

REPUBLIC OF KOREA

Safety Research Center Project of the National Institute of Health

Report Date: November 1998

Field Survey: Not implemented

1 Project Summary and JBIC's Cooperation

This project, in order to secure safety and efficiency in pharmaceuticals in Korea, aims to create a safety research system for pharmaceuticals and other products of the same level as those existing in advanced nations, by newly establishing Safety Research Center capable of comprehensive research and evaluation of the effects of such substances on living organisms, and providing required facilities and research equipment needed for each type of research, while providing training and guidance for personnel (researchers and engineers).

The ODA loan covered the entire foreign currency amount required for the provision of the required facilities, research equipment, and the training and guidance of personnel, while Korea financed the entirety of local currency costs and all the costs for the construction of a new Safety Research Center.

Borrower / Executing Agency	Government of Republic of Korea / The National Institute of Health (The National Institute of Safety Research)
Exchange of Notes / Loan Agreement	June 1984 / August 1984
Loan Amount / Loan Disbursed Amount	· 2,400 million / · 2,226 million
Loan Conditions	Interest: 4.75%, Repayment period: 25 years (7 years for grace period), General Untied
Final Disbursement Date	August 1992



2 Evaluation Results

(1) Project Implementation

(i) Project Scope

Due to a reorganization of the executing agency, which resulted to an expansion in the number of research fields, there were minor design changes in the construction of the Safety Research Center (civil works were not covered by the ODA loan), but basically it went as initially planned. The number of items covered by the ODA loan decreased because some of the required facilities to be covered by the ODA loan were procured with local currency funds added at this time. The number of experimental equipment items increased due to the expansion of research fields. The Korean government (responsible for budget) did not approve the application of ODA loan to the dispatch of technical experts for air conditioning equipment, and it was abruptly replaced by JICA technical cooperation (dispatch of technical experts by JICA). Regarding this point, it is believed that a full understanding should have been reached not only with the executing agency, but also with the government (responsible for budget) at the time of appraisal.

(ii) Implementation Schedule

Taking the completion of equipment procurement to be the completion of the project, the implementation schedule was five and a half years behind schedule compared to the initial plan, and the L/A disbursement deadline was pushed back three years, from August 1989 to August 1992. This was mainly caused by delays in the construction of the research center due to the reorganization of the executing agency, and since this reorganization is a matter of national policy, the causes of this delay cannot be attributed entirely on the executing agency. However, separate from this, the procurement of research center facilities and experimental equipment is suffering delays. These delays are thought to be due to the fact that the executing agency and the Procurement Agency of Korea are insufficiently experienced in the procurement of the facilities and equipment in question. It is considered that, this being a project to procure the latest equipment in a field being handled for the first time by Korea, consultants should have been used.

(iii) Project Cost

As additional budget were approved for the expansion of research fields resulting from the reorganization of the executing agency, part of the required equipment for the center covered by the ODA loan were provided for, and due to fluctuations in the exchange rate (strong yen, weak dollar), no cost overrun was incurred for the additional purchase of experimental equipment.

Comparison of Original Plan and Actual

(1) Project Scope	Plan	Actual
Safety Research Center construction	Four floors above ground, 1 floor underground, total floor surface of 7,467m ²	Except for minor changes, almost as planned.
Equipment for Safety Research Center	(i) 56 materials and equipment (ii) Training of operation for air conditioning system 8M/M	(i) 28 items (the remaining 28 items were procured with the Korean budget) (ii) Stopped (JICA technical cooperation provided)
Experimental equipment	(i) 176 items used for experiments (ii) Overseas technical training 112 M/M	(i) 391 items (ii) 185M/M
Dispatch of technical experts Rearing of experimental animals, research and guidance	24 M/M	3 M/M
(2) Implementation Schedule (Start of Construction ~ Completion)		
Safety Research Center construction	Jan. 1983 ~ Dec. 1984 (24 months)	Jan. 1983 ~ Dec. 1986 (48 months)
Enlargement of Safety Research Center		Jan. 1990 ~ Sep. 1992 (33 months)
Procurement and installation of equipment for Service Research Center	Mar. 1984 ~ Dec. 1987 (46 months)	Oct. 1986 ~ Apr. 1987 (7 months)
Procurement and installation for experimental equipment	Mar. 1984 ~ Jun. 1987 (40 months)	Jun. 1986 ~ Dec. 1992 (79 months)
Training and guidance	Jan. 1985 ~ Dec. 1987 (36 months)	Jun. 1986 ~ May 1992 (72 months)
(3) Project Cost		
Foreign currency	· 2,400 million	· 2,226 million
Local currency	· 3,391 million	· 2,963 million
Exchange Rate	· 1 = 3.25 won	· 1 = 6.16 won

