Sida Evaluation 00/9

Lao National Drug Policy Programme

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Sida Evaluation 00/9
Commissioned by Sida, Department for Democracy and Social Development

Registration No.: DESO-1996-0577
Date of Final Report: February 2000
Printed in Stockholm, Sweden 1999
ISBN 91 586 8904 4
ISSN 1401–0402

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Abbreviations

ADB	Asian Development Bank
ASEAN	Association of South East Asia Nations
CD	Curative Department
CMS	Council of Medical Sciences
DAP	Action Programme on Essential Drugs (WHO) formerly,(now EDM)
DTC	Drug Therapeutics Committee
EDL	Essential Drugs List
EDM	Essential Drugs and other Medicines, (WHO)
FDB	Food and Drug Bulletin
FDD	Food and Drug Department
FDQCC	Food and Drug Quality Control Center
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPP	Good Pharmacy Practice
GWP	Good Wholesalers Practice
HSR	Health Systems Research
HTA	Health Technology Assessment
IEC	Information, Education, Communication
IHCAR	Division of International Health, Department of Public Sciences, Karolinska Instiutet, Stockholm
INRUD	International Network for the Rational Use of Drugs
IOCU	International Organisation of consumer Unions, (formerly) now Consumers International
LFA	Logical Framework Approach
LP	Luang Prabang province
LTA	Long Term Advisor
LWU	Lao Women's Union
MCH	Mother and Child Health
MoF	Ministry of Finance
MoH	Ministry of Health
MPSC, MSC	Medical Products Supply Centre
Msek	Million Swedish crowns
NDP	National Drug Policy
PCU	Project Co-ordination Unit
PHC	Primary Health Care
RUD	Rational Use of Drugs
SAREC	Swedish Agency for Research Cooperation, (formerly), now Department for Research Cooperation, Sida
Sek	Swedish crowns

Sida	Swedish International Development Cooperation Agency
SOP	Standard Operating Procedures
STC	Short Term Consultant
STG	Standard Treatment Guidelines
TM	Traditional Medicine(s)
TOR	Terms of References
UNICEF	United Nations Children's Fund
USD	United States dollar
WB	World Bank
WHO	World Health Organisation
WPRO	World Health Organisation, Regional Office for the Western Pacific, Manila

Executive Summary

1. NDP and its implementation – general findings

Thorough preparation, the external technical input under the Swedish support, its strong catalytic effect, and the wide national consultation and participation, headed by key policy makers, were among the factors contributing to Prime Ministerial NDP approval in March 1993 (decree No. 49/PM 13.03.93). This came only a few months after the 1992 November National Drug Seminar in which the 80 participants adopted the Lao National Drug Policy and its 13 technical and administrative elements. The NDP became the guide for action in implementation.

Substantial progress can be recorded in implementation of the NDP since its approval in 1993. The regulatory framework has been extended and now it covers certain key areas. A drug law is expected to be passed by the National Assembly in the Spring of this year. This marks a milestone in the development of the regulatory framework. The Swedish support has been instrumental in this development.

The system for drug registration and licensing is now developed and computerised although a substantial number of unregistered drugs are still found in the market.

The financing system of drugs for the public health services has been reformed. Drug revolving funds have been set up in provincial and district hospitals as well as in many health centres and health posts. The availability of drugs in the public health system has improved compared to the situation when the reform was decided.

The quality assurance system has been strengthened by development of methods and tools for inspection such as GMP, GWP and GPP. Inspection according to GPP standards is done in some 7 provinces. National coverage of regular inspection and a reasonable frequency of inspection are yet to be achieved. The FDQCC is now increasingly capable of playing its crucial role in the quality assurance system. The Sida support has played a decisive role in this development

Understanding of the concept of rational use of drugs is spreading. The strategy of developing and introducing standard treatment guidelines for the most common diseases through the Curative department and representatives of the prestigious hospitals has been successful. The parallel development of monitoring instruments and procedures, as well as an institutional mechanism and organisation (DTC) to manage the system, has created necessary prerequisites for nation wide application. DTCs are now starting to implement and monitor STG and RUD in some 15 hospitals. The Swedish support has been instrumental in this development.

The system will require substantial support from the Curative department and the Provincial Health Offices to be spread, monitored and improved.

Much remains to be done to develop and implement appropriate and effective measures to raise awareness and knowledge on RUD both in the health system and among the general public. The steps taken to publish the Food and Drug Bulletin, disseminate health messages through TV, radio and posters can be seen as necessary initial measures. Given the limited resources available for IEC, the priorities need to be analysed thoroughly.

Revision and updating of the essential drug list (Drug selection element) was also done in 1994 and 1997. The WHO ethical criteria for medicinal drug promotion was translated, widely disseminated

and used as a guide for controlling drug promotion (Drug Advertisement and Promotion).
A banned drug list was produced at an early stage; availability of such drugs is one of the main GPP indicators in pharmacy inspection. This was also an important part of the Swedish support.

Some areas and elements of the NDP have received less attention such as, control of drug pricing, adequate and efficient budgetary mechanisms, basic and continuous curricula development of health personnel, and a broader and more integrated approach to both national and international technical and financial collaboration.

Time has come to review the NDP in the light of achievements made and future challenges. The mission fully supports the intention to undertake such a review[1]. We would like to draw attention to the need for particularly addressing issues under new or expanded policy elements such as:

- Economic Strategies for Drugs, including financing and sustainability of regulatory and other activities
- Human Resources Development, including both university and continuous education in the whole pharmaceutical sector
- Operational Research
- Organisation, Management and Overall Co-ordination and Monitoring of the NDP and its implementation process
- Internal and External Technical Collaboration, including the use and application of WHO recent guidelines on national drug policies, effective drug regulation, quality assurance, rational drug use, and financing mechanisms.

2. The NDP Programme

Project 1. Quality of Drugs

a) Enactment of a law on drugs is a major achievement. The law itself will, however, not change the reality. A number of regulations need to be put in place for the law to be enforceable. Furthermore, there is a need to prepare an implementation strategy and priority plan for the next few years; to make the law an effective instrument for safe, effective, good quality drugs, rationally used. Such a strategy should include**;** a written mission statement; an information campaign; an enforcement strategy to promote compliance with the law (persuasion, warning, penalty, license suspension, license revocation); a regulatory strategy (self regulation, enforced self regulation, command regulation with punishment); directions for co-operation and involvement of the public, public and professional interest groups and the health profession.[2]

b) Without inspection and the capacity to enforce various degrees of sanctions, the regulations will be "toothless". Now when methods and tools for inspection are in place, the improvement of efficiency and effectiveness of inspection is to a large extent depending on the cycle of planning, follow-up and implementation of corrective measures. This requires knowledge of modern management methods. It also requires substantial financial resources to carry out nation wide inspections, with a reasonable frequency, plus investment in training of the inspectors.

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[1] See Report of the WHO Expert Committee on National Drug Policies. Geneva, 19–23 June 1995. Contribution to updating the WHO guidelines for developing national drug policies WHO/DAP/95.9

[2] See WHO publication: Effective Drug Regulation: what can countries do? WHO/HTP/MAC(11)/99.6, March 1999 and Quality Assurance of pharmaceuticals, A compendium of guidelines and related materials Volume 1,WHO 1997

c) FDQCC plays one of the key roles in the quality assurance system. Its capacity to undertake analyses of drug samples is now more constrained by inadequate funding, than by lack of know-how and equipment. To find ways and means to secure a level of funding that corresponds to the need for pre- and post-marketing testing of drugs is urgent.

Project 2. Rational Use of Drugs

a) Methods and tools (STG, STG and RUD indicators, DTC,) for rational use of drugs in hospitals are being introduced and implemented in some hospitals. This should be seen as a major achievement of the project. One challenge for the future is to develop STG for other diseases and to spread the use, eventually to all hospitals. An even more challenging task is to improve the application of STG through monitoring and to continuously improve the whole system.

b) IEC are essential means to promote rational use of drugs. It is, however, difficult to identify and assess effects of IEC measures. In a resource constrained environment it is therefore vital to identify only a few measures that are considered to be effective. Results from the health systems research should help to identify the most effective means and methods in this area.

Project 3. Traditional medicine

The project has been successful in achieving most of the planned outputs. The on-going study will be the final output of the project. The Mission appreciates the high priority the Government puts on TM. It is, however, doubtful if Swedish support in this field has a comparative advantage. Regional co-operation and linkages to institutions specialising on TM is most likely more fruitful for the development of TM in Lao PDR.

Project 4. Management of drug supply

A Medical Product Supply Centre (MPSC) was created in 1998 to integrate planning and monitoring of central and provincial drug procurement, distribution and storage. The one year support to the new system by a project technical adviser just ended. A Procedure Manual for the Procurement and Distribution of Essential Drugs and Basic Medical Supplies was produced, along with training of the staff. This has been an important and timely technical input to the Programme, in collaboration with the WHO office in Lao PDR.

It is now a matter of making the new system fully operational, which may take some time. Periodical technical expertise will be needed. The mission recommends that such support, when needed, could be provided under the ADB/WB collaboration and from WHO.

Project 5. Strengthening the institutional framework for National Drug Policy

(this is the current title used; the original project title is "Strengthening the National Drug Policy")

a) A great success under this project has been the training in English of more than 40 central and provincial health officers working in the NDP Programme. Increased knowledge of English has greatly contributed to easier communication with consultants, and the ability of staff to participate in many international meetings and study tours carried out under the Programme. This has led to gaining of experience and knowledge in technical, managerial and policy matters. The view of the mission is that this area merits continued support.

b) Health Systems research also falls under this project. This is an important, innovative and recently (October 1998) introduced element and approach in Laos. Its purpose is to obtain data towards an evident based National Drug Policy. The data from the extensive pharmacy study in the Savannakhet province has already provided very important input to the Programme and have have resulted in corrective measures. Five HSR projects carried out in 1999 are now also being analysed.

The results will serve as basis for review of the NDP, and the introduction of changes in the various projects under the whole Programme. The Health Systems research and its capacity building should continue. The methods, the experience gained and the application could be shared with others in the Region and elsewhere.

