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PILOT PRODUCTION OF MEDICINES USING INDIGENOUS RAW MATERIALS

DP/VIE/80/032

THE SOCIALIST REPUBLIC OF VIET NAM

Technical report: Findings, work performed and recommendations*

Prepared for the Government of
the Socialist Republic of Viet Nam
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

Based on the in-depth evaluation mission of
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* Mention of company names and commercial products does not imply the endorsement of UNIDO. This document has not been edited.

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C O N T E N T S

SUMMARY OF PROJECT EVALUATION
(Period: August 6 - 22, 1990)

PART A

Project Number and Title

Pilot Production of Medicines using Indigenous Raw Materials, VIE/80/032.

Executing Agency

United Nations Industrial Development Organization (UNIDO)

Government Implementing Agency

Institute of Materia Medica (IMM), Ministry of Health (MOH)

UNDP Budget	Government Budget (in kind)
Original US$ 1,180,552	Dong 1,550,000
Revised US$ 1,389,323	Dong 203,818,000

Prior Phase (s)

Initial project request July 1980. First UNIDO project formulation mission 1982. Second UNIDO-WHO project formulation mission 1983/84.

Date Project Approved	Date Project Began	Date Project Terminated
02 December 1985	April 1986	April 1989

I. Project Objectives

(A) Development Objective:

To enable Vietnam to develop pharmaceutical products from indigenous raw materials up to industrial scale production.

(B) Immediate Objectives:

(i) strengthening the R & D capability of IMM;
(ii) upscaling and optimization of the process technologies through a modern pilot plant;

(iii) demonstration of good manufacturing practice (GMP);
(iv) transfer of proven technologies to pharmaceutical factories for commercial production of medicines;
(v) validating by modern scientific methods the efficacy and safety of Vietnamese traditional and herbal drugs and developing suitable formulations and dosage forms for administration.

(C) Expected outputs

(i) A modern pilot plant and galenicals formulation facility and through this develop:

- in modern dosage form, with appropriate efficacy and safety data, nine important traditional Vietnamese drugs at present used in crude form;
- production technology for two phytochemicals of established economic value and of two products discovered by IMM to possess biological activity;

(ii) Strengthened and updated R & D capability of IMM

(iii) Development of improved agrotechnology and post-harvest and seed storage practices for some important medicinal plants.

II. Purpose of Evaluation

To assess:

(a) the achievements of the project against the set objectives and expected outputs and identify the factors which had an impact on these achievements;

(b) the adequacy of data on the efficacy and safety of drugs and formulations developed from Vietnamese traditional drugs to meet drug regulatory requirements;

(c) the adequacy of GMP in the pilot plant and its demonstration to industry;

(d) the supply position of raw materials;

(e) the strengthened R & D capability of IMM to produce herbal drugs using indigenous raw materials;

(f) cost of indigenous production vs international market prices.

III. Findings of the Evaluation Mission

The project implementation has by all counts been very satisfactory, as evidenced, among other criteria, by the following:

(i) Both sides have fully met their obligations;

(ii) All objectives and envisaged outputs of the project have been largely achieved;

(iii) The project progress has been satisfactorily monitored by a local steering committee, by TPR meetings and by visits of the Backstopping Officer;

(iv) There has been an excellent rapport and mutual appreciation between local project staff, the CTA and UNDP/UNIDO.

Outputs

(i) The following advanced training as proposed in the project document has been provided to the staff of the IMM:

(a) Study tour of 5 senior scientists to research institutions, universities and pharmaceutical manufacturers concerned with medicinal plants/traditional drugs in India, Federal Republic of Germany, Holland and Thailand;

(b) Fellowships to 9 younger scientists, to India and Europe for higher training in pharmacology, chemistry, galenical formulation, pharmaceutical production, pilot plant operation and equipment maintenance;

(c) In-country training workshops: nine training courses have been organized so far with a total of 131 participants and the topics of workshops included different aspects of research management and economic accounting; installation, operation and maintenance of pilot-plant equipment and good manufacturing practice (GMP); standardization and safety of drugs; seed production and conservation of medicinal plants. These workshops have enabled scientists from all over Vietnam to enhance their knowledge of the theory and practice of pilot-plant operation and agrotechnology.

(ii) Enhanced R & D capability of the IMM, particularly in the area of pilot-plant operation and including galenical formulation and production, with a feeling of self-confidence and self-reliance.

(iii) A fully operational pilot plant with different unit processes required for the extraction and processing of different types of plant materials to produce extracts or pure phytochemical drugs and their formulation in different dosage forms. The pilot plant area and operation had a reasonable level of concern for GMP.

Hard outputs

(i) Process technologies on a pilot scale have been developed for the following phytotherapeutic agents, some of which are of established economic value: rutin, berberine, palmatine, tetrahydroberberine, tetrahydropalmatine, D-strophanthin and artemisinin. The experimental production of artemisinin, though not included in the project document is a noteworthy achievement in view of the complexities of the operations involved.

(ii) Laboratory methods have been developed for the isolation of diosgenin and its conversion to 16-DPA and progesterone.

(iii) The following eleven products have been developed from indigenous plants/traditional remedies and formulated in standardized modern dosage forms for administration:

Vietnamese/Generic name	Constituent plants	Use
1. Bach Dia Can	Angelica dahurica Kaempferia galanga Pueraria thomsonii	Antipyretic
2. Nguu Tat	Achyranthes bidentata	Hypocholesteraemic
3. Ba Gac	Rauvolfia canescens	Antihypertensive
4. APD	Solanum procumbens Achyranthes bidentata Eleutherina subaphylla	Antiperidontitic
5. Gindarin	Stephania spp. (Tetrahydropalmatine)	Sedative/ Schizophrenia
6. Berberine	Coscinium usitatum	Antidiarrhoeal
7. Tetrahydroberberine	By hydrogenation of berberine	Sedative Tranquillizer
8. Istamin	Sargassum	For goitre
9. Abilin	Adenosma indianum	Hepatoprotector
10. Xuyen Tam Lien	Andrographis paniculata	Hepatoprotector
11. D-Strophanthin	Strophanthus divaricatus	Cardiotonic

(d) Inter-institutional linkages: The IMM is a multidisciplinary institute. It would greatly benefit its working if it could have the benefit of advice from a National Scientific Advisory Committee consisting of senior representatives of institutions and organizations whose interests impinge upon the work of the IMM. Amongst others, this committee should have representatives from the Ministries of Health, the State Planning Committee, the Colleges of Pharmacy, Chemistry and Medicine (including Traditional Medicine), the National Centre for Scientific Research, (NCSR) and Industry. This committee should meet at least twice a year, approve the projects of the Institute, review the progress of R & D programmes and help in the technology transfer programmes. This committee could even have a few international experts.

