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Report No: 19072

PERFORMANCE AUDIT REPORT

CHINA

PHARMACEUTICAL PROJECT
(Loan 2943-CHA)

March 23, 1999

Operations Evaluation Department

Currency Equivalents (annual averages)

Currency Unit = Yuan

1988	US$1.00	Yuan 3.72	1993	US$1.00	Yuan 5.76
1989	US$1.00	Yuan 3.76	1994	US$1.00	Yuan 8.62
1990	US$1.00	Yuan 4.78	1995	US$1.00	Yuan 8.35
1991	US$1.00	Yuan 5.32	1996	US$1.00	Yuan 8.31
1992	US$1.00	Yuan 5.51	1997	US$1.00	Yuan 8.29

Abbreviations and Acronyms

CIB	China Investment Bank
FDA	US Food and Drug Administration
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GOC	Government of China
GSP	Good Shop Practice
ICB	International Competitive Bidding
ITC	International Tendering Company
MCI	Ministry of Chemical Industries
MOF	Ministry of Finance
MOPH	Ministry of Public Health
QCC	Henan Provincial Pharmaceutical Quality Control Center
R&D	Research and Development
SOE	State Owned Enterprise
SPAC	State Pharmaceutical Administration of China
SPC	State Planning Commission
TCM	Traditional Chinese Medicines
tpd	tons per day
tpy	tons per year
WHO	World Health Organization
ZYPF	Zhong Yuan Pharmaceuticals Factory

Fiscal Year

Government: January 1 - December 31

Director General, Operations Evaluation:	Mr. Robert Picciotto
Director, Operations Evaluation Department:	Ms. Elizabeth McAllister
Manager, OEDCR:	Mr. Ruben Lamdany
Task Manager:	Mr. Farrokh Najmabadi

The World Bank
Washington, D.C. 20433
U.S.A.

Office of the Director-General
Operations Evaluation

March 23, 1999

MEMORANDUM TO THE EXECUTIVE DIRECTORS AND THE PRESIDENT

SUBJECT: ***Performance Audit Report on China: Pharmaceutical Project*** **(Loan 2943-CHA)**

Attached is the Performance Audit Report (PAR) on the China Pharmaceutical Project (Loan 2943-CHA approved in FY88), prepared by the Operations Evaluations Department.

This project was designed to assist the Government of China in its efforts to introduce modern technology in its pharmaceutical industry, improving and upgrading the manufacturing practices as well as quality control, and improving the efficiency and competitiveness of the industry. The project consisted of three components: (i) a large pharmaceutical manufacturing facility for the annual production of 5,000 tons of vitamin C as well as quantities of other products such as starches, dextrose, sorbitol, etc.; (ii) introduction of procedures and equipment for upgrading two demonstration plants to achieve the internationally acceptable Good Manufacturing Practice (GMP) standards of the pharmaceutical industry; and (iii) upgrading the testing capability of the Henan Pharmaceutical Quality Control Center (QCC).

This project suffered from serious cost overruns during implementation. While the foreign exchange cost of the project increased by 20 percent (US$159.2 million actual versus US$130 million estimated), the cost of the project in Yuan terms escalated even more from ¥888.7 million at appraisal to ¥2396.7 million at completion because of devaluation of the Chinese currency and rapid inflation during implementation. The major component of the project—Zhong Yuan Pharmaceutical Factory (ZYPF) at Zhengzhou City, Henan Province, designed to produce annually 5,000 tons vitamin C—was completed with a delay of 22 months. The delay in the start up of other components ranged from 24 to 56 months.

Due to problems with process design and equipment, the Zhong Yuan Pharmaceutical Factory has experienced serious difficulties in achieving sustained production at capacity. These difficulties arose from the incomplete process knowledge and the inexperience of the foreign suppliers of process design and equipment, necessitating repeated modifications to the design even during the implementation stage. They were also caused by inappropriate scaling up from pilot plant operations, and the inexperience of both the contractors' technical staff and ZYPF's operational team. By early 1996, after nearly three years of operational experience, the Zhengzhou Municipality decided to shut down the plant because of the progressive deterioration of ZYPF's financial situation, and its inability to effect the necessary modifications to the plant.

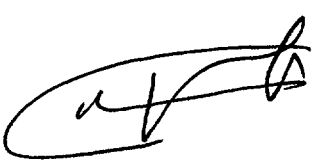
The GMP demonstration plants at Shanghai and Xinhua were satisfactorily completed, though their capacities remain underutilized because of the intense competition in the domestic market. They have created considerable interest on the part of the pharmaceutical manufacturing enterprises which tend to emulate their approach. The GMP training courses were carried out in China at a number of joint venture pharmaceutical plants that received Food and Drug Administration (FDA) approval. There has also been extensive overseas training for trainers at engineering and design consultants, and at foreign companies' formulation plants. Although the Chinese pharmaceutical institutions have now developed

the necessary expertise in designing facilities to international GMP standards and inspecting facilities for GMP compliance, there has been slippage in the original GMP schedule. The Henan Pharmaceutical quality Control Center has lost some of its clients because of a relaxation in Government's regulatory mandates and as the pharmaceutical plants have increasingly assumed the responsibility of carrying out the routine analytical work for quality control.

Though the project was well conceived, it did not achieve its major objective. Given the investment overruns, the production history, the accumulated losses, the state of the vitamin C market and the uncertain future of the Zhengzhou factory, it is unlikely that the project will ever show a positive economic and financial rate of return.

The implementation and commissioning of this plant coincided with a period during which, with Government's encouragement, large vitamin C production capacity was created in China. The Government is now hesitant to restart the plant, thereby adding production capacity to an already glutted domestic and international market for vitamin C. Should the Government decide to proceed, there are several options: (a) to reinvest in modifications; (b) to sell the whole plant to a domestic investor through bidding; and, (c) to seek joint venture partners for the whole or a part of the plant.

Major lessons from the project include: (i) borrowers and the Bank should avoid embarking on an industrial project utilizing unproven technology and a design that is based on the scaling up of a laboratory- sized pilot plant; (ii) there are high risks inherent to embarking on a greenfield and technologically complex project without ensuring that both the project management and operational teams are sufficiently skilled with long experience in the subsector; and, (iii) the need for allocation of sufficient supervisory resources by the Bank, specifically for projects that are facing serious technical and managerial problems.



Contents

This report was prepared by Farrokh Najmabadi, Task Manager, who audited the project in July 1998. Brigitte Wittel and Betty Casely-Hayford provided administrative support.

Annex

Preface

1. This is the Performance Audit Report (PAR) for the Pharmaceutical Project in China for which the Bank approved a US$127.0 million loan in May 1988. The loan was closed on December 31, 1994, one year later than originally anticipated. Final disbursement took place in May 1995, at which time a balance of US$0.344 million was canceled.

2. The PAR was prepared by the Operations Evaluation Department (OED). An OED mission visited China in June/July 1998 and discussed the effectiveness of the Bank's assistance with representatives of the Government of China, Henan Provincial Authorities, Zhengzhou Municipality, Zhong Yuan Pharmaceutical Factory, Henan Pharmaceutical Quality Control Center, and Shanghai No.4 Pharmaceutical Plant. Their kind cooperation and assistance is greatly appreciated and acknowledged.

3. The ICR was prepared by the Industry and Energy Division, China and Mongolia Department, East Asia and Pacific Region Office. The Borrower and the implementing agencies provided Part II. The PAR complement the ICR by providing a fuller account of the achievements, problems and further steps that are needed to revive and ensure the sustainability of this ill-fated project.

4. The PAR reflects the comments received from the State Economic and Trade Commission of People's Republic of China. These comments are also reproduced as Annex O. The Region agrees with the PAR's findings.