Project 0: Co-ordination

Programme management
The management of the programme was not given the attention it would have required at the start of Phase II of the NDPProgramme. A lot of efforts have since been made by all parties – MoH, Sida, IHCAR – to make up for the initial neglect. Programme planning and management, including progress and financial reporting have, however, received much attention during annual reviews. This attention was caused by plans and reports being overly detailed, and at the same time lacking in overview. The mission has noted improvement in progress reporting. Financial reporting is, however, weak, especially in follow up of consolidated expenditure against the programme budget. The Mission has spent a great deal of time in trying to establish a picture of total expenditure of the different projects up until September 30, 1999, as compared to the agreed April 1997 project document budget. The Mission has managed to arrive at a consolidated picture of total expenditures which, however, needs to be verified.

The continued support by Sweden during a third phase, as recommended below, will require that due attention is given to the scope, content and issues of project management, right from the start.

3. Need for continued Sida support

The Mission has found that implementation of the NDP will continue to need financial and technical support. The achievements made in the different areas reported above are commendable and were attained by the MoH and through a combination of technical and financial support. The technical support through IHCAR has been crucial for the development and implementation of new methods, tools and approaches. The technical competence of the FDD and other Government actors involved in NDP implementation is, however, not yet sufficient to improve and further develop the methods and tools. Neither is the capability to manage and develop the whole system and its components. Technical and financial assistance should therefore be provided in certain key areas over a period of 3 years. A seamless transition from the current phase to Phase III should be made, in order not to jeopardise the momentum now obtained in implementation of the NDP. In the medium term, the MoH will have to find ways to ascertain financial sustainability of the regular activities supporting quality and rational use of drugs. Unless this can be obtained, the achievements in building institutional capacity is highly threatened.

4. Prerequisites for long term sustainability

4.1 Financial sustainability of current operations
The major problem facing the core functions in quality assurance is the financing of current operations, of inspection, and of FDQCC. Fees charged for registration of drugs, and licensing of drug manufacturers, wholesalers and pharmacies have not been adjusted to compensate for the fall of the value of the KIP. The fees, when set, were not based on the condition that they would fund the operations of the quality assurance system. FDD has proposed certain revision of fees based on a comparison of fees charged in neighbouring countries. The financial regulations governing the determination and use of fees do not now allow MoH to retain the revenue to finance current operations.

The Mission strongly recommends that MoH and MoF jointly undertake a thorough study, with external assistance. Such a study should be a follow-up and expansion of the 1998 consultancy (Bremer) and lead to agreement for an operational plan for funding the quality assurance system from fees (Annex 11). It should outline and discuss the modalities and requirements for implementing such a system. Retention of collected fees in drug regulatory control is current practice in most countries today. Such practice would be in line with the Lao Government policy on drug revolving funds.

4.2 Management and organisational development of core functions

A new financing mechanism would require development of new management tools for planning, implementation, follow-up and evaluation of quality assurance activities. There will also be a need to establish mechanisms for co-ordination of actors involved (FDD, FDQCC and Provincial health departments). The system for financial management – including budgeting, accounting, cash management and financial decision making – will need to be developed to match the new requirements. The leadership of MoH, managers and staff of the concerned organisations will need to acquire new managerial and technical skills. Technical assistance will be required for this development.

5. Direction of Sida support during a third phase

Recommended Sida support would need to cover:

5.1 Technical assistance to meet the prerequisites for long term sustainability

5.2 Technical assistance to consolidate and improve methods and tools as well as to enhance competence to apply and manage the methods and tools

5.3 Financial assistance to meet local costs for programme implementation

6. Next step

The Mission recommends that the following steps are taken before the final annual review of PhaseII:

a) Seminar with MoH, Sida and IHCAR to agree on a joint strategy for continued support during a third phase

b) Study of financing operations of the quality assurance system

c) Preparation of a project document for Phase III.

1. Programme context

1.1 The development context

Lao PDR is one of the least developed countries of the south-east Asia region and of the world. It has a population of around 4,6 million. The vast majority, more than 80%, of the population lives in rural areas. In the region, only Cambodia scores lower on the UN human development index. The following main social indicators illustrate the level of development:

Population growth	2.4% per annum
Life expectancy at birth	51 years
Fertility rate	6.7 children per mother
Infant mortality rate	estimated 68 to 169 per 1000 live births
Under 5 mortality	160 per 1000
Maternal mortality rate	650 per 100,000 births
Population per doctor	average 8500 (varies from 1260 to 20.800)
Mean years of schooling	2.9 years
Adult literacy rate	60%
GNP per capita	USD 350

During the first years of independence Lao PDR established a centrally planned economic system. A new economic mechanism, based on market economic principles was adopted in mid 1980s. More radical economic reforms were introduced at the end of the decade. Positive economic growth followed in the 1990s with growth rates ranging between 6–7% annually until the Asian economic crises hit the country from mid 1997.

The economic growth rate has been reduced to around 4%. Inflation has reached a level of almost 100% in 1998 and the currency, kip, has lost value against the dollar from just below 1000 kip/dollar at the end of 1996 to around 7500 kip/dollar in January 2000. The government has encountered increasing fiscal problems. The fiscal deficit has grown during the last years resulting in increased dependence on donor funding, increased uncertainty in funding of recurrent expenditures and reduced real value of civil servant salaries. In this resource constrained environment all development programmes are likely to encounter financial sustainability problems.

Lao PDR health indicators are among the worst in the world. The country is totally dependent on donor contributions. Donors are many, ranging from multilaterals to bilaterals to over 50 non-government organisations. The Ministry of Health is organised into departments centrally, and the same at provincial and district levels. The tiered health system has dispensaries and health centres at the base. District hospitals have 5–30 beds and some of the 18 provincial hospitals have up to 200 beds. Mortality and morbidity figures show malaria, acute respiratory infections and diarrhoea on the top. Great regional variations, low health status of people and lack of knowledge of health issues are major constraints to development. The more than 2000 private pharmacies serve as the first contact point for a large section of the population seeking advice or remedies for illnesses.

1.2 The Project history

Leading up to Lao National Drug Policy approval in 1993

Several problems occurred in the pharmaceutical sector after Lao PDR changed its economic system in the mid 80's. Uncontrolled private pharmacies and drug vendors spread rapidly throughout the country. Counterfeit, dangerous and substandard drugs appeared in the private sector and in the illicit market. The public sector lacked essential drugs. Irrational drug use among consumers and prescibers became wide spread. The country lacked infrastructure, a regulatory control system, a modern quality control laboratory and trained human resources to cope with these urgent and serious problems.

The Lao government turned to Sida for help in 1991, initially focusing on support for building and equipping a Drug Quality Control Center. Sida had until then only been involved in funding procurement of 84 drug items for districts in four provinces, as part of support to the UNICEF administered MCH services.

During the fiscal years 1991/92, Sida assigned IHCAR/Karolinska Institutet, Stockholm to present, discuss and plan strategic contributions within the pharmaceutical sector, in co-operation with Ministry of Health officials. Proposals were to include "support to the preparation of a national drug policy, routines for control and handling of drugs and prerequisites for construction and equipment of a control laboratory".

In March 1992, an IHCAR team reviewed the drug situation in Lao PDR together with the then vice-director of the MoH department of Pharmacy. The external team consisted of a senior IHCAR staff member, the director of the Thailand FDA Technical division, and a senior lecturer at the Faculty of Pharmaceutical Sciences, Bangkok Chulalongkorn University. It recommended and outlined a number of programme activities. The team concluded, that Lao needed a comprehensive National Drug Policy (NDP) instead of the very brief supply oriented document that the Ministry had prepared. Missing elements such as drug legislation, rational drugs use, IEC, human resources development and monitoring systems must be included.

The findings from the March 1992 mission served as an essential input to Sida's assessment of needs, extent and forms for future support to the Lao drug sector.

In April 1992 a Lao delegation of four, headed by the MoH vice-minister for planning, visited Sweden to discuss co-operation in the Health Sector in management and drug control.

June 1992 was another important event in Lao NDP development. The MoH vice-minister and the vice-director of the department of Pharmacy participated in a Colombo, Sri Lanka "Workshop for Ministry of Health officials of Asian and Pacific countries focusing on National Drug Policy". International Organisation of Consumer Unions (IOCO), Regional Office for Asia and the Pacific, organised the meeting. It provided basic lessons and knowledge on how to prepare and organise a national seminar on NDP.

A major milestone was the November 1992 Lao NDP National Seminar. This was the fourth and final of the consultative seminars "Towards a NDP" in Lao PDR. The over 80 participants reached consensus on, and adopted, the Lao National Drug Policy including 13 elements. Results from quick surveys carried out before the seminar had revealed great problems in self-medication, dispensing and prescribing practices. The seminar recommended to create a National Committee

(and subcommittees) responsible for NDP implementation. Further, to reorganise and strengthen existing MoH departments and institutions.

Good and thorough pre-seminar planning contributed to the positive outcome of the November 1992 seminar. Those who helped to prepare were, among others, Ministry of Health officials, IHCAR technical consultants from Thailand National Epidemioloy Board (later renamed Thai Health Research Institute) and Sweden. One essential ingredient in the successful seminar outcome was the high level of Lao political commitments (ministerial decrees No. 699, 29.7.92 and No. 817, 3.9.92).

Lao National Drug Policy approval

In March 1993, the Lao PDR Prime minister approved the National drug Policy and signed a state decree (No. 49/PM 13.03.93). Under this decree a 10 member committee, in charge of the national drug policy was formed.

Phase I of the NDP Programme: 1992–1995:

On 21 May 1993 representatives of the Swedish and Lao governments signed a specific agreement in Vientiane for the period 1 July 1992 to 31 December 1995. The agreement covered two programme areas: Support to Develop and Implement a National Drug Policy in Lao PDR and; Management and Planning support to the Lao PDR Health Sector.

The aims of the support were to improve the health situation of the Lao population. The objectives were to develop capacity for planning, management, co-ordination, communication, training and implementation within specific areas and departments of the Ministry of Health.

The specific objectives of the Swedish support to the NDP Phase I programme were to strengthen the capacity to implement the policy within the Department of Pharmacy and its Food and Drug Administration Commission. This included:

- development and ratification of a National Drug Policy
- to prepare a strategy and plan of action for IEC regarding rational use of drugs
- construct and equip a drug control laboratory and equipment for field control
- training of staff at various levels in technical and administrative matters through participation in courses, workshops, seminars and conferences
- installation of a computerised system for drug registration

The specific objectives of the Swedish support to the programme "Management and Planning Support to the Health Sector" were to strengthen the capacity of planning and management at central and provincial levels.

The total budget for the period 1992 to 1995 was 9 million Swedish crowns. The NDP Programme budget was 3.790.000. The Management and Planning Programme was assigned 2.965.000 Swedish crowns and IHCAR budget for fees, travels, etc. was 1.845.000. For Sida monitoring and review 400.000 Swedish crowns was set aside.

