

UNITED NATIONS DEVELOPMENT PROGRAMME

**Project of the Government of
the Socialist Republic of Viet Nam**

PROJECT DOCUMENT

Number and Title: VIE/96/033/D/01/31 and GLO/96/452/A/15/31-
International Scientific Development of the Anti-Drug
Medication HEA(N)TOS (Phase 1)
Duration: GLO: 16 months, VIE: 8 months
Project Site: Hanoi.
ACC/UNDP Sector and Sub-Sector: Social Development (1700) & Drug Abuse Control (1760)
Government Sector and Sub-Sector: Drug Abuse Control
Executing Agency: United Nations Office for Project Services (UNOPS)
Implementing Agency: National Centre for Natural Science and Technology
(NCNST)
Expected Starting Date: GLO: January 1996, VIE: May 1997
Government Input: VND356,500,000 (in kind)

Brief Description:



Drug abuse has become one of the most pervasive social problems and a phenomenon of both the global and national dimensions. The lack of an effective medication represents a continuous challenge to the treatment and rehabilitation of drug-abusers. Only recently, a group of Vietnamese scientists has developed the herbal preparation "HEA(N)TOS" which is effectively applied in Vietnam as a medication and therapy against drug addiction.

A three-phase project has been designed to establish the scientific conditions for the national and international use of HEA(N)TOS through substantiating its safety and efficacy claims with the scientific support of Johns Hopkins School of Medicine, a lead agency in this area. At the same time the project will strengthen the endogenous scientific capacity in Viet Nam to develop herbal medicine. Phase I of this project aims at developing a programme framework to verify and substantiate the claims of HEA(N)TOS and establishing improved conditions in Viet Nam for effective interactions with the international scientific community and the implementation of a testing programme which is at the core of phases II and III.

UNDP and Co-Financing

<u>UNDP:</u>		
TRAC:		US\$ 200,000
GLO:		US\$ 200,000
Cost sharing:		Nil
Total:		US\$ 400,000

<u>AOS Costs:</u>		
TRAC		US\$ 18,527
GLO		US\$ 18,346

On behalf of	Signature	Date	Name/Title
The Government (for TRAC resources)		14/5/1997	Prof. Dang Vu Minh Director General, NCST of VN
The Executing Agency (for TRAC & GLO resources)	(signed)	19/12/1996	Ingolf Schuetz-Mueller Chief, ENVP, UNOPS HQs
The UNDP HQ/BBPS (for GLO resources)	(signed)	19/12/1996	Anders Wijkman Assistant Administrator & Director, BPPS, UNDP HQs
The UNDP CO (for TRAC resources)		14/5/1997	Nicholas Rosellini Deputy ResRep, UNDP VN

United Nations official exchange rate at date of signature of Project Document : US\$ 1.00 = VND 11,320

A. CONTEXT

1. Description of Sub-sector

a. The global context:

Nature and Scope of the Problem

At the end of this century, drug abuse has become one of the most pervasive social problems from a global perspective. As a social problem in Western industrialized countries and a socio-cultural element in some developing countries in past decades, drug abuse has recently become a widely spread phenomenon of international dimension. In its cross-cultural expansion, it appears to be an inherent element of the current economic globalization under the cultural values of Western societies, in particular, with regard to conspicuous style of life and consumption patterns.¹ It can be found in virtually all national societies, though the intensity and nature of drug abuse (marijuana, opium, heroin, crack cocaine) varies from country to country. For instance, in the United States in 1988 -according to a National Household Study on Drug Abuse- almost 28 million Americans over the age of 12 years, about one in every seven persons, had used illicit drugs one or more times in the preceding year. Among those Americans more than 21 million had been users of marijuana (including hashish), 600,000 of heroin, more than one million persons had used crack cocaine, the most addictive drug, coupled with the emergence of acquired immunodeficiency syndrome (AIDS) among intravenous drug users.²

Economic Costs of Drug Abuse, Cost Effectiveness and Financing

Drug abuse causes high increasing costs for any national society, where it occurs. There are direct and indirect economic costs. The former include costs such as personal health care for persons suffering from drug abuse, development of necessary knowledge and skills of physicians and nurses and other related direct costs incurred by society (e.g. the criminal justice system, drug control, private legal defense, property destruction, and social welfare administration). The latter include morbidity costs, i.e. the value of reduced or lost productivity due to the drug abuse, and mortality costs, i.e. the value of lost productivity due to premature death resulting from drug abuse.

In the United States, economic costs of drug abuse, based on the above-mentioned elements factored into computations, may be today in the order of \$70-\$80 billion, as earlier estimates in 1985 and 1988 suggest.³ According to these two surveys, it was estimated that economic costs related to drug abuse in the United States amounted to \$44.1 billion in 1985 and \$58.3 billion in 1988. Direct treatment costs amounted to 4.7% (1985) and 4.6% (1988), other related direct costs (crime) to 30% (1985) and 28.8% (1988). Indirect costs related to morbidity amounted to 13.6% (1985) and 12.3% (1988) and those related to mortality to 5.8% (1985) and 5.2% (1988).

¹ United Nations International Drug Control Programme, "Bulletin on Narcotics", Volume XLVI, No. 2, 1994, p. 48

² National Institute of Drug Abuse, "Economic Costs, Cost-Effectiveness, Financing, and Community Based Drug Treatment", Research Monograph 113, 1991, p. 10

³ Ibid, p. 22

Indirect economic costs related to crime in connection with drug abuse (victims of crime, etc.) amounted to 43.7% (1985) and 43.6% (1988). Economic costs of drug abuse related to AIDS amounted to 2.2% (1985) and 5.6% (1988) with a rising trend.

Other more recent estimates of drug abuse related costs in the United States in 1990 amount to \$66.9 billion, including costs for health care, accounting for 4.8%, loss of productivity due to illness of 12%, loss of productivity due to premature death of 5%, crime, criminal justice, property loss of 68.8%, AIDS/Fetal Alcohol syndrome of 9.3%.⁴

Regarding treatment costs, based on a resource allocation model for treatment with methadone, costs for one patient over a treatment of two years are estimated to be in the amount of US\$ 5,500. These costs include: medical drug management \$1,000; counseling treatment integration \$1,000; psychological/social services \$1,000; counseling and self-help \$1,000; relapse prevention \$500; monitoring and self-help groups \$1,000.⁵

Cost benefit computations demonstrate that although social costs of treatment are positive and treatment is not 100% successful at curbing drug use and associated social costs, substantial savings can be achieved compared to social costs of drug abuse without intervention.

Societal and Scientific Challenge

The effective countering of drug abuse requires a broad range of actions at local, national, regional and international levels which include:

- Strengthening of drug control administration, including the promulgation of a comprehensive drug control legislation and ratification of UN Conventions on drug control, and measures to combat illicit trafficking and drug-related crime.
- The reduction and control of the supply of illicit drugs, in particular, the gradual elimination of the illicit cultivation of opium poppy, and introduction of alternative cultivations.
- The propagation and dissemination of preventive education on drug abuse.
- Treatment and rehabilitation of drug addicts.

While all of these actions are inter-related and affect each other, medical and pharmacological aspects of treatment and rehabilitation of drug addicts present a special challenge to the scientific community at national and international levels.

The focus on the curative measures is of particular relevance in this context for the absence of an effective pharmacological treatment for addiction. Specifically,

- there is no medication to reduce withdrawal symptoms of addicted persons to cocaine, as

⁴ Public Health Service, US Department of Health and Human Services, "Substance Abuse and Mental Health Statistics Source Book", Beatrice A. Rouse, p.3

⁵ National Institute on Drug Abuse, "Economic Costs, Cost-Effectiveness, Financing, and Community Based Drug Treatment", p. 105

⁶ Ibid, p.75

- well as to eliminate the craving of addicted persons (recidivism). Medications applied only reduce withdrawal symptoms of opiate addicted persons;
- medications and treatment applied in Western industrialized countries in order to detoxify drug addicted patients, are extremely costly and represent an increasing factor of public expenditure; and
 - any scientific and medical progress in developing and introducing a new or alternative medication and therapy, which is more efficacious and cost-effective would not only reduce direct costs of treatment, but would also have a major impact on indirect and other drug-related social and economic costs.