(2) Organization of the Executing Agency (implementation and operation/maintenance after completion)

(i) Implementation Scheme

Although the executing agency (National Institute of Health) underwent a reorganization in December 1987 while the project was being implemented, there were no major changes in the portion directly related to this project. Following Korean custom, consultants were not used for procurements, and OSROK made procurements in bulk. Of the research center equipment, procurements covered by the ODA loan were performed divided among 7 loans, with Korean and British firms receiving orders. There were no delays in the installation schedule, and both construction and installation were completed as planned. Thus the performance of the contractors was reported as satisfactory by the executing agency.

(ii) Operations and Maintenance

As a result of the reorganization, the National Institute of Safety Research was put in charge of the operation and maintenance of the project. Concretely, the institute performs by itself the replacement of consumables, periodic inspections and overhaul of equipment, the periodic purchase of spare parts, management of experimental animals, etc. It also performs after-service through the suppliers of the equipment. Moreover, the budget for operation and maintenance was maintained close to the initially estimated level, and is considered to have been handled properly. Based on the above, operation and maintenance is not thought to have been affected by problems in particular.

(3) Project Effects and Impacts

(i) The introduction of the equipment and materials required for research into fields such as toxicology, pharmacology and pathology enabled testing of the safety and efficacy of new chemical constituents in drugs and other products. It also established good laboratory practice (GLP) in South Korea and started the development of new research and testing methods.

(ii) By supporting the field of research into safety and efficacy through the provision of information and high-quality laboratory animals, this project strengthened the system of cooperation between private companies, universities and other bodies. This development made it possible to carry out research into toxicity and efficacy in place of private companies, and supply the research findings to

Movements in the Number of Research Cooperation			
Total between 1987 and 1998			
	Companies	Universities	National bodies
Acute toxicity test	73	13	82
Quasi-acute toxicity test	12	2	0
Skin itch test	11	0	0
Eye itch test	6	0	0
DNA toxicity test	51	9	52
Others	44	7	3
Total	197	31	137

(Source) The National Institute of Safety Research

those companies at economical prices. The research staff of companies can participate in research conducted at research institutes, which contributes to the training of specialists in the field of safety research and has transferred safety research technology to the private sector.

(iii) The basic scientific techniques have been put in place for state approval of imported chemicals, new drugs etc. and it is possible to disseminate information on pharmacology.

(iv) The re-evaluation of drugs that have already been approved has helped to improve the health of the public.

3 Lessons Learned

(1) Regarding the procurement of materials and equipment in fields where the borrower/executing agency are inexperienced, the use of consultants for assisting in procurement is necessary.

The procurement of research center equipment and experimental devices for this project was handled by the executing agency and the Procurement Agency without consultants, due to strong wishes expressed by the South Korean side at the time of the appraisal. However, this was the South Korean side's first project in this field and it was difficult for them to set technical specifications. These difficulties delayed the procurement procedures. As the executing agency and the borrower were unfamiliar with the field, and as the number of items to be procured was large, the assistance of a consultant was a necessity in this project.

In ODA loan projects today it is standard practice for the loan to cover procurement assistance, including consulting services.

(2) When providing loans for projects that involved the procurement of materials and equipment, it is important to study beforehand the need for training and guidance (dispatch of technical experts).

Where a field is entirely new for the borrowing country, as safety research was in this project, the opportunity should be taken to provide training and guidance, and the borrower and executing agency must be readied for running the project by themselves after that.

In projects of this type, much more emphasis is now given to the software of the project, including the use of consulting services.



(1) DNA-related Research Equipment
(Source: Brochure of the National Institute of Safety Research)



(2) Tumor-related Research Equipment
(Source: Brochure of the National Institute of Safety Research)