Ratings and Responsibilities

Performance Ratings

	Pharmaceutical Project (Loan 2943-CHA)
Outcome	Unsatisfactory
Sustainability	Unlikely
Institutional Development Impact	Modest
Bank Performance	Unsatisfactory
Borrower Performance	Unsatisfactory

Key Project Responsibilities

	TM	*Division Chief*	*Director*
Appraisal	D.A. Caplin	Nicholas Hope	Shahid Javed Burki
Completion	R. Heath	Jane Loos	Nicholas Hope

ICR was prepared by:	R. Heath

Abstract

Since the early 1950s, China's reliance on Western synthesized medicine has been on the rise. While all pharmaceuticals on the World Health Organization (WHO) list of 200 essential drugs were being produced in China by the mid-1980s, the manufacturing technologies were becoming increasingly out of date and inefficient, affecting quality and competitiveness. This project was designed to assist the government of China to achieve its objections through the expansion of production using modern technologies and the introduction of Good Manufacturing Practice (GMP) for quality and management enhancement in the pharmaceutical industry. Unfortunately, a combination of factors including the selection of second rate process engineering contractors, supply of key equipment and technologies from different countries, failure to match western and Chinese technologies, non-performance of suppliers in meeting required specifications, and weak and unskilled construction management and operational teams led to the unsuccessful commissioning of the 5,000 ton capacity Vitamin C plant at Zhengzhou and its eventual shut down in January 1996. The project had more success with the institutional development associated with the GMP. The Chinese pharmaceutical institutions have now developed the necessary expertise in designing facilities to international GMP standards and inspecting facilities for GMP compliance. The two pilot projects for GMP, however, are operating well below capacity because of the intense competition in the domestic market.

1. Introduction

1.1 Since the reforms of 1978, the Chinese Authorities have adopted an industrial development strategy that emphasizes the introduction of up-to-date technology in order to enhance quality of industrial products while economizing on the use of raw materials and energy. In addition, China has been following a two track approach of opening the economy for the rapid growth of the nonstate enterprises while prodding the State Owned Enterprises (SOEs) towards higher productivity by exposing them to market forces.

1.2 By the mid-1980s, the Chinese pharmaceutical industry was producing some 60,000 tons of 1400 bulk active substances of which about 55-60% was being processed into 4000 pharmaceutical formulations, primarily for the domestic market. While all the pharmaceuticals on the World Health Organization's (WHO) list of 200 essential drugs (including Vitamin C as a nutritional supplement) were being produced in China, the technology with which those drugs were manufactured was becoming increasingly out-of-date and inefficient, affecting competitiveness, not only from the points of view of costs and yields, but also that of quality. This situation, combined with a sizable increase in life expectancy and the rising proportion of older people in the population, created the need for considerable investment in the acquisition and implementation of new technology in the pharmaceutical industry.

1.3 To promote public health, the Government of China (GOC) relies on both the Traditional Chinese Medicines (TCMs) and western synthesized medicines. In the mid-1980s, the Government's broad objectives for western medicines consisted of: (a) raising quality; (b) expanding and diversifying supply to meet changing demand; (c) improving research and development capacity; and (d) increasing export potential. In addition to encouraging the acquisition of foreign technologies and expertise through international contacts, imports of modern technologies and joint ventures with foreign firms, the Government also embarked on a program of introducing the Good Manufacturing Practice (GMP) to the pharmaceutical industry through an ambitious plan for retrofitting a large number of plants and closing down plants which did not meet the viability test.

The Project

1.4 The project was designed to assist the Government of China to achieve its objectives in the pharmaceutical subsector through the expansion of pharmaceutical production using modern technologies, the introduction of improvements in the quality of pharmaceutical products and the manufacturing practices and improvements in the quality of training in plant operations, maintenance, manufacturing, management and GMP in the pharmaceutical industry.

1.5 The project comprised three components: (a) construction of a new and large Vitamin C plant at Zhong Yuan (a suburb of the City of Zhengzhou in the Province of Henan) using 150,000 tons of corn as a feedstock to produce 41,750 tons of starch, 25,000 tons of dextrose, 20,450 tons of Sorbitol (50% solution) and 5000 tons of Vitamin C together with a range of by-

products such as corn oil and gluten meal and feed[1]; (b) provision of advanced analytical equipment for the Henan Provincial Pharmaceutical Quality Control Center (QCC); and (c) implementing investments, procedures and training for the adoption of GMP in two demonstration factories at Xin Hua and Shanghai. In parallel with the project, a training program was undertaken by the State Pharmaceutical Administration of China (SPAC) for the training of staff from SPAC, design institutes and enterprises in the techniques and methodology of GMP so that they would be able to effectively disseminate GMP practices. This training program was to be funded from other sources and monitored by the Bank.

[1] PAR uses production figures as reflected in the SAR. The Chinese State Economic and Trade Commission maintains the starch and Sorbitol producing capacities to be 43000 tons per year and 15000 tons per year (70% solution), respectively (See Annex O – letter from State Economic and Trade Commission of People's Republic of China).

2. Implementation Experience

Procurement

2.1 Given the complexity of the process[2], the process units were procured as packages with the suppliers responsible for design, engineering, equipment and material supply, assistance in construction supervision, training, commissioning and start-up. Because the Chinese already possessed their own technology for the production of ketogulonic acid (KGA) from Sorbitol (Annex B) and many such units were in operation in China, this package together with the KGA Recovery and Purification unit was initially selected to be supplied domestically. However, it was later decided to award the KGA Recovery and Purification package contract to the supplier of the Vitamin C plant.

Delays

2.2 Although the project was well prepared and the Borrower displayed a high degree of commitment, project implementation encountered enormous difficulties with considerable delays. The delays ranged from 22 month in the case of Zhong Yuan Pharmaceutical Factory (ZYPF) to 56 months for the Shanghai No. 4 Pharmaceutical Plant (Annex C). Overall, the construction phase did not proceed smoothly. To forestall the construction difficulties associated with a greenfield plant of such complexity, the Henan Provincial Authorities and the State Pharmaceutical Administration of China (SPAC) persuaded the Ministry of Chemical Industry (MCI) to assign one of its most experienced construction companies for the construction of ZYPF facilities. Detailed engineering design interface was provided by the Shanghai Pharmaceutical Design Institute. Despite such precautions, the mechanical completion of the Starch and Dextrose plants was delayed because of late supply of key equipment by the contractor. This, in turn, caused a hiatus and impacted the construction of the KGA and Vitamin C facilities which were already being affected by the delayed supply of equipment including those subcontracted to Yugoslav suppliers who declared force majeure on account of the break-up of Yugoslavia.

2.3 For a variety of reasons, none of the other subcomponents were completed on time. Once the GMP audit was completed by expatriate GMP specialists, the need for the relocation of the Shanghai No.4 Pharmaceutical Factory expansion to a new site caused a lengthy delay and the new lines for the production of capsules and powder for injection (in vials) did not come on stream until December 1996. At Xinhua Pharmaceutical Factory, the trial runs for the new GMP facilities were carried out in April 1994. Later inspection of the plant by GMP specialists indicated that the GMP facilities at both locations meet the United States Federal Drug Administration (FDA) GMP regulations. The Henan Provincial Pharmaceutical QCC subcomponent was completed with 27 month of delay and the new analytical equipment was installed at the Center by October 1991.

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[2] The process requires the sequential manufacturing of a number of inter-mediate products (some of which are also sold as final products) as follows: corn to starch; starch to dextrose; dextrose to sorbitol; sorbitol to ketogulonic acid (KGA); and KGA to Vitamin C (ascorbic acid).

Project Cost

2.4 The total cost of the project increased by 170% from the appraised estimate of 888.7 million yuan to the actual of 2396.7 million yuan. All subcomponents of the project were completed with cost overruns, though ZYPF alone accounted for nearly 93% of the total (Annex D). These cost increases were caused by: a) the high domestic inflation rate; b) the steep depreciation of the local currency during construction; and c) the increased cost of imported equipment and the accrued interest. In dollar terms, while the foreign exchange costs of GMP subcomponents and the Henan Quality Control Center remained within the appraisal estimates, those of the ZYPF subcomponent rose from US$117.5 million at appraisal to US$148 million at completion.

Start-up Problems

2.5 Despite the intense interest initially shown by the internationally well-known contractors, particularly for the Wet Corn Milling/Starch and Dextrose plants, only few participated in the bidding. The contract for the Starch and Dextrose plants was awarded to the lowest bidder that had far less of a track record than the industry leaders. As a result, the design of the plants proved to be very deficient and more than forty modifications had to be introduced up to and even during the trial runs. The contractor was not only very slow in solving the problems which delayed the production of intermediates for the other process units, it also reportedly withdrew its technical staff at the expiration of the contract when many problems remained unsolved and no performance tests has been carried out[3].