Therefore the search for an effective treatment of addicted persons also needs to include alternative medications, if they indicate a potential of efficacy. It is against this background that the international scientific community is challenged to bridge cultural differences and to develop cross-cultural methods, in order to create the scientific conditions for the global use of such medications.

b. Vietnamese Context

Situation of Drug Abuse in Vietnam

While opium production has been known in Viet Nam for a long time, drug abuse problems have re-emerged comparatively recently. According to the "Viet Nam Drug Control Master Plan, 1995", there are an estimated 185,000 drug addicts (0.3% of population) in the country, of which roughly 135,000 smoke opium and 50,000 inject. There is a high concentration of drug abuse in the mountain provinces of Yen Bai, Lao Cai, Lai Chau, Son La and Cao Bang, which are all provinces in Northern Vietnam with a high proportion of tribal minority population. This suggests that drug abuse in Vietnam is still very much an ethnic and cultural phenomenon and concentrated in those areas where opium is traditionally grown and used.

However, the statistics also reveal a dramatic increase of drug abuse in urban agglomerations, in particular, in Ho-Chi-Minh City, which accounts for almost one sixth of total drug abusers in Vietnam, in recent years. Drug abuse in urban centers is widely spread among male adults, representing all social strata. An increasing prevalence of drug abuse among the young have been observed.

In contrast to traditional methods of drug abuse, there are changes in its patterns. First, there is increasing tendency of using heroin. Second, the drugs are increasingly injected. As indicated in the above-mentioned Vietnam Drug Control Master Plan, the use of contaminated needles and other injecting equipment has been a major vector of the rapid spread of HIV/AIDS in Viet Nam. According to WHO, 150,000 persons are estimated of having been infected by the HIV virus in Vietnam, and that this number is projected to increase to 570,000 by the year 1998⁷.

A specific group of drug users are veterans, respectively war invalids, who had been medically treated with morphine against war injuries, and as a result became addicted to morphine. It can be assumed that their number is close to the number of registered drug abusers, i.e., in the vicinity of 40,000. In contrast to other groups of drug abusers, addicted veterans and invalids have free

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UNDP, "Briefing Note on the Socialist Republic of Vietnam", Hanoi, April 1995, p. 18

access to morphine, which is distributed on a monthly basis by the Ministry of Labour, War Invalids and Social Affairs.

The Medication

One major aspect of the Vietnamese context of the project is the medication HEA(N)TOS itself. The development of HEA(N)TOS as an anti-drug medication and therapy has its roots in extensive research work conducted by the herbal scientist Dr. Tran Khuong Dan, which dates back to the early eighties. This research work resulted in the formulation of HEA(N)TOS, which was evaluated by an Interministerial Committee under the former Vice-Minister of Health, Professor Dr. Nguyen Van Dan, in late 1990. On the basis of this evaluation HEA(N)TOS was initially authorized as a safe and efficacious medication for clinical application about one year later. Since 1991 more than 3,000 patients, mainly addicted to opium and heroin, however, in a few cases also to cocaine, have been treated successfully with regard to withdrawal symptoms and apparently also with some success to the elimination of craving to the addicted drug. The latter claim is based on anecdotal evidence and on some statistical evidence regarding the treatment of war invalids addicted to morphine. Of more than one hundred war invalids who have free access to monthly distributed rations of morphine, 70% did not return to claim their ration once they underwent one single treatment with HEA(N)TOS.

As an herbal product, HEA(N)TOS is composed of various plants and other ingredients, which exist in Vietnam in abundance. HEA(N)TOS can be produced cost effectively. The duration of in-house treatment of addicted patients is about one week. Costs for the treatment (including hospitalization) of one person are estimated to be about \$70 under the present costs in Vietnam. This high-cost effectiveness gives HEA(N)TOS a competitive edge compared to Western medications.

Laboratory tests conducted in the United States indicate that HEA(N)TOS is not a drug substitute. The Seminar on HEA(N)TOS, jointly held by Vietnamese and American scientists at Johns Hopkins University in Baltimore in January 1995, recommended that although HEA(N)TOS has been initially authorized in Vietnam, its claims still need to be reviewed under Vietnamese standards and verified and substantiated in compliance with international scientific standards as a pre-condition for its national and international use on a commercial basis. Such an effort requires an international effort involving scientists and institutes of international reputation in the treatment of addiction and in the development of anti-drug medications. For the testing outside of Vietnam it will be treated as a new preparation.

As Vietnam has time-honoured use of traditional medicines, many other herbal prescriptions have also been claimed to possess therapeutic effects on drug addiction such as PHUHUSA and BIMIN. PHUHUSA, also a herbal medicine, has been officially recommended by the Ministry of Health to be used nationwide in drug detoxification, while BIMIN has been developed on a business basis.

2. Host Country's Strategy

Since its establishment, the Government of Viet Nam has given a high priority to the prevention and control of drug production, trafficking and abuse. The Government's policy framework reflected in the Viet Nam National Drug Control Programme (1993) is based on the following:

- Elimination of illicit opium poppy and cannabis cultivation and narcotic drug production;
- Drug abuse prevention, treatment, rehabilitation, aftercare and social reintegration;
- Drug abuse preventive information and education;
- Improvement of drug control legislation; and
- Promotion of international cooperation in drug control.

In particular, the Government has taken efforts to promote the treatment of drug addicts. Compulsory treatment of drug addiction is stipulated in the 1989 Law on the Protection of the People's Health, Chapter IV, Article 29 and re-affirmed by the Government's 1993 Resolution No 6/CP on Strengthening the Direction of Drug Abuse Prevention and Controls. About 30 government-funded drug treatment centres at the central and provincial levels are in operation, most of them established only in the last three years. In addition, nearly 20 other social centres are also involved in drug treatment and rehabilitation. Patients are admitted both voluntarily and involuntarily. The latter is applied for drug abusers who have received three warnings by the local authority to seek voluntary treatment or who have been caught in opium dens.

It is the Government's policy to encourage combination of traditional medicine with modern medicine and use of medicinal plants in drug treatment. In particular, the Government has encouraged the development and improvement of HEA(N)TOS as an medication for drug abuse treatment since it beginning. It also promotes the cooperation between Vietnamese and international scientists in this area.

3. Prior and On-going Assistance

There is still limited foreign assistance extended to this sector of Viet Nam. Efforts have been made by Australia, the UK and France to support law enforcement through training of personnel from Customs and Police. Save the Children UK, Care International and other NGOs provide assistance in preventive education, treatment and rehabilitation.

The United Nations Drug Control Programme (UNDCP) has assisted the Government in development of the National Drug Control Master Plan and strategic plan for the period between 1996-2000, which was approved in November 1995. Several technical assistance projects so far have been formulated covering different aspects of narcotic drug control, such as alternative socio-economic development for opium replacement, strengthening of institutional capacity and national drug control coordination, law enforcement, drug abuse prevention among ethnic minority peoples, drug prevention in schools, drug-related harm reduction, data analysis and drug treatment and rehabilitation training. Under several national and regional projects, UNDCP provides the Government with assistance in collecting and analysing data, training of staff for the implementation of the Master Plan. Especially, UNDCP is assisting the Government in drug-abuse prevention through the integrated rural development in Ky Son district, Nghe An.

During previous Government/UNDP Country Programmes (1977-1992), UNDP assisted the Government in strengthening capacity of the Ministry of Health in conducting relevant pharmaceutical researches through projects VIE/80/032 - Pilot plan to Produce Indigenous Medicines at the Institute of Materia Medica and VIE/84/006 - Drug quality control at the National Institute of Drug Quality Control. UNDP also assisted the Government in strengthening capacity in chemical analysis through projects VIE/80/050 - Chemical Analysis under the National

Centre for Natural Sciences and Technology and VIE/88/012 - Faculty of Chemistry of Hanoi Teachers' College under the Ministry of Education and Vocational Training.

