No.

Ex-Post Evaluation Report

Tianjin Pharmaceutical Inspection Center Project in China

September 2002

Japan International Cooperation Agency
Planning and Evaluation Department

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CONTENTS

Preface

In regard to the ODA evaluation, it has been pointed out that the establishment of a consistent evaluation system from the preliminary stage to ex-post is important. Therefore, JICA has been implementing full-fledged ex-ante evaluations for each project-type technical cooperation project,[1] grant aid project and development study since fiscal 2001 after going through an experimental introduction in fiscal 2000. On the other hand, terminal evaluation has been implemented for each project--mainly project-type technical cooperation projects--in the past. However, the effects arising at a certain period after the end of the cooperation (impacts) and sustainability at that time have not necessarily been verified or analyzed. In order to implement projects more efficiently and effectively, it is important to conduct ex-post evaluation for each project and to also give feedback of the evaluation results to the recipient countries.

Against this background, it was determined that the "ex-post evaluation for individual projects" would be implemented for project-type technical cooperation projects and grant aid projects from fiscal 2002. In preparation for full-fledged implementation, the evaluation was experimentally implemented for Indonesia and China in fiscal 2001. The knowledge acquired through the evaluation was organized to prepare the "Manual for Implementing Ex-post Evaluation for Individual Projects (Compendium of Case Studies)." This report is a compilation of the results of ex-post evaluations for projects that were subject to experimental implementation.[2]

In the past, the monitoring survey (post-project monitoring) had been carried out for project-type technical cooperation projects, grant aid projects and the independent provision of equipment (already abolished as a cooperation form) at a certain period after the end of cooperation (after two years and six years). Materials acquired through post-project monitoring have been utilized to consider the implementation of follow-up cooperation. The new "ex-post evaluation for individual projects" is a progressive reorganization of the "post-project monitoring." In the survey, post-project conditions are surveyed and an evaluation is made, as mentioned above, through the more comprehensive survey and analysis of the effects of cooperation and sustainability by the recipient countries.

September 2002

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[1] The name was changed to "technical cooperation project" in fiscal 2002.

[2] Three ex-post evaluations (two for project-type technical cooperation and one for grant aid cooperation) were implemented in Indonesia and China respectively, and separate reports were made.

Meeting at Tianjin Pharmaceutical Inspection Center

A room of Tianjin Pharmaceutical Inspection Center

1. The Outline of the Ex-post Evaluation Study

1.1 Background and the Purpose of the Study

Tianjin Pharmaceutical Inspection Center is responsible for control of the pharmaceutical imported at the Tianjin port. The center is the leader of the inspection centers in Huabei region, and it is also the primary inspection center in the northern regions (North China, the north-west and north-east).

In 1984, the Basic Laws for Administration of Medical Products ("Pharmaceutical Administration Law") were established. Although the government claimed that the seventh and eighth five-year plans (1986 – 1995) had strengthened the administration of the equality control of pharmaceuticals, the quality at that time did not reach international standards. Because of these circumstances, the China government requested that Japan provide the technical cooperation necessary for guaranteeing the effectiveness and the safety of pharmaceutical products through strengthening the quality control and inspection management. In response to the above request, JICA dispatched a Preliminary Survey Team in March 1993 in order to verify the content of the request. Based on the result of the preliminary survey, long-term study team was dispatched in September 1993 to examine the implementation plan in detail. In November 1993, in accordance with the results of the surveys to date, the Implementation Survey Team was sent in order to confirm the implementation plan for the project-type technical cooperation, and signed the Record of Discussions (hereinafter referred to as the R/D). Based upon the R/D, the project was implemented from November 6, 1993 to November 5, 1998.

The ex-post evaluation study, which is to start in a full scale from FY 2002, has been conducted in China and Indonesia in trial basis. The objectives of this study are to verify mainly the sustainability and impact of some projects after certain periods have past since the completion of JICA cooperation. Through the activities above, this study seek to obtain lessons in order to utilize them to feed back for the formulation of similar projects in the future. The projects were selected based on the following criteria:

- Project-type technical cooperation and grant aid
- Project after 3 to 6 years have past
- Project which was not covered by the ex-post evaluation by Ministry of foreign affairs or JICA in three years

1.2 Evaluation Team and the Study Period

Name (Affiliation)	Responsibility
Kazuhiro Yoshida (Office of Evaluation and Post-project Monitoring, Planning and Evaluation Department, JICA Head Office)	Team leader/Evaluation plan
Tsuyoshi Ito (IC Net Ltd.)	Analysis of post-project evaluation
Liu Ran (JICA China Office)	Interpretation and study assistance
Li Wei (Beijing Manyo Consultants Co. Ltd.)	Analysis of post-project evaluation (local consultant)

Field study: Field study in China was carried out from February 24 to March 9, 2002. Field study for this Tianjin project was carried out during this time, on February 25, 26 and March 5.