In July–August 1993 an unusual method of "jump starting" implementation was tried, quite effectively it seems, in a two week workshop in Thailand. For purpose of capacity building, over 20 Lao participants from different ministries, the medical school, NGO's etc. examined their approved NDP and the approaches to implement the policy. This was done with help of consultants from

Thailand (who could easily communicate with the Laotians who hardly spoke any English at the time), IHCAR and WHO.

On 17 September 1993 Sida Health Division signed a contract with IHCAR for 1992/93–1994/95. It included technical and managerial support to the Lao Ministry of Health. IHCAR's role as advisor to the MoH meant assistance to the Ministry to implement plans, mainly through competence development.

End of Phase 1 and preparation for Phase II

In August 1995 an external consultant from the College of Public Health at the Chulalongkorn University in Bangkok reviewed the NDP project, but did not do an analytical evaluation of the project.

The Programme was however well on its way and a number of things had been achieved, which is discussed in total in chapter 3. In 1994 the Department of Pharmacy had been reorganised into the Food and Drug Department (FDD) including the Food and Drug Commission. FDD was responsible for the management of the Drug Policy and Control project under Phase I.

Sweden then decided to continue its support for a Phase II, extending implementation to a majority of the elements under the NDP. The management support project under the responsibility of the MoH Cabinet had given little results and was stopped.

The Specific agreement between Sweden and Lao PDR for Phase II of the National Drug Policy programme was signed on 30 may 1996 and amounted to 15 million Swedish crowns. This agreement was valid for payments and reporting up to 30 June 1999, with an activity period up to 31 December 1998.

Because of Sida's rules of competitive bidding, IHCAR could not assist the Lao Ministry of Health to develop a new project document. Sida asked the WHO Action programme on Essential Drugs to assist the MoH with the new plan, on behalf of Sida. A WHO staff member and a Sida LFA consultant produced a new project document: "The National Drug policy Programme, Sida support for 1996–1998". The document was presented in a Logical Framework format including explanatory texts.

The WHO and Sida consultants had difficulties convincing the Lao MoH that such a complex and comprehensive programme required substantial external technical assistance; likely because of the comparatively high costs involved in using external help. The Lao MoH eventually accepted and agreed to a proposed number of weeks. These, as it later turned out, had to be increased considerably (in 1997 from 35 to 47 weeks and more in 1998), when everyone realised that the initial estimates were grossly underestimated.

The processes related to the project document approval, the signing and the tendering in 1996 for technical assistance lasted about a year. This considerably shortened the planned 1996–1998 Phase II implementation period, which did not really effectively start until mid 1997.

IHCAR was finally selected as winner of the tender for technical assistance. IHCAR and Sida signed the contract on 15 November 1996. The contract covered the period, 15 November 1996 to 31 December 1998. The contract included a total of 59 consultant weeks: 35 for "year 1" and 24 for "year 2". The total budget for the two years was 2.015.240 Swedish crowns.

In spite of the various delays in 1996, FDD continued to carry out and co-ordinate activities in Laos with some help from IHCAR for activities scheduled up to June 1996. Money from Phase I could be disbursed until 31 December 1996.

Annex 9 gives a chronological listing of Phase I and Phase II project documents, agreements, contracts, annual review minutes, annual review reports, work plans etc.

1.3 The project document for Phase II

In January 1997, an IHCAR team assisted the MoH to do a comprehensive review of the November 1995 LFA project document, as over a year had passed since that had been developed. Activities and results planned for 97–98 were revised, updated, added to or excluded. STC requirements and support were updated and specified with terms of references and time schedules. The revised project document "The National Drug Policy Programme: Sida support for 1996–1998", got the subtitle "revised in January 1997".

At the annual review in Vientiane 4–12 April 1997, the revised project document and its Plan of Operations for 1996–98 were reviewed. FDD was asked to include proposed modifications agreed upon during the annual review. The project document resulting from this was recognised as the final NDP document, that of April 1997.

The major aim of the Swedish support to the NDP Programme is to promote the building up of Lao competence and institutional capacity to develop and sustain the implementation of the Policy.

Phase II overall, long term objective is to contribute to good health through the availability of good quality drugs at low cost. Specific objectives, in line with the country's health policy and National Drug Policy, are to:

- ensure that drugs used by the population are safe, effective and of good quality;
- increase the rational use of drugs;
- improve knowledge and rational use of traditional medicines;
- improve the drug supply system in the public sector;
- improve the capacity and knowledge of the Food and Drug Department, and
- to implement, monitor and follow up all the activities related to the Programme

The National Drug Policy Programme for 1996–1998 addresses five main areas or projects, corresponding to the above objectives. Three of the projects are divided into separate components, shown in parenthesis in *italic* after the project titles below.

1. Quality of drugs (*Drug law and regulation, Inspections, Food and Drug Quality Control Center or FDQCC*)
2. Rational use of drugs (*Standard treatment guidelines, IEC, Monitoring and supervision in rational use of drugs or RUD*)
3. Traditional medicines
4. Managing drug supply
5. Strengthening the institutional framework for the National Drug Policy, original title was "Strengthening the NDP"(*Strengthening the NDP in general*, *Health systems research for implementing NDP*)

0. Co-ordination; this project was added out of necessity in 1997

Annex 4 gives details on project and component objectives and indicators, as included in the original LFA matrix in the approved project document. In a tabular format it also compares actual and planned results or outputs.

An extension of the NDP Programme until 2001 led to an addendum to the original contracts between Sida and the Ministry of Health, and Sida and IHCAR.

1.4 Phase II budget and expenditure

In the project document a total of Msek 14,9 was budgeted of the total frame of Msek 15, agreed upon in the specific agreement entered into in May 1996. Of the budgeted amount, Msek 11,7 was to be channelled through MoH mainly for local costs and through Sida for direct procurement. An amount of Msek 2,7 was allocated to technical assistance through IHCAR. In the contract between Sida and IHCAR signed in November 1996 a ceiling amount of Msek 2 was agreed upon. Sida's part for review and evaluation was 500.000 Sek.

As implementation proceeded, it became obvious that the time frame for the programme had to be extended. In the beginning of 1999, the specific agreement between Sweden and MoH was extended to June 2001, with activities to be terminated by December 2000.

An extension of the contract with IHCAR was subsequently agreed upon in May 1999, but valid from October 1998. The ceiling amount agreed upon for the period October 1998 to December 2000 was Msek 3,75. Included here was the allocation of Msek 0.980 for the long-term adviser at the Medical Product Supply Centre (MPSC) under Project 4. It was decide that a long-term adviser would be of greater benefit to the Centre than the planned external study visits for personnel at the Centre. Also included in the amount of Msek 3,75 was the re-allocated funds in favour of needed technical assistance and short term consultants for institutional and capacity building Health System Research. This re-allocation became possible and was agreed to because of lower than budgeted and estimated costs for local activities, and a deletion or shifting of study tours abroad to local courses. According to a report by IHCAR a total of Msek 2,1 was spent up to September 1998. The total allocation to IHCAR therefore amounts to Msek 5,85, almost three times the amount agreed upon in the original contract, explained by the above mentioned re-allocations.

The pace of implementation of Phase II activities is reflected in the reported expenditures. The table below provides a summary of expenditure up to September 1999 compared to the original budget.

Table 1.4.1
Summary Follow up of expenditure against Project document budget of April 1997

	Budget	% share	Expend	Expend	Expend	Expend	**Expend 95/96**	% share
			1995/96	1996/97	1997/98	1998/99	**to 98/99**	
MoH	**11683600**	78%	625500	403200	521688	1694170	**3244558**	34%
IHCAR	**2704720**	18%	0	1142157	958668	2567812	**4668637**	49%
Sida	**0**		0	1237147	189750	204694	**1631591**	17%
Sida rev.	**500000**	3%	0			48783	**48783**	1%
Total	**14888320**		625500	2782504	1670106	4515459	**9593569**	

It should be noted that the expenditure figures reported by MoH for 1995/96 and 1997/98 shown in the above table 1.4.1 are uncertain. Especially for 1995/96 the reported expenditures are the same as budget amounts. Therefore the total expenditures up to September are not totally correct. It should, however, be possible to reconstruct fairly correct accounts for 1995/96 and 1996/97. The auditing report, reviewing expenditure until November 1997 could be used. The project manager of that time would likely be in a position to assess the actual expenditures and reconstruct a picture as correct as possible.

Two observations can, however, be made. First, the pace of implementation increased sharply in 1998/99 and is expected to be kept at this level during the last year. Second, the technical assistance share of total expenditure has increased substantially compared to the original estimates as explained above.

Table 1.4.2 below shows original budget and expenditure for the various sub-projects. It should be noted that the original budget of IHCAR was not distributed on the sub-projects. The budget figures only show the estimated expenditures by MoH and those that were to be spent by Sida for direct procurements etc. The expenditure columns include expenditures made both by MoH and IHCAR, but not those direct expenditures made by Sida. Thus, it is not possible to obtain a complete picture of expenditure on the different sub-projects. However, the direct expenditure by Sida of Msek 1,6 has mainly been used for vehicles and equipment belonging to project 1. The extent to which the actual expenditures reflect the original priorities is difficult to assess because of the undistributed IHCAR budget and the undistributed Sida direct payments

Table 1.4.2
Follow up of expenditure against Project document budget of April 1997

	Budget	% share	Expend	Expend	Expend	Expend	**Exp95/96**	%
			1995/96	1996/97	1997/98	1998/99	**to 98/99**	share
Project 1	**4399600**	30%	239000	621765	350088	1005949	**2216802**	23%
Project 2	**2825500**	19%	160000	305653	223818	548913	**1238384**	13%
Project 3	**381000**	3%	50000	100000	56000	63504	**269504**	3%
Project 4	**1180000**	8%	75000	89875	220000	1212923	**1597798**	17%
Project 5	**2897500**	19%	101500	135600	307022	1092622	**1636744**	17%
Project 0				292464	323428	338071	**953963**	10%
IHCAR	**2704720**	18%						
Sida	**0**		0	1237147	189750	204694	**1631591**	17%
'Sida Rev.	**500000**	3%	0			48783	**48783**	1%
Total	**14888320**		625500	2782504	1670106	4515459	**9593569**	

2. Evaluation methodology

2.1 Background to the evaluation and terms of reference

The reasons for the evaluation are given in the terms of reference *(Annex 1)*. The NDP programme is approaching the end of the second phase. Since its inception the programme has been going on for 8 years. This fact, in itself, justifies an evaluation. Sweden has also decided to withdraw from the health sector in the future but is prepared to consider a final period of support. The evaluation is therefore to serve as a basis for discussion and preparation of a possible final phase of support to implementation of the NDP.