2.6 The KGA Recovery/Purification and the Vitamin C plants met a similar fate. Despite the claims made by the contractor, its technology had only reportedly been tested in laboratory and the plants installed at Zhong Yuan were the first scaled up units based on that technology. Since this contract expired in mid-1992, ZYPF entered into three service agreements with the contractor in order to ensure the start-up and commissioning phases of the project. During trial production of Vitamin C which started in November 1992, serious process and mechanical problems were experienced in both the KGA Recovery/Purification and Vitamin C plants. Although the former unit could produce products to specification, it could not operate continuously because of blockages in the system, thus reducing the KGA recovery. The latter unit could also not be operated continuously because decomposition during the processing resulted in high impurity levels and off specification final product.[4]

2.6 Throughout 1993 several unsuccessful attempts were made to modify the process parameters. Actual production of Vitamin C, however, remained at a fraction of the design value. In the meantime the contracting company went into bankruptcy and was absorbed by a

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[3] In fact, at the time of their departure, part of the Dextrose plant which was designed to produce anhydrous dextrose was not even commissioned and the other units had not reached the design capacities.

[4] The contractor claimed that the output from the Chinese designed fermentation plant contained a lower concentration of KGA and that, in addition, the impurities were also greater than specified. Conversely, ZYPF maintained that process parameters such as high temperature of evaporation led to the decomposition of KGA during the recovery process, thus reducing the yield. Reportedly the contractor's chief process design engineer in charge of the technology development had left the company toward the end of 1992 to join a large competing industrial producer of Vitamin C.

different entity which, by late 1994, admitted that the technology required modification and proposed a compromise solution. This solution, which consisted of the conditional supply of additional equipment against the release of all other funds previously withheld, was not agreed to, because the Chinese authorities had lost all confidence in the contractor's ability to improve the technology. Furthermore, ZYPF had already started its own modification with relatively promising results and did not wish to allow any disturbance in its own program. All contracts with the contractor were, therefore, discontinued after the end of 1994. At the time the expatriate technical personnel left the plant, little product of the specified quality had been produced.

2.8 The Sorbitol Plant was the only one of the large process packages that was completed reasonably on time and tested for performance. During the test the plant produced at design capacity (55 tpd) and was accepted by the ZYPF management.

3. Project Results

ZYPF Subcomponent

Production Performance and Technical Indicators

3.1 The inability of ZYPF and its contractors to solve the technical problems in the KGA Recovery/Purification and the Vitamin C plants have seriously affected the capacity utilization of the upstream units, especially the Starch and Dextrose plants. The largest plant wide capacity utilization was achieved during 1995 when the corn input into the Starch plant (69,706 tons) reached 46.5% of the designed value and the production of other products such as common starch and dextrose monohydrate also amounted to 68% and 48%, respectively, of the nameplate capacity (Annex E). Vitamin C production, however, amounted to only about 88 tons which was just under 1.8% of the designed level.[5] The Modified Starch unit never produced starch at the correct specification for the domestic market and its output remained unsold for a long period. The Anhydrous Dextrose unit, which was never commissioned and tested, remained shut down.

3.2 After the departure of expatriate technical personnel during 1992 and 1993, and the fruitless negotiations with the Vitamin C plant contractor, considerable efforts were focused on resolving the problems. To this end, the Central and Provincial Authorities convened a meeting of the technical experts from other pharmaceutical enterprises and engineering institutions. A plan was thus drawn up which specified certain modifications to the KGA and Vitamin C plants based on a blend of Chinese technologies. The cost of modification was estimated at yuan 60 million which would cover new equipment for the KGA Recovery/Purification plant as well as the ionization exchange section of the Vitamin C synthesis plant.

3.3 In response to the recommendations of the expert group, the plant, in the second half of 1994 and early 1995, started introducing some partial modifications in the KGA plant with its available funds while making a request for extra financing for the complete program. Discussions with the Central Government resulted in an agreement to provide the plant with yuan 40 million to continue the modification project. Although reportedly allocated by the Central Authorities, the funds never reached the plant. By early 1996, after nearly three years of operational experience with the plant since start-up, a technical judgment had been reached that without any modification to either the process or the equipment, the various units would only be capable of producing at best the following ratios to their designed capacity: 80% for starch and dextrose; 80% for modified starch; 90-95% for sorbitol; and, 30% for vitamin C. The progressive deterioration of ZYPF's financial situation, together with the inability to effect the necessary modifications eventually led to the Municipality's decision to shut down the plant.

3.4 The trend in the average yields of the various process units are shown in the following Table 3.1.

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[5] In addition to this quantity of Vitamin C, the KGA Recovery/Purification plant also produced some 894 tons of KGA which was sold to other Vitamin C manufacturers in China.

Table 3.1 - ZYPF Average Process Yields

	Design value % D.S.**	1993 %	1994 %	1995 %	1996 %
Starch to Corn	64.5	60.47	59.16	64.55	64.30
Dextrose to Starch	104	78.06	58.26	74.28	95.49
Sorbitol to Dextrose	98	77.83	92.47	94.35	---
KGA to Sorbitol	62.8[6]	7.80	21.32	21.75	---
Vitamin C to KGA	84	N/A	45.73	56.93	---

* D.S. - Dry Substance

With the reversion to the Chinese technology and the introduction of a cooling vessel after each heating/crystallization stage, the yield of the KGA plant began to increase in 1994, resulting in an overall improvement in the KGA recovery, as yet not close to the design value, but a vast improvement on the yields achieved in 1993. Notwithstanding the problem of reaching full capacity utilization, by 1995-96 the process yields of the upstream units were approaching design values as indicated above.

Manpower and Training

3.5 At appraisal it was expected that ZYPF would employ about 3000 people during construction from which some 70% would transfer to positions in the operational organization at the end of the implementation phase. This group was to receive substantial training on site and elsewhere including training by the expatriate staff, especially during commissioning and start up. While the enterprise organized extensive training courses for the operators of various plants and the maintenance staff, as well as those attending to the offsite and supporting facilities, the training by expatriate staff of the contractor was marred by the problems encountered during the start up which had created a strained relationship between the ZYPF management and the contractors (notably the KGA and Vitamin C plant's contractor). The training program as implemented by ZYPF is shown in Annex F.

3.6 Despite these concentrated efforts, the weak management and its unfamiliarity with the pharmaceutical industry, combined with the complexity of the process and the total lack of relevant experience by the recruited staff, did not provide the plant with a group of operators who could solve the commissioning and start-up problems. Of the technical managers of the plant at the time of start-up, only few had previously worked in a pharmaceutical factory and only one had some experience in fermentation processes. This situation was exacerbated by a similar lack of experience by the expatriate contractors who seemed to be using the plant, as it were, as a learning venue for their own technical staff.

6 The notional yield is made up of the yield in the first and second stages of recovery (78.5% and 87%, respectively) and the final crystallization of KGA (92%).

Environmental Protection

3.7 The ZYPF subcomponent was designed to meet environmental standards required by the State, Henan Province and the Municipality of Zheng Zhou. An Environmental Impact Analysis was prepared and approved by the State Planning Commission. Prior to appraisal, the Municipality in turn issued its waste water discharge standards. The construction of the Waste-Water Plant was completed in time for the start-up of the Starch and Dextrose units. During the period when the plant was operational (1992-96), the Waste-Water Treatment unit operated smoothly and the discharged effluent remained within the limits of the water quality standards. A system of regular monitoring was put in place for measurement of different parameters at various stages in order to ensure the suitability of the effluent discharged into the river. Air quality is also being monitored by mobile equipment. A safety manual has been prepared and training has been given to all operators including those who might come into contact with hazardous materials.

GMP Subcomponents

3.8 At both the Xin Hua and the Shanghai No. 4 Pharmaceutical Factories, the investment costs were far in excess of the appraised figures, partly because of the revisions that were made in the design of the buildings to bring them totally in line with the GMP requirements. The corporate structure of both these enterprises was changed to a joint stock company (Xin Hua in 1992 and Shanghai No. 4 in 1993) making it possible for their listing on the stock exchange.