2. Study Methods

2.1 Outline of the Project

Project Summary	Indicators	Means of Verification	Important Assumption
Overall goal The effectiveness and safety of Pharmaceutical products distributed in China is guarantee through appropriate quality control activities.	• Number of Chinese regulations are added to, revised and brought into conformity with international standards. • Quality management standards for Chinese pharmaceuticals satisfy international standards.	• Statistical information from the Health Department • Project documents • Compendium of pharmaceutical supervisory laws • China's pharmaceutical codex	Formation of cooperative relationship between the central government and Tianjin city's related administration institutions
Project purpose Level of pharmaceutical quality management at the Tianjin Pharmaceutical Inspection Center and the work technology standards are improved.	• Standard of pharmaceutical analysis technology. • Extent to which GLP and validation concepts have spread. • Number of testing methods developed.	• Project documents • China's pharmaceutical codex	Formation of cooperative relationship between the central government and Tianjin city institutions involved in maintaining inspection administration
Output 1. GLP is understood and implemented.	1.1 Number of GLP seminars and lectures held. 1.2 Regulations and organizations set up for GLP. 1.3 Separation between laboratories, equipment rooms and offices. 1.4 Equipment is distributed in rooms according to type. 1.5 Implementation of Cleaning and dust management. 1.6 Appropriate electricity generation. 1.7 Maintenance of glass apparatus and appropriate cleaning. 1.8 Maintenance of reagents, performance and management of equipment. 1.9 Water quality management. 1.10 Disposal of hazardous waste. 1.11 Number of crosschecks and their results.	1.1 Project report 1.2 Project report, Tianjin Pharmaceutical Inspection Center's annual report 1.3 Project report 1.4 through 1.11:Same as 1.3	• Counterparts transmit training results to other employees • Receives sufficient funding from domestic Chinese administrative institutions • Receives sufficient cooperation from China's Authorization Center for Pharmaceutical and Biological Products and provincial inspection centers
2. Analysis method validation is understood and disseminated.	2.1 Number of seminars. 2.2 Number of experiments and evaluations, and their precision.	2.1 , 2.2:. Same as 1.3	
3. Pharmaceutical inspection technology improves.	3.1 Type and quality of inspection technique. 3.2 Number of inspection tests and their level of achievement.	3.1 Project report, Tianjin Pharmaceutical Inspection Center's annual report 3.2 Same as above	
4. Inspection facilities are set up and expanded.	4.1 Extent to which laboratories are equipped. 4.2 Degree of computer usage. 4.3 Degree of utilization of provided equipment. 4.4 State of preparation of consumables and spare parts and their maintenance management.	4.1 through4.4 :Same as 3.1	
5. Technicians involved in pharmaceutical inspection are trained.	5 Number of staff trained.	5 Same as above	
6. Joint research of pharmaceutical quality management is carried out.	6.1 Number of research papers published. 6.2 Number of joint research topics	6.1 Reports on academic conference and seminar reports 6.2 Project report, Tianjin Pharmaceutical Inspection Center's annual report	
7. Technology and research information is exchanged between pharmaceutical inspection centers in other provinces.	7.1 Number of academic conferences and seminars held. 7.2 Number of technicians from other provinces trained. 7.3 Increase in observers from other institutions. 7.4 Track record in educational training given to researchers in other provinces.	7.1 Reports on academic conference and seminar reports 7.2 Project report, Tianjin Pharmaceutical Inspection Center's annual report 7.3, 7.4: Same as 7.2	

2.2 Stakeholders and Study Methods

In this project, the study plan and evaluation questionnaire were prepared in advance based on the project effect and anticipated impact as described in the Japan-China joint evaluation results at project completion. The specific study targets and study methods for the field study are described below.

Due to time constraints in this survey study, only ten manufacturing companies in the Tianjin surrounding area were studied and it was not possible to gain a statistically significant conclusion from these survey results.

Table: Study targets and study methods

Study target	Study method
Responsible agency China Pharmaceutical Supervisory Management Division; Tianjin City Pharmaceutical Supervisory Management Division	Hearings based on evaluation questionnaires
Implementing agency Tianjin City Pharmaceutical Inspection	Request to collect data; Hearings based on evaluation questionnaires
Other related institutions and organizations Pharmaceutical companies in areas surrounding Tianjin	Hearings, survey study

3. Study Results

3.1 Sustainability

3.1.1 Current Situation of Counterpart Personnel

Out of the 28 people who received technology transfer in this project, 23 remain at the Inspection Center and the transferred technology is not being lost. Most of the former counterparts are employed in key positions such as Center Director. Although there is no practical effect, only 1.74% of the 172 employees are above Masters degree.