The terms of reference specify the scope and focus of the evaluation. The following issues are to be covered:

- an overall assessment of the NDP,
- implementation of the Sida supported programme,
- prerequisites for long term sustainability,
- programme organisation and technical assistance,
- cost-efficiency,
- co-ordination with other on-going support programmes,
- importance of the programme for the poor,
- importance of programme for gender equality,
- regional and global aspects and
- recommendations regarding a final phase of Sida support.

The full text of the terms of reference is in *Annex 1.*

2.2 Approach and methods

The mission has collected facts about the programme from documents, through presentations by involved people, interviews and direct observation. During a first phase of about one-week the team studied documents provided by Sida and IHCAR. Representatives of Sida and IHCAR and others were met, or interviewed through correspondence, in Stockholm and Geneva, in December 1999. Schedule and people met in Stockholm and elsewhere are found in *Annex 2(i) and 3 (i).* Documents reviewed are found in details in *Annex 9 and in Annex 10,* sections I to III..

A second phase took place in Thailand and Lao PDR from 16 January to 5 February 2000. It included visits to Department of Medical Sciences, Ministry of Public Health in Thailand; meetings with two IHCAR consultants in Bangkok; and the visit to Laos, its Ministry of Health as well, as the Swedish Embassy in Vientiane. Meetings were held with MoH staff, who has been or is currently involved in the programme in various capacities. The mission also met representatives from WHO, UNICEF, Lao Women Union, Lao and Swiss Red Cross, and the Lao Primary Health Care Co-ordination Office for ADB and WB support. Visits were made to hospitals and pharmacies in Vientiane. A field trip to Luang Prabang province included visits to the health department, the provincial and a district hospital, public sector dispensaries and private pharmacies. The mission's itinerary-agenda, and the list of people met in these places are found *in Annexes 2(ii) and Annexes 3(i) and 3(ii).* Before leaving Vientiane, the mission reported its main findings and preliminary recom-

mendations to a meeting of MoH senior officials. They were the Minister of Health, members of the National Drug Policy Steering Committee, directors and managers involved with the NDP Programme, and the Sida representative from the Swedish Embassy.

The major part of report writing has been done in Geneva and Stockholm.

In order to facilitate a fair assessment of the results achieved, the mission has found it necessary to go back to the situation as it was, when the first phase started in 1992. The situation at that time represents a base line against which the current situation should be compared.

In evaluating the programme the mission has assessed the findings by asking the following type of questions:

- Was the national drug policy relevant to the situation in Laos when it was adopted in 1993? Is the policy still relevant?
- To what extent has the policy been implemented? In what way and to what extent has the NDP Programme contributed to this? Has the NDP Programme focused on relevant elements of the policy?
- Were the projects components relevant, adequate and sufficient to achieve the project objectives?
- To what extent has institutional capacity of MoH been enhanced to sustain achievements made and to continue implementation and development of the national drug policy?
- Have the programme objectives, implementation measures and resource inputs been combined in a realistic and appropriate way?
- Has the chosen model of co-operation between MoH, the consultant and Sida been appropriate to the task?

The assessment of the NDP has been made against international guidelines and experiences as documented by WHO and others.

In assessing the institutional capacity and sustainability the mission has used the approach described in the report "Diagnosis of Organisations in Development Co-operation, Guidelines for application of the Staircase Model"(see ref. under section IV, Annex 10).

2.3 Limitations

The overall objective of the NDP is to promote the availability of safe and affordable drugs of good quality, and the rational use of drugs. The mission has not assessed the achievement of this objective. However, important research has already been conducted to assess the effects of the NDP implementation. This research, carried out in Vientiane and Savannakhet provinces (Stenson et al.), has resulted in publications and finalised analyses. The conclusions from the studies, also discussed elsewhere in the report, clearly demonstrate that major improvements are still very much needed in areas concerning drug quality, in the perceptions about drug quality, and in the quality of private pharmacy practice. The continued implementation of the policy will increasingly generate information, which can be used to assess the achievement of the overall objective and which in turn must lead to intensified actions. Dramatic improvements was for example seen in Savannakhet province after little more than one and half years, after interventions in the problem areas.

The evaluation has, according to the Terms of References, focused on the impact the NDP, and the implementation measures are likely to have on the overall objective. This distinction is important to keep in mind

3. Findings

3.1 Introduction

The Lao National Drug Policy Programme is a complex multilevel and multisectoral programme. It is carried out at central, provincial, district and village levels with the help of many actors and external technical advisors. In Phase II it covers 5 out of 18 provinces. They are: Champassak, Luang Prabang, Savannakhet, Vientiane, and Vientiane Municipality. In Phase I 3 provinces were covered: Champassak, Luang Prabang and Vientiane Municipality.

A NDP Steering Committee of 14 senior ministry of health officials, headed by the Minister, oversees progress of the National Drug Policy implementation. A NDP Programme Management Committee of five, with members from the FDD, the Curative Department and the Cabinet, is responsible for co-ordination and monitoring of projects and components. Responsible officers are assigned for these.

The findings cover the period 1992 to the end of 1999. Emphasis is on Phase II.

The findings are presented as follows:

3.2 The National Drug Policy and its implementation, -and -under the NDP Programme as follows

3.3 Project 1 Quality of drugs and 3 components

3.4 Project 2 Rational Use of Drugs (RUD) and 3 components

3.5 Project 3 Traditional Medicines

3.6 Project 4 Managing Drug Supply

3.7 Project 5: Strengthening the institutional framework for the National Drug Policy and 2 components

3.8 Project management including Project 0

3.9 Institutional capacity

Table 3.1 gives an overview of the 13 NDP elements and corresponding Sida support for Phase I and Phase II.

Annex 4 is intended to give a quick tabular overview of what the Phase II programme was set out to do or produce, and what it actually did produce. The annex includes the mission's tabular assessment of project and component results (output) and indicators, at the time of evaluation in January 2000. It is compared with the LFA matrix in the April 97 Phase II project document. Project and component objectives, planned results and indicators are shown in the table.

Table 3.1
NDP elements and corresponding Sida support for Phase 1 and Phase II

National Drug Policy Elements in 1993 NDP	Phase I Sida support 1992–1995	Phase II Sida support 1996–2000
	-Development and ratification of a **National Drug Policy**	
1. Drug Legislation and Regulation		**Project 1: Quality of drugs** Component1: Establishment of law and regulations (also part of 10)
2. Drug Selection		(addressed in project 4)
3. Drug Nomenclature (Drug Denomination)		
4. Drug Registration and Licensing for Sale	-Installation of a computerised system for drug registration	
5. Drug Procurement		(addressed in project 4)
6. Financial Resources		(addressed in project 4)
7. Drug Distribution and Storage		**Project 4: Managing drug supply** (also part of 2, 5 and 6)
8. Quality Assurance of Drug Substances and Pharmaceutical specialties	-Construction and equipment of a drug control laboratory and equipment for field control	**Project 1: Quality of Drugs** Component 2: Inspection Component 3: Food and Drug Quality Control Center (FDQCC)
9. Rational Drug Use	-Development of strategy & plan of action for IEC regarding rational use of drugs	**Project 2: Rational Use of Drugs (RUD**) Component 1: Development of standard treatment guidelines: Component 2: IEC; (part of 10) Component 3: Monitoring and Supervision in RUD
10. Drug Advertising and Promotion		(included in project 1, components 1 and 2; and in project 2, component 2)
11. International Technical Co-operation		**Project 0: Co-ordination**: partly included
12. Traditional Medicine		**Project 3: Traditional Medicines**
13. Drug Monitoring and Evaluation		**Project 5: Strengthening the institutional framework for National Drug Policy** Component 1: Strengthening the NDP in general; Component 2: Health Systems Research for implementing the NDP
	-Training of staff and at various levels in technical and administrative matters through participation in courses, workshops, seminars and conferences	
	Phase I covered 3 of 18 provinces	Phase II covers 5 of 18 provinces

In Phase 1 Management and Planning (MAP) was also included. It was discontinued in 1995.

3.2 The National Drug Policy and its implementation

Substantial progress can be recorded in implementation of the NDP since its approval in 1993.

The *regulatory framework* has been extended. It now covers certain key areas. A *drug law* is expected to be passed by the National Assembly in the Spring this year. This marks a milestone in the development of the regulatory framework. The Swedish support has been instrumental in this development.

Within the *drug selection* element, revision and updating of the essential drug list (EDL), originally created in 1978, took place in 1994 and 1997. The official, published list is in French. An English version of the EDL exists. It is included as annex (ii) in the recently finished "Procedure Manual for the Procurement and Distribution of Essential Drugs and Basic Medical Supplies in Lao PDR". Authorised level of use (central, provincial, district, health centre and village levels) is indicated in this procurement list. The EDL can therefore easily be officially published also in English, after review of this procurement list, and be presented under drug therapeutic classes (the WHO classes) and in alphabetic order. A banned drug list was produced at an early stage; availability of such drugs is one of the main Good Pharmacy Practice (GPP) indicators in pharmacy inspection. So is the availability of the most essential drugs, indicated on a list that each pharmacy in the five pilot provinces must have. This development work has been an important part of the Swedish support. In the public sector today, it is estimated that 80% of the 141 districts in Lao PDR follow the identified Lao EDL, and that 17 out of 18 provincial hospitals do the same.

Under *drug nomenclature* (drug denomination) there is still work to be done on the use and promotion of generic name in prescribing. This is difficult to implement, also in the most developed countries. One needs to strike a balance on what can be realistically expected and implemented. Labelling of drugs has greatly improved thanks to the GPP inspections and follow up, developed under Sida support. Today one hardly finds any drugs without a readable generic name, that is the active ingredient of the drug. In 1992 only about one third of all drugs are reported to have had a readable generic name, particularly those drugs that came from China, Vietnam and East European countries. The policy requirements that brand names can only appear after the generic names, and in brackets, need to be reviewed, as it seems unrealistic to expect that to happen in Laos.