3.9 ***Shanghai No. 4 Pharmaceutical Plant-*** This new unit was located at Pudong Industrial Zone and consisting of two parallel production lines, each with a capacity of 50 million vials per year (2 shifts operation). The plant was completed at the end of 1994, and commercial production started two years later in December 1996. This delay was caused by the need to introduce modifications to the plant and to the buildings to bring them in line with the GMP requirements and to carry out operator training. Once both lines were working, this unit produced nearly 50 million vials during 1997. The factory could not keep that rate of production during 1998,[7] due primarily to machinery break-down as well as a softer market and more intense competition. Currently the new factory is manned by 170 employees.[8]

3.10 ***Xinhua Pharmaceutical Plant*** - This company is arguably the first in China to convert an existing plant to international GMP standards, a feat that is more difficult than building a new plant to GMP standards. It is therefore acting as a demonstration project for the pharmaceutical industry in China and other plants attempting conversion to GMP standards. The new tableting plant which was put into commercial operation in mid-1994 has not yet reached full capacity utilization. During 1997 it produced at a rate of approximately 50% of its design capacity of 3 billion tablets per year. Softness of the market and competition from other domestic producers and joint venture companies are mentioned as the root causes for depressed production.

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[7] During the first 6 month of 1998, production dropped to around 19 million vials.

[8] 30 supervisory staff with university and college degrees; 100 operators with training at trade schools; and, 40 employees that have been transferred from other units in the company.

3.11 ***SPAC GMP Program*** - While the Ministry of Public Health (MOPH) has, since 1989, promulgated regulations in support of GMP, price control by the Government and its investment policies create obstacles to the wider propagation of GMP in the pharmaceutical industry. In 1992, a revised GMP standard was promulgated by the MOPH based on the recommendations of the special committee for GMP. Subsequently, SPAC announced an outline of the schedules by which substantial conversion to GMP was to be achieved throughout the industry during the 9th Five Year Development Plan (1994-1999). The outline was revised again in 1995 thereby extending the time table which now stands as follows:

Powder Products	1997
Vials	1998
Small Volume Injections	2000
Oral Preparations	2005

Currently, some 1,050 enterprises—out of a total of 5,600—are engaged with the production of Chinese traditional medicines while the remaining plants produce basic pharmaceutical substances and preparations of modern drugs. Of the 300 units producing powder products, 150 have already introduced GMP and the rest are in different stage of progress. GMP has also been introduced to a small number of vial manufacturers which number roughly 250. Approximately 4000 enterprises producing oral preparations and small volume injections have not, as yet, started conversion. The schedule appears to be slipping as the State and Provincial authorities show flexibility toward the pharmaceutical companies, because of the financial difficulties being experienced by firms in the subsector.

Henan Quality Control Center Subcomponent

3.12 The equipment for the Center were ordered in 1989 and arrived in China in July of 1990. The Center became operational at the end of 1990 and is currently run by a staff of 22, carrying out quality testing on some 780 batches of product per year (Annex G). The Center suffers from low capacity utilization because, in the early years of its existence, new regulations obviated the mandatory quality testing of some products. Instead, the pharmaceutical manufacturers were given discretion to use the facilities as they wished and they, in turn, limited their demands to only quality testing of new drugs, which are only occasionally introduced. However, there are still regulatory mandates that create demands for the services of the Center such as: (i) quality control of products manufactured by the newly established enterprises (usually small); (ii) sampling and testing of some products existing in the market at the request of the Provincial Pharmaceutical Bureau ; (iii) quality testing of the products produced after firms introduce GMP; and (iv) quality control of specific products being produced in the old factories. The Center is looking to the Chinese traditional medicine and the pharmaceutical research centers in order to increase its workload.

4. Overall Assessment

4.1 Over the last decade and since this project was approved in FY88, China has become one of the largest manufacturers and exporters of Vitamin C in the world. In fact, the production of Vitamin C has grown some sixfold from 4,578 tons in 1988 to around 27,500 tons in 1996 while exports have increased from 1,986 tons to about 23,000 in the same period (Annex H). In reaching these levels, the Chinese industry has depended largely on its own technology—except for the ZYPF facilities—while taking advantage of machinery and equipment imports to upgrade its processes in order to produce Vitamin C with a higher quality. In the meantime, the domestic consumption of Vitamin C has increased at an average annual rate of 7-8 percent, increasing from 2,300-2,400 tons in 1987 to 5,000 tons in 1997. Thus the major objectives of the strategy pursued by the Chinese authorities, namely : large scale production, lower unit costs and better product quality have all been substantially realized, albeit not through the operation of Zhong Yuan Pharmaceutical Factory.

Process Design and Operational Experiences

4.2 Although the project's concept was in line with the country's public health and industrial strategies (by introducing modern technology and improved manufacturing practices in a large market in need of better and more effective pharmaceuticals) and a great deal of efforts were expended in the preparation of the project, the implementation of the critical units was entrusted to foreign contractors that were not the leaders in the field, with less than the required track records. In the case of the contract for the KGA Recovery/Purification and Vitamin C synthesis plants, the design was a brand new scaling up of a small pilot plant at laboratory scale with no other similar plant (with the same technical parameters) installed anywhere in the world.

4.3 Throughout the preparation period, what remained unappreciated was the fact that the pharmaceutical industry is dominated by a relatively small number of international companies and the engineering/contracting firms, at times, prefer not to jeopardize their close relationship with these companies in the interest of their future business (hence the bidding situation for Starch and Dextrose plants). Moreover, the lack of operating and technical experience with various plants meant that the contractors could not deliver on their obligations and were happy to withdraw their technical staff once the contract period had expired without any recourse by the customer (ZYPF). Matters were not helped by the fact that a part of the plant was built with the Chinese technology which affected the integrity of the whole Vitamin C production process.

Management Capability and Institutional Development

4.4 Instead of bringing together a core of experienced technical staff from other pharmaceutical plants, ZYPF relied mostly upon the training of inexperienced personnel which it had recruited from the local job market. Given the nature and complexity of pharmaceutical processes, this approach proved to be wanting. The problem was exacerbated by the departure of the expatriate technical staff before the plants had even been stabilized or, in certain instances, commissioned. In the case of the KGA Recovery/Purification and Vitamin C plants, the contractor had little experience with the process because the plant was a scaled up design from a laboratory pilot project.

4.5 The project had more success with the training and institutional development associated with the GMP and the Henan Pharmaceutical Quality Control Center. Through the implementation of these pilot projects and the training program carried out by SPAC, the Chinese authorities and institutions have now developed the necessary expertise in designing facilities to international GMP standards and auditing facilities for GMP compliance. The introduction of GMP at Xin Hua and Shanghai No.4 pharmaceutical plants have demonstrated the practicability of achieving results and meeting international standards. However, in view of the problems facing the pharmaceutical industry, the Government has allowed a slippage in the original GMP schedule. Considering the situation at ZYPF and the GMP scheduling revisions, **the project's institutional development impact is rated as modest.**

Cost Structure and Profitability

4.6 The cost structure for the various products and the profitability of ZYPF is given in Annexes I and J. The balance sheet appears as Annex K. The analysis of product costs indicates the extent to which production at ZYPF has suffered from the inability to produce at capacity and the low yield of various processes. It is also clear that throughout the period (1993-96), the cash costs of producing a ton of each of the main products, remained well above the selling price. The income statement for the same period also shows the excess of expenditure over sales revenue and the annual losses. This is all without taking into account the financial charges and depreciation.[9] No attempt was made to calculate an economic or a financial rate of return for this report. There can be no assurance as to when the plant will be recommissioned and it is uncertain when production might stabilize or what level of capacity utilization will be attained, making calculation of returns meaningless.

4.7 Despite their salutary demonstration effects, the GMP subcomponents also show disappointing financial results. Capacity utilization at both plants is low, reducing the profitability of their parent companies over the last few years. In the case of the Shanghai No. 4 Pharmaceutical company, operational profit has declined from 22.4 million yuan in 1994 to 20.9, 17.8, 6.7 million yuan in 1995, 1996 and 1997, respectively (Annex L). The general decline in profitability of the pharmaceutical sector is due, in part, to the intense competition in the domestic market emanating from other SOEs, joint venture operations and the marketing activities of the multinational pharmaceutical companies. What most companies are desperately looking for are new drugs that can employ their producing capacities as the older drugs lose market share and, hence, profitablity.