3.1.2 Organizational Aspects

In 1998, nation wide structural reform positioned the Pharmaceutical Supervisory and Management Department at the top combining two different pharmaceutical management responsibilities for inspections and quality control. Tianjin City also went through similar structural reforms and the inspection center fell under the jurisdiction of the city's Pharmaceutical Management and Supervisory Agency. This did not, however, cause any significant organizational changes to the inspection center itself.

Out of 172 employees, 71 (41%) of the Tianjin inspection center are involved in inspection work. The Management Division of the center is responsible for coordinating the six divisions

(chemistry one, chemistry two, biochemistry, pharmacology, Chinese medicine and antibiotics); it has been no significant problems in the coordination.

The number of inspection tests has increased from the level at project completion. Considering the expected growth in the medical product sector (Tianjin city place the medical product industry to be an important industry for the city), it will be difficult to respond to this growth at the current scale of facilities. Accordingly, plans for expansion and rebuilding of the inspection center are progressing. However, only a portion of the budget necessary for this has been secured (3 million yuan out of 6 million for facility renovations; the other 3 million and 7 million for additional equipment has not been determined).

3.1.3 Financial Aspects

Each inspection center depends on the regional government for their budgets. Out of the Tianjin Inspection Center's annual budget, a maximum of 35% represents owned capital (the "revenue from commissioned inspections" and "other revenue" shown below) but this figure is not fixed. The Tianjin City government allocates an annual budget of more than 3.5 million yuan for the center. Roughly the same budget can be expected in the future, but there are limits to the city government's ability to provide financial source, as the public finances are comparatively weak. Equipment maintenance expenses are around 800,000 to 1.1 million yuan (approximately 20% of the budget) and work level at project completion can be maintained. Recently the percentage of the maintenance expenses for the spare parts has risen and its increase rate is remarkable. This tendency is expected to become more serious as the provided equipments during the project become close to their end of the lifetime.

The Pharmaceutical Supervisory and Management Department plans to provide financial support in the amount of some billion yuan in fiscal 2002 to provinces with particularly weak financial bases to improve their pharmaceutical inspection centers. However, while there is a possibility that the Tianjin Inspection Center will receive some support due to its function of portside inspection, and the center is a key center in the central-west region, it is unlikely that it will receive sufficient support to complete the expansion plans described above.

Table: Revenue (Unit: 10,000 yuan)

Fiscal year	1993	1994	1995	1996	1997	1998	1999	2000	2001
Government budget	185	256	287	335	379	361	358	359	398
Revenue from commissioned inspections	7	24	8	15	55	91	62	92	87
Other revenue	0	10	18	29	5	8	3	28	57
Total	192	290	313	379	439	460	423	479	542

Table: Material and Equipment Administration Expenses (Unit: 10,000 yuan)

Fiscal year	1993	1994	1995	1996	1997	1998	1999	2000	2001
Spare parts	3	1. 5	3	3	5	36	40	52	68
Consumables such as reagents	23	7	25	27	33	35	34	35	26
Others	3	1. 5	3	4	6	13	14	17	23
Total	29	10	31	34	44	84	88	104	117

3.1.4 Technical Aspects

Research activities related to pharmaceutical quality standards have been continuing (out of 589 cases from 1998 to 2001, 311 cases were related to the pharmaceutical codex). A rapid inspection method for detecting counterfeit medicine, by applying the transferred technology has been developed by own effort. However, since there is insufficient access to the latest information, it is possible that competition with other key inspection centers could be severer, and technical level of the center could fall behind that of the private pharmaceutical companies in near future.

While the provided equipment can still be operated currently, the load on this equipment will increase with the increase in work (the number of inspection tests has reached to 138% of that of 1995). Although some equipment is being newly introduced (inspection machines and computers, etc.), the use of equipment such as HPLC and spectrophotometers is particularly high and work must often be interrupted for repairs and spare parts replacement.

3.1.5 Sustainability of Project Effects

The sustainability of the project effects from completion to present is expressed below.

(↗ : very high; → : maintained, sustained; ↘ : lower than at completion.)

(1) GLP is understood and implemented.

