

INITIAL REPORT

**GROUP OF INTERNATIONAL
EXPERTS
OBSERVING THE USE OF
THE ANTI-DRUG MEDICATION
“HEANTOS”
IN VIETNAM**

*UNDP PROJECT
VIE/96/033*

HANOI, VIETNAM

9-15 MAY 1999

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I. INTRODUCTION

The United Nations Development Program (UNDP) and the Government of Vietnam have signed an international scientific cooperation agreement (VIE/96/033) on "International Scientific Development of the Anti-Drug Medication HEANTOS". The United Nations Office for Project Services (UNOPS) is the Executing Agency for this project. The coordinator for this project is Dr. Lutz Baehr of UNOPS.

The project concerns a program for the scientific development of Heantos, an anti-drug medication composed of thirteen locally grown medicinal plants which has its origin in the traditional medicine of Vietnam.

The Ministry of Health of Vietnam determined the original formulation of Heantos to be safe and efficacious during an official evaluation in 1991. The product, in various formulations, has been used since 1991 on an experimental basis to treat several thousand Vietnamese drug addicts who have an opiate dependency.

The results to date in Vietnam are impressive, but there is concern that the evidence of safety and efficacy are not sufficiently rigorous according to Western medical standards. The project for international cooperation, therefore, was initiated to:

- A. Establish scientific conditions for the global use of Heantos as a proven effective anti-drug medication.
- B. Provide scientific recognition to proven traditional medicines, such as Heantos.
- C. Strengthen the institutional and endogenous scientific and technological capacity of Vietnam for development of products based upon locally available medicinal plants.

One of the important components of this project is the provision for the evaluation of Heantos by experts from internationally recognized scientific institutes and national drug treatment organizations.

UNOPS invited a group of experts from UNESCO, Western Europe and the United States to participate in a special program in Hanoi, Vietnam during the period 9-15 May 1999 to witness the utilization of Heantos on drug addicts.

This is the *initial report* of the group of experts who participated in this study and evaluation mission. The observations, conclusions and recommendations of this mission team are those of the participating individuals themselves, and do not constitute or imply any official endorsement or commitment of their parent organizations.

II. MISSION PARTICIPANTS

Team Leader: Dr. Lutz Baehr, UNOPS
Dr. Minella Alarcon, UNESCO Jakarta Office
Mr. Thomas Dodd, Drug Treatment Counselor (USA)
Dr. Peter Ege, Drug Dependence Treatment System, Copenhagen, Denmark
Dr. Paula Liljeberg, Methadone Maintenance Treatment Service, Stockholm, Sweden
Dr. Victor Rosenberg- Medical Doctor, New York, NY, USA
Mr. Andrew Sundberg, Specialist in Management of S&T, Geneva, Switzerland
Dr. Gabrielle Welle-Strand, Methadone Treatment System, Oslo, Norway

Official Host: Prof. Dr. Tran Van Sung, Deputy Director, Institute of Chemistry, National Center for Natural Science and Technology

III. SPECIFIC MISSION OBJECTIVES

The specific objectives of the Mission to Hanoi by the group of experts were:

1. To learn first-hand how the Heantos treatment works.
2. To assess the utilization and efficacy of the treatment.
3. To get a better understanding of the history of the project, how it has evolved, what changes have been made in the formulation, and what has been planned and carried out in terms of substantiating drug safety and clinical trials in Vietnam.
4. To explore the potential interest of the western experts in the utilization of Heantos in foreign countries.
5. To learn from the Vietnamese partners what product safety test data is available which would be necessary to satisfy requirements for clinical use in foreign countries.
6. To become acquainted with the Vietnamese personnel and institutions involved in the project, learn how they work, and assess how best to interact with them and their institutions as potential longer-term research and development partners for international scientific and technology cooperation in the treatment of drug abuse.

IV. INSTITUTIONAL VISITS DURING THE MISSION

Visits were made to a number of different institutions during the mission. These included:

- A. Hoa Binh Treatment Center: This center for the treatment of drug addicts, located at Hoa Binh, 1.5 hours outside of Hanoi, is run by the Ministry of Labour, Invalids and Social Affairs (MOLISA). It is one of the designated locations for experimental use of Heantos. The experts made three visits to the center. One was at the beginning of a Heantos treatment of nine addicts, the second was two days later in the middle of the treatment, and the third was four days later at the end of the treatment. The experts had the opportunity to observe and interview the doctors and the addicts.
- B. The National Psychiatric Hospital: This hospital, run by the Ministry of Health (MOH) of Vietnam, is the principal location for the on-going clinical tests of Heantos that are being carried out by the MOH under the terms of a special decree of the Chairman of the Office of the Government, Mr. Lai Van Cu, dated 22 June 1998. The experts talked with the Vietnamese staff supervising these clinical tests.
- C. National Institute of Drug Quality Control: This institute, run by the Ministry of Health, is responsible for conducting tests of toxicity and other parameters of Heantos. The visit enabled the experts to view the clinical conditions, safety standards, methods and protocols used for testing toxicity and safety of the product.
- D. National Center for Natural Science and Technology: This center is at the heart of the scientific research in Vietnam. The director, Prof. Dang Vu Minh, holds Cabinet rank in the Government. The experts were able to discuss scientific research in Vietnam with Dr. Minh, and how the development and evaluation of Heantos fits into the national S&T system.
- E. Institute of Chemistry: The Institute of Chemistry is one of the many components of the National Center for Natural Science and Technology. It has primary responsibility for Heantos development and production. The experts were able to learn how and why the formulation of Heantos has evolved to its present state and how the production process takes place from the preparation of the basic herbal raw materials up to the finished product capsules.

V. OBSERVATIONS OF THE TEAM MEMBERS

The observations of the team members are as follows:

A. The Hoa Binh Treatment Center

First visit: During the first visit, the experts met, examined and interviewed nine opiate addictive male patients. The experts saw evidence of scars of injections, and the starting of typical withdrawal symptoms. The addicts being treated with Heantos were long-term users of heroin and opium (3-15 years). Some of these patients had previously made serious attempts to stop using drugs but without success. The ages of the addicts ranged from 18-44 years. They were examined and interviewed prior to the first administration of Heantos. All patients undergoing Heantos treatment were volunteers who had been recommended by

doctors who were already familiar with the use of Heantos. These nine volunteers were not subjected to any special restraint and were free to leave the treatment at any time.

Of the patients normally treated at the center, half come on a voluntary basis and half are brought by the police. All patients normally have to stay for at least 3 months when undergoing treatment by other therapies. Those brought by the police are typically kept from 3-6 months depending on the results of their treatment and the evaluation of the doctors at the center.

Second visit: Two of the team members revisited the center 53 hours after the first visit and observed that the nine patients had been treated with Heantos 1 and Heantos 2 in three medication intervals. One of the nine patients had received additional medication due to psychiatric problems (diazepam). The patients were treated by the standard protocol and the treatment went without complications. The patients all reported that they experienced no withdrawal symptoms. All patients had good appetites and were relaxed and in good physical condition. The patients sat for the interview during 1.5 hours and did not show any objective withdrawal signs and reported that they were feeling at ease. The patients reported no thoughts, dreams, urge or craving for opiate drugs). Most were pure opiate addicts. The team learned that there were four other patients who received the Heantos treatment a month earlier. At Hoa Binh they were receiving only Heantos 3 to determine the right dosage for the re-evaluation of Heantos now underway at the National Psychiatric Hospital under the control of the MOH.

Third visit: The team returned to Hoa Binh four days after the start of the Heantos treatment and once again interviewed the nine patients and the staff doctors. The patients again confirmed that they still had not experienced any withdrawal symptoms, had good appetites, were sleeping well, were relaxed and in good condition. The doctors considered that the Heantos treatment had achieved a successful detoxification and the non-recurrence of cravings for drugs was a very promising sign that the longer term effects of Heantos were also working as expected so far. The team learned that several of the nine patients had previously been treated for detoxification by other technologies.

B. The Treatment of Foreign Patients at a Hotel

During the mission, the foreign experts observed the Heantos treatment of three occidental females and two occidental males who had voluntarily come to Vietnam at their own expense to seek treatment for their drug addiction. The treatment took place in a private hotel in Hanoi.

The western patients were treated under the 24-hour supervision of a team of Vietnamese specialists in the use of Heantos including Dr. Lang, Mr Danh, a Vietnamese female doctor, a male assistant, and an interpreter.

The experts observed that in addition to Heantos, the western patients were also given doses of theralene (aliminazin), aminazine (chlorpromazin), and atropin.

In order to better understand all of the therapeutic steps involved in the use of Heantos, including the sizes of the dosages of Heantos 1, 2 and 3 and the application intervals, the experts prepared the questionnaire for the doctors administering the Heantos treatment shown in Appendix 1.

The doctors provided the detailed answers to these questions shown in Appendix 2.

The experts observed that the use of Heantos with this additional medication may have been due to an anticipated heightened sensitivity of western addicts to pain. The Vietnamese doctors had had previous experience with western patients who had been much more vocally expressive of the pain they experienced compared to Vietnamese patients being treated with Heantos at Hoa Binh and elsewhere.

Treatment of the western patients was observed by the team prior to the first use of Heantos and followed thereafter on a regular basis for 5-6 days. Follow-up included extensive conversations with the patients and the Vietnamese doctors.