[9] The income statements do not contain depreciation and financial changes related to the capital investment and the balance sheets are currently drawn up without showing the investment in the production units. The claim is that as long as these fixed assets have not been formally accepted by the owners (the Municipality of Zheng Zhou), they cannot be reflected in the accounts of the enterprise. They are in effect kept in a separate account together with accrued interest, awaiting the resolution of the basic issues. As a result, the cost and expenditure figures only include the interest accruing on the working capital which has been borrowed since 1993.

Outcome and Sustainability

4.8 The project was well conceived, but except for helping the introduction of GMP in the pharmaceutical sector and creating a well equipped quality control center, it did not achieve its major objective. Given the investment overruns , the production history, the accumulated losses, the state of the Vitamin C market and the uncertain future of the Zhengzhou factory, it is unlikely that the project will ever show a positive economic or financial rate of return. If the plant is recommissioned and gradually brought up to capacity while remaining as a state owned enterprise, it will continue to require assistance with its debt servicing probably until all the capital investment is paid off. Based on these considerations, and despite the beneficial effects of the GMP endeavor, **the outcome of the project is rated as unsatisfactory and its sustainability as unlikely.**

Bank/Borrower Performance

4.9 While the Bank played an important role in the identification and preparation of the project and both the Bank and the Borrower maintained an amicable and cooperative relationship during implementation, neither side appears to have fully realized the complexity of this project and the risks involved in entrusting its implementation to contractors with less than impeccable track records. It is unfortunate that under these circumstances and during a difficult inflationary period in China, the costs were allowed to skyrocket. Eventually, the weak organizational structure combined with the lack of skills, both on the part of the Chinese staff and the contractors technical personnel brought about a wholly unsatisfactory start up and commissioning experience, leading to an ongoing litigation between ZYPF and the Vitamin C plant contractor. Despite the urgency of taking remedial steps, the Borrower only took steps to strengthen management of the enterprise in 1995, i.e. at a time when the factory was facing serious financial difficulties and the Vitamin C market had already been taken over by other State pharmaceutical enterprises. It is important to note that the Bank carried out only 5 supervision missions for this very troubled project with only two visits during the very sensitive start up and commissioning period (1992-93). There is a surprising note of optimism in the ICR (dated June, 1996) in which, despite all the problems being faced by ZYPF and even the GMP facilities in respect of overruns, delays and capacity utilization, the outcome is rated as satisfactory and the sustainability as likely. Given these considerations, **the Bank and the Borrower performances are rated as unsatisfactory.** The status of legal covenants is shown in Annex M.

5. Current Situation and Major Issues

5.1 The enormous increase in Vitamin C producing capacity and production in China has been accompanied with the construction of much larger plants (up to 5,000 tons/year capacity). Moreover, the new capacity is all based on the scaling up of the Chinese technology including the two-stage fermentation of sorbitol. In the early 1990s, despite the invasion of the Vitamin C market by Chinese manufacturers, prices remained fairly strong at around $14 to $16 per kilogram for superior quality products. But toward the end of 1994, the pressure from lower-priced Chinese Vitamin C forced international prices to drop to about $10 to $12 per kilogram and won the Chinese producers an increasing market share. Thereafter, Vitamin C prices continued to decline, stabilizing in 1997 at about $6-7 per kilogram (Annex N).

5.2 The State, having encouraged other state-owned pharmaceutical enterprises to increase their Vitamin C producing capacity, is now reconsidering this position in view of the steep decline in the international prices. After losing market shares in 1997 (exports dropped from around 23,000 tons in 1996 to 19,000 tons in 1997), the Central Authorities appear to be ambivalent about the recomissioning of the Zhong Yuan Pharmaceutical Factory as its entry into the market might further depress prices. On the other hand, the Provincial and Municipal Authorities who have had to partially service the loan to the Bank (Table 5.1) and other creditors, as well as shouldering the annual losses, are keen to find a solution to production problems and quick recommissioning of the plant.

Table 5.1 - Repayment of Bank loan for ZYPF

	Million Yuan
1994	50
1995	10
1996	150
1997	112
1998 - (up to and of June)	82.39
Total	404.39
Equivalent in dollars (million)	48.72
Principal repaid in dollars (million)	31.64

Source: Henan Provincial and Municipal Governments

5.3 Prior to the eventual closure of the plant, the Provincial and Municipal authorities had already contemplated a number of approaches to resolve ZYPF's problems. These approaches have included: sale of assets, either in whole or part, to another pharmaceutical concern; introduction of a local investor; and, joint ventures with local or foreign enterprises for the whole or individual processing units. Authorities seem to have concluded that joint ventures with reputable international companies may provide the best solution. But joint ventures for Vitamin C production (including the Sorbitol to KGA fermentation plant) is not likely to become a reality because China has already sold its two stage fermentation technology, on an exclusive basis, to an international company with a large claim on the Vitamin C market. This would effectively preclude a workable relationship with a third party for the duration of the patent agreement which will, reportedly, terminate in the year 2000.

5.4 Despite these complications, contacts were established between ZYPF and the IFC towards the end of 1996, resulting in a series of meetings at which the IFC explained to the Provincial and Municipal authorities their approach and the kind of advisory services they could offer in searching for foreign joint venture partners. While the discussions also envisaged a possible investment by the IFC under suitable conditions, the discussions came to an abrupt halt in mid-February 1997 when the management of ZYPF informed the Corporation that they were about to enter a contractual arrangement with an entity from Hong Kong. Unfortunately, with the onset of the Asian financial crisis, the proposal was withdrawn and the matter remains in abeyance. When the problems were again reviewed during the audit mission, the Zhengzhou Municipal Authorities indicated that they were interested to restart discussions with the IFC, subject to the approval of the Provincial and Central Government authorities.

6. Conclusion and Lessons Learned

6.1 With the major subcomponent of the project (ZYPF) out of operation for nearly two years and the other subcomponent facilities grossly underutilized, efforts should be focused on finding a way to solve the issues and on getting the plants into gainful operation. While the GMP subcomponents have already acted as demonstration pilots, their full utilization remains a matter of concern and the managements of the two enterprises (Xin Hua and Shanghai No.4) should continue to search for joint venture partners who can employ the installed capacities by introducing new drugs so that profitability can be restored. The Henan Pharmaceutical Quality Control Center also needs to become much more proactive in finding markets for its services, rather than depending on the government's mandates for its survival.

6.2 As for the future of ZYPF, the situation is more complex and problematic and requires a decision on the advisability of restarting the plant and adding producing capacity to an already glutted domestic and international market for Vitamin C. Should the government decide to proceed, there are several options:

a) To invest in modifications using Chinese technology and restart the plant, settling for a Vitamin C quality somewhat inferior to the highest international standards;

b) To sell the whole plant to a domestic investor through a bidding process;

c) To break up the plant into several production units or into two upstream and downstream units and sell each part to domestic or international joint venture partners (assuming that the patent issue can be satisfactorily resolved).

Whichever the chosen option, the State should be willing to engage in a realistic asset valuation and/or debt restructuring whereby a good portion of the loans are written down and assumed by the Government.

6.3 The major lesson of this project is that the Bank should avoid embarking on an industrial project utilizing unproven technology and a design that is based on the scaling up of a laboratory-sized pilot plant. The pharmaceutical industry suffers from an added problem in that technologies are often available from few sources and are covered by patents and restrictive know-how secrecy agreements.

6.4 An equally important lesson of the project is that the Bank should avoid embarking on a greenfield and technologically complex project without ensuring that both the project management and operational teams are well versed and sufficiently skilled with long experience in the subsector. This risk was not ever considered in the SAR and no mitigatory steps were envisaged.

6.5 In the case of problematic projects, especially, the Bank should assume responsibility and make resources available for a much higher supervisory effort in order to render advice and technical counsel to the Borrowers. The Bank's annual supervision missions were too infrequent, given the myriad of technical and managerial problems being faced by ZYPF.