Sustainability: ↘

Adaptation of GLP was not achieved during the project or at the time of the study. Nevertheless, the adaptation was primary a part of the goal for the pharmaceutical safety management, and the central government's Pharmaceutical Safety Evaluation Center is in charge of this issue and currently there is a on-going project. This indicates that it was too premature policy-wise to include as one of the project purpose the establishment of a safety administration structure ahead of the central government's effort. In this respect, this issue should be examined from the viewpoint of the relevance of the project purpose.

(2) The analysis method validation is understood and disseminated.

Sustainability: ↗

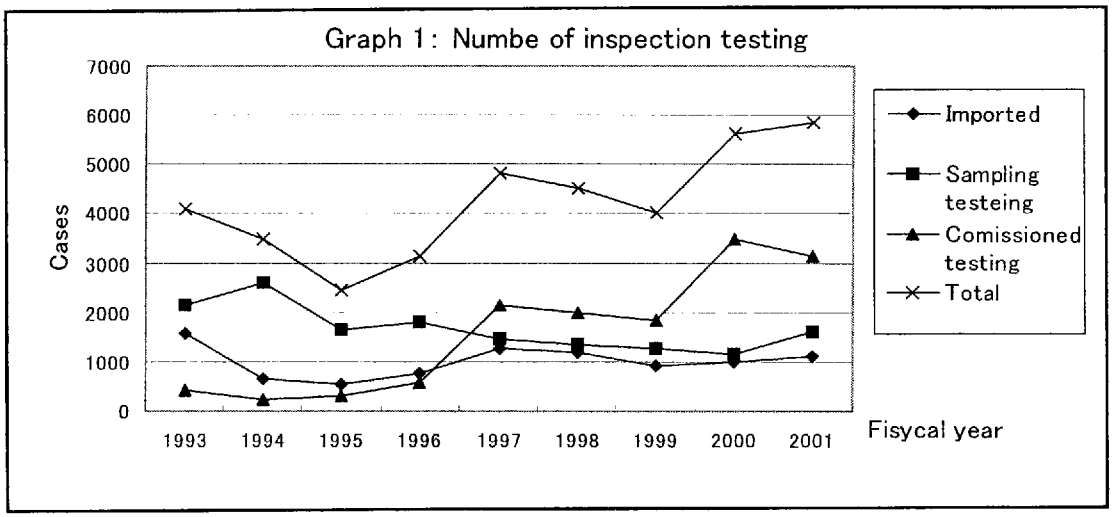
The advanced nature of the HPLC technique of the Tianjin center is recognized nation wide, and

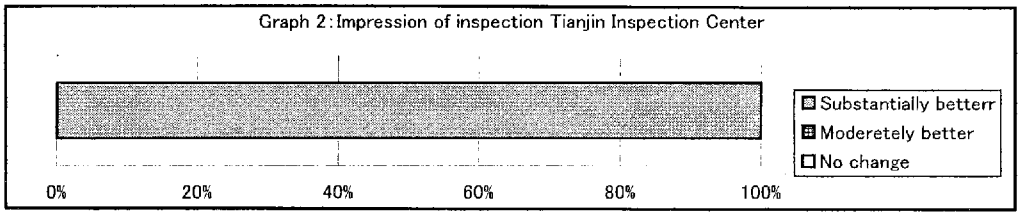
the Tianjin center is responsible for reexamining the standardization of HPLC analytical methods at other inspection centers.

(3) Pharmaceutical inspection Technology improves.

Sustainability: ➡

Most of the former counterparts who received technical transfers remain in the center. Number of inspection testing — in particularly, commissioned inspections — are increasing, and accordingly, the workload is increasing (the number of inspections increased 38% compared to 1995). As a result, the burden on analytical equipment has grown. According to the survey study for private pharmaceutical companies carried out in this evaluation study, it is recognized that the inspection system of the Tianjin Inspection Center has become more advanced.





(4) Inspection facilities are set up and expanded.

Sustainability: ➡

Out of 171 employees, 71 (41%) are involved in inspection work. It is expected that growth in the pharmaceutical industry will increase the workload, and the inspection center is currently being renovated, with a completion date of September 2002. However, only part of the budget for these renovations has been secured (3 million yuan out of a total of 6 million yuan). The equipment is

currently operable, but the load on the equipment will increase with a higher amount of work. Some new equipment has been supplemented, but equipment such as HPLC and spectrophotometers are used particularly often and work must often be interrupted for repairs and replacement with spare parts. The budget for additional equipment is estimated at 7 million yuan but the source for these is uncertain.