(e) Cost structure : While the extraction and processing of extracts to pure phytochemicals of pharmacopoeial standard appeared to be well done and the processing parameters seemed adequate, it was not found possible to arrive at a satisfactory understanding or estimate of the costs of the products. The actual costs of raw materials (plants) or locally produced products were difficult to obtain, and so it was difficult to compare their prices with those on the international market. Though costs given to us seemed unacceptably low, the facts that the processes carried out had reasonable time and solvent consumption cycles, that the raw materials are locally cultivated and that man-power is cheap, suggest that the costs would not be higher than those elsewhere. With the change in policy towards more open international trade it would help if the prices of products were based on realistic costs.

Project concept and design:

Drug research directed towards development of new drugs and products from natural products/traditional system drugs covers a very wide spectrum of activity: from collection/cultivation of raw materials at one end to industrial production and marketing at the other end of one stream and clinical trials and clinical use at the other end of another stream, and with many disciplines in between. Even development in all disciplines is necessary to be able to develop new products/drugs, as any weak link will break the chain. The IMM is among those few unique institutes which have practically all the disciplines required for the development of new drugs. For

upgrading its R & D capability, all-round strengthening of all the disciplines/departments is required. One way in which support can be provided is to distribute it evenly among all the disciplines, but this would be spreading it too thinly. Another way is to make a comprehensive plan, but prioritize the phasing and build part by part: Successful completion and demonstrable results of one component in the first phase would provide justification for a second phase, in which more components could be upgraded and strengthened. The IMM chose the second alternative for this UNDP/UNIDO project support, and in retrospect it appears rightly so. The original project document was much more comprehensive, to the extent of being too broad and diffuse, but in the finally approved document it was chiefly oriented towards the pilot plant, which would provide both direct and indirect economic benefits. It was also mentioned in the project document (para k, p. 20) that subject to satisfactory performance in the first phase, a second phase of the project could be visualized. In spite of the delays in the realisation of the project, we are fully of the opinion that it has progressed very satisfactorily in the first phase, achieved all the objectives and targets set for it, and has all the justification to move into a second phase. This will also help to consolidate the gains made in the first phase. As in the first phase, there should be a selective but intensive strengthening of a few areas (mentioned in the recommendations) in the second phase, so that demonstrable results can be achieved. Development of modern formulations based on traditional drugs should, of course, likewise be maintained in this phase as a part of the continuing R & D activity.

IV. Recommendations

1. The project has been well implemented and should be considered as very successful.

2. There is an urgent need by the IMM in its ongoing R & D programme for: (i) a strip packing machine, (ii) a pilot-scale filter press; and (iii) some spare parts for pilot-plant equipment already received. These would cost a total of about US$25,000 and should be funded as a continuation of phase I or as post-investment support.

3. There is strong justification for a Phase II for this project. In this phase, UNIDO support should be provided for the following in the order of priority mentioned:

(a) Further strengthening of the pilot plant with special consideration for the experimental production of diosgenin and its conversion to 16-DPA, DHA and hormonal and contraceptive steroids used in Vietnam.

(b) Upgrading the R & D infrastructure at Van Dien Farm particularly for seed storage, post-harvest treatment and drying of plants. The specially designed rooms required for storage and hot-air drying have already been builtyb the IMM, and what is now needed is installation of heating facilities, blowers, etc., which should be provided by UNIDO. This facility will be particularly necessary and useful for experimental post-harvest processing and the preservation of the dioscorea tubers required for diosgenin production.

(c) Strengthening and upgrading the R & D capability of the IMM biology departments, with special emphasis on:

- Preclinical toxicological studies required for the regulatory clearance of new drugs and formulations;
- Cardiovascular drugs.

(d) The project document of Phase II would need to be redesigned in keeping with the above recommendations. This document should list, apart from the work on steroids, the new formulations based on traditional system remedies that would be developed in Phase II and that would reflect the continuing fulfilment of the development objectives, mentioned in the project document.

4. Strengthening of the IMM library and documentation services

The critical role of an up-to-date library for R & D programmes cannot be over-emphasized. The institute staff must have access to special monographs and current journals on all aspects of natural products concerned with their use as drugs.

5. There is need to further upgrade and strengthen the enforcement of GMP and safety measures particularly in the IMM pilot plant and Galenical Formulation Laboratories.

6. The IMM should have a Scientific Advisory Committee representing among others the MOH, The State Committee for Science, Hanoi University (Schools of Medicine, including Traditional Medicine, Pharmacy and Chemistry), the NCSR and Industry, which should review and advise the IMM on its R & D programmes.

7. As a matter of urgency, steps should be taken to ensure that there are adequate precautions against the possibility of fire, so as to protect the investment (buildings, equipment, products, etc.) which the project represents.

V. Lessons learnt

1. This project has been an unquestioned success. This is to a large extent due to a sharply focussed project in a narrow, rather than broadly diffused, subject area, to the special interest and expertise of UNIDO in this area, the rapport and mutual appreciation between the project staff and the CTA, which have all greatly contributed to its success. This project could serve as a demonstration model.

2. In the fluid world economic situation, there should be the least possible delay between the preparation of a Project Document and its acceptance by the UNDP and host Government, otherwise it creates difficulties of cost adjustments and budget overruns.

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II. PROJECT CONCEPT AND DESIGN

A. CONTEXT OF THE PROJECT

The Government of Vietnam recognizes the important role of traditional medicine within the overall health-care system and is very keen to promote the production of modern dosage forms of remedies based on indigenous plant materials. A major reason for encouraging the project is the continuing difficulty of importing drugs owing to the lack of foreign currency.

It is the Government's declared policy "to evolve and promote a Vietnamese system of medicine", by which is understood an integrated system combining the use of modern and traditional drugs. The Government is attempting to achieve this goal by:

(i) integrating the teaching of traditional medicine as a component (up to 2 years) of the courses given in colleges training practitioners of modern medicine.
(ii) supporting research into medicinal plants in both modern and traditional institutes.
(iii) producing traditional medicines in bulk in conventional and/or modern dosage forms. Such drugs are produced throughout the country in factories which belong to Central Government, as well as to Municipal and Provincial Authorities. The products from these factories cater for the needs of about 90% of the population.
(iv) a clear-cut policy to increase production of traditional drugs in the coming years by 28%.

Pharmaceutical production is controlled by the Ministry of Health. The production units are divided into two categories:

- Group I : Those controlled directly by the Ministry, and

- Group II: Those in the hands of the provincial authorities.