4. Institutional Framework

The National Drug Control Programme, which was established in pursuance of the Government's Resolution No. 06/CP dated 29 January 1993, provides a framework for Viet Nam's efforts to combat drug abuse. The Committee for Ethnic Minorities and Mountainous Areas (CEMMA) is the national focal point responsible for the overall management and implementation of the Programme. Under the Programme, a Management Committee which consists of representatives from 18 ministries and national agencies is established for policy planning and coordination. The Management Committee is chaired by the Minister/Chairperson of CEMMA. Vice-Ministers of three key ministries, namely the Ministry of Labour, War Invalids and Social Affairs (MOLISA), the Ministry of Health (MOH) and the Ministry of Interior (MOI) are vice-persons of the Management Committee.

MOLISA is responsible for treatment and rehabilitation of drug addiction. The Ministry runs most of the government institutions for treatment and rehabilitation of drug addicts.

By its mandate, MOH is responsible for the medical part of the detoxification process in the treatment institutions. In particular, MOH and its institutions such as the Institute of Materia Medica (IMM) and Institute of Drug Quality Controls are responsible for defining medicines, methods for drug addiction treatment, and management and control of licit drugs in accordance with its legal responsibilities, authority and professionalism. In particular, IMM is a single scientific research institute assigned with the specialized following tasks in inventory survey, botanical screening and classification of medicinal plants, phytochemistry and analytical chemistry of active principles, pharmacological (on experimental animals) and clinical (on humans) study of medicines developed from herbal origins, testing evaluation, processing and formulation of new dosage-forms, and pilot production before transferring technology to industrial manufacture. In addition to its task in drug control, the Institute of Drug Control (NIDC) is also assigned to set up drug testing standards and monitor their implementation. The Central Psychiatric Hospital in Vietnam (CPH) has a mandate to carry out both treatment of drug abuse and research on it.

As mentioned above, the National Centre for Natural Science and Technology (NCNST)/Institute of Chemistry (IOC) plays the leading role in developing HEA(N)TOS and has recently been officially assigned by the Government to be the focal point for the preparation for its further development. IOC disposes a major chemical analysis capacity in the country. As a body of the NCNST, IOC has established a close collaboration and coordination with MOH, MOLISA and CEMMA as well as some international institutions in this matter.

B. PROJECT JUSTIFICATION

1. Problems to Be Addressed:

As indicated at the joint seminar on HEA(N)TOS at Johns Hopkins University in 1995, the current "pre-project" situation precludes a wider national and international use of HEA(N)TOS because:

- the preparation and its application are poorly documented;
- its claims of safety and efficacy are insufficiently substantiated with regard to scientific standards, which are applied in industrialized countries;
- Viet Nam presently lacks the clinical conditions to undertake the respective studies and tests to meet these standards. It also partly lacks both scientific expertise, particularly in modern methodology and techniques, and international scientific linkages necessary for the studies and tests,
- There are still limited cooperation and coordination between the related Vietnamese research institutions as well as between Vietnamese and foreign scientists in this field; and
- Viet Nam also lacks capacity in programming, organising and managing such a comprehensive research.

2. Expected End-of-Project Situation

The project will be implemented in three phases. At the end of phase I, interested Vietnamese and foreign parties will be able to conduct necessary studies and tests to verify and substantiate safety and efficacy claims made by HEA(N)TOS in accordance with international scientific standards, namely:

- a testing programme and an underlying scientific methodology for the verification of safety and efficacy tests will be developed and concurred by the concerned parties;
- the settlement of national and international intellectual property issues will be initiated;
- capacity of NCNST/IOC and key Vietnamese research institutions concerned will be strengthened to be able to initiate the implementation of the testing programme in Viet Nam and maintain effective cooperation with their international scientific counterparts;
- an initial study will be conducted under MOH to review earlier testing results of HEA(N)TOS, which has been scientifically more advanced since its introduction a few years ago. The study will also test the methodology and prepare for the following full-scale implementation of the testing programme;
- project documents(s) for phase 2 will be prepared with identified sources of funds and submitted to the Government and the potential donors for their consideration.

Phases II and III will focus on the implementation of the testing programme which will provide a complete set of well-documented data on the safety and efficacy of HEA(N)TOS. At the same time, the national capacity in conducting clinical research and tests will also be enhanced for the development of herbal medicine and for the treatment of drug-addicted patients.

3. Target Beneficiaries

Target beneficiaries will ultimately be individuals in Viet Nam and worldwide, who are addicted to drugs. Beneficiaries will be Viet Nam's economy and national economies worldwide, which could produce savings in direct and indirect costs related to drug abuse, in introducing and applying HEA(N)TOS as a more cost-effective treatment for addiction.

Direct beneficiaries will be scientists of NCNST/IOC and other research institutions involved in the project, particularly those under MOH. They will benefit from better research opportunities and improved working conditions, including international cooperation, in the use of herbal medicine.

4. Particular Strategy and Implementation Arrangements

The project's strategy is based on the scientific dialogues and recommendations made at the seminar on HEA(N)TOS at Johns Hopkins University in Baltimore in 1995 (see Appendix I) as well as on extensive preparatory work and consultation with the Government conducted in the course of 1995-1996.

The strategy is two-pronged. First, the project focusses on making an important contribution to the establishment of necessary scientific conditions and pre-conditions for the wider national and international use of HEA(N)TOS. It will be achieved through promoting scientific cooperation for the substantiation and further development of HEA(N)TOS as an anti-drug medication. This cooperation is guided by a strategic demand to verify the safety and efficacy of HEA(N)TOS in compliance with the highest scientific standards and under observance of the most strict national regulations for the authorization of medications, as well as with the involvement of the most reputed scientific institutions in the area of treatment and pharmacological development against drug addiction. This consideration will be reflected in a testing programme and its underlying scientific method, which will be implemented in both the United States and in Vietnam. On the other hand, the implementation of the testing programme will also require closer inter-actions between Vietnamese and international scientists, based on a continuous inter-cultural scientific dialogue. These inter-actions are likely to facilitate and accelerate the process of verification and substantiation of claims of the safety and efficacy of HEA(N)TOS.

Second, the project will also strengthen the scientific and technological capacities in the scientific development of HEA(N)TOS and other herbal preparations in Vietnam. It is likely that such a capacity will contribute to the industrial and commercial development of HEA(N)TOS under Vietnamese terms, once its claims as a safe and efficacious medication against drug addiction are verified as a result of the three-phase process.

With this general strategic approach the project pursues a global orientation, but is also of Vietnamese relevance. Both orientations are reflected in the objectives of the project and partly in its categorization and budgetary provisions.

Taking into account the risk-taking nature of such a scientific research as well as the need to mobilise a large funding, a long process of preparatory works was carried out in consultation with the Government in 1995-96 to develop the project concept and general design and build up consensus among interested parties. As a result, the project is proposed to be implemented in three sequential phases, which are inter-related but also generate distinctive outputs. The overall objectives of the project (through phases I to III) are as follows:

- (1) The scientific substantiation of safety and efficacy claims of the HEA(N)TOS preparation, which is a pre-condition for its global use, as such contributing to the global objective;
- (2) The establishment of an appropriate medical facility for testing in the combination of training and treatment of addicted patients, offering adequate clinical conditions, and as such contributing to both objectives;
- (3) The development of HEA(N)TOS as an uniform and standardized product as a pre-condition for its scientific, industrial and commercial use, contributing to both objectives;
- (4) The detection of scientifically and biologically active principal(s) of HEA(N)TOS, in order to facilitate its scientific and industrial development, contributing to both objectives; and

- (5) The establishing of a method for the scientific development of herbal medicine, which is based on the experience of the scientific substantiation of HEA(N)TOS and which complies with scientific standards to allow the international use of this medicine. The achievement of this immediate objective would also lay the foundation for Vietnam to take an international lead in herbal medicine development. As such it will primarily contribute to the national objective.