The system for *drug registration and licensing* is now developed and computerised and about 70% of drugs are adequately registered. A substantial number of unregistered drugs are still found in the market. The majority, or about 95% of pharmacies and wholesalers are registered and licensed today. Phase 1 Sida and WHO support helped to start the drug registration and licensing system in Laos. The start-up system is now replaced. In 1999, the Food and Drug Department installed a more suitable and comprehensive computerised drug registration and licensing system. It has been developed with support from WHO and the Philippines Drug regulatory control authority.

For *drug procurement*, the 1993 National Drug Policy states that "a Central Drug Procurement Unit for the public sector may be institutionalised within the MOH". The Medical Products Supply Centre (MPSC) created in 1998 is a response to this. Early Swedish advocacy for this, together with short and lately long term technical assistance helped in the creation and operation of the Centre.

Financial resources for drugs in the Lao public sector are extremely limited. Central allocations to provinces and districts cover generally only 20% of expenditures. The policy states that " the government should encourage the establishment of the revolving fund system …". The financing

system of drugs for the public health services was reformed to respond to the great needs for a constant supply of medicines. Starting in 1994, the Ministry of Health, in collaboration with UNICEF, Japan, Lao and Swiss Red Cross, Médecins sans Frontières and Lao Women Union, set up revolving funds. These were introduced in provincial and district hospitals, as well as in many health centres and health posts. The availability of drugs in the public health system has therefore improved, compared to the situation when the reform was decided.

Measures for improvements in *drug distribution and storage* in both public and private sector are proceeding. The Medical Product Supply Centre is focusing on implementing a drug management and reporting system for the public sector. In the private sector, where an estimated 90% of all drugs are handled and sold, measures for improvement include licensing and GPP inspection of the over 2000 pharmacies or drug sellers. Laos has three categories of pharmacies. Category I, 15 in the whole country, is headed by a pharmacist and can sell all drugs registered in Laos, including drugs classified as narcotics. In Category II there are 98 pharmacies, which are headed by pharmacist assistants or other health personnel. Some restrictions are imposed on this category of pharmacy. The last group, category III is the most common one. There are 1929 in this group, which in principle is only allowed to sell a limited number of drugs. In practice, GPP inspectors help to monitor this only in the five pilot provinces.

The quality assurance system has been strengthened by development of methods and tools for inspection. These are, Good Manufacturing Practices (GMP), Good Wholesale Practices (GWP) and Good Pharmacy Practices (GPP). Inspection according to GPP standards is done in five pilot provinces and in the two provinces supported by ADB and WB. National coverage of regular inspection and a reasonable frequency of inspection are yet to be achieved. The Food and Drug Quality Control Center, the FDQCC, did not exist in 1992. It was inaugurated in 1995 and is now increasingly capable of playing its crucial role in the quality assurance system. The Sida support has played a decisive role in this development.

Understanding of the concept of *rational use of drugs* is spreading. The strategy of developing and introducing standard treatment guidelines for the most common diseases, through the Curative department and representatives of the prestigious hospitals, has been successful. The parallel development of monitoring instruments and procedures, as well as an institutional mechanism and organisation (DTC) to manage the system, has created necessary prerequisites for nation wide application. Drug Therapeutic committees (DTCs) are now starting to implement Standard Treatment Guidelines (STG) in some 15 hospitals, and monitor their use through STG and Rational Drug Use (RUD) indicators. The system will require substantial support from the Curative department and the Provincial Health Offices to be spread, monitored and improved.

The Swedish support has been instrumental in this development. Much remains to be done to develop and implement appropriate and effective measures to raise awareness and knowledge about *rational use of drugs*, both in the health system and among the general public. The steps taken to publish the Food and Drug bulletin, disseminate health messages through TV, radio and posters can be seen as necessary initial measures to establish an effective long term strategy. This is an area which requires considerable knowledge of local conditions and attitudes. Swedish support has assisted in this complex area. Given the limited resources available for IEC, priorities now need to be analysed thoroughly.

In a measure to control *drug advertisement and promotion* at an early stage in the NDP implementation, Lao Ministry of Health translated and widely disseminated WHO ethical criteria for medicinal

drug promotion. It appears to have been an effective move. Hardly any drug advertisement or promotion seems to be found, at least not in the GPP inspected pharmacies in the pilot provinces.

The 1993 National Drug Policy calls for *international technical co-operation* and specifically spells out areas where this can be done in the Asia- Pacific regions. Sida has provided major direct bilateral support and technical assistance to the NDP Programme through IHCAR. This has been complemented with WHO regular and extra budgetary resources for development of some NDP elements. The same applies to help from UNICEF, Japan, NGO's and others, such as the Asian Development Bank and World Bank Project for Primary Health Care. However, there have been little efforts to jointly plan and co-ordinate activities related to NDP.

Sida support under Phase II made it possible to do a mapping of an important number of Lao medicinal plants. Use of *traditional medicines* is a declared government policy, which is reflected in the National Drug Policy of 1993.

Drug monitoring and evaluation is the last of the 13 elements in the Lao 1993 National Drug Policy. It contains a mixture of technical and managerial activities. These need to be reviewed, reduced and put under a title that reflects the activity of monitoring and implementation of the NDP. In this area, the Sida support has greatly contributed to build up Lao capacity for health systems research, to assess progress and to identify problems in implementation.

Some areas included in some of the elements of the 1993 Lao NDP have received less attention. These are for example: control of drug pricing; adequate and efficient budgetary mechanisms; basic and continuous curricula development of health personnel; an overall view towards human resources development in the pharmaceutical sector; and a broader more integrated approach to both national and international technical and financial collaboration as already mentioned above.

Assessment of Findings: National Drug Policy and its implementation

The Lao NDP development process has been just as important as the actual adoption and implementation of the policy. This is also the experience from other countries that have developed a relevant and workable policy, that can serve as a guide for implementation.

At the start of the policy development in 1991–92, Laos had a fragmented and piecemeal approach towards improvement in the pharmaceutical sector. Sida and the Swedish external technical support has had a strong catalytic effect in changing this in a positive way. Data from quick surveys, a number of analytical reviews and seminars in Laos, and visits to other countries convinced policy makers and stakeholders, that the country needed a comprehensive approach. It needed a National Drug Policy that covered many technical and administrative elements important for development in Laos. The 1993 NDP thus resulted from thorough preparation, involvement of high level policy makers and wide national consultation and acceptance. When the Prime Minister approved the NDP in March 1993 (decree No. 49/PM 13.03.93), only a few months after the 1992 November National Drug Seminar, Lao got a policy suited to its needs. The policy has not been a theoretical document, but a guide for action to improve the overall drug situation in the country. Overall, total implementation of the 13 elements in the 1993 Lao NDP has been impressive.

It is well documented, that a comprehensive NDP takes up to ten years and more to implement in many least developed countries.

The Lao 1993 NDP has served the country well for almost seven years. Time has now come to review the NDP in the light of achievements made and future challenges. The mission fully supports the intention to undertake such a review[3] in 2000.

New international developments and knowledge have evolved in the 90's. Experiences from more than 60 countries implementing NDP's are now available in WHO. WHO updated guidelines for developing national drug policies should therefore be a useful reference in this work.

The mission draws attention to the need for the future Lao NDP review group, to cover and particularly address issues under new, or expanded policy elements, such as:

- Economic Strategies for Drugs, including financing and sustainability of regulatory and other activities
- Human Resources Development, including both university and continuous education in the whole pharmaceutical sector
- Operational Research
- Organisation, Management and Overall Co-ordination and Monitoring of the NDP and its implementation process
- Internal and External Technical Collaboration, including the use and application of WHO recent guidelines on national drug policies, effective drug regulation[4], quality assurance, rational drug use, and financing mechanisms.

The NDP Programme: findings and achievements under projects and components

Annex 10 includes all consultant reports grouped according to project and component subjects.

As already mentioned, *Annex 4* presents in a tabular format objectives and indicators of projects and components, as well as results or outputs achieved compared to planned results included in the April 97 project document and LFA matrix.

3.3 Project 1: Quality of Drugs

3.3.1 Component 1: Establishment of law and regulations

The first attempt to draw up a Lao drug law was made by a WHO short term consultant in 1995.

The October 1997 mission, the first of four missions by the same IHCAR technical consultant, resulted in three drafts regarding drugs and legislation. One was the actual drug law draft with the provisional title "National Drug Policy and Authority Act". Another was the "Draft law on the Profession of Pharmacy" and a third was a draft for a "Code of Ethics for the Pharmaceutical Profession in Lao PDR".

This drug law draft included creation of an autonomous "National Drug Authority", common in developed and a few developing countries, but quite unfamiliar in the Lao environment. It was not completely acceptable to the recently, 1994, established FDD, with its Food and Drug Commission, set up by the Council of Ministers in 1990. This concept of an autonomous body was therefore

[3] See Report of the WHO Expert Committee on National Drug Policies. Geneva, 19-23 June 1995. Contribution to updating the WHO guidelines for developing national drug policies WHO/DAP/95.9

[4] See WHO publication: Effective Drug Regulation: what can countries do? WHO/HTPP/MAC (11)/99.6, March 1999 and Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials Vol. 1, WHO, 1997 and Vol. 2.

abandoned. Many drafts later including translations from English to Lao and vice versa, extensive discussions within the Lao drug law committee and with the consultant, a new draft was available in July 1999. It was essentially the same as the draft which had been produced in January 1999 by the consultant on his then third mission.

The current draft drug law now includes the legal provisions regulating the profession of Pharmacy, as it was considered easier to aim at passing one law concerning drugs instead of two separate ones. This final drug law draft is called "Law on Pharmacy, Drugs and Medical Products". It is clear, short and manageable and now suitable to the Lao environment and circumstances. Details for enforcement and adherence of the law are rightly planned to go into regulations.

All divisions of the FDD, the Council of Medical Sciences, the MoH Cabinet and of course the Ministry of Justice have been involved in the development of the draft law. Provincial offices and others have made comments on the drafts.

The draft drug law is expected to be adopted by the National Assembly at its meeting in March 2000.

Assessment

Enactment of a law on drugs is a major achievement

Laos does not yet have in place an appropriate legal framework, the objective of this component (see *Annex 4*). In the three years since the work on the drug law started, this can hardly be expected. But the country is well on its way to have this legal framework.