The Group I units, the Central Pharmaceutical Factories, are primarily geared to the production of modern dosage forms from bulk materials, both indigenous and imported. The provincial pharmaceutical factories are mainly oriented towards the production of traditional medicines. The National Plan also provides for four companies trading in pharmaceutical and one import-export company. It is recognized that the factories in the southern part of the country are better equipped than those in the north.

Up to now, capital investment has been carried out under a subsidy system. Similarly, the pricing policy for the products made by the pharmaceutical factories pursued by the Ministry of Health is based on a subsidy system and no clear picture of how the prices of individual products were arrived at could be obtained. However, with the current opening up of the country and the development of private pharmacies, alongside those run by the State, the situation is in a period of flux and it will be some time before a clearer picture emerges.

A more recent development is the permission for the IMM to engage in joint ventures with outside companies, the realization being that in this way the IMM will be able to acquire some of the funding it requires for the continuation of its work. It is also possible now for joint ventures to be undertaken with overseas companies.

In 1983 the Ministry of Health indicated the following order of priority for drug requirements:

- Drugs against influenza
- Antitussives
- Antirheumatics
- Antidiarrhoeals
- Anti-inflammatories
- Drugs for treating infertility

On this basis, in drawing up the project document, the drugs selected for inclusion in the production programme of the pilot plant were divided into:

I. Standardized plant extracts.
II. Purified active principles (phytochemicals)
III. Pharmaceutical intermediates.

It was expected that category III, which would require more complex technology and greater experience and capability would be dealt with at a later stage. However, by the time the project came to be implemented some of the drugs selected had been sufficiently investigated by the Institute of Materia Medica for their production to be transferred to the pharmaceutical factories. Moreover, the Ministry of Health requested that antimalarials and steroid intermediates for contraceptive drugs be included in the pilot plant programme.

B. Project Document

1. The problem and the technical approach

The project VIE/80/032 originated in a request from the Government of Vietnam dated 19 July 1980 for help in establishing and equipping a pilot plant for the production of plant-based drugs. The draft project document produced by the first UNIDO formulation mission held in February March 1982, was not approved. For various reasons, the second mission, which included a representative of WHO, did not take place until December 1983/January 1984 and although UNIDO authorized signature of the project document, the UNDP Office in New York raised a number of objections. Nevertheless, a CTA for the project was fielded in July 1985 and after a final revision, the project document was signed in December 1985. It proposed a 2-year project in which the co-operating government agency would be the Institute of Materia Medica (IMM) in Hanoi, which comes under the Ministry of Health.

The extensive background and justification section of the project document explains that in Vietnam there is a rich flora, with over 1500 species being used in folk and traditional medicine. Research into these indigenous drugs has been carried out by the IMM and a number of preparations have been identified as being effective for the treatment of certain common ailments. Facilities for improving the agrotechnology of the plants involved, the laboratory facilities for the phytochemical, pharmacological, toxicological, etc. study of the plants and their preparations, and the technology for the development and production of modern dosage forms, along with the infrastructure, are all identified as in serious need of strengthening and modernization. The justifiable assumption was made that by enhancing the capability of the IMM and its staff, the above-mentioned shortcomings would be largely removed.

There are no obvious alternatives to the technical approach adopted in the project to deal with the problem it was designed to solve.

2. Objectives, indicators and major assumptions

The development and immediate objectives were set out in the finally accepted project document as follows:

(a) Development objective

The development objective of this project corresponds to the national development orientation developing health work mentioned in para 9 h) of the approved 1982-1986 Country Programme for Vietnam. The project, which is included in the Country Programme under para 63, will contribute to attaining this objective by enabling the country to develop pharmaceutical products from indigenous raw materials up to industrial scale production.

(b) Immediate objectives

To upgrade the infrastructure and strengthen the research and development capabilities of the staff of the Institute of Materia Medica to enable it

(i) to establish scientific proof and credibility regarding the efficacy and safety of Vietnamese traditional herbal remedies through conduct of pharmacological, toxicological and clinical trials as required under the 1981 legislation of Vietnam on the lines of Rule 563 of WHO;

(ii) to develop and demonstrate through a modern pilot plant the concept of "good manufacturing practice" by establishing and introducing the concept of:

a) quality control both at raw material and finished product stage;
b) monitoring, standardization and optimization of process technology to ensure reproducibility of therapeutic efficacy of finished products;
c) better presentation of finished products in modern dosage forms;

(iii) to obtain clearance of new drugs developed at the institute from the Government through data generated under (i) above and to act as an agent of technology transfer through data generated under (ii) above with the pilot plant acting as an interface between research and industry.

The objectives are clearly expressed, as are also the expected outputs. These are certainly in accord with the function of the project which is that of institution building. Where appropriate, quantified targets for outputs are specified. In the view of the evaluation team, the relationships between the inputs, activities, outputs, and objectives are quite clear and justifiable. The project activities and inputs were phased over a 2-year period. In view of the lengthy and tortuous proceedings that led to the signing of the project document after a 5-year period (see above) and of experience with similar projects elsewhere, it was scarcely realistic to expect them, and hence the outputs and objectives of the project, to be accomplished within the comparatively short time-scale of two years. It is to be noted that in the UNDP 1982/86 Country Programme for Vietnam (1981, paragraph 63) the estimated duration of the project was given as four years.

On the other hand, it may be said that the activities and inputs were indeed commensurate with the results expected of the project.

The production programme for the pilot plant included both Category I and Category II drugs. Estimated quantities to be made were given for each product, so that the actual amounts made would be an indication of the progress in achieving the outputs, and hence objectives, set.

The lengthy "Background and Justification" section of the project document explains the situation regarding the major role of indigenous (traditional) medicines in the overall health-care system. Lack of foreign currency is a serious limitation in making available modern drugs. It also sets out the important part that the IMM has been playing in attempts to modernize the application of these medicines by the development of improved dosage forms in conformity with current legislation governing clinical trials and licensing of new drugs. The infrastructure of the IMM covers most of the activities that are required in the development of modern dosage forms from traditional medicines, but it is in urgent need of strengthening so that the institute can carry out its task more effectively. The design of the project as recorded in the project document takes into account the considerable advantages that would accrue from locating a project dealing with the production of modern dosage forms of indigenous drugs in the IMM and fully justifies the assumptions made.

3. Beneficiaries

The direct beneficiary of the project is the IMM, and through the IMM the benefits would be spread to the Pharmaceutical Industry, who would utilize the technologies developed by the IMM, the farms and farmers, who would be called upon to cultivate the plants needed for processing by the industry, and ultimately the people of Vietnam who would have access to the drugs thus produced.

4. Work plan

The project document included work plans for the project activities, training programme and deployment of international experts.