For this purpose, phase I (which this project document addresses) aims at developing a framework, including a testing programme and an underlying scientific methodology, for the verification and substantiation of safety and efficacy claims of HEA(N)TOS, as well as in improving conditions for the implementation of the testing programme in Vietnam, including international scientific cooperation.

Phases II and III focus on the implementation of testing programmes, enhancing at the same time the scientific expertise and increasing the standards for testing in Vietnam, as well as improving the conditions of clinical research for the development of herbal medicine and for the treatment of drug-addicted patients and as such, contributing also to Vietnam's National Drug Control Programme. Specifically, phase II will be designed to scientifically demonstrate the safety claims of HEA(N)TOS and to provide scientific indications of its efficacy. Subject to an evaluation of phase II by independent scientists, phase III is programmed to further substantiate safety and efficacy claims, including claims of HEA(N)TOS to prevent recidivism, as a result of tests conducted in Vietnam.

The overall project is scheduled to be implemented as follows:

- Phase I (up to 16 months/incurred costs of US\$ 400,000, not including the Government in kind contribution)
- Phase II (12 months/incurred costs of approximately US\$ 1.6 million)
- Phase III (16 months/incurred costs of approximately US\$ 2.9 million)

The strategy and underlying method which will be applied through this project are likely to be more cost-effective than a commercial operation with a similar purpose. In particular, the project will make efforts to utilize existing capacities, especially those strengthened under UNDP-assisted projects in the past.

The scientific method will be developed in close cooperation with Johns Hopkins School of Medicine, specifically with its Center for Chemical Dependency, which will also take a lead in conducting the testing programme in the United States. Furthermore, it will provide scientific advice and technology transfer to the Vietnam National Center for Natural Science and Technology and other Vietnamese research institutions selected to conduct a parallel testing programme in Viet Nam.

Experience of relevant UN agencies will be taken into account. For this purpose, further consultations are envisaged to agree on the modalities and areas of cooperation with WHO and UNDCP. WHO has indicated its interest in contributing to the evaluation of costs and effects of the treatment approach related to the application of HEA(N)TOS. UNDCP is likely to be involved in the further development of the extra-pharmacological therapeutic treatment. UNOPS will play an important role in assisting the Government and UNDP in executing the project.

Integration of the Project in the Institutional and Policy Framework

The project under consideration is with its specific orientation and design, unique and without precedent in Vietnam or elsewhere. Subsequently, it differs from activities which are carried out under the National Drug Control Programme, which are primarily of a preventive nature. However, as the project will strengthen the endogenous scientific capacity in Vietnam to develop and produce HEA(N)TOS and other herbal preparations for more effective treatment of drug abusers, it will contribute to and supplement the implementation of the programmes. It will also increase scientific standards for testing, and improve clinical conditions. As a result, Vietnam's efforts to develop herbal medicine will increasingly acquire international acceptance. In more broad terms, the project will support Vietnam's endeavors for self-reliant development and will promote Vietnam's international scientific integration.

In order to ensure long-term sustainability, in phase I a special attention will also be given to the integration of NCNST/IOC initiatives to develop HEA(N)TOS into the Government/MOH general system established for development, verification, standardisation, approval, etc . . . of herbal medicines, particularly those for drug treatment.

5. Reasons for Assistance from UNDP

Considering the political sensitivity of such an international scientific cooperation and Vietnam's pronounced orientation towards self-reliant development, an international cooperation with the United Nations, here represented by UNDP/UNOPS, is indicated due to its political neutrality and due to the universal character of drug abuse.

In pursuit of sustainable human development and social strategies, UNDP devotes high priority to the combat of drug abuse as one of the most pervasive emerging social problems at the end of this century which equally affects industrialized and developing countries. UNDP also attaches special attention to global activities, which are based on the potential and initiative of a developing country. This explains the reasons for external assistance from UNDP/UNOPS in this international scientific cooperation.

6. Special Considerations

UNDP/UNOPS have decided to involve in this international scientific cooperation the Center for Chemical Dependency which is part of the Johns Hopkins School of Medicine, located in Baltimore, Maryland, USA. The decision to involve this United States-based center has been taken on the following grounds:

- (1) The United States has a long-standing scientific history in the treatment of opiate addicted patients and in the development of chemical substitutes for morphium, in order to reduce withdrawal symptoms. These scientific efforts dating back to the 1920s, resulted in the involvement of the National Research Council in the opiate problem from 1928 to 1971, as well as in the creation of the US Laboratory on the Study of Addictions. This laboratory developed, in collaboration with other scientific institutes, academia and industries, scientific methods to conduct clinical investigations in humans, which have

been also adopted by other countries. These studies also resulted in the development of specific drugs to treat opiate addiction, which are applied internationally such as: Methadone, Naloxone, Neltroxone and Buprenorphine.

- (2) The Center for Chemical Dependency of Johns Hopkins School of Medicine, under the leadership of Dr. Donald Jasinski, is presently one of the leading scientific institutes in the world in the treatment of drug addiction and in the development of medications against drug abuse.

Dr. Jasinski, who was in charge of the human investigation programme in the Addiction Center at Lexington, Kentucky from 1965 to 1976, and Director of the US Laboratory on the Study of Addiction from 1976 to 1985, joined Johns Hopkins School of Medicine in 1985. In his present function he is an internationally reputed scientist in human studies on efficacy against drug addiction. Recently, he has focused his research activities in developing new treatments against drug abuse.

Dr. Jasinski has been highly recommended by the US National Institute on Drug Abuse for this international scientific cooperation. His scientific guidance and reputation are instrumental in the implementation of the project. This applies for investigations at the Center for Chemical Dependency to substantiate, in compliance with scientific standards, the claims of HEA(N)TOS as a safe and efficacious medication. However, this also necessitates technology transfer services in support of the Vietnamese counterpart, which will be basically in three areas:

- (a) to share scientific knowledge and expertise with Vietnamese scientists;
- (b) to assist and provide consultancy services to the National Centre for Natural Science and Technology and to the Ministry of Health, in the development of procedures for the conducting of clinical investigations to demonstrate the safety and efficacy of the HEA(N)TOS preparation; and
- (c) to develop with the support of the Center for Chemical Dependency in the National Centre for Natural Science and Technology, a common information and data base, in order to facilitate the exchange and analysis of clinical research data.

7. Institutional and Coordination Arrangements

UNDP will contribute funding from the globally centralized and Viet Nam's TRAC resources and provide local administrative support and monitoring to the project. The UNDP Country Office will also facilitate international cooperation, in particular, with regard to the political sensitivity of the project. The UNDP Office of the Resident Representative and Coordinator in Vietnam also assist the Government in coordinating related issues.

The project will be executed by the United Nations Office for Project Services (UNOPS) which will be responsible for both overall, technical and financial management of the project, including TRAC and GLO resources. Technical and managerial assistance of UNOPS includes mainly monitoring the complex process of inter-related scientific activities, and in coordinating interactions, to be partly conducted in Vietnam and partly in the United States, by NCNST and Johns Hopkins School of Medicine, respectively. UNOPS will also involve WHO and UNDCP, in order

to benefit from the scientific expertise and experience which the United Nations system offers. Both UN organizations have indicated an interest in such a cooperation. Further consultations are envisaged, in order to agree on the modalities and areas of cooperation. UNOPS will also assist the Government and UNDP in mobilising funds for phase II and III. An Office of an International Project Coordinator will be established within UNOPS for these purposes and funded by the UNDP contribution from its central funds.

The Government implementing agency will be the Vietnam National Centre for Natural Science and Technology (NCNST), particularly, its Institute of Chemistry (IOC).

As the project implementing agency NCNST/IOC will closely cooperate with:

- the Ministry of Planning and Investment on issues related to coordination with other activities and efforts of the Vietnamese Government, funds mobilization and project management;
- the Management Committee for the Vietnam National Drug Control Programme, in particular, with the Minister/Chairman of CEMMA to coordinate with the Programme;
- MOLISA on the use of HEA(N)TOS in treatment centres and;
- MOH, including the Central Psychiatric Hospital in Viet Nam (CPH), National Institute of Drug Control (NIDC) and Institute of Materia Medica (IMM), on testing programmes, standards and methods, and clinical researches.