(5) Technicians involved in pharmaceutical inspection are trained.
Sustainability: →

Out of 28 people who received technology transfer in the project, 23 remain at the center. The center is actively training young staff members by allowing them to receive an education at the graduate level. Also, staff members who gained technical information overseas are intentionally given higher responsibility in the work. Currently, 19 of such personnel are committed in managing new research projects.

(6) Joint research of pharmaceutical quality management is carried out.
Sustainability: →

Research activities are continuing (589 cases from 1998 to 2001). There were 52 cases of incentive awards given to encourage particularly promising research results. There were 525 presentations in academic papers and journals, for an average of 1.58 presentations annually per technician. There is also independent research development such as a rapid inspection method to detect counterfeit medicine using transferred technology. However, there is not yet reached the situation that they develop new techniques or method adopting the up-to-date technical information. As access to the latest information is insufficient, if the technical level of the inspection center is not constantly updated, the heightened competition that is expected to follow accession to WTO membership will shrink the gap between the inspection center's and the commercial company's technical levels.

(7) Technology and research information is exchanged between pharmaceutical inspection centers in other provinces.
Sustainability: ↘

The number of seminars held for inspection centers in the vicinity and other pharmaceutical center technicians, and the number of participants have been falling. In particular the number of seminars held for technicians of inspection centers in the vicinity have decreased drastically. The Tianjin Inspection Center is the focal inspection center in China, and other inspection centers at

the provincial level do not necessarily aim to attain the same level at the Tianjin Inspection Center. Along with this situation, many seminars on HPLC and other inspection methods have been held and technology transfer activities have been held. It was not possible to ascertain improvement in individual technology strengths at inspection centers that might have been gained through these activities.

3.2 Impact of the Project

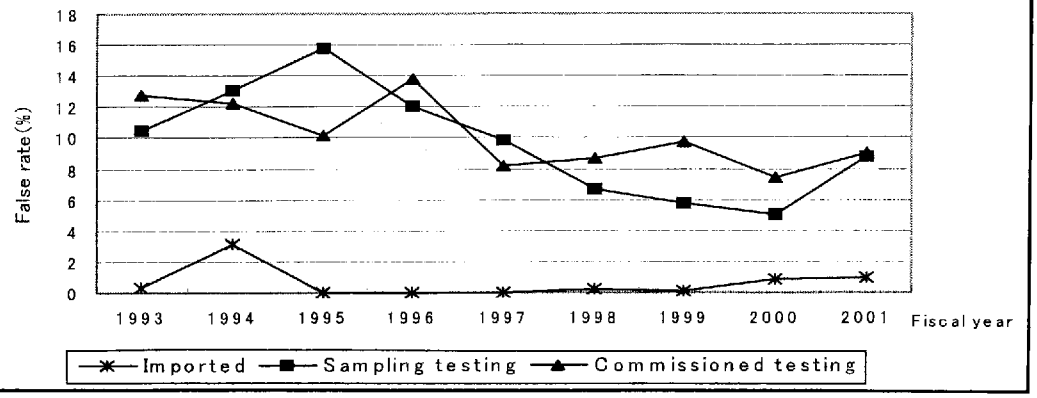
3.2.1 Impacts Attained by Overall Goals

Impact	Yes/No	Current status
Supplement and revise the China Pharmaceutical Codex is supplemented and revised to align it with international standards.	Yes	A revised edition of the Pharmaceutical Codex was published in 1995 and 2000, and the 1995 edition was judged comparable to international standards. Six staff members from the Tianjin Pharmaceutical Center participated on the pharmaceutical codex revision committee (out of a total of 200) and were in charge of establishing the standards for 80 pharmaceutical and quality measurement methods. The Tianjin Pharmaceutical Center is also reexamining all of the items related to HPLC method that were allotted to other inspection center.
China's pharmaceutical quality management standards meet international standards.	Yes	The Pharmaceutical Management Law was completed in 2000. Staff members from the Tianjin Pharmaceutical Inspection Center participated in the Study Committee when the legislation received government approval.
The safety of pharmaceutical products in China improves.	No	Currently GLP has not been adopted and there has been no impact regarding the safety. However, this project's primary focus was improving the quality of pharmaceutical products and raising the ability to carry out efficient inspections, and even before the project started, national policy had determined that the National Pharmaceutical Supervisory and Management Department would ensure pharmaceutical safety. It can be pointed that positioning the overall goal of "raising the safety of China's pharmaceutical products" was not appropriate. Although there was no impact as regards improved safety, since it was not in keeping with the project's focus, it can be concluded that the lack of an impact is not a significant problem.