III. PROJECT IMPLEMENTATION

A. Activities

The work plan shown in the project document and detailing the schedule of activities was drawn up with a 2-year duration in mind and with the expected starting date July 1985. However, the start of the project was delayed until December of that year when the document was signed.

The project terminated in April 1989, by which time most of the scheduled activities had taken place and had been completed. As indicated in the project document, the expected date of completion was July 1987, so that, including the initial 6-month delay, the effective overrun was 16 months.

The two principal causes of the delayed completion of the project were delays in carrying out construction work and making available increased supplies of water and electricity required for the pilot plant, together with depreciation in the value of the US$ between ordering the major items of equipment and their delivery from US$1 = 2.33DM to US$1 = 2.1DM (Budget lines 41 and 42). This led to delays in ordering equipment as well as cancellation of certain essential items. An outline of the initial and final budgets is given in Annex V.

To correct the anomalies the Technical Advisory Committee (see Internal Evaluation Report dated 21/11/86, Part IIIA) proposed to drop the pharmacologist/toxicologist expert (BL 11.06) and to reduce expenditure on the other experts to less than half that originally specified. This still left insufficient funds for purchase in the field for accessories necessary for commissioning the pilot plant as well as laboratory chemicals and other items. An additional budget provision of US$ 150,000 to restore the expert requirement to its original figure and to allow necessary local purchases was therefore requested. Government in March 1987 authorized an additional US$100,000, which still left a shortfall of US$50,000 required for essential smaller items. In spite of these changes, the prolongation of the project, requiring extra m/m for the CTA, as well as the pilot plant engineer and short-term consultants, meant that the sub-total remained approximately the same. Some saving was realized in the fellowships budget. The major budget increase was about US$ 250,000 in the cost of the equipment, both expendable and non-expendable, largely determined by the fall in the value of the US$.

At the Tripartite Meeting held in May 1988 a further budget increase of US$ 116,000 was requested for additional equipment and chemicals to complete installation and commissioning of the pilot plant as well as additional funds for the expert's involved.

All the government inputs have been fully realized with in some cases a certain delay which in turn delayed project activities, inputs, and outputs which depended upon them. Thus, at the Tripartite Meeting held in December 1986 it was noted that the project was about 6 months behind partly due to a shortage of building materials. However, as the arrival of equipment from overseas was also delayed, the consequences were not serious.

At the Technical Advisory Committee meeting held in June 1987 it was pointed out that the existing power and water supplies for the equipment being installed were quite inadequate. Whether earlier awareness of this problem would have made much difference to the progress of the project is a moot point. The contract to renew the public utility supplies, including the construction of a new electricity substation, was awarded to a local firm before the end of the year and the work was completed by the end of March 1988. This enabled the equipment to be partly operational by May 1988 and it was hoped that the final extension of the project would be till December of the same year.

Delays by Government in the selection of trainees meant that the fellowship training programme did not take place until the period April 1987 to April 1988, and this meant that the international experts involved in commissioning the pilot plant and other equipment and in giving in-plant training could not be fielded until the trainees had returned.

The extra time resulting from the delays was usefully, employed by the CTA, among other things, in giving an extensive lecture programme on subjects connected with the project to the national project personnel.

B. Monitoring

The progress of the project has been satisfactorily monitored. A local Technical Advisory Committee comprising representatives of the various organizations connected with the project met regularly to discuss and respond to the difficulties encountered and to propose necessary changes in activities and inputs in order to keep the project on course. So far, there have been three project Progress Reports. The Backstopping Officer has made two technical appraisals and has also attended a tripartite meeting. It is clear that the project has been closely monitored and no problems have been encountered in its development as at present conceived.

IV. PROJECT RESULTS

The project results have been commendable. All the envisaged activities have gone on more or less as proposed. There have been some delays in the execution of some jobs, which led to considerable time and budget overrun. This is not unusual and is understandable in a project which involves building construction and the provision of services and ordering of equipment from varied international sources in an unstable financial climate.

All the study tours and training fellowship programmes were fielded in time, and the itinerary seems to have been quite well thought out, so as to derive maximum benefit from the visits. These have been followed by national training seminars and workshops which have helped to disseminate the benefits among participants from many more institutions within Vietnam.

All the equipment proposed for the project (except for those which were dropped due to the devaluation of the US$) has been received, installed, commissioned and is in operation; the pilot plant is fully functional. This has upgraded tremendously the pilot-plant production capability of the IMM.

The hard outputs proposed for the project have been achieved; there has been some change in specific items from the project document, which it was explained was due to the delay in acceptance of the document by the UNDP and the host government, during which period some of those outputs had already been achieved. In fact, some new items were included in the project which were not in the original document, indicating the self-confidence achieved by the staff of the IMM in solving their own problems once the facility was operational. One such item was the pilot-scale production of artemisinin, the antimarlarial from Artemisia annua, needed urgently in Vietnam for the treatment of chloroquine-resistant malaria. The IMM has already prepared about 18 kg of artemisinin and the known process has been modified to use solvents more readily available in Vietnam. This is a noteworthy achievement.

A. Outputs

Strengthened and updated R & D capability of the IMM

(i) Study tours and training fellowships

The following study tours and advanced training fellowship were provided to the staff of the IMM:

(a) Study tour of 5 senior scientists to research institutions, universities and pharmaceutical manufacturers concerned with medicinal plants/traditional drugs in India, Federal Republic of Germany, Holland and Thailand;
(b) Fellowships to 9 younger scientists, to India and Europe for higher training in pharmacology, chemistry, galenical formulation, pharmaceutical production, pilot-plant operation and equipment maintenance;
(c) In-country training workshops: nine training courses have been organized so far, with a total of 131 participants, and the topics of workshops included different aspects of research management and economic accounting; installation, operation and maintenance of pilot plant equipment and good manufacturing practice (GMP); standardization and safety of drugs; seed production and conservation of medicinal plants. These workshops have enabled scientists from all over Vietnam to enhance their knwoledge of the theory and practice of pilot-plant operation and agrotechnology.