Basic Data Sheet

CHINA PHARMACEUTICAL PROJECT (LOAN 2943-CHA)

Key Project Data *(amounts in US$ million)*

	Appraisal estimate	*Actual or current estimate*	*Actual as % of appraisal estimate*
Total project costs (yuan million)	888.7	2396.7	269.7
Loan amount (US$ million)	127.0	126.7	99.7
Date physical components completed	Dec. 1992	July 1995	---
Economic rate of return	34 %	NA	---

Cumulative Estimated and Actual Disbursements *(amounts in US$ million)*

	FY89	*FY90*	*FY91*	*FY92*	*FY93*	*FY94*	*FY95*
Appraisal estimate	10.2	34.6	44.5	32.0	5.7	---	---
Actual by year	4.1	19.3	64.8	19.5	12.2	4.9	1.9
Accumulated Appraisal Estimate	10.2	44.8	89.3	121.3	127.0	127.0	127.0
Accumulated Actual .	4.1	23.4	88.2	107.7	119.9	124.8	126.7
Accumulated Actual as % of appraisal	40.2	52.2	98.8	88.8	94.4	98.3	99.8

Date of final disbursement: March 29, 1995

Annex A
Page 2 of 3

Project Timetable

Steps in project cycle	Date planned	Date actual/latest estimate
Identification	November 1986	November 1986
Preparation Project Brief	July 1987	July 1987
Appraisal	December 1987	December 1987
Negotiations	April 1988	April 1988
Board Presentation	May 1988	May 1988
Signing	N.A.	December 1988
Effectiveness	September 1988	February 1989
Project Completion	December 1992	July 1995
Loan closing	December 1993	December 1994

Bank Resources: Staff Inputs

	Actual	
Stage of Project Cycle	**Weeks**	**$**
Through Appraisal	75.9	n.a.
Appraisal to Board	6.5	n.a.
Board of Effectiveness	1.0	n.a
Supervision	53.2	n.a.
Completion	13.0	n.a
Total	149.6	n.a.

Bank Resources: Missions

Stage of Project Cycle	Mo./Yr.	No. of Persons	Days in Field	Staff Skills	Performance Rating Implementation Status	Performance Rating Development Impact	Types of Problems
Through Appraisal	Nov-87	6	166	Eng. Fin. Pharm. Econ. Marketing			
Appraisal Through Board	n.a.	n.a.	n.a.	n.a.			
Board Through Effectiveness	n.a.	n.a.	n.a.	n.a.			
Supervision	Jun-89	2	14	Eng.Econ. Fin	1	1	F
	Oct-90	2	28	Eng.Econ. Fin	1	1	F
	Nov-91	1	6	Eng.	2	1	M
	Oct-92	2	28	Eng.Econ. Fin	2	1	M/T
	Dec-93	2	22	Eng.Econ. Fin	2	1	M/T
Completion	Jan-95	2	26	Eng.Econ. Fin			F/T

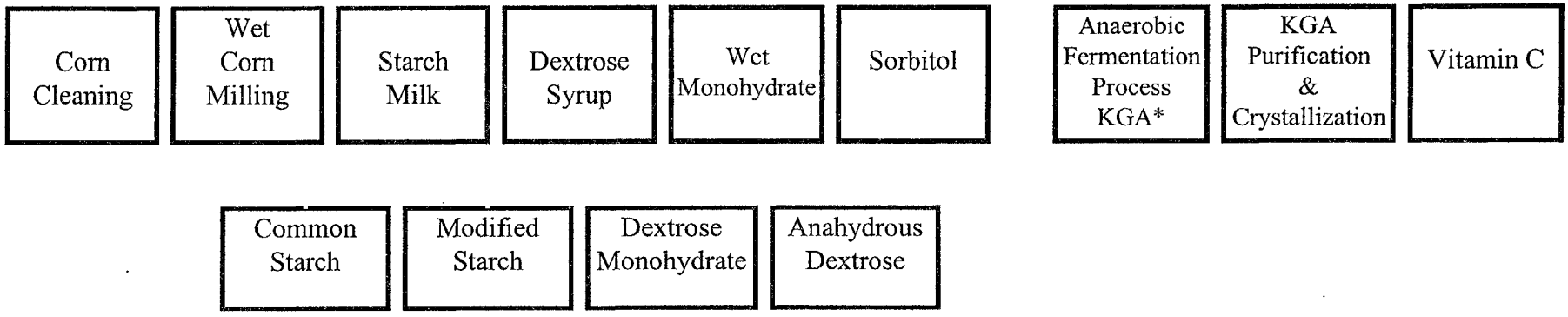
Eng. = Engineer
Pharm. = Pharmaceutical Specialist
Econ. = Economist
Fin. = Financial Analyst

Related Bank Loans

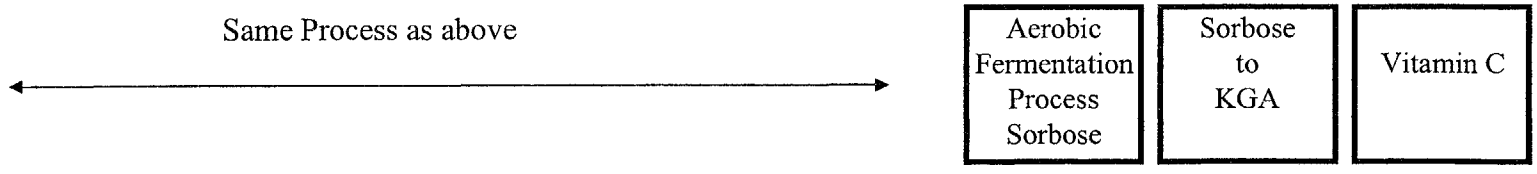
There were no preceding nor following operations in the China Pharmaceutical Sector.

China Pharmaceutical Project: ZYPF Process Diagram for Manufacture of Vitamin C

Chinese Process



Standard Process



*This anaerobic process has been developed by the Chinese for the direct production of Ketogulonic acid (KGA) from sorbitol, thus eliminating one stage in the process, i.e. the production of sorbose. However, given the amount of impurities produced in the anaerobic (2 stage) fermentation process, the output needs to be purified prior to the crystallization of KGA.

Annex C

Project Dates

Key Implementation Indicators in SAR	*Estimated*	*Actual*
A. Zhong Yuan Pharmaceutical Factory		
Major Process Packages Contract Award	Jan-89	Aug-89
Commencement of Major Civil Works	Dec-89	Jun-90
Commencement of Major Equipment Erection	Jul-90	Jun-91
Completion of Equipment Testing	Sep-91	Oct-92
Completion of Commissioning	Dec-91	Oct-92
Commencement of Vitamin C Production	Jan-92	Nov-93
Commercial Operation, 100% Capacity	Jun-93	uncertain
B. GMP Components		
Xinhua		
Selection of Design and Implementation Consultants	Dec-88	Jan-90
Completion of Major Equipment Deliveries	Feb-91	Nov-92
Commencement of Major Civil Works	Apr-89	Aug-91
Completion of Erection	Jul-912	Jun-93
Completion of Commissioning	Dec-91	Dec-93
Commencement of Commercial Operation	Mar-92	Apr-94
Shangai No. 4		
Selection of Design and Implementation Consultants	Dec-88	Jan-90
Completion of Major Equipment Deliveries	Feb-91	Jul-94
Completion of Major Civil Works	Apr-89	Jun-93
Completion of Erection	Jul-91	Dec-94
Completion of Commissioning	Dec-91	Apr-95
Commencement of Commercial Operation	Mar-92	Dec-96
C. Henan Quality Control Center		
Initiation of Procurement	Jun-88	Jun-89
Final Equipment Delivery	Apr-89	Sep-90
Completion of QCC	Jun-89	Oct-91

Annex D

Project Costs

(US$ million and Yuan million equivalent)

Component	Estimated			Actual		
	Local (yuan)	Foreign ($)	Total yuan Equivalent	Local (yuan)	Foreign ($)	Total (yuan)
1. ZYPF Component						
Installed Cost	222.6	98.2	645.4	800.0	116.0	1786.0
Interest During Construction	17.7	19.3	99.3	36.9	32.0	308.9
Working Capital	72.5	0.0	72.5	110.0	0.0	110.0
Total Financing	312.8	117.5	807.2	946.9	148.0	2204.9
2. GMP Component						
Xinhua						
Installed Cost	13.5	5.0	35.4	26.3	5.0	68.7
Interest During Consruction	----	0.9	3.6	6.0	0.8	12.5
Working Capital	1.9	----	1.9	3.5	----	3.5
Total Financing	15.4	5.9	40.8	35.8	5.8	84.7
Shanghai No.4						
Installed Cost	10.2	4.9	31.5	52.5	4.2	87.9
Interest During Construction	----	0.8	3.2	4.7	0.5	8.7
Working Capital	1.7	---	1.7	3.6	----	3.6
Total Financing	11.9	5.7	36.4	60.8	4.6	100.2
3. Henan Quality Control Center	----	1.0	4.3	----	0.8	6.8
Total Financing Required	340.1	130.0	888.7	1043.5	159.2	2396.7