The law itself will, however, not change the reality. Apart from already issued regulations, a number of new regulations are needed to be put in place for the law to be enforceable. The LFA indicator in the 1997 project document called for 5 new regulations. Three were actually issued; one on drug advertisement (1997), another on procurement (MPSC in 1998) and a third on Good Manufacturing Practices (GMP). Two others are in process of preparation; regulations on drug donations and drug prescribing. Two existing regulations, one on pharmacy from 1988, and another from 1994 on sanctions need revisions. Still two others, the ones on drug import-export and on manufacturing, need updating.

There is now a need to prepare an implementation strategy and priority plan for the next few years; to make the new drug law an effective instrument for safe, effective, good quality drugs, rationally used. Such a strategy should include**;** a written mission statement; an information campaign; an enforcement strategy to promote compliance with the law (persuasion, warning, penalty, license suspension, license revocation); a regulatory strategy (self regulation, enforced self regulation, command regulation with punishment); directions for co-operation and involvement of the public, public and professional interest groups and the health profession[5].

The mission agrees with the consultant views in his last, January 2000 draft mission reports in which he says: "One must express concern at the limited capacity available in FDD to carry out the large volume of work which will be needed for operations established or expanded under the new law. Careful attention needs to be given to developing sufficient income from fees to enlarge and develop staff".

The 1997 study on "Pharmaceutical regulation in context: the case of Lao People's Democratic Republic" (Stenson et al.), and the Savannakhet "real world" pharmacy studies, one published in

[5] WHO publication: Effective Drug Regulation: what can countries do? WHO/HTPP/MAC (11)/99.6, March 1999

1998 on the effect of government regulation on the quality of drugs and another in 1999 on the quality of private pharmacy practice, must guide the new and developing Lao drug regulatory control environment. The 1997 regulation study demonstrated that "what is required next is to expand the early step of structure-oriented regulation into more sophisticated practice-oriented regulation". The mission agrees with this and also with the conclusion that "this is a more complex undertaking closely related to the socioeconomic development of the country and requiring not only more resources, but also a deeper understanding of the issues involved, a more thorough scientific basis and strong political support". The Savannakhet studies did lead to a deeper understanding of problems on the effect of government regulations. They demonstrated that enhanced government interventions are needed in order to improve quality of drugs and quality of private pharmacy services, and that the Lao government needs to " focus on regulatory action of a limited number of aspects, to ensure that drugs can be traced before trying to establish a comprehensive system".

3.3.2 Component 2: Inspections

Without inspection and the capacity to enforce various degrees of sanctions, the regulations will be "toothless".

Inspection, and Good Pharmacy Practice (GPP) indicators (see below) were developed during Phase I. Extensive studies and testing in over a hundred pharmacies in three provinces preceded the GPP adoption. Swedish technical assistance has been crucial in this important work. It has included competence development, with training of trainers, the production of guidelines and the setting of criteria for selection of central, provincial and district inspectors. The target groups for GPP are the three categories of pharmacy owners. Most of these have minimal or no pharmaceutical education before they started their drug selling activities. A February 1996 seminar laid the ground work for the GPP programme development, training and inspections in the pilot provinces.

The ten Good Pharmacy Practice (GPP) Indicators from 1995

1	**Order in Pharmacy**: consists of sub indicators such as cleanliness, order, presence of drug advertisements etc.,
2	**Existence of banned drugs**: consists of verifying absence of these
3	**Existence of Essential Drug (ED)List + Generic names + Correct Labels**: now monitors presence of ten most common essential drugs and label content
4	**Quality of Drugs + Expire Date**: monitored with no.3 above
5	**Existence of Bill + Correct Bill**: monitors if drugs are being purchased through the correct sources, using proper documents.- tracing for illegal and counterfeit drugs
6	**Correct Dispensing**: shows if drug-and patient-information is given and is indicated on sold medicine
7	**Knowledge of Drugs for Diarrhoea and Malaria**: tries to measure what treatment is advised and what drugs are in reality sold
8	**Percentage of Antibiotics with a Prescription**: monitors the use of prescriptions for antibiotics
9	**Availability of Necessary Equipment**: monitors the presence of record books and materials
10	**Presence of Professional Staff**: monitors what kind of staff is present at the time of inspections

With four years of experience from inspections and training, the FDD has now started to revise the ten GPP indicators. This is proceeding with help from the same IHCAR consultants, who have given technical assistance all along. The revised "Lao GPP-2000 indicators", will be printed and launched this year. The titles have largely been kept, but the criteria have been sharpened and made more specific. For example indicator 3 will now monitor 20 instead of 10 essential drugs.

As the new law about drug registration is in the pipeline, this indicator will also include a part on this. The drug seller knowledge indicator, number 7, is another one, on which increased attention is focused.

The highest score for an indicator is 10. Between 1996 and 1999 scores differ among the five provinces. There are also variations over the years within each province. Mostly, but not always, towards a better score.

For four of the provinces, the average score for the total of ten indictors is between 6 and 7. For the fifth province it is less than six.

The most problematic GPP indicators are those, that concern the bills, the correct dispensing with information to the customer, and the prescription, i.e. indicators 5,6, and 8. The scores for these remain generally very low, between 1 and 3. This shows that regular inspection and reinforcement is needed, and that knowledge of drug sellers must increase. Also, that changes happen slowly and perhaps only more quickly after the new law has become effective and enforced. In another country in the Region, Nepal, drug sellers are since long trained for several weeks. The Ministry of Health, in co-operation with the drug seller association, is responsible for the training, the issuing of a certificate and monitoring of drug seller knowledge and practice, which has improved considerably since the training first started some fifteen years ago. Lao MoH may be interested to exchange views with Nepal on experience in training drug sellers.

The strategy under inspection has been to train trainers who in turn will train others at provincial and district levels. Since the start in 1994, 13 training workshops have been conducted. IHCAR consultants led and took part in 4, and FDD conducted 9 alone. Training consists of class room teaching with new and modern learning methodologies, and on the spot training through visits to pharmacies, wholesalers and drug manufacturers. Apart from GPP, training has therefore also included, but to a lesser extent since there are few premises, Good Wholesaling Practice (GWP) and Good Manufacturing Practices (GMP). Laos has today 32 licensed whole-sellers, 6 modern and 3 traditional manufacturers. Inspection of imported drugs at the custom is also undertaken. The GPP inspection should with time cover all 18 provincial and 111 district hospital pharmacies, and the over 2000 private pharmacies.

A total of 13 trainers (10 planned), five from the central FDD division and eight from the five pilot provinces, are now in place.

Twenty three inspectors from the Ministry of Health and the pilot provinces have been trained at least twice in GMP, GPP and GWP. Inspectors from other provinces were invited to participate in one workshop covering the three areas.

More than 100 inspectors from 55 districts in the pilot provinces were trained once in GPP.

In 1998 the FDD Inspectorate Division published the Manual for Drug Inspectors.

The Swedish support assisted with five Toyota Hilux double Cabs, 45 motorbikes and four computers. All vehicles and printed material from the NDP Programme carry the programme logo.

The mission visited five pharmacies in Vientiane and five in Luang Prabang. All produced the record books and other material that the NDP Programme disseminates for use during inspection, and as reference material for the pharmacy owners. The in depth studies undertaken in the Savannakhet province give of course a much more representative picture and evidence of the situation, than these isolated and anecdotal examples from the mission's short visit in Lao PDR.

The component objective (Annex 4) is not, and cannot yet be expected to be reached. However, the indicator of this component, which notes (Annex 4) that at least 50% of the pharmacies in the five pilot provinces should be inspected once a year, has been reached. However, in Savannakhet province, one of the richest in the country, all 214 pharmacies were inspected at least once, most of them 2–4 times over the period of the Savannakhet research project. Gaps, in the knowledge of pharmacy staff in relation to regulation were noticed as mentioned earlier. Availability of major documents was also low in the sample of 106 pharmacies studied. Moreover, the quality of dispensing practices was found to be considerably below standards (e.g. 59% no drug information to customers, 47% no drug labels and 26% different drugs mixed without possible identification). All this gave evidence for and led to improving training and inspection, and revision of the GPP indicators. The findings and conclusions from the SAREC supported Savannakhet research project thus made a very important contribution in measuring effectiveness of core activities.

Assessment
The GPP system, development and implementation of inspections in five pilot provinces is a major achievement. Methods and tools for inspection are in place. But improvement of efficiency and effectiveness of inspection is now to a large extent depending on the cycle of planning, follow-up of provincial and district findings, FDQCC analyses, research, implementation and monitoring of corrective measures. This area is generally weak and needs strengthening, both at central and at provincial levels. Knowledge of modern management methods is required. Computerised systems for monitoring and analysis of data are needed. Inspectors must have money to pay for drug samples from pharmacies, now a big problem. Substantial financial resources are also required to carry out nation wide inspections, with a reasonable frequency, plus investment in training of the inspectors.

In the Savannakhet province it is clearly demonstrated that within one and a half year, dramatic improvements occurred after interventions, as customer information improved, more essential material was available, knowledge about its content increased and mixing of drugs in pharmacy dispensing diminished. This is proof of effectiveness of the NDP Programme and a good example of synergy between SAREC, supporter of the Savannakhet research project, and the Health Division at Sida. Preliminary results from another research study "Towards an effective NDP in Lao PDR, case study in two provinces" (Project 5: component 2) reveal marked differences in for example dispensing, but also prescribing practices between a NDP pilot and a non-pilot provinces. Such information will serve as proof for the need to expand inspection and other activities countrywide.

In view of the above discussions, focused and intensified GPP training and regular pharmacy inspections, based on findings and recommendations from health systems research, must continue to be a central activity in the Lao NDP Programme.

3.3.3 Component 3: Food and Drug Quality Control Center (FDQCC)

The Food and Drug Quality Control Center (FDQCC), was inaugurated in 1995. It now plays one of the key roles in the quality assurance system. The FDQCC had a staff of 8 of 1993. Today there are 32 persons *(Annex 7, table Annex 7.1)*

The activity of the FDQCC covers testing of food, drugs, suspected narcotics and some related other work. The total number of analysed samples were 224 in 1995 and 1410 in 1999. This is a 629% staff increase (*Annex 6* FDQCC production statistics, *table Annex 6.2*).

Drug analyses make up the major part of FDQCC activities.

Drug samples in 1995 were 150 out f a total 224 samples. In 1999 the corresponding figures were 826 and 1410. This is a 551% increase over a four year period (*Annex 6, table Annex 6.2*).

Total number of substandard samples in 1999 were 319. The mission could not get the figure for the exact number of substandard drug samples.