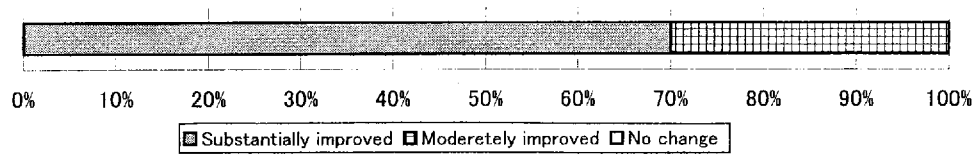
3.2.2 Impact not Anticipated at Project Completion

Impact	Current status
Contribution to improving the management of pharmaceutical quality. (impact manifested in the market and consumers)	It is not possible to quantitatively evaluate the extent of the specific contribution made by the revision and compilation of the pharmaceutical codex and pharmaceutical management regulations to higher quality of the pharmaceutical products distributed in China. To raise the efficiency of inspections, inspection work places more priority on commissioned inspections than on sampling inspections. Therefore, the inspection track record has dropped somewhat. The inspection failure rate has moved to about 6% since the project completion (Graph 3). However, since the parent group is not fixed for commissioned inspections, the higher number of commissioned inspections is not appropriate as a monitoring indicator. More importantly, it is thought that technical guidance from the Inspection Center led to an improvement in improved quality management technology within the factories of the Chinese capital pharmaceutical manufacturing companies in the Tianjin vicinity (Graph 4). On the other hand, these accelerated efforts made by pharmaceutical manufacturing companies in quality management been influenced by external factors such as stricter governmental action regarding quality management of pharmaceutical products beginning in 1998 due to the structural reforms in the sector, accession to the WTO membership, and the introduction of Good Management Practice (GMP) as the company evaluation indicator for pharmaceutical manufacturing companies.
Contribution to development of new medicine. (impact manifested in pharmaceutical manufacturing companies)	There is a high possibility that the Tianjin Inspection Center made specific technical contributions to the efforts of Chinese capital pharmaceutical companies manufacturing for their new products development. From 1998 to 2001, there were 400 cases of reference for new medicine approval. Some companies responded to the questionnaire survey that they have received assistance from the Tianjin Inspection Center for development of all the new medicines from 1993.
Management of counterfeit medicine. (impact manifested in market and consumers)	One of the largest issues in quality management of pharmaceuticals in China today is dealing with counterfeit medicine, however, there is no reliable data of the extent of its distribution. The number of seizures peaked in 2000, and began to decrease significantly in 2001 (Graph 5). Recently the pharmaceutical manufacturing companies in the Tianjin vicinity expressed the general impression that the distribution of counterfeit medicine had been declining. It seems that as pharmaceutical management becomes stricter, the main destination of the counterfeit medicine moved to rural areas where government control is rather weak. It is more difficult to control them at the distribution than at the manufacturing stage, and role of the Tianjin center and manufacturing companies are insufficient for the overall solution of this problem.
Spillover effect in other regions.	The Tianjin Inspection Center holds activities to spread its skill and knowledge — in particular, HPLC method and the rapid inspection method for counterfeit medicine — through seminars and training. This counterfeit detection method is recognized as the national standard inspection method, and efforts are being made to develop an inspection kit for dissemination. There is also a possibility that this project may have become a model for development plans at other focal inspection centers. Currently, it has improved to the extent that the Beijing, Shanghai and Guangdong inspection centers are being comparable to the Tianjin center.
Development of new inspection methods.	The rapid inspection method for counterfeit medicine that can be used by all inspection centers at the provincial level has been developed. The Pharmaceutical Management and Supervision Department is preparing to disseminate this as the national standard method.
Contribution to the Tianjin Inspection Center.	Although it comprises only a small portion of the overall budget, the revenue from commissioned work has increased.

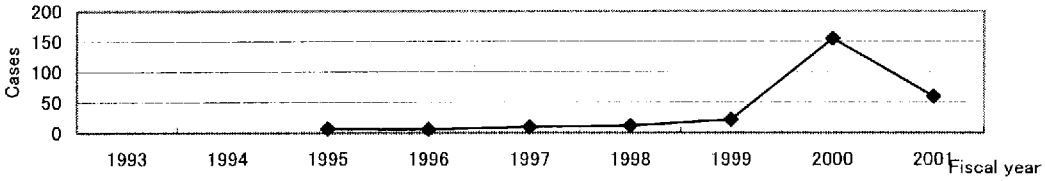
Graph 3 : False rate in the inspection testing