ZYPF-Production Performance
Tons per Year

	Design Capacity	1992		1993		1994		1995		1996	
		Production Value	% of Capacity	Production Value	% of Capacity	Production Value	% of Capacity	Production Value	% of Capacity	Production Value	% of Capacity
Corn Input	150000	18620	12.4	63629	42.4	57810	38.5	69706	46.5	35625	23.7
Final Products											
Common Starch	33000	4698	14.2	16392	49.7	17535	53.1	22482	68	14009	42.4
Modified Starch	10000	166	1.6	11	0.1	---	---	---	---	---	---
Dextrose Monohydrate	15000	2290	15.3	5050	33.7	3152	21.0	7236	48.2	487	3.2
Dextrose Anhydrous	10000	---	---	---	---	---	---	---	---	---	---
Sorbitol (70% D.S.*)	15000	563	3.7	1574	10.5	2237	14.2	613	4.1	---	---
Vitamin C	5000	0.1	---	4.6	0.1	98.7	2.0	87.9	1.8	6.0	**0.1
Gluten Feed	36300	2902	8.0	10846	29.9	9185	25.3	11130	30.7	6302	17.4
Corn Oil	3260	401	12.3	698	21.4	561	17.2	732	22.4	475	14.6
Intermediate Products											
Starch Milk	49000	5070	10.3	16698	34.1	11877	24.2	16214	33.1	5691	11.6
Dextrose Input to Sorbitol	*D.S. 21190	1260	5.9	1705	8.0	5400	25.5	4600	21.0	---	---

Source - ZYPF

* D.S. - Dry Substance

** Vitammin C production stopped in January 1996

Annex E
Page 2 of 2

ZYPF-Periods of Highest Capacity Utilization

	Actual Best Performance Tons	Date of Best Performance
Starch		
24 Hours Period	109	April 10, 1996
Weekly Period	583	April 1-7, 1996
Monthly Period	2360	April, 1996
Dextrose Monohydrate		
24 Hours Period	49	June 5, 1996
Weekly Period	280	June 10-16, 1996
Monthly Period	1214	June, 1996
Sorbitol 50%		
24 Hours Period	55	June, 1995
KGA		
24 Hour Period	145	July, 1995
Vitamin C		
24 Hour Period	5	December, 1995

Source: ZYPF

Annex F

ZYPF-Training Programs

Type of Courses	Total number trained *				
	1989	1990	1991	1992	Total 4 Years
Operational					
Corn Washing	35	35	40	42	152
Starch Plant	115	155	156	205	631
Dextrose Plant	73	93	95	95	356
Sorbitol Plant	38	38	48	48	172
KGA and Vitamin C Plants	101	141	258	338	838
Corn Oil Section	20	21	25	25	91
Power Station	10	45	50	70	175
Chemical Water Plant	4	40	50	56	150
Waste Water Plant	3	35	40	45	123
Compressed Air	4	40	50	60	154
Laboratory	42	42	92	92	268
Maintenance					
Instrumentation	30	100	120	127	377
Mechanical	20	25	25	25	95
Electrical	3	40	68	68	179
Steam and Power	5	53	70	73	201
Turbine	3	38	58	58	157
Coolers and Chillers	4	40	45	45	134
Automatic Control	5	10	20	27	62
Specialized Courses					
Supervisory Staff	5	60	100	202	367
English Language	---	52	52	52	156
Overseas Training	---	68	---	---	68
Others	93	105	109	122	429
Total	626	1286	1581	1885	5378

Source - ZYPF

* The same individual could have attended different courses in successive years.

Annex G

China Pharmaceutical Project - Henan Quality Control Center

Year	No. of Personnel	No.of Batches tested	Income Yuan (thousand)	Expenditure Yuan (thousand)
1991	25	950	250	350
1992	25	720	160	280
1993	24	700	150	260
1994	24	730	160	270
1995	23	750	180	270
1996	22	750	200	300
1997	22	780	220	330

Source - Henan QCC

Annex H

China - Production and Export of Vitamin C

tons/year

	Production	Export	Apparent Domestic Consumption **
1987	4178	1815	2363
1988	4578	1986	2592
1989	5794	3041	2754
1990	6056	4376	1680
1991	7356	4823	2533
1992	9977	7388	2589
1993	11866	9179	2687
1994	17364	13645	3719
1995*	22000	18000	4000
1996*	27500	23000	4500
1997*	24000	19000	5000

Source: SPAC

* Estimates

**Apparent domestic consumption has been calculated by deducting exports from production. While the figures appear erratic, the increasing trend for domestic consumption is unmistakable.

ZYPF - Analysis of Product Costs and Prices
1993 - 1996
Sales and Production in Tons - Cost and Prices in Yuan per Ton

	Total Sales Tons	Unit Cost of Manufacturing Yuan/ton	Unit Cost of Marketing Yuan/Ton	Unit total Cost Yuan/ton	Unit Sales Income Yuan/ton	Unit Profit/Loss
Corn Starch						
1993	7943.5	1501.8	105.8	1607.6	1394.5	(213.1)
1994	18406.7	1597.5	46.3	1643.8	1568.3	(75.8)
1995	24116.6	2480.7	27.6	2508.3	2467.9	(40.4)
1996	13326.9	2554.1	66.3	2620.4	2207.4	(413.0)
Mono Dextrose						
1993	3094.4	3278.9	254.2	3533.1	3350.1	(183.0)
1994	2855.8	5706.1	99.3	5805.4	3365.3	(2440.1)
1995	6175.9	5596.0	49.4	5645.4	4425.9	(1269.4)
1996	5941.6	5628.3	121.9	5750.2	4058.0	(1692.2)
70% Sorbitol						
1993	622.2	4205.4	305.7	4511.1	4028.1	(483.0)
1994	1953.2	6109.6	117.6	6227.2	3983.1	(2244.0)
1995	393.6	6352.7	55.4	6408.1	4961.6	(1446.5)
1996	167.7	7433.3	134.3	7567.6	5003.2	(2564.4)
Vitamin C						
1993	2.0	102,500.0	---	102,500.0	102,500.0	---
1994	91.7	90610.5	---	90610.05	89666.4	(944.1)
1995	5.1	69427.7	---	69427.7	69164.9	(262.8)
1996	110.1	53298.9	1430.8	54729.7	53298.9	(1430.8)
Refined Corn Oil						
1993	48.0	5626.6	---	5626.6	6283.8	657.2
1994	225.1	6237.6	---	6237.6	7239.5	1001.9
1995	90.1	6327.2	326.3	6653.5	8425.1	1771.6
1996	392.5	6375.9	162.5	6538.4	6053.1	(485.2)
Crude Corn Oil						
1993	336.3	3600.0	---	3600.0	3842.3	242.3
1994	499.0	3746.2	---	3746.2	5695.1	1948.9
1995	289.2	3812.2	457.6	4269.8	5075.8	806.0
1996	456.7	4387.3	128.3	4515.6	4791.9	276.3
Gluten Feed <15%						
1993	4543.0	589.9	---	589.9	451.2	(138.7)
1994	9497.5	679.5	---	679.5	602.4	(77.1)
1995	10747.0	733.3	---	733.3	1071.4	338.1
1996	6240.1	1151.4	22.0	1173.4	819.0	(354.4)
Gluten Feed >15%						
1993	1878.4	556.7	---	556.7	516.2	(40.5)
1994	514.6	607.3	---	607.3	618.8	11.4
1995	357.6	865.1	---	865.5	1047.5	182.0
1996	124.1	393.8	32.4	426.2	1207.3	781.1

Source - ZYPF

Annex J

ZYPF - Income Statement (million yuan)

	1994	1995	1996
Income			
Sales Revenues	71.16	143.70	79.67
Other Revenues	---	---	---
Total Revenue	71.16	143.70	79.67
Expenditure			
Cost of Sales	82.42	154.70	97.99
Marketing	1.36	1.31	2.13
Depreciation*	---	---	---
Interest**	5.20	6.68	11.64
Other	1.79	19.45	(2.98)
Total Expenditure	90.77	183.14	108.78
Net Profit (loss)	(19.61)	(38.35)	(29.11)

Source: ZYPF

* No depriciation has been calculated.