The FDD registration of drugs reached its peak in 1996 and 1997 when a total of 1153 drugs were registered. *(Annex 6, table Annex 6.4)*. Many of these needed to be tested. In 1997 the FDQCC analysed about a third of these, classified as "pre-marketing analysis". Most of these drugs were in fact already on the market, but FDD had not registered them until then. With a decrease in registered products and an increase of inspections with samples from inspected pharmacies, there has now been a shift to "post-marketing" samples. In 1999 these were 746 or ninety percent out of a total of 826 drug samples *(Annex 6, table Annex 6.3)*.

Results from an International Proficiency Testing (the National QC laboratories in Sweden, Thailand and Laos), were analysed at a meeting in Chiang Mai in Thailand, in 1995.

With the help of Thai and Swedish experts training and refreshment training in drug analyses, training in the use of new equipment, and in administration and regulations has taken place. In the first phase of the programme, 3 persons trained for 2 months at the Department of Medical Science at the Ministry of Health in Bangkok. Swedish and Thai experts trained 19 persons during a total of two months, at the FDQCC under 1995–1996. Refreshment training on chemical and instrumental methods and analysis took place at the FDQCC in 1997, during a total of 7 weeks. Four senior staff had more specific laboratory technique training and two senior staff members spent 2 to 4 weeks in Bangkok to learn drug quality control administration and regulation.

In January 1998 an IHCAR/WHO/DAP consultant was asked to develop a financial and managerial plan for the FDQCC in order to ensure cost-effective and sustainable operation within the drug management system. The basis for such a plan was developed by the consultant who assessed the financial and managerial situation at the laboratory, examined registration fees at the FDD and presented options for a cost-recovery scheme towards sustainability of FDQCC. Strategies for post-marketing sampling, for methods of analyses, and for closer co-operation between the two institutions were also proposed by the consultant. Revision of FDD drug registration mechanism and fee system was a major recommendation for the Lao PDR government, which since 1998 has only marginally addressed these issues.

High performance liquid chromatography equipment (HPLC), UV spectrophotometer and other equipment planned have been installed. FDQCC cannot get spare parts locally, nor maintenance of the instruments. This is a great problem. The mission was told, that until now there had only been one critical incidence of a break down of an instrument. The problem could with some ingenuity be solved over the telephone. FDQCC must, however, assure maintenance of all equipment.

Chemicals have been procured under the Swedish support. Reference substances, which are expensive came through WHO support.

The Food and Drug control Center got one Toyota, 2 motor bikes and one computer under the Swedish support.

Assessment

FDQCC is a major achievement in the Lao NDP Programme. The Center plays one of the key roles in the quality assurance system.

The FDQCC capacity to undertake analyses of drug samples is now more constrained by inadequate funding, than by lack of know-how and equipment. To find ways and means to secure a level of funding that corresponds to the need for pre- and post-marketing testing of drugs is urgent.

FDQCC has gradually increased its collaboration with other institutions. In 1995 "customers" were only four: the FDD, hospitals, the private sector and certain government institutions receiving specialised drugs from abroad. In 1999 the number of collaborating institutions have increased to nine. The additional ones are: pharmaceutical factories, the narcotic center, the customs, some provinces, the ADB project, the Ministry of Interior and the municipality police. In spite of this, FDQCC is far from sustainable.

The 1998 IHCAR/WHO consultant analysed the situation at that time and proposed alternative solutions for cost recovery and sustainability. Since little has happened in this area since then, there is now an urgent need for the Lao government to examine the situation anew, particularly with regard to the overall government financing mechanism and the FDD retention of fees for licensing and registration. The Ministries of Health and Finance must now collaborate, seriously address and resolve this matter. A small team of senior officials from the two ministries should be assigned the responsibility to gather detailed financial and managerial data which will be needed in, and for the decision process. With help of external consultants the information should then be analysed, resulting in an operational plan and procedures for retention of fees in Ministry of Health. An updated and expanded mission to the one in 1998 is therefore urgently required. This is discussed further on in the report and an outline and basis for preparation of terms of references for the follow up and expansion of the 1998 study is included in Annex 11.

3.4 Project 2: Rational Use of Drugs (RUD)

3.4.1 Component 1: Development of Standard Treatment Guidelines

Components 1 and 3 are under responsibility of the Curative Department in the Ministry of Health. Since some time the components are handled together. It is more practical to do so, as activities under the two components are closely linked. However, for the purpose of evaluation, they are separated. That way it is easier to compare planned output in the LFA matrix in the project document, with actual output or results *(Annex 4)*.

Standard Treatment Guidelines (STG)

The Committee for the development of National Standard Treatment Guidelines (STG) was established in April 1995. The Minister of Health chaired this Committee and also issued a decree regarding its activities (MoH decree 1270/95). Committee members were representatives from the Curative Department in the Ministry, from FDD, the Department of Hygiene, from major hospitals of Vientiane and from faculties of Medicine and Pharmacology. Seven subcommittees with a total of 58 persons developed draft STGs which were widely distributed for comments. The STGs were produced after wide consultation and eight major meetings in which a total of 109 persons participated. Participants came from the major hospitals: the Mahosot, Friendship and Sethathirath military hospital, the police hospital and specilaized therapeutic centers for diseases such as, leprosy and tuberculosis.

Standard Treatment Guidelines now exist for the following seven diseases:

1. Malaria
2. Tuberculosis
3. Diarrhoea
4. Dengue fever
5. Leprosy

6. Parasitoses
7. Pneumonia

3000 copies of this first set of STGs were printed, distributed and introduced in late 1998.

The second set of standard treatment guidelines is now under preparation. This second volume will include guidelines for emergency, internal medicine, and obstetrics and gynecology.

Development of STG indicators
Indicators are used to measure the effect of STGs. During 1997–98 a Development Indicator Team (DIT) headed by the newly appointed head of the Curative department produced 11 STG indicators; again after wide consultations, and in very close collaboration with the external technical consultant. These, and a set of 10 Lao adjusted, commonly used WHO indicators to assess rational use of drugs (RUD), were tested in 9 meetings at Mahosot hospital. A total of 94 persons took part in these meetings.

The 11 STG indicators are intended to monitor diagnosis and subsequent quality of treatment for the diseases above. The indicators are11 because the clinical picture and treatments differ for four of the diseases: diarrhoea simple and severe; pneumonia simple and severe; dengue fever and dengue hemorrhagic fever; for tuberculosis and for follow up tuberculosis.

Rational Use of Drugs (RUD) indicators at the time of evaluation
The RUD indicators are:

1. Number of drugs per patient (prescription)
2. Percentage drugs from the Lao Essential Drug List (EDL)
3. Number of antibiotics (AB) per patient (prescription)
4. Correct dosage and treatment duration time of antibiotics (AB)
5. Number of injections per patient (prescription)
6. Percentage of justified injections
7. Percentage of patients treated with traditional medicines
8. Percentage of drugs that have generic names
9. Percentage of drug used in hospital
10. Percentage of clear drug prescriptions

250 copies each of the STG and the RUD indicators were printed and distributed at several workshops held at the provincial hospitals in five pilot provinces, and in the two central hospitals in Vientiane; the Mahosot and the Friendship hospitals. A total of 239 medical and pharmaceutical staff was introduced to the indicators.

The mission visited the two central hospitals mentioned and the provincial hospital in Luang Prabang. From records and data analysis presented, one could assess the positive impact that the guidelines and indicators have. Not only towards improvements in rational use of drugs, but equally important towards correct management of the most common diseases in Laos.

See further under component 3 for monitoring and supervision of rational use of drugs (RUD).

Assessment
Like in the NDP development, process and involvement of key national persons, such as leading physicians in the case of STGs, were very important. This has contributed to the acceptance and success of this first set of standard treatment guidelines for the seven diseases.

The considerations, strategies for development, and application of the STGs were also sound from the start. Considering the particular situation in Laos, it was wise to introduce STGs at the hospital levels, setting standards for all levels of care. In many developing countries STGs are usually introduced at the first level of care, that is the health center or the dispensary. Discrepancies between drug treatments at hospitals, particularly their outpatient departments, and the primary health care level are then often seen. The thoughts behind the Lao strategy and the IHCAR technical consultant recommendation can be illustrated with the following quote from a December 1995 IHCAR report. "It is important to consider the different levels of care: national, provincial, PHC (district and village) levels. PHC levels do not have as much resources as the "higher" levels. It is nevertheless important to have similar strategies. Even at "higher" levels the basic treatments – that may be used at the PHC levels – should first be considered when treating a not complicated case. The STG should be structured in such a way that the basic treatment may be used at all levels".

Component 1 objective has been met, and the component indicator has been surpassed. STGs are available for not only three to four, but for all seven most common diseases. The work on STGs and indicators, with IHCAR technical expertise and input, is impressive and a major achievement in the NDP Programme.

3.4.2 Component 2: Information Education and Communication (IEC)

When looking at the findings and output under this important component, one should keep its very broad objective in mind. That is that "health personnel and the public will be better informed about drug use". The indicator to measure this is " information material should be available". A whole string of various activities have produced such materials towards reaching the objective. The area is complex and different strategies have been proposed by different technical consultants. The NDP Programme is now doing health systems research to assess which kinds of communication seem to have been the most effective to transmit a number of health messages. Among the mass media, it was found that radio had been most effective. Also that people in Laos like when messages are presented in the form of dramas and plays. A drama on the rational use of antibiotic is a regular feature on television, but radio is still the most widely used mass media.

It was planned to have four issues per year of the Food and Drug Bulletin. The maximum so far has been two issues per year. This seems a much more realistic target, considering the time it takes to produce a publication of this kind, and current staff available. Number 10, the latest FDD bulletin issued in January 2000, includes a main feature article on the Lao National Drug Policy, written by the National NDP Programme Director. This article should be used as a tool for the inspectors explaining and promoting the NDP Programme implementation to health personnel.

The considerable achievements in IEC include in summary the following:

IEC to the public:

- One page handout for consumers consisting of 7 health messages
- Calender 1998 and 2000 (1000 and 2000copies)
- Radio and TV spots 1996–99 and 3 Newspaper articles

Drug information to the health personnel

- 1–2 issues per year of Food and Drug bulletin – a total of 6000 copies, over time increasingly more attractive in presentation
- A formal reader response questionnaire inserted with each Bulletin
- T-shirt with NDP logo (80 in 1999) given for good reader response to FDD bulletin

Training and training material for health personnel and drug sellers

- Visit to Philippines for 5 members of Curricula Revision Committee
- 25 trainees from pilot provinces trained for 2 weeks in June 1999 for simplest way of communication on drug use – for inspectors and health personnel
- Two days workshops at provincial and district levels for health staff, monks, village leaders, teachers, Lao Women Union staff, journalists, TV and radio
- Six person trained at International Network Rational Use of Drugs (INRUD) courses in Nepal and Thailand in 1998 and 1999
- First edition of Guidelines: Drug Seller Manual for training of trainers, 1999, 3000 copies

Two computers and other equipment were also provided.