(ii) A fully operational pilot plant and staff trained to run it

The pilot plant is highly functional and fully operational now. It incorporates most of the unit operations and processes which are required for the extraction of different types of plant materials, processing of extracts to prepare pure phytochemical products and their conversion to various pharmaceutical dosage forms: tablets, capsules, syrups, ointments or injectables. The pilot plant is versatile and can be used for upscaling and yield optimization of bench-scale processes, for training, demonstration and technology transfer to industry and for the experimental production of products for preclinical and clinical studies. Special attention has been given to the power supply (separate power substation) and utility service lines in order to ensure a smooth operation of the pilot plant. The CTA has given special attention to on-the-job training of the local staff. According to him, the staff of the IMM was intimately involved, along with the international experts, not only in the assembling, installation and commissioning of the different units but also in laying the service lines and process piping network system. This

seems to have given them a feel of the total system and a great deal of confidence and experience. The fact that the project finished more than a year ago, that there is now no CTA or international expert, and that the pilot plant has been in continuous operation since then, speaks highly of the experience and confidence gained by the staff, and gives assurance of the sustainability of the project. Some new processes have also been independently developed by the staff during this period, which are commendable; these include a process for the production of artemisinin solvents and the high-pressure aqueous extraction of rutin instead of the conventionally used ethanolic extraction. These achievements are an indication of the qualitative R & D strengthening and upgrading of the IMM.

Hard outputs

(i) Process technologies on a pilot scale have been developed for the following phytotherapeutic agents, some of which are of established economic value: rutin, berberine, palmatine, tetrahydroberberine, tetrahydropalmatine, D-strophanthin and artemisinin. The experimental production of 15 kg of artemesinin from Artemisia annua, which grows spontaneously in Vietnam and is now also being cultivated, is a creditable achievement in view of the careful processing required for its isolation on account of the unstable nature of the product. This product was not included in the project document but added later, when information about the antimalarial activity of artemisinin against acute forms of chloroquine-resistant falciparum malaria became available. Again, it shows the confidence and capability which the IMM has developed and its ability to respond to new challenges. The use of high-pressure aqueous isolation of rutin instead of the conventional ethanol extraction is also noteworthy.

(ii) Laboratory methods have been developed for the isolation of diosgenin and its conversion to 16-DPA and progesterone. These intermediates are required for the preparation of sex steroids, corticosteroids and some of the important contraceptive steroids. These processes should now be upscaled and optimized and enlarged into the target products.

(iii)The following eleven products have been developed from indigenous plants/traditional remedies and formulated in standardized modern dosage forms for administration:

Vietnamese/Generic name	Constituent plants	Use
1. Bach Dia Can	Angelica dahurica Kaempferia galanga Pueraria thomsonia	Antipyretic
2. Nguu Tat	Achyranthes bidentata	Hypocholesteraemic
3. Ba Gac	Rauvolfia canescens	Antihypertensive
4. APD	Solanum procumbens Achyranthes bidentata Eleutherina subaphylla	Antiperidontitic
5. Gindarin	Stephania spp. (Tetrahydropalmatine)	Sedative/ Schizophrenia
6. Berberine	Coscinium usitatum	Antidiarrhoeal
7. Tetrahydroberberine	By hydrogenation of berberine	Sedative Tranquillizer
8. Istamin	Sargassum	For goitre
9. Abilin	Adenosma indianum	Hepatoprotector
10.Xuyen Tam Lien	Andrographis paniculata	Hepatoprotector
11.D-Strophanthin	Strophanthus divaricatus	Cardiotonic

Dossiers on nine of those products were presented, providing background information and details of the studies carried out on their biological and pharmacological activity, their toxicity and in a few cases on their clinical response. These data were required to meet the drug regulatory requirements for registration of new products developed from traditional remedies.

(iv) Transfer to industry

Processing of the following products has been transferred to industry and we could see the production of some of them when we visited the Pharmaceutical Factories No.1 and No.2 :
Rutin, berberine, gindarin (tetrahydropalmatine), artemisinin, saponins of Achyranthes bidentata, D-strophanthin and Bach Dia Can; the production of APD is being carried out by another factory in Hanoi. The transfer of some other products is being negotiated. The rest were being manufactured by the recently commissioned IMM pilot plant to meet the country's needs till such time as industry undertakes to manufacture them.

B. Immediate Objectives

It is very gratifying that all the immediate objectives have been largely met as judged by the outputs of the project described in Section A.

C. Development Objective

The development objective viz "to enable Vietnam to develop pharmaceutical products from indigenous raw materials up to industrial scale production" is a goal and has a long-term perspective, and whether it is being met can only be judged from the direction, movement and momentum of the project. From the outputs of the project and the results achieved so far it can certainly be said with confidence that the project is moving in the right direction, has the correct perspective and momentum and should continuously deliver results fulfilling the long term goal of the development objective.

D. Unforeseen effects

There have been no particular unforeseen effects of the project except for the fact that the need to undertake R & D work on some items arose during the course of the project and these problems could be expeditiously solved on account of the strengthening of the infrastructure facilities and R & D capability that had taken place in the course of the project implementation.

E. Sustainability

The hard outputs are important, but what is of the utmost significance is the feeling of self-reliance that has been created by the successful commissioning of the pilot plant in which Vietnamese staff has been involved in the installation, operation and maintenance. This has given the local staff a great deal of confidence to do new things on their own and to face new challenges. There is no doubt that the direction, quality and momentum in R & D generated by this project will be sustained, which holds promise for the future.

One point which was often raised in discussion was regarding the availability of crude drugs, by cultivation or by collection. On enquiries and by visits to the Central Medicinal Herb Trading Co., Hanoi, which has a well organized network of cultivation, collection and storage centres all over Vietnam, we are of the view

that the supply of raw materials is a properly organized trading activity in Vietnam and that the supply of raw material is not likely to be a big hurdle in the carrying out of any project.

F. Follow up

The performance of the IMM in Phase I has been commendable. The R & D work at the IMM covers a wide spectrum of scientific activities, with cultivation and storage of plants at one end to extended pharmacological evaluation and toxicological studies at the other end of one stream and pilot scale, upscaling and experimental production at the other end of another stream. The strengthening of the IMM R & D capability can only be done in phases, and in this project Phase 1 it is mainly the pilot-scale upscaling capability that has been upgraded. In retropect, this appears to have been a wise decision, because upgrading of production capability has a large industrial and economic impact. The need for a follow-up phase was visualized even when the present project document was formulated (para k, page 20). The successful and confident execution by the IMM of the present project gives justification for Phase II of the project which it needs and fully deserves. In this phase, as in Phase I, the support should not be too thinly spread but given to a few areas so that specific and showable results are obtained.

As the IMM is the main R & D institute of the MOH for development of health-care products, any follow up action at the IMM should be such as would equip it well to match the public health needs of Vietnam.

The Public Health Sector Programme for the period 1991/1995 includes six key projects:

1. The consolidation of the primary health care network, including the promotion and improvement of Community Health Centres.

2. Family planning: In 1989 the excess of births over deaths (population growth rate) was 22.9/1000. The target is to reduce this to 19.3/1000 by 1991, through technical measures, including the use of contraceptives, and mass education. It is expected that the population will stabilize at about 100,000,000 towards the end of the century, as compared with a current population of about 65,000,000.