** Interest refers to the working capital and not the borrowing for capital investment.

Annex K

Balance Sheet
Zhong Yuan Pharmaceutical Plant
(in thousand yuan)

	1993	1994	1995	1996
Assets				
Current Assets				
Cash	6,907	3,993	3,679	4,439
Net Receivables	16,372	8,036	27,103	27,085
Advanced Payments	---	7,770	13,499	9,962
Inventory	39,381	47,706	50,580	50,208
Others	362	6,675	7,729	10,556
Total Current Assets	63,022	74,180	102,590	102,250
Fixed Assets				
Construction	---	4,824	7,742	17,535
Deferred Intangibles	---	---	39,346	47,353
Total Fixed Assets	---	4,824	47,088	64,888
Total Assets	63,022	79,004	149,678	167,138
Liabilities				
Current Liabilities				
Short Term Loans	55,391	46,962	94,504	114,960
Payable	20,946	67,153	117,591	141,368
Others	28	(2,177)	8,074	10,749
Total Current Liability	76,365	111,938	220,169	267,077
Long Term Borrowing	---	45	829	497
Equity				
Capital	30	---	---	---
Accumulated Project (loss)	(13,373)	(32,979)	(71,320)	(100,436)
Total Equity	(13,343)	(32,979)	(71,320)	(100,436)
Total Liability	63,022	79,004	149,678	167,138

Source - ZYPF

Annex L

Income Statement - Shanghai No.4 Pharmaceutical Company

(million yuan)

	1994	1995	1996	1997
Revenue				
Sales	241.2	337.3	321.0	339.8
Expenditure				
Cost of Production	205.8	291.9	270.4	291.8
Marketing	1.9	2.9	3.9	3.7
Administrative	6.4	12.0	15.9	15.1
Financial Cost	3.9	8.9	12.0	20.9
Taxes	0.7	0.7	1.0	1.6
Total Expenditure	218.7	316.4	303.2	333.1
Profit (loss)	22.4	20.9	17.8	6.7

Source: Shanghai No.4 Pharmaceutical Plant

Annex M

Status of Legal Covenants

Section	Present Status	Original Fulfillment Date	Description of Covenant	Comments
Loan Agreement				
3.04	C	Dec-90	Furnish an industry wide program for introduction of GMP during 8th plan period, and exchange views.	Completed
4.01	C		GMP enterprises to furnish audited accounts, audit of Special Accounts and SOEs within 6 month of the close of the financial year.	In compliance
Schedule 5	CD	Jun-89	GMP enterprises to furnish implementations	Completed
Schedule 5	NC		GMP enterprises to maintain: debt service ratio of at least 1.5, debt/equity of greater than 60:40; current ration of not less than 1.3	Not in compliance
Project Agreement				
2.01 (c)	C	Dec-90	Establish Zhong Yuan Factory (ZYPF) and enter into a transfer agreement satisfactory to the Bank.	Completed
4.01			Furnish audited accounts, audits of special Accounts and SOEs within 6 month of the close of the financial year.	In compliance
Schedule	C	Jun-89	ZYPF to furnish recruitment and training program	Completed
	C		ZYPF to appoint marketing staff one year prior to plant start up	Completed
	C		ZYPF to prepare plant safety manual for hazardous materials and emergency procedures by one year prior to start up	Completed
	NC	Jan-94	In operation, ZYPF to maintain debt service to ration of at least 1.5, maintain a debt to equity ratio of at least 70:30, and a current ration of not less than 1.25.	Not in compliance

Present Status:
C = Covenant complied with
CD = Complied with after dealay.
CP = Complield with partly
NC = Not in compliance

Annex N

China - Trend of Average Prices for Corn, Vitamin C and Other Products

Yuan/ton

	1992	1993	1994	1995	1996	1997	1998
Corn	N/A	850	1300	1550	1300	1350	N/A
Common Starch	1200	1400	1570	2470	2210	2010	2050
Dextrose Monohydrate	2200	3350	3370	4430	4060	3550	3650
Sorbitol	3100	4030	3980	4960	5000	4500	4700
KGA	30,000	40,000	50,000	43,000	21,000	19,000	17,000
Vitamin C	90,000	102,000	89,700	69,200	53,300	50,000	50,000
Gluten Feed	400	450	600	1070	820	700	600
Corn Oil	4600	6280	7240	8420	6050	5900	5900

Source - ZYPF

中华人民共和国国家经济贸易委员会

State Economic & Trade Commission of People's Republic of China

26 Xuanwumen Xidajie, Xuanwu District, Beijing 100053, China. Tel: 086/10/63193573 Fax: 086/10/63193626

To: Roger J.Robinson
Country Evaluations and Regional Relations
Operations Evaluation Department, The World Bank
Fax: 001-202-5223124
From: Yu Mingde
Pharmaceutical Department
State Economic and Trade Commission
Tel: 86-10-6319- 3844
Fax: 86-10-6319-3801
Date: March 1, 1999

Dear Mr.Robinson

Re: China:Pharmaceutical Project (Loan 2943-CHA)

I received your letter and the draft Performance Audit Report (PAR) at the end of January, 1999. Thank you very much for your contributions made on this project.

As far as PAR concerned, I think it relative completely and objectively reflected the actual situations of the project Loan 2943-CHA and the problems existed.

2943-CHA Loan was the first one that the Pharmaceutical Industry of China used the World Bank's loan since China opened its door to the outside. We feel very regret that it failed to reach the expected objective due to various reasons. However, it did provide valuable experience and lessons for our future further reform and open, and for using foreign capital.

In addition, the information on this project I learned is a little bit different from those you mentioned in PAR. I'd like to refer them as follow for your reference:

a. It is not quiet correct that there was no international well-known manufacturers tendering in the call for tender of starch and dextrose facility,

the fact is that there were a few of such manufacturers tended. Among the tenders, the price offered by Starcosa Engineering Co., of Germany was much lower than those offered by other international tenders, and also the bidding documents were in conformity with the requirements. In the selection of contractor, Zhongyuan Pharmaceutical Plant put much emphasis on the factors of price, and readily believed the promise of the contractor.

b. As to the production facility, the technology and equipment in respect of KGA concentration separation units and the Vc refinery and transfer apparatus were imported from ENCO of Switzerland. The technology was really the pilot one in laboratory, and the company was purchased by an Italy company. The latter one recognized that the technology has problems and agreed to modify the facility conditionally. It required conditional supply of additional equipment against release of all other funds previously withheld. Actually, ENCO unscrupulously withdrew the last installment of its performance fund without the consent of Zhongyuan.

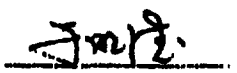
c. In PAR, it mentioned that none of the technical and managerial staff once worked in pharmaceutical plant while the start-up of Zhongyuan Project. It is not completely in conformity with the actual situation. The fact is that there were some technical and managerial staff had work experience in pharmaceutical plants.

d. The designed capability of Zhongyuan Plant is: 43,000 metric tons/year of starch (41,750 tons/year in PAR); 25,000 metric tons/year of dextrose; 15,000 metric tons/year of sorbital with 70% of content (20,450 tons/year in PAR) and 5,000 metric tons/year of Vc.

Among the projects of 2943-CHA loan, all the other subcomponents are in normal production except Zhongyuan Plant. The critical reason for failing production of Zhongyuan plant is that the contractor breached the contract. Now Zhongyuan is claiming against the contractor through the procedure of arbitration. We hope the World Bank could give support to Zhongyuan Plant's claim.

China is a country with population of more than 1.2 billion, we sincerely hope that the World Bank could give support to China's pharmaceutical industry consistently.

Truly yours,



Yu Mingde

Director of the Pharmaceutical Department