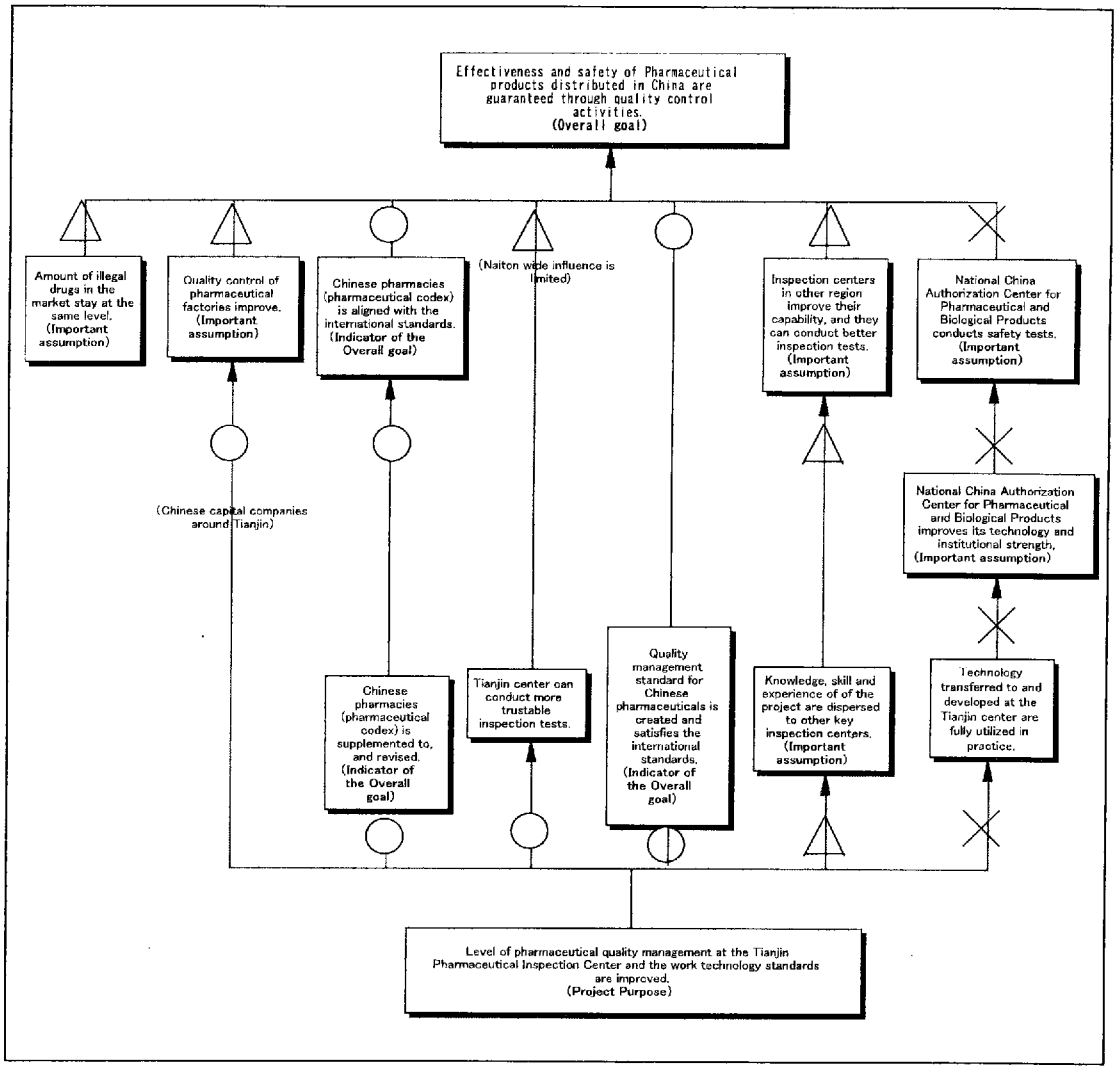
Graph 4 : Self evaluation on improvement of quality management in pharmaceutical companies



Graph 5 : Number of arrested cases of counterfeit drugs



3.3 Analysis of Factors of Impact and Sustainability



Promoting factors

- The government's efforts in the quality management of pharmaceutical products became more rigorous around 1998 due to the structural reforms and the accession to the WTO. In 2001, new pharmaceutical management laws were executed and these pushed the effort of quality management among the pharmaceutical companies. Similarly, the government strongly committed to the countermeasures against counterfeit medicine from 2000; consequently, the target (both the regions and product variety) expanded. In this respect, these favorable environments toward pharmaceutical management brought about the overall impact.
- Although this was not clarified in the PDM, technical instruction was actively carried out for the private pharmaceutical manufacturing companies in the Tianjin city vicinity. In particular, the study received a great deal of information attesting to the significant contribution made to the quality management technique of Chinese capital companies and the development of new medicines. In the PDM's "overall goal (indicators)," much weight is given to the

contributions toward the revision and compilation of the pharmaceutical codex and pharmaceutical management law, however, the technical improvement of the inspection at the center can lead to another impact — improvement in the quality of ordinal market medicine. This impact is manifested in the process described below:

A Process leading to the impact of improvement in quality of ordinal market medicine

① Abilities of staff members at the Tianjin Inspection Center are improved; necessary hardware is provided. (beneficiary: Tianjin Pharmaceutical Inspection Center)

② Development and establishment of highly accurate inspection methods becomes possible. (beneficiary: Tianjin Pharmaceutical Inspection Center)

③ Pharmaceutical manufacturing companies in the region under jurisdiction receive technical guidance. (beneficiary: pharmaceutical manufacturing companies)

④ Quality management of pharmaceutical manufacturing companies receiving technical guidance improves. (beneficiary: pharmaceutical manufacturing companies)

⑤ Quality of the pharmaceuticals manufactured by the companies improves. (beneficiary: pharmaceutical manufacturing companies)

⑥ Effectiveness and reliability of ordinal market medicine improves (beneficiary: consumers)

As the scale of the sample for this questionnaire survey was not statistically sufficient, no definite conclusion can be made, but there is certainly a high likelihood that this process to unexpected impact has been occurring. This can be attributed to the fact that the Tianjin Inspection Center actively offered technical support service to the private companies, on top of the project's plans.

Inhibiting factors

There have been no significant inhibiting factors that might affect realization of the impact. However, the increased load on equipment due to worn-out and increased demand for inspections is becoming an inhibiting factor.

3.4 Issues, Problems

The primary issue of this project was maintaining financial and technical sustainability. In particular, there is uncertainty on how to ensure access to the latest information and supply for additional facilities in order for the further technical development.

3.5 Conclusion

Since the project completion to the time of this study, there has been sustainable development and direct contributions made to the overall goal. The external factors of a stronger pharmaceutical management system put in place by the central government and accession to the WTO caused synergies that contributed to technical improvements in pharmaceutical manufacturing companies in the Tianjin city vicinity and the reductions in counterfeit medicine. Although there was no impact observed in the drug safety aspect, this can be attributed to the misunderstanding during the PDM designing rather than any problems during the project implementation.

Tianjin city's public finances are weak compared to other cities under direct jurisdiction, and it is likely that there will be difficulties in future development of the Tianjin center.

Overall, a foundation for sustainable development has been built up through the independent efforts of the Tianjin Inspection Center during and after the project. However, the increase in demand is higher than anticipated when the project started, making funds and additional input for technology essential in maintaining sustainability into the future.

4. Recommendations and Lessons

4.1 Recommendations

- There is a gap between the exact meanings of the overall goal description and that of its indicators. Compared to the description, shorter objective items were set for the indicators. Although this was good in terms of clarifying the project's focus, it made difficult to understand the role of the project in achieving the real overall goal —improvements in the quality of the pharmaceuticals.
- The priority of the financial support form the central government should be carefully examined by looking at the role and importance of each inspection center and the public finance abilities of the regional governments together, rather than simply dividing it by regions.

4.2 Lessons

Lessons relevant to the project formulation of similar projects in the future

- Not only the improved inspection work at the inspection center but the technical assistance they provided to private companies led to the higher impact. In some cases, direct approach to private companies is an essential step to extend the impact to the consumers — the final beneficiaries. In such cases, it is best to clearly mention in the PDM that these efforts to actively affect the private companies will be dealt with within the project.
- Technical progress in the medical field — including pharmaceutical management — is swift, and if administrative institutions are not constantly catching up the latest information, they

cannot monitor and guide the activities of private companies. Therefore, it is strongly recommendable that any form of constant mechanism for information exchange is established by the end of the project implementation. For example, a JICA technical cooperation project could be an initial base for the longer lasting organization - to - organization relationship with a Japanese organization that is capable of providing technical information.

- The central government determines China's pharmaceutical management policies, and the respective local governments do their implementations. Due to this setting, sustainability of the policy implementation greatly depends on the state of public finances in each local government. In particular, coastal region has not been prioritized for support from the central government, therefore, when a project is implemented in this area with a regional government that has a weak public finance foundation like Tianjin city, much attention must be given to sustainability.
- The most important problem in this project is the sustainability, and one factor that threatens the sustainability is changes in the external factors such as increased demand. In such cases, it is recommended to search possibilities of follow-up assistance in order to enhance the institutional capability of the implementing agency that the completed project built up.