3. Improvement of medical examination techniques and treatment.

V. Findings

The project has run very successfully as judged by the relatively smooth implementation of all its activities, the fulfilment of the objectives set in the project document and the hard outputs achieved. The project inputs have greatly upgraded the process technology and the dosage-formulation capabilities of the IMM. The institute is moving in the right direction. There are still some technological capability gaps in the IMM, discussed below, which should be filled if the institute is to fully meet the developmental objective of the project. The performance of the IMM during Phase I of the project has been commendable and it has justified its claim for Phase II support. This will also help to consolidate the gain of the first phase. There were some deficiencies also noticed which are pointed out below:

Some deficiencies

(a) Good Manufacturing Practice: The pilot plant and galenical formulation area and operations were being conducted with good care and under reasonable hygienic conditions, but perhaps not adequate for a pharmaceutical plant manufacturing products for human consumption. It is important to enforce more rigorous practices in a pharmaceutical manufacturing plant. Here, it is all the more necessary, as this pilot plant is meant to act as a model for industry to emulate.

(b) Pharmacology and Toxicology expertise: Thepharmacology and toxicology sections need to be further strengthened, both as regards the infrastructure facilities and human expertise for preclinical toxicology studies and for cardiovascular pharmacology.

(c) Inter-institutional linkages: The IMM is a multidisciplinary institute. It would greatly benefit its working if it could have the benefit of advice from a National Scientific Advisory Committee consisting of senior representatives of institutions and organizations whose interests impinge upon the work of the IMM. Amongst others, this committee should have representatives from the Ministries of Health, the State Planning Committee, the Colleges of Pharmacy, Chemistry and Medicine (including Traditional Medicine), the National Centre for Scientific Research (NCSR) and Industry. This committee should meet at least twice a year, approve the projects of the Institute, review the progress of the R & D programmes and help in the technology transfer programmes. This committee could even have a few international experts.

(d) Cost structure : While the extraction and processing of extracts to pure phytochemicals of pharmacopoeial standard appeared to be well done and the processing parameters seemed adequate, it was not found possible to arrive at a satisfactory understanding or estimate of the costs of the products. The actual costs of raw materials (plants) or locally produced products were difficult to obtain, and so it was difficult to compare their prices with those on the international market. Though costs given to us seemed unacceptably low, the facts that the processes carried out had reasonable time and solvent consumption cycles, that the raw materials are locally cultivated and that man-power is cheap, suggest that the costs would not be higher than those elsewhere. With the change in policy towards more open international trade it would help if the prices of products were based on realistic costs.

VI. Recommendations

1. The project has been well implemented and should be considered as very successful.

2. There is an urgent need by the IMM in its ongoing R & D programme for: (i) a strip packing machine, (ii) a pilot-scale filter press; and (iii) some spare parts for pilot-plant equipment already received. These would cost a total of about US$25,000 and should be funded as a continuation of Phase I or as post-investment support.

3. There is strong justification for a Phase II for this project. In this phase, UNIDO support should be provided for the following in the order of priority mentioned:

   (a) Further strengthening of the pilot plant with special consideration for the experimental production of diosgenin and its conversion to 16-DPA, DHA and hormonal and contraceptive steroids used in Vietnam.

   (b) Upgrading the R & D infrastructure at Van Dien Farm particularly for seed storage, post-harvest treatment and drying of plants. The specially designed rooms required for storage and hot-air drying have already been built by the IMM, and what is now needed is installation of heating facilities, blowers, etc., which should be provided by UNIDO. This facility will be particularly necessary and useful for experimental post-harvest processing and the preservation of the Dioscorea tubers required for diosgenin production.

   (c) Strengthening and upgrading the R & D capability of the IMM biology departments, with special emphasis on:

      - Preclinical toxicological studies required for the drug regulatory clearance of new drugs and formulations;
      - Cardiovascular drugs.

   (d) The project document of Phase II would need to be redesigned in keeping with the above recommendations. This document should list, apart from the work on steroids, the new formulations based on traditional system remedies that would be developed in Phase II and that would reflect the continuing fulfilment of the development objectives mentioned in the project document.

4. Strengthening of the IMM library and documentation services

The critical role of an up-to-date library for R & D programmes cannot be over-emphasized. The institute staff must have access to special monographs and current journals on all aspects of natural products concerned with their use as drugs.

5. There is need to further upgrade and strengthen the enforcement of GMP and safety measures, particularly in the IMM pilot plant and galenical formulation laboratories.

6. The IMM should have a Scientific Advisory Committee representing among others the MOH. The State Committee for Science, Hanoi University (Schools of Medicine, including Traditional Medicine, Pharmacy and Chemistry), the NCSR and Industry which should review and advise the IMM on its R & D programmes.

7. As a matter of urgency, steps should be taken to ensure that there are adequate precautions against the possibility of fire, so as to protect the investment (buildings, equipment, products, etc.) which the project represents.

VII. Lessons learnt

1. This project has been an unquestioned success. This is to a large extent due to a sharply focussed project in a narrow, rather than broadly diffused, subject area, to the special interest and expertise of UNIDO in this area, the rapport and mutual appreciation between the project staff and the CTA, which have all greatly contributed to its success. This project could serve as a demonstration model.

2. In the fluid world economic situation, there should be the least possible delay between the preparation of a Project Document and its acceptance by the UNDP and host Government, otherwise it creates difficulties of cost adjustments and budget overruns.

Acknowledgement

The evaluation team would like to thank Prof. Doan Thi Nhu, the NPD, Prof. Nguyen Gia Chan, Director of the IMM, Dr. Atal, the CTA, who provided all the background documents and arranged the programme of visits and discussions so thoughtfully; the Project Secretary Mr. Nguyen Tuong Dung, who not only made all the arrangements for the visits, but also carried out the difficult task of interpreting. The mission would also like to express its thanks to UNDP/UNIDO, Hanoi, and particularly to Mr. Phan Duc Thang, Programme Officer, for help during our stay in Hanoi. We would also like to express our appreciation to Ms. Pham Thi Ngoc Lan, for her efficient typing of our report; without her help, it would not have been ready in time.

In-Depth evaluation of: Projects (I) DP/VIE/80/032 Pilot Production of Medicines using Indigenous Raw Materials and (II) DP/VIE/84/010 Processing of Vietnamese Essential Oils and related Natural Products

TERMS OF REFERENCE

1. BACKGROUND

The Government of Vietnam cognisant of the fact that the country has abundant resources of plants containing valuable phytochemicals, seeks to develop this resource base by indigenous technology. In seeking to achieve this end, two projects were initiated: project (I) to develop medicines using indigenous raw materials and; project (II) to develop the industrial production of Essential Oils and related Natural Products.