Assessment
IEC are essential means to promote rational use of drugs. It is, however, difficult to identify and assess effects of IEC measures. In a resource constrained environment, it is therefore vital to identify only a few measures that are considered to be effective. Results from the health systems research should help to identify the most effective means and methods in this area. More human resources are needed in FDD in the future to develop and assess the work.

In the next phase of the programme , some of the activities now under IEC, such as curricula development for doctors and pharmacists, should be part of the overall human resources development element proposed for the revised Lao NDP. The curriculum work should then be assigned to the university to develop in collaboration with the NDP Steering and Management committees.

3.4.3 Component 3: Monitoring and Supervision in RUD

In practice, as mentioned above, this component and component 3.4.1 go together.

Planning and development to establish Drug Therapeutic Committees (DTC) in major hospitals started in March 1997, along with the testing of the STG and the RUD indicators. A DTC team was formed with staff from the Curative department and the FDD. The purpose of Lao DTCs is to monitor and supervise Standard Treatment Guidelines and rational use of drugs, through use of the indicators. The DTC team produced tasks and functions of a drug therapeutic committee and set criteria for its members.

An important boost to the development of DTCs and indicator use occurred at a visit in January 1998 to Uong Bi hospital in Vietnam. Nine senior medical and pharmaceutical hospital and ministry officials, headed by the Minister, were much impressed and influenced by what they saw in Uong Bi and wanted to do the same in Laos. It was decided to make Mahosot hospital in Vientiane a model hospital for DTC development.

Organised DTCs have now spread beyond the five pilot provinces. Thirteen provincial and two central hospitals now have DTCs; a "contamination" to use the Laotian term, in this context in a positive sense.

Each DTC has about 10 members. With 15 DTCs in the country, a critical mass of 150 exists, that will further the development and application of the STG and RUD indicators.

Assessment
Data on indicator assessments are now available from a number of hospitals. The mission saw several STG indicator charts, that include individual and total scores for clinical assessment and treatments for the seven diseases. The same methods of scoring also exist for the RUD indicators.

DTC work and analysis is a learning process, which needs to be continuously developed and reinforced over a long period of time, also in developed countries. Feedback to doctors is essential. The interest in Laos for DTC is now very strong and is gaining momentum country wide. STD and RUD indicators point to problems, but do not solve them. What to do to solve the problems, and who will do what in a DTC committee, are areas in which Lao DTCs will need considerable continued technical assistance. One of the HSR projects (Effectiveness of feedback for improving quality of treatment based on STGs) is addressing most of the aspects mentioned and the questions raised by the mission and are expected to be answered through this research project.

Methods and tools (STG, STG and RUD indicators, DTC,) for rational use of drugs in hospitals are being introduced and implemented in the key central and in the provincial hospitals. This should be seen as another major achievement of the NDP Programme.

One challenge for the future is to develop STG for other diseases and to spread the use, eventually to all hospitals. An even more challenging task is to improve the application of STG and RUD by monitoring through indicators, to continuously improve clinical management and drug treatment in the whole Lao health system.

3.5 Project 3: Traditional Medicines

The Lao National Drug Policy includes the element of traditional medicines. In accordance with Lao government policy and the NDP, the objective of this project was therefore increased knowledge of traditional medicines and their rational use.

Under the project, surveys in four provinces of 648 plant species, 105 herbarium and 50 recipes were completed. Maps from the four surveys of medicinal plants now exist and were printed in 50 copies, in 1999. Survey reports (2 in 1998, 1in 1997 and 1 in 1997) are now available. The publishing of books (600 copies) on traditional prescriptions (recipes) is now planned

A study on traditional medicine in treatment of malaria was conducted in 1996. Planned studies or clinical trials on anti-hyperglycaemic and anti-inflammatory remedies were however not carried out. A pilot study on remedy for skin disease is under consideration in three major hospitals

Six persons went on study tour to Uong Bi Hospital in Vietnam in 1997

The first book "Pharmacognosia" of medicinal plants of Laos became available in 1998: Six hundred copies in two volumes were printed and disseminated for use by students and others to promote traditional medicines use

Assessment
The project has been successful in achieving most of the planned outputs. The on-going health research study on use of traditional medicine in Champasack province will be the final output of the project. The Mission appreciates the high priority the Government puts on TM. It is, however, doubtful wheter Swedish support in this field has a comparative advantage. Regional co-operation and linkages to institutions specialising in traditional medicines, such as the ones in Vietnam, Korea and the University of Chicago are likely to be more fruitful for the development of traditional medicines in Lao PDR.

3.6 Project 4: Managing Drug Supply

Sida has provided technical support for the Lao drug supply system since the early nineties. Consultant studies on overall drug supply organisation, in 1996 and 1997, proposed to have a separate Drug Supply Unit. This led to creation of the Medical Product Supply Centre (MPSC). A Ministry of Health decree to this effect was issued in 1998 MoH decree No. 3174 of 14.12.98). The old logistics department in the FDD was thus disestablished.

The objective in creation MPSC is to improve the drug supply system in the public sector. *Annex 8* gives information on the organisation and staff of MPSC.

Public sector expenditures for drugs account for less than 10% of total drug expenditures in Laos. The government drug budget is very limited. The central and provincial hospital that the mission visited provided figures that show that this budget covers about 20% of the needs in these hospitals. To cover remaining needs the institutions practise cost recovery systems, through the revolving drug funds which seem to be working well. The mission was informed that the government money is just about enough to provide the drugs for those who are not able to pay for their medicines. With such limited resources, co-ordination and planning of drug procurement and distribution based on a modern information system become vital ingredients for managing drug supply.

An experienced long term adviser in managing drug supply just ended his assignment. He started in 1998 and worked for about one year in MPSC under the Sida/IHCAR support to the NDP Programme. After that, he was funded by WHO for a few months until January 2000, when he finished his assignment. The MPSC operation is now on its way towards an improved drug supply management system after workshop training and institutional capacity strengthening, at central and provincial levels

Plan of operations have been prepared and are included in the "Procedure Manual for the Procurement and Distribution of Essential drugs and Basic Medical supplies", produced by the long term adviser.

Planned study tours were partly replaced by recruitment of the long term adviser:

Instead of studies planned abroad, five staff members of FDD and the former Logistics Division trained locally in commercial English and business management, marketing and international procurement systems.

A Procurement Committee, chaired by the Director of Cabinet of MoH, was further established.

The planned system for assessing the continuous availability of essential drugs is not yet in place. The new manual and the long term adviser's study on "the Availability and distribution of basic drugs and medical supplies in the Lao PDR:" lay the foundation for such a system.

Three computers and a photocopy machine were purchased with Swedish support.

Assessment
The contribution of earlier and now the long tern technical adviser has been essential in the planning and reorganisation for the future drug management supply system in the public sector in Laos. The Procedure Manual for the Procurement and Distribution of Essential Drugs and Basic Medical Supplies will guide the MPSC staff, who will need continued training. The Swedish support to start up the MPSC and its activities has been an important and timely technical input to the NDP Programme.

It is now a matter of making the new system fully operational, which may take some time. Periodical technical expertise will be needed. The mission recommends that such support, when needed in the future, could be provided under the ADB/WB collaboration and from WHO.

3.7 Project 5: Strengthening the Institutional Framework for the National Drug Policy

(the current title; – the original project title is "Strengthening the National Drug Policy")

3.7.1 Component 1: Strengthening the NDP in general

The objective of the project and the component under its original title was to improve the capacity and the knowledge of FDD to implement and monitor all the components of NDP. This objective has been met with regards to capacity building and knowledge of English among a core group of person involved in NDP Programme in the Ministry of Health and in the five pilot provinces.

More than 40 persons, from central and provincial levels were trained in English locally. The mission was told that until about 1997, interpretation was required during most activities and at meetings. Apart from functions at districts and some provincial levels, English is reported to be used widely in the NDP Programme activities. A core group, including the project director, the project manager and the project responsible persons, is also well versed in writing English, producing reports and other documents in the language. The ability to read, write and communicate in English has greatly helped in breaking the professional isolation that earlier prevailed in Lao PDR.

The NDP Programme staff had prepared well for this mission. In English, the group presented orally and in writing, technical and other data and achievements at joint sessions during the first week of the mission.

Training under this component has also included sending a FDD staff member for a course in epidemiology and field research methods in Umeå, Sweden in 1997. The Umeå training, and the former Programme manager's current Master Degree training in Sweden, are examples and follow ups of the capacity building and institutional strengthening created through the research projects. The master thesis will use data on the quality of drugs from the Savannakhet private pharmacies study.

Because of reorganisation within the MoH as well as the IEC Division, it was decided that a planned study tour on the control of drug promotion, in the region and in five Thai provinces, should not take place. This activity was replaced with a matter of higher priority and urgency to the Ministry, that to develop a Lao National Health Policy. It was felt that much could be learnt from the experience of the NDP development, adoption and implementation. It was therefore agreed to carry out a Health Technology Assessment study and a study visit to start addressing an important health policy component. In this context IHCAR hosted a visit in Stockholm, in June 1999, by the Minister of Health accompanied by the Heads of the MoH Human Resources department and the Cabinet.

Assessment

A great achievement is the fact that more than 40 persons, from central and provincial levels now are able to communicate in English. This has been a success under this project, and of course in the NDP Programme. Increased knowledge of English has greatly contributed to easier communication with consultants, and the ability of staff to participate in many international meetings and study tours carried out under the Programme. This has led to gaining of experience and knowledge in

technical, managerial and policy matters. The view of the mission is that this area merits continued support.

3.7.2 Component 2: Health Systems Research for implementing NDP

The objective of this component is to strengthen the national capacity and the knowledge through health systems research (HSR), for implementing all components of NDP. Discussions on the need for HSR were first held in November 1997 between the FDD, Sida and IHCAR consultants. In June 1998, the FDD, the Council of Medical Sciences (CMS) and IHCAR clarified the needs more distinctly in relation to certain programme objectives. Based on the rationales and justification given after the first HSR course in Laos in the fall of 