This cooperation will be specified in service agreements between NCNST and other institutions concerned, in particular MOH, which will be the core partner in the implementation of the project.

The project will also benefit from the expertise of other Governmental organizations such as the Ministry of Science, Technology and Environment.

The Johns Hopkins School of Medicine will operate as a major contractor to the project.

8. Counterpart Support Capacity

The National Centre for Natural Science and Technology is fully committed to the project and the international scientific cooperation. Although it operates on a tight and limited budget, it is prepared to make considerable contributions *in-kind*. These contributions *in-kind* encompass the secondment of professional and supporting staff, the provision of laboratory materials, means of transportation and premises, including offices and laboratories.

In this context, equally important is the Centre's capacity to mobilize scientific support within and outside of the Centre. The Centre also disposes specific scientific qualifications, in particular, in areas such as bioorganic chemistry. The Centre is therefore well positioned to ensure the sustainability of the achievements made under this project, once it is completed.

C. Development Objective

To measurably reduce drug abuse through developing effective addiction treatment medications and therapies.

D. Immediate Objectives, Outputs and Activities of Phase I

Immediate Objective 1: To establish a programme framework to verify and substantiate safety and efficacy claims, which are made by HEA(N)TOS, based on an international scientific cooperation

Success criteria for Objective 1:

- ▶ *A testing programme and methodology, and a project document for phase II (with identified funding sources) developed and concurred by the concerned parties;*
- ▶ *A common understanding established among the parties, especially between NCNST, MOH and JHU*

Output 1.1: A programme framework for the verification and substantiation of safety and efficacy claims made by HEA(N)TOS prepared.

Activities:

- 1.1.1 Specify testing requirements and standards.
- 1.1.2 Prepare a testing programme and its underlying scientific methodology.
- 1.1.3 Prepare a project document for phase II.
- 1.1.4 Organise seminar/workshop to build consensus among stakeholders.
- 1.1.5 Mobilise funds for phase II.

Responsible parties: NCNST/IOC, International Project Coordinator, International Consultant, MOH, MPI

Output 1.2: A programme to strengthen the validity of data generated from testing in the framework of the scientific cooperation

Activities:

- 1.2.1 Prepare a programme to comply with the Helsinki Principles and Nuremberg Declaration in conducting the testing programme in Viet Nam.
- 1.2.2 Organise a study tour of senior scientists and officials of the concerned Vietnamese institutions to the relevant institutions in the United States such as JHSM, VCU, FDA and NIDA to be familiarized with the regulatory and scientific conditions, standards and methodologies applied for drug testing programmes in the United States (please also refer to other outputs).

- 1.2.3 Establish a Review Board in Vietnam to oversee and ensure quality control of data generated from this programme.
- 1.2.4 Develop a scientific and technology transfer programme with the objective to strengthen the validity of data generated from this testing programme.

Responsible parties: NCNST/IOC, International Project Coordinator, International Consultant, MOH.

Immediate Objective 2: To establish conditions in Vietnam for effective scientific inter-actions in the implementation of this cooperation, including in the implementation of an exercise under the Ministry of Health with the objective to review the claims of HEA(N)TOS in the light of previous testing and in compliance with Vietnamese standards

Success criteria for Objective 2:

- ▶ *IOC and other key research institutions concerned are capable to initiate the testing programme in accordance with the established standards and methodology;*
- ▶ *Claims of HEA(N)TOS and other existing herbal drug treatment medications such as PHUHUSA and BIMIN, if necessary, are initially reviewed in light of previous testing results and in compliance of Vietnamese standards.*

Output 2.1: Improved non-physical conditions in Vietnam for the implementation of the scientific cooperation.

Activities:

- 2.1.1 Develop procedures for clinical research.
- 2.1.2 Introduce the Minnesota Multiphasic Personality Index (MMPI) and the Addiction Severity Index in order to assess psychiatric and psycho-social factors and other pre-disposing factors for drug addiction.
- 2.1.3 Introduce a scientific method to standardize HEA(N)TOS for clinical research purposes.
- 2.1.4 Register intellectual property rights in Viet Nam and the United States.

Responsible parties: NCNST/IOC, International Project Coordinator, International Consultant, MOH.

Output 2.2: Improved physical processing and clinical research conditions in Vietnam for the implementation of the scientific cooperation

Activities:

- 2.2.1 Upgrade a pilot plant at the premises of NCNST, in order to establish conditions for a more standardized processing of HEA(N)TOS (and other herbal preparations).

- 2.2.2 Upgrade clinical research and laboratory facilities as a first step to meet minimal requirements, to effectively conduct the testing programme in Vietnam.
- 2.2.3 Set up a monitoring unit for the implementation of the testing programme and in order to facilitate scientific interactions.

Responsible parties: NCNST/IOC, International Project Coordinator, International Consultant, MOH.

Output 2.3: A review of claims of HEA(N)TOS in the light of previous testing results

Activities:

- 2.3.1 Develop a concept and scientific approach.
- 2.3.2 Conduct a pilot testing programme to review the claims of HEA(N)TOS and other existing herbal drug-treatment medications such as PHUHUSA and BIMIN, if necessary, by relevant institutions under the Ministry of Health and in compliance with Vietnamese standards.

Responsible parties: NCNST/IOC, International Project Coordinator, International Consultant, MOH, JHU.

E. Inputs

1. Government Inputs

Although it operates on a tight and limited budget, NCNST/IOC will make considerable contributions *in-kind* as follows:

Personnel:

- a part-time National Project Director (NPD);
- a full-time National Project Manager responsible for daily operation of the project;
- a part-time project interpreter/secretary;
- a part-time National Scientific Supervisor
- a part-time Herbal Scientist
- three part-time Chemists;
- two part-time Scientific Assistants;
- 50 work-months of other national professional staff of IOC and other relevant institutions who are selected to participate in the project's activities.
- release for staff of IOC and other relevant institutions selected to participate in workshops and training programmes under the project.
- 12 work-months of three part-time supporting staff of IOC (driver, cleaner and guard).

Others:

- necessary office, laboratory, pilot production and training facilities necessary for the project activities, including air-conditioned office space, furniture, telephone,

- electricity and water supply;
- provision of laboratory equipment and materials, including chemicals, solvers, etc...;
- transportation for project personnel including international and national consultants;
- travel and per diem of government personnel;
- provision of data and information necessary for the project activities as required by the project team;
- administrative supports such as arrangement of visa for international consultants; and
- local and international communication costs.

Estimated Government Contribution:

VND 348,500,000.

2. UNDP Inputs:

UNDP inputs from TRAC and GLO resources for the project are outlined below and details are contained in the respective budgets for the UNDP contributions.