1.1 Project (I) DP/VIE/80/032 Pilot Production of Medicines using Indigenous Raw materials

The Vietnamese Government aims to evolve and promote a "Vietnam System of Medicine", combining the use of modern and traditional drugs. The Government strives to accomplish this by the following:

a) Integrated teaching of traditional medicine as a compulsory component in the colleges training modern practitioners;

b) supporting research on medicinal plants in traditional as well as modern institutes;

c) bulk producing traditional drugs in conventional and for modern dosage forms;

d) a clear-cut policy statement to increase production of traditional drugs by 28 per cent during the coming years.

The project, which was included in the Country Programme 1982-1986 for Vietnam under para. 63 will contribute to develop the country's pharmaceutical products from indigenous raw materials up to industrial scale production.

The immediate objectives as formulated in the project document were to upgrade the infrastructure and strengthen the research and development capabilities of the Institute of Materia Medica to enable it to accomplish the following specific objectives:

i. Establish scientific proof and credibility regarding the efficacy and safety of Vietnamese traditional herbal medicines through conduct of pharmacological, toxicological and clinical trials as required under the 1981 legislation of Vietnam on the lines of rule 563 of WHO;
ii. develop and demonstrate through a modern pilot plant the requirement s of "good manufacturing practice";
iii. meet regulatory requirements for new drugs developed at the institute, from the appropriate authorities of government, through data under i. and ii. above as an interface between research and industry.

1.2 Projects (II) DP/VIE/84/010 Processing of Vietnamese Essential Oils and related National products

Vietnam had during the term of the country, a reputation for production of essential oils. The events of the past decades had left the country bereft of the resource base that once was well developed. Accordingly, the resuscitation of the industry became one of the governments main aims and an important means of developing the rural economy. Distillation stills old and in need of renovation have been used over the years by the local community and the governments' intention as set

out in the Five-year plan of 1986-90 is to improve, by the application of modern technology, the earnings of the provincial as well as the national sectors. The policy required technical assistance in the form of the project whose objectives are defined as follows:

The development objective of the project is in line with the national development orientation consistent with the Five-year Plan for the period 1986-90 and will contribute to the increase in the production of Vietnamese essential oils and related natural products. This will serve in enhancing rural development and providing raw materials for local industries and ensuring their controlled development. It will also be contributing towards the increase of foreign exchange earnings.

The project is included in the Third Country Programme of Vietnam, para. 68, in the Chapter on "Assessment and Exploitation of Natural Resources".

Immediate Objectives are:

i. The first immediate objective will be to increase the production of Vietnamese essential oils of internationally acceptable quality. This is to be achieved by the use of improved processing techniques derived from means of transfer of technology and the application of appropriate parameters for improvement of both yields and quality.

ii. The second immediate objective seeks to forge an effective link between the CNRS and the Ministry of Foreign Trade so as to enable the latter to service requests from external markets particularly in regard to:

   - Information on essential oils produced;
   - The ability to provide the required quantity and quality of products; and
   - Forwarding of standard samples.

Enhancement of the research and technological competence of CNRS, as well as the field distillation units will serve to accomplish this objective.

iii. A third objective will be the development of an investment policy which will indicate the manner in which future production will be realized and how the transfer of technology from CNRS to the provincial production centres will be effected. This policy will include provisions to ensure that the production units have access to sufficient resources for re-investment.

5. THE EVALUATION

In order to assess the overall achievements of the projects and to identify the needs for further assistance, it has been agreed by all parties concerned to undertake an in-depth evaluation.

5.1 Scope, Purpose and Methods of Evaluation

In accordance with provisions contained in the UNDP Policies and Procedures Manual (PPM), the purpose of the evaluation mission would be to:

a) Assess the achievements of the projects against the set objectives and expected outputs. This will include a re-examination of the projects designs;

b) Identify and assess the factors which facilitated the achievements of the project's objectives, as well as those factors that impeded the fulfillment of those objectives;

c) Examine the extent to which the results/outputs produced by the projects have contributed towards the building up of Government capabilities to produce herbal medicines on pilot-scale using indigenous raw materials;

d) Examine if the approach utilized in both projects have led to optimum results;

e) Assess the cost of present pilot-scale production and estimate cost of future commercial scale production of products as compared with international market prices thus deriving the potential economic impact of the projects. Due consideration should be given to socio-economic benefits that can be derived from domestic production using indigenous raw materials.

In addition, the mission would also assess the technical progress made in relation to the following (for project 1): DP/VIE/80/032 - Indigenous medicines.

i) Establishment of efficacy and safety of products
ii) Demonstration of GMP via use of pilot plant
iii) Clearance of Regulatory requirements to provide a source of technology transfer to industry.
iv) Manpower build-up to form a satisfactory R&D team.
v) Procurement of Raw material supplies on a continuing basis.

for project (2) DP/VIE/84/010 - Processing of Vietnamese Essential Oils and related National products

i) The extent to which compositional analyses of Vietnamese produced essential oils have been conducted by CNRS as a continuing R&D exercise.
ii) The progress made with the construction/installation and use of pilot-scale equipment for distillation and rectification.
iii) The extent training of manpower conducted towards ensuring acceptable competence in distillation technology, instrumental analyses and organoleptic assessment.
iv) The Potential for services to the Industry by CNRS in the future and its continuing R&D role
v) Liaison between CNRS and the project DP/VIE/86/033 in HCMC.
vi) Identify any gaps in the technical assistance inputs hitherto delivered or programmed.

While a thorough review of the past in itself is very important, the evaluation is expected to also lead to detailed suggestion for further assistance to the industry within the country, realisation of the benefits to the target groups.

3. COMPOSITION OF THE MISSION

The mission will be composed of the following:-

One representative of UNDP

One representative of the Government of Vietnam

One representative of UNIDO

These representatives should not have been directly involved in the design, appraisal or implementation of the project.

4. Consultation of the Field

The mission will be maintain close liaison with the UNDP Resident Representative in Vietnam, the UNIDO SIDFA, the concerned Government organizations and the project's national and international staff.

Although the mission should feel free to discuss with the authorities concerned all matters relevant to its assignment, it is not authorized to make any commitments on behalf of UNDP or UNIDO.

5. Timetable and Report of the Mission

The UNDP and UNIDO representatives will receive briefings at their respective headquarters. Upon arrival in Hanoi, the mission will be briefed by the UNDP Resident Representative and the UNIDO Country Director, who will also provide the necessary substantive and administrative support. The mission will attempt to complete its work within 2 - 3 weeks starting in Hanoi in August 1990. Upon completion of its work, it will be debriefed in Hanoi by the UNDP Resident Representative, as well as the UNIDO Country Director. At the end of the mission, the UNDP Resident Representative will organize a meeting involving senior Government officials where the mission will present its initial findings, conclusions and recommendations, and be ready to discuss these. The mission would also discuss its preliminary findings during debriefing at UNIDO Headquarters, with the concerned officers.