There was no physical retention of the patients, but each of the patients had agreed to submit to the treatment regime and generally they stayed at the hotel most of the time, with some breaks out for meals starting on the 3rd or 4th day. These excursions from the hotel normally were for a period of 1-2 hours and the patients were accompanied by an expert or doctor.

The report format typically used by the Vietnamese doctors to interview patients prior to treatment and to record medication used during treatment is shown in Appendix 3.

The experts observed that all of the patients slept most of the time during the 1st and 2nd days, waking up at intervals for the next medication. When questioned, the western patients reported no withdrawal symptoms as were previously experienced when undergoing detoxification under other methods. No objective signs of withdrawal were observed by the experts on the team.

The team members expressed some scepticism, however, as to whether two of the five western patients had followed the treatment as strictly as they should have. These two patients, however, denied any abstinence symptoms.

VI. CONCLUSIONS

The experts wished to note that: they had only a limited amount of time to observe the effects of Heantos on Vietnamese and foreign patients treated with Heantos during their visit to Vietnam; they were able to observe only a limited number of patients in special circumstances; and that they faced certain complexities due to the necessity to have recourse to interpreters. They also wished to note that they had had the benefit of some additional information provided to them concerning previous use of Heantos on other western and Vietnamese patients.

Having noted the above, the experts concluded that:

1. Heantos appears to be a better agent for detoxification than the standard methods used in their respective countries and other parts of the western world.
2. Using Heantos under the prescribed dosage scheme does not appear to generate any objective signs of withdrawal. Few or no subjective complaints were made by the patients themselves.
3. While little can be concluded with respect to probability of relapse for the western or Vietnamese patients observed during this visit, because of the short observation period, few or no cravings were reported when the patients were treated with Heantos.
4. Research on Heantos as an appropriate and effective treatment for drug addiction not only in Vietnam but also in Western countries should continue.
5. If the efficacy of Heantos can continue to be substantiated, the use of this product would be appropriate and welcomed in Western countries for the treatment of drug addiction.

VII. RECOMMENDATIONS

A. Treatment of Foreigners in Vietnam

Based upon their observations of the treatment of the five western patients, the experts believe that in the future, the Vietnamese doctors should try to use only Heantos and not additional Western medicines, especially neuroleptics. Patients should be given a thorough prior written explanation of the procedures that they will experience during the treatment. They should be required to sign a commitment to submit voluntarily to the treatment and follow the treatment regulations. Rather than using a commercial hotel, patients should be brought to a more suitable place, such as a clinic or hospital, where the treatment could proceed undisturbed.

B. Treatment with Heantos outside Vietnam

The experts noted that the international scientific cooperation project for Heantos includes the eventual experimental clinical use of the product outside of Vietnam. To prepare for such eventual use in western countries, the experts recommend that their Vietnamese counterparts produce English language translations of the currently available and future reports of research carried out in Vietnam on the toxicity and safety of the latest formulations of Heantos in animals and in humans.

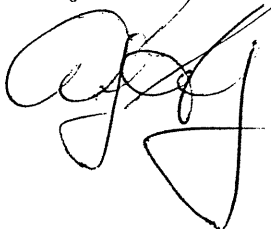
The experts agreed to provide a detailed description of the necessary types of information that will be required to satisfy the relevant authorities in the western world before any such clinical tests can be carried out in their respective countries.

APPENDICES

- Appendix 1: Questionnaire about the use of Heantos prepared by the team of experts.
- Appendix 2: Responses of the Vietnamese doctors to the questionnaire.
- Appendix 3: English version of the formats used to record patient pre-treatment information and to record medication used during the Heantos treatment.

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The International Team of Experts
Heantos Project VIE/96/033
Hanoi, Vietnam
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QUESTIONS ABOUT USE OF HEANTOS

I. Questions Concerning Use During the First 72 Hours

1. How many hours after the last intake of addictive drugs (heroin, etc) do you start the treatment with Heantos?

A. Does the delay in starting the treatment with Heantos differ by the type of addictive drug being taken:

1. How many hours delay if taking Methodone _____
2. How many hours delay if taking heroin _____
3. How many hours delay if taking opium _____
4. How many hours delay if taking cocaine _____
5. How many hours delay if taking other drugs (please indicate which other drugs _____)

2. What factors determine the amount of Heantos I and Heantos II that you give to a patient at the start of the treatment:

- A. Age
- B. Sex
- C. Weight/Height
- D. Condition of Health
- E. Nationality of the patient (whether the patient is Vietnamese or a foreigner)
- F. Amount of addictive drug that has been used
- G. Other conditions of the patient

3. What is the starting dose (first dose of Heantos I)

- A. Normal starting dose
- B. Maximum starting dose
- C. Minimum starting dose

4. What is the starting dose (first dose of Heantos II)

- A. Normal starting dose
- B. Maximum starting dose
- C. Minimum starting dose