2.1 UNDP Inputs from TRAC resources

Budget line 11. Personnel

	US\$
11.01 International Project Coordinator: 4 work-months, based in New York to (i) liaise with and maintain effective working relations between interested parties; (ii) supervise the implementation of the project; (iii) prepare a project document for phase 1 and 2 of the project, based on the test programme and methodology developed under phase I; (iv) assist the Government and UNDP in mobilising funds for phase II and III of the projects; and (v) assist the NPD in preparing documents and reports, and maintaining public relations.	56,000
11.97 Short-term International Consultant: 1 work-month. The consultant will assist the International Project Coordinator in preparing and finalising the project document for phase 2.	14,000

Note: The proforma costing for the above two consultants also includes international travel costs and DSA while they are on official mission

Budget line 15. In- country travel

15.01 In- country travel of national and international consultants and project staff such as airfare and DSA, when applicable	2000
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Budget line 20. Sub-Contracts

2.2. UNDP Contribution from Global Resources

In view of the global orientation of HEA(N)TOS, UNDP will also provide financial support from its central resources to support the project's preparation and the coordination of international cooperation under the project. The assistance has been approved by UNDP HQ under code number GLO/96/452 and is directly executed and implemented by UNOPS. Specifically, the UNDP inputs funded by the global resources are as follows:

- | | | |
|----|---|---------|
| a. | 12 work-months of an International Project Coordinator to carry out preparatory work in 1996 and to promote international scientific cooperation in this area. Specifically, this input focuses on (i) developing the project concept and its overall design; (ii) preparing necessary initial documentation; and (iii) liaising between and carrying out necessary negotiations with the concerned parties; | 135,300 |
| b. | 4 work-months of a Junior Professional Project Officer to assist the International Project Coordinator in the management and implementation of the above project such as (i) monitoring, (ii) reporting, (iii) liaising and coordinating with various partner-organizations, (iv) establishing a database on project-related information and (v) administering the office of the International Project Coordinator within UNOPS. | 14,948 |
| c. | Logistical support for the office of the International Project Coordinator within UNOPS | 49,752 |

UNDP contribution from GLO/96/452: US\$200,000

Total UNDP contribution to the project: US\$400,000

F. Risks

1. The risks of the project are by definition of scientific nature and are related to the scientific substantiation of the claims of HEA(N)TOS and/or other existing herbal drug-treatment medications such as PHUHUSA and BIMIN as safe and efficacious anti-drug medications: *medium*. The risks have been taken into account in the project strategy. A special attention will be given to a careful preparation of the testing programme and methodology and training of staff to ensure quality of the data collected under the project.
2. Unavailability of a large amount of funds totaling US\$4.5 millions subsequent to phase I for phases II and III: *medium*. This risk is reduced by the active fund raising activities of stakeholders, especially the Government, UNOPS, specifically the International Project Coordinator and UNDP.
3. Limited access of the project research team to data collected by government institutions under previous tests: *low*. NCNST/IOC has developed a close working relationship with the institutions which will also participate in the project. The project also initiate the settlement of intellectual property protection of HEA(N)TOS.

21.10	Sub-contracts for scientific expertise from JHU in support of project outputs, totaling 2 w/m.	40,000
21.20	Sub-contracts for the implementation of a pilot testing programme in compliance with Vietnamese standards with the Ministry of Health (possibly, with the Central Psychiatric Hospital in Viet Nam, National Institute of Drug Control and/or Institute of Materia Medica).	14,000

Budget line 30.00 Training

32.00	Study tour(s): Up to five Vietnamese senior scientists and official(s) will undertake a study tour to JHSM, VCU, FDA, NIDA, etc. in the United States, in order to inform themselves of the regulatory and scientific conditions and standards under which testing programmes are conducted in the United States.	30,000
33.00	In-country training:	
	▶ an interagency workshop to discuss the testing programme and methodology;	3,000
	▶ seminar(s) and/or workshop(s) to introduce modern research methods and share experience and lessons learnt through the study tour.	7,000

Budget line 40. Equipment

45.00	Local purchase of equipment:	32,100
	▶ a set of standard office equipment (including a computer with software, CD-ROM, an internal fax modem, a laser printer, an air-conditioner and other equipment) to the IOC's project office.	
	▶ most urgently needed laboratory equipment such as an extraction unit, filter, pulverizer and a rotary evaporator to be located in the NCNST/IOC.	

Budget line 50. Miscellaneous:

51.00	Operation and maintenance costs of the equipment	400
53.00	Sundries: translations and other miscellaneous expenditures, including property registration fees, support to international communication, if necessary.	1,500

UNDP Inputs from TRAC:

US\$200,000

G. Prior Obligations and Prerequisites

There are no prior obligations and prerequisites which need to be observed for the implementation of phase I. However, prior to the launching of testing programmes in and outside of Vietnam, intellectual property rights related to HEA(N)TOS and other legal pre-requisites need to be clarified.

H. Project Reviews, Reporting and Evaluation

Prior to its completion, phase I will be subject to a Project Performance Evaluation Report which will constitute the basis of a Tripartite Review. The PPER will be prepared by the NPD in consultation with the International Project Coordinator. A full-fledged evaluation by independent experts will be conducted in the course of the implementation of phase II.

I. Legal Context

1. This document shall be the instrument referred to as such in Article 1 of the Standard Basic Assistance Agreement between the Government of the Socialist Republic of Viet Nam and the United Nations Development Programme, signed by the parties on March 21st, 1978. The host country Implementing Agency shall, for the purpose of the Standard Basic Assistance Agreement, refer to the Government co-operating agency described in the Agreement.
2. The following types of revisions may be made to this project document with the signature of the UNDP Resident Representative only, provided he or she is assured that the other signatories of the project document have no objections to the proposed changes:
 - 2.1 Revisions in, or addition of, any of the annexes of the project document;
 - 2.2 Revisions which do not involve significant changes in the immediate objectives, outputs or activities of a project, but are caused by the rearrangement of inputs already agreed to, or by cost increases due to inflation; and
 - 2.3 Mandatory annual revisions which re-phase the delivery of agreed project inputs, or reflect increased expert or other costs due to inflation, or take into account agency expenditure flexibility.

J. Budget

I. Annexes:

1. Institutional abbreviations
2. Project objective tree
3. Terms of Reference of key personnel
4. List of project equipment
5. Project work-plan

BL	Description	TOTAL		1997	
		m/m	Input 000	m/m	Input 000D
10.00	PERSONNEL				
11.00	National Counterparts				
11.01	NPD (part-time)	4.0	2400	4.0	2400
11.02	National Project Officer (full-time)	8.0	4400	8.0	4400
11.03	Project Interpreter/Secretary (part-time)	4.0	1800	4.0	1800
11.04	Supporting staff (part-time)	12.0	4200	12.0	4200
11.99	<i>Sub-total: Project management staff</i>	28.0	12800	28.0	12800
17.01	National Scientific Supervisor (part-time)	2.0	1200	2.0	1200
17.02	Herbal Scientist (part-time)	4.0	2200	4.0	2200
17.03	Chemists (three persons, part-time)	12.0	6600	12.0	6600
17.04	Scientific Assistants (two persons, part-time)	8.0	3200	8.0	3200
17.05	Other national professional staff	50.0	22500	50.0	22500
17.99	<i>Sub-total: professional staff</i>	76.0	35700	76.0	35700
11.99	<i>Subtotal: National Counterparts</i>	104.0	48500	104.0	48500
15.00	Travel		30000		30000
19.00	Component total	104.0	78500	104.0	78500
30.00	TRAINING				
33.00	In-country training		10000		10000
39.00	Component total		10000		10000
40.00	EQUIPMENT				
43.00	Premises & Furniture & office equipment		80000		80000
45.00	Vehicles, laboratory equipment & materials (chemicals, solvents, etc...)		100000		100000
49.00	Component total		180000		180000
50.00	MISCELLANEOUS				
51.00	Maintenance and operation		40000		40000
53.00	Sundries		48000		48000
49.00	Component total		88000		88000
90.00	PROJECT TOTAL				
99.00	Total Govt contribution (in kind)	104.0	356500	104.0	356500

PROJECT BUDGET COVERING UNDP CONTRIBUTION

BUDGET REVISION : D

Country : VIETNAM
 Project Number : VIE/96/033/01/31
 Project Title : HEA(N)TOS

Duration:

Previous Revision was approved on

24-Apr-97

Printed on 14 May 97 at 08:10:47

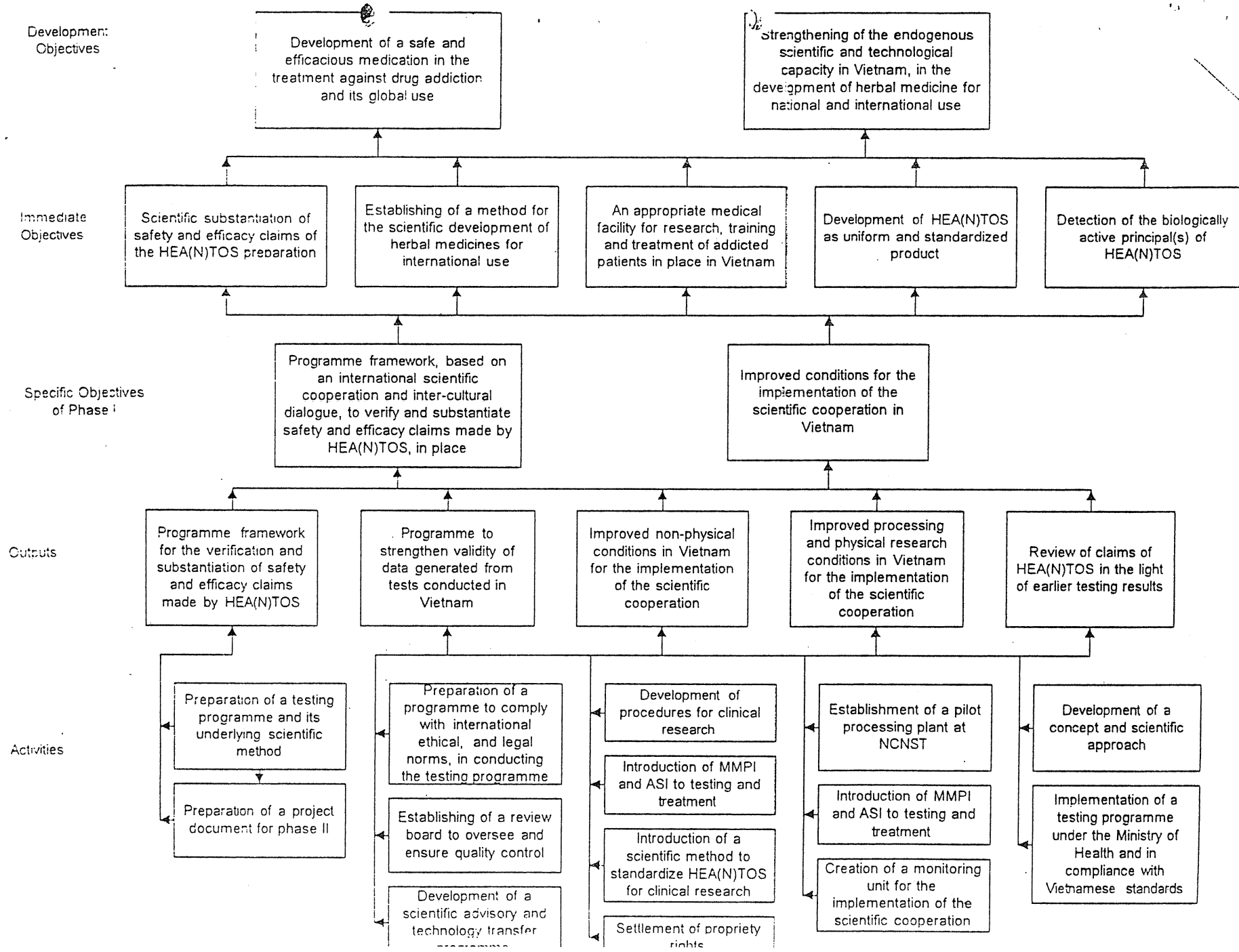
Budget Line Description	Total		1996		1997		1998		1999		2000	
	w/m	US\$	w/m	US\$	w/m	US\$	w/m	US\$	w/m	US\$	w/m	US\$
10 PROJECT PERSONEL												
11 INTERNATIONAL EXPERTS												
11.51 Int. Project Coordinator	4.0	56,000	2.0	22,550	2.0	33,450						
11.97 International Consultants	1.0	14,000			1.0	14,000						
11.98 Sub-Total (Consultancies)	5.0	70,000	2.0	22,550	3.0	47,450						
11.99 Sub-Total	5.0	70,000	2.0	22,550	3.0	47,450						
15 TRAVEL												
15.01 Official travel		2,000				2,000						
16 MISSION COSTS												
17 NATIONAL EXPERT												
19 Component Total	5.0	72,000	2.0	22,550	3.0	49,450						
20 SUB-CONTRACT												
21.01 Johns Hopkins University		40,000				40,000						
21.02 MOH		14,000				14,000						
29 Component Total		54,000				54,000						
30 TRAINING												
32.01 Study Tours		30,000				30,000						
33.01 In-country Training		10,000				10,000						
39 Component Total		40,000				40,000						
40 EQUIPMENT												
45.01 Local Procurement		32,100				32,100						
49 Component Total		32,100				32,100						
50 MISCELLANEOUS												
51.01 Maintenance and Operation		400				400						
53.01 Miscellaneous/Sundries		1,500				1,500						
59 Component Total		1,900				1,900						
99 Project Total		200,000		22,550		177,450						
999 NET UNDP CONTRIBUTION		200,000		22,550		177,450						

BUDGET FOR PHASE I (1 January 1996 - 30 April 1997) of project:
 GLO/96/452/A - "International Scientific Development of the Anti-Drug Medication 'HEA(N)TOS'"

BL	Description	m/m	TOTAL	AOS	m/m	1996	AOS	m/m	1997	AOS
10	Personnel									
1101	International Project Coordinator	12.0	135,300	12,177	10.0	112,750	10,148	2.0	22,550	2,030
1103	Project Officer	4.0	14,948	1,345	3.0	11,548	1,039	1.0	3,400	306
1501	Official Travel		22,300	2,007		22,300	2,007		0	0
19	Component Total	16.0	172,548	15,529	13.0	146,598	13,194	3.0	25,950	2,336
20	Subcontracts									
2101	Premises/Rent		24,000	2,640		18,000	1,980		6,000	660
29	Component Total		24,000	2,640		18,000	1,980		6,000	660
40	Equipment									
4501	Office equipment		2,952	177		2,952	177		0	0
49	Component Total		2,952	177		2,952	177		0	0
50	Miscellaneous									
5301	Miscellaneous		500			500			0	
59	Component Total		500			500			0	
90	Project Total		200,000	18,346		168,050	15,351		31,950	2,996
99	Grand Total		200,000	18,346		168,050	15,351		31,950	2,996

ANNEX I
INSTITUTIONAL ABBREVIATIONS

CCD	=	Center for Chemical Dependency [at Johns Hopkins School of Medicine], in Maryland
CEMMA	=	Committee for Ethnic Minorities and Mountainous Areas in Vietnam
CPH	=	Central Psychiatric Hospital in Vietnam
FDA	=	Food and Drug Administration in Maryland
IMM	=	Institute of Materia - Medica in Vietnam
JHSM	=	Johns Hopkins School of Medicine in Baltimore
MPI	=	Ministry of Planning and Investment in Vietnam
MOH	=	Ministry of Health in Vietnam
MOLISA	=	Ministry of Labour War Invalids and Social Affairs in Vietnam
MOSTE	=	Ministry of Science, Technology and Environment in Vietnam
NCNST	=	Vietnam National Centre for Natural Science and Technology in Vietnam
NIDA	=	National Institute on Drug Abuse in Maryland
NIDC	=	National Institute of Drug Control [under the Ministry of Health] in Vietnam
UNDCP	=	United Nations International Drug Control Programme in Vienna
UNDP	=	United Nations Development Programme in New York
UNDP/BPPS	=	UNDP/Bureau for Policy and Programme Support in New York
UNOPS	=	United Nations Office for Project Services in New York
VCU	=	Virginia Commonwealth University in Virginia
WHO	=	World Health Organization in Geneva



ANNEX III TERMS OF REFERENCE

1. UNDP funded personnel

1.1 International Project Coordinator

Under the general guidance of the Executive Director of UNOPS and in close cooperation with the Chief, Division for Environmental Programmes, the International project Coordinator shall manage and supervise the above-mentioned project, in particular, with regard to:

- maintaining effective working relations between UNOPS, Johns Hopkins School of Medicine and the Vietnam National Centre for Natural Science and Technology, which needs to be based on mutual faith and confidentiality;
- liaising with other actors in the implementation of the project, in particular, within the United Nations system (UNDP, UNDP country office in Vietnam, WHO, UNDCP);
- supervising all activities in accordance with the work plan and budgetary provisions, relating results of scientific studies and tests to the project context and making the necessary adjustments, overlooking the quality and timely delivery of each activity;
- developing the project concept and general design
- preparing a project document for phases I and II including detailed work plan and budgets. The project document for phase II will be based on the testing programme and methodology developed and the results of pilot tests under the phase I;
- assisting the Government and UNDP in raising the necessary funds and inter-acting financial sponsors (preparation of documents, presentations of progress reports, etc.)

1.2 Junior Professional Project Officer

Under the overall guidance of the project coordinator and the Chief, Division for Environmental Programmes, the project officer shall assist the project coordinator in the management and implementation of the above-mentioned project, in particular, with regard to:

- preparing progress and evaluation reports, including those reports to be submitted to funding organizations;
- monitoring daily project activities (drafting of correspondence, recruitment of consultants, budgeting, etc.);
- liaising and coordinating with various partner-organizations involved in the implementation of the project
- establishing a documentation library and database on project-related information;

In addition, the junior professional project officer shall be responsible for the administration of the office of the project coordinator within UNOPS.

2. **Major personnel funded by the Government/NCNST**
 - 2.1. National Scientific Supervisor
 - exercises scientific supervision of all activities conducted by or under NCNST; and
 - exercises and develops scientific quality standards.
 - 2.2. Herbal Scientist
 - supervises the preparation, manufacturing of HEA(N)TOS and
 - establishes records of contents of HEA(N)TOS.
 - 2.3. Chemist 1:
 - assists the Herbal Scientist in establishing records of contents of HEA(N)TOS;
 - undertakes compound and stability analysis; and
 - undertakes analysis to detect effective principle(s) of HEA(N)TOS
 - 2.4. Chemist 2:
 - develops an appropriate processing technology for HEA(N)TOS;
 - optimizes processing method, develops a pilot unit for manufacturing of HEA(N)TOS; and
 - assists in the preparation of a plan for an extraction and manufacturing unit
 - 2.5. Chemist 3:
 - undertakes investigations on toxic substances in traditional herbal medications;
 - assists in developing a scientific method for meeting the requirements to use herbal medicine internationally; and
 - assists in the preparation of the International Symposium on Herbal Medicine Development.
 - 2.6. Scientific Assistant 1:
 - involves him(her)self in the renovation of existing extraction unit; and
 - services and maintains existing unit.
 - 2.7. Scientific Assistant 2:
 - involves him(her)self in the renovation of two laboratories for plant analysis;
 - oversees procurement of new equipment; and
 - services and maintains the two laboratories.
 - 2.8. National Project Officer
 - Assist the NPD in conducting all administrative activities related to the project;
 - Assist the NPD in mobilizing and managing NCNST inputs;
 - Assist the NPD in monitoring the project progress, NCNST budget and UNDP financial contributions;
 - Assist the NPD in preparing project progress reports.
 - Assist the NPD in maintaining public relations, publications and documentation

No	Description	Quantity (Unit)	Unit Price US\$	Total cost US\$
	Local Purchase			
A	NEX standard equipment			
1	Computer (CPU 586, 100Mhz, 1GB HD, 1.44Kb, CD ROM and Data/Fax Modem, SVGA, Mouse)	1	2,000	2,000
2	Standard Software 1 unit/computer	1	560	560
3	UPS (750VA)	1	170	170
4	Voltage regulator (1500 w)	1	50	50
5	Air-conditioner (12000 BTU, 2 blocks)	1	1,200	1,200
6	Laser Printer with toner	1	600	600
7	Expendable equipment (standard set)	1	1,000	500
	<i>Sub-total: NEX equipment</i>			5,080
B	Laboratory equipment			
1	Extraction Unit (2001)	1	15,000	15,000
2	Filter equipment	1	6,000	6,000
3	Pulverizer	1	4,000	2,000
4	Rotary evaporator	1	4,000	4,000
	<i>Sub-total: Laboratory equipment</i>			27,000
C	TOTAL EQUIPMENT			32,080

Note: All equipment will be purchased using UNDP standard specifications.

No	Activities	Resp party	1997											
			MONTHS											
			1	2	3	4	5	6	7	8				
			May	June	July	Aug	Sep	Oct	Nov	Dec				
A PROJECT OPERATIONALIZATION														
1	Agreements & set up institutional environment	NCNST/UNOPS/UNDP	xxx											
2	Appoint core Vietnamese management and professional staff	NCNST/UNOPS	xxx											
4	Identify and recruit international consultants	UNOPS/NPD/NCNST	xxx											
5	Identify and recruit subcontractors	UNOPS/NPD/UNDP	xxx											
6	Working space and facilities	NPD/NCNST	xxx											
7	Acquire office equipment	UNOPS/NPD/UNDP	xxx											
8	Mobilization strategy and vehicle mobilization	NPD/Int'l Prj Coord (IPC)	xxx											
9	Publicity and motivation strategy	NPD/IPC	xxx											
B OBJ. 1: TO ESTABLISH A PROGRAMME FRAMEWORK														
1 OUTPUT 1.1: A programme framework prepared														
1.1	Specify testing requirements and standards	NPD/Int'l cons's		xxx	xxx									
1.2	Prepare a testing programme and methodology	NPD/Int'l cons's			xxx	xxx				xxx				
1.3	Prepare a project document for phase II	NPD/IPC/Int'l cons's/UNDP											xxx	
1.4	Organize a consensus building seminar/ workshop	NPD/Int'l cons's/IPC											xxx	
1.5	Mobilise funds for phase II	GOVN/UNOPS, IPC/UNDP		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	
2 OUTPUT 1.2: A programme to strengthen validity of testing data														
1.1	Prepare a programme to comply with Int'l ethical & legal norms in conducting testing in VN	NPD/Int'l cons's			xxx	xxx				xxx				
1.2	Organise a study tour of senior researcher and officials to relevant ins's in USA	NPD/IPC/UNOPS												
1.3	Establish a Review Board to oversee and ensure quality control of data generated	NPD/NCNST/IPC							xxx					
1.4	Develop a scientific and technology transfer programme	NPD/Int'l Cons'ss/IPC											xxx	
C OBJ. 2: ESTABLISH CONDITIONS FOR EFFECTIVE COOPERATION														
1 OUTPUT 2.1: Non-physical conditions in VN improved														
1.1	Develop procedures for clinical research	NPD/Int'l cons's				xxx								
1.2	Introduce MMPI & ASI to assess psychiatric & psycho-social factors of drug additions	NPD/Int'l cons's				xxx								
1.3	Introduce a scientific method to standardize HEA(N)TOS for research purposes	NPD/Int'l cons's				xxx								
1.4	Register intellectual property rights on HEA(N)TOS in VN and the USA	NPD/Int'l cons's/IPC				xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	
2 OUTPUT 2.2: Improved physical processing & clinical conditions														
2.1	Upgrade a pilot plan	NPD/Int'l Cons'ss/IPC					xxx							
2.2	Upgrade clinical and laboratory facilities	NPD/Int'l Cons'ss/IPC					xxx							
2.3	Set up a monitoring unit for the implementation of the testing programme	NPD/Int'l Cons'ss/IPC					xxx							
3 OUTPUT 2.3: Claims of HEA(N)TOS reviewed														
3.1	Develop concept and scientific approach	NPD/Int'l Cons'ss/IPC				xxx								
3.2	Conduct a pilot testing programme to review the claims	NPD/Int'l Cons'ss/IPC					xxx	xxx	xxx	xxx	xxx	xxx	xxx	
D PROJECT MONITORING AND EVALUATION														
1	Quarterly reports	NPD/IPC/Int'l Cons's				xx					xx			
2	Project Performance Evaluation Reports	NPD/IPC/UNOPS											xxx	