The mission will complete its report in draft in Hanoi in accordance with the UNDP policies and guidelines. The mission will be required to leave behind a copy of the draft with the Resident Representative in Hanoi and one with the UNIDO Special Technical Adviser at UNIDO Headquarters.

The final version of the report in a format ready for reproduction will be submitted simultaneously to UNDP and UNIDO Headquarters (3 copies each) and to the UNDP Resident Representative in Hanoi, who will be responsible for formal submission of the report (6 copies) to the Government.

Annex II

Evaluation Team

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Mr. Dinh Trung Dinh
Specialist in R & D Management
Department of Industrial Development
State Committee for Science
Hanoi, Vietnam.

Itinerary: Annex III

6.8.90	Joint meeting of the team members at UNDP, Hanoi Meeting with CTA, NPD, Director and senior staff of the Institute of Materia Medica (IMM) Visit to the Pilot Plant and Laboratories.
7.8.90	Meeting at IMM and visit to the Labs.
8.8.90	Visit to Pharmaceutical Factory No. 2 Visit to Pharmaceutical Factory No. 1
9.8.90	Visit to the Central Medicinal Herb Trading Co., Hanoi Visit to the Van Dien Farm of the IMM Visit to the National Institute of Drug Quality Control, Hanoi
10.8.90	Meeting with Prof. N. G. Duan, Vice-Minister Visit to the Institute of Traditional Medicine Health
11.8.90	File Reading at UNDP, Hanoi
12.8.90	File Reading at UNDP, Hanoi
13.8.90	Meeting with CTA, NPD and Management of ENTEROIL at NCSR and visit to Distillation Labs and Workshop Discussion at the IMM
14.8.90	Meeting with Prof. N.V. Hieu, President of the NCSR Visit to private farms at Me So district Hai Hung
15.8.90	Visit to Ha Trung State Farm, Thanh Hoa Province
16.8.90	Report writing at UNDP
17.8.90	Report writing at UNDP Discussion at the IMM
18.8.90	Visit to the Faculty of Chemistry, Hanoi University and the Hanoi College of Pharmacy and meeting with staff of the NCSR Institute of Natural Product Chemistry
19.8.90	Report writing
20.8.90	Tripartite meeting
21.8.90	Final discussion at UNDP
	Discussion at the IMM

Annex IV

VIE/80/032

KEY PERSONS MET

Name	Designation and Institutional Affiliation

I. **UNDP, Hanoi**

Mr. J.M. Bonnamy	UNIDO Country Director
Mr. Lars Aldermalm	Field Officer
Mr. Phan Duc Thang	Programme Officer

II. **Institute of Materia Medica (IMM), Hanoi**

National Project Staff of IMM

1. Prof. Doan Thi Nhu, National Project Director (Pharmacology)
2. Prof. Nguyen Gia Chan, Director (Phytochemistry)
3. Mr. Pharm. Le Tung Chau, Deputy Director
4. Mr. Pham Duy Mai, Deputy Director
5. Mrs. Pharm. Khuong Bang Tuyet, Project Officer (Pharmacist Social Medicine)
6. Mr. Truong Canh, Deputy Director
7. Mr. Nguyen Tuong Dung, Project Secretary (Interpreter of English)
8. Mr. Nguyen Thuong Dong, Chief of Extraction Unit, Pilot Plant (Phytochemistry)
9. Mr. Pharm. Ho Dac Trinh, Chief of Galenical Formulation Unit, Pilot Plant (Pharmacist/Galenical Formulation)
10. Eng. Vu Quoc Linh, Civil Engineer
11. Mr. Pham Kim Man, Head of Planning Section (Phytochemistry)

UNIDO Staff

1. Mr. C.K. Atal, Chief Technical Adviser

III. **Ministry of Health, Government of Vietnam, Hanoi**

Prof. Nguyen Van Dan, Vice-Minister

IV. Pharmaceutical Plant No. 1, Hanoi

1. Mr. Trinh Xuan Tuan, Deputy Director

V. Pharmaceutical Plant No. 2

Mr. Tran Nguyen Huu, Deputy Director
& Mrs. Ngo Thi Tam, Head of Production

VI. Van Dien Farm, IMM

Mr. Nguyen Ba Hoat, Manager

VII. Central Medicinal Herb Trading Company, Hanoi

Mr. Tran Bin Duyen, Deputy Director

VIII. Department of Traditional Medicine, Medical University, Hanoi

Prof. Tran Thuy, Head, Department of Medicine

IX. National Institute of Drug quality Control, MOH, Hanoi

Prof. Doan Huy Khac, Director

BUDGET REVISION
VIE/80/032

ANNEX V

	Original Budget Revision I		Latest Budget Revision 1	
10. PERSONNEL	m/m	-	m/m	
11.01 CTA	25	199,310	31.1	221,676
11.02 Civil Engineer	1	7,000		
11.03 Pilot Plant Engineer	6	42,000	8.2	63,822
11.04 Industrial Pharmacist	6	42,000	3	20,658
11.05 Organic/Analytical Chemist	6	42,000	3	19,331
11.06 Pharmacologist/Toxicologist	4	28,000		
11.50 Short-term Consultants	3.8	29,798	4.8	37,977
11.99 Subtotal Experts	51.8	390,109	50.1	363,464
15.00 Project Travel		2,500		12,151
16.00 Mission Costs		15,465		33,453
18.00 Surrender PY Obligs.				-4 227
19.99 Total Personnel	51.8	408,073	50.1	404,841
30 TRAINING				
31.00 Fellowships		80,000		39,848
32.00 Study tours		35,000		38,469
33.00 In-service training				4,000
38.00 Surrender PY Obligs				-857
39.99 Total Training		115,000		81,460
40 EQUIPMENT				
41.00 Expendable		50,000		94,484
42.00 Non-expendable		600,000		830,905
48.00 Surrender PY Obligs				-27,115
49.99 Total Equipment costs		650,000		898,274
50 MISCELLANEOUS				
51.00 Operation and Maintenance				13,900
52.00 Reports		1,000		
53.00 Sundries		6,479		
58.00 Surrender PY Obligs				-152
59.99 Total Miscellaneous		7,479		13,748
99.99 Project Total		1,180,552		1,398.323

*) This is the budget as given in the signed project document. It includes expenditure for the years 1981-1984, amounting to US$ 39,797.