语、汉语和蒙语、汉语和藏语）	87.5 万张
8	打印机	482 台

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	口服抗结核组合包装药物	参阅下表
2	注射用抗结核药物	
3	注射用水	
4	注射器	
5	台式计算机	缺乏计算机的项目县
6	宣传画	100 张/省，100 张/地区，50 张/县，5 张/乡，2 张/村
7	宣传册	患者数乘 20 张
8	打印机	与计算机配套

2006 年计算病人的标准

经过会谈协商，中日双方一致认为：日本援助项目为中国的结核病规划服务，应当遵从《规划》的 2006 年病人发现测算数量。《规划》在确定各省 2006 年的发病人数后，估算 2006 的病人发现率为 75%，因此得出 2006 年各省的初治涂阳病人发现数。双方协商认同：2006 年复治涂阳病人占总涂阳病人数的 15%，重症涂阴病人占初治涂阳病人数的 15%。因此得出 2006 年的总病人发现数，加上 25%的药品库存缓冲，得出 2006 年的药品需求人份数。

附件 2

日本无偿资金援助制度

1 无偿资金援助制度的实施程序

我国的无偿资金援助制度按照如下程序进行。

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，研究其作为无偿资金援助的适当性，当确认其作为项目的优先高度时，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 原则上采取我国咨询公司签订合同的方法进行调查。

第三阶段的审查和批准，根据第二阶段 JICA 编写的基本调查报告书，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，对受援国政府给与协助。

2 调查的定位

（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歧适当性，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，申请的内容并不完全成为援助的对象，而是考虑我国无偿援助的方式等，确认计划的基本构想。

另外，作为无偿援助项目，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，既使该措施超过主管实施机构所管辖的范围，也要求该机构确保该项措施的实施，最后将以会谈纪要方式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）所必需的资金，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

实施无偿援助是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公司及承包单位签约，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，原则上应合理地购买日本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口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，既咨询公司、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以下措施。

1）实施建设设施的项目时，落实建设设施所需要的土地，并平整用地。

2）平整用地时，应进行只用地的供电、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要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但是，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 3

日中两国政府的主要分担事项

	负担事项	日本	中国
1	银行协定 B/A 的手续费 （1）支援授权书 A/P 发行手续费 （2）支付手续费		 ● ●
2	（1）用无偿资金援助采购的产品自日本到中国的运输 （2）到中国港口卸货业务和报关业务相关的经费及尽快办理相关手续 （3）用无偿资金援助采购的产品到计划省会间的国内运输费用 （4）用无偿资金援助采购的产品到计划省会后在国内运输所需要的经费	● ●	 ●
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、国内税款及其他财政捐款		●
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	为实施本计划，合理而有效的使用、及维修管理由无偿资金援助所购买的器材所需要的经费		●
6	无偿资金援助没有包括的器材安装费等其他所需经费		●

4. List of References

No.	Title	Type
1	Reference material for Japan's Grant aid Project for Phase V (draft) (version 2005.2.23)	Brochure
2	2004 China Health Statistics annual book (Chinese)	Book
3	2004 Joint TB Monitoring Mission: Findings and Recommendations (23 November 2004) (Presentation)	Copy
4	12 Province at High level Meeting (by WHO) (Presentation)	Copy
5	貴州省(Guizhou)：Progress of TB control (Presentation)	Copy
6	四川省（Sichuan）：Progress of TB control (Presentation)	Copy
7	四川省（Sichuan）Notice TB control and assistance of Japan's grant aid	Copy
8	Notice: TB information system by Ministry of Health	Copy
9	Specification of PC and Printer procured by GF	Copy
10	Development of Japanese support (Presentation: Power point file)	e-data
11	Progress of TB control (Presentation: Power point file)	e-data
12	TB Information System (Presentation: Power point file)	e-data
13	TB Information System, Operation manual (for training) issued by China CDC TB prevention and control	Brochure
14	TB Information System, Operation manual (for manager) issued by China CDC TB prevention and control	Brochure
15	TB control in China 2003, issued by China CDC TB prevention and control	Brochure
16	National TB treatment strategy TV meeting report (Sep. 2004) issued by Ministry of Health	Brochure
17	TB treatment daily record for patients (2005)	Brochure
18	陝西省(Shaanxi) Progress of TB control supported by Japanese Grant Aid (dated February 28 2005)	Copy
19	陝西省延安市(Shaanxi): Progress of TB control supported by Japanese Grant Aid (dated March 1 2005)	Copy
20	陝西省渭南市(Shaanxi): Progress of TB control supported by Japanese Grant Aid (dated March 1 2005)	Copy
21	陝西省延安市宝塔区(Shaanxi): Progress of TB control supported by Japanese Grant Aid (dated February 28 2005)	Copy
22	陝西省(Shaanxi) Drug management notice (dated March 26 2004)	Copy
23	陝西省延安市宝塔区(Shaanxi):Notice of patient aid fee by GFATM	Copy
24	陝西省(Shaanxi) TB record card Table of monthly report etc	Copy
25	陝西省(Shaanxi) TB information system, Text for training	Copy
26	TB information system Operation manual (for training) issued by 陝西省(Shaanxi)	Brochure
27	雲南省(Yunnan) Presentation Information: Progress of TB control supported by Japanese Grant Aid (dated March 4 2005)	Copy
28	瀋陽紅旗製薬有限公司 Maker pamphlet	Brochure
29	華北製薬集団有限責任公司 Maker pamphlet	Brochure
30	石薬集団石家庄有限公司 Maker pamphlet	Brochure
31	Chinese PC maker pamphlet (legend etc)	Pamphlet
32	Year 2005 Budget for Ministry of Health (Japanese assistance)	Copy
33	Cost estimation for design and translation for Mongolian and Tibetan (submitted by Ministry of Health, dated March 10 2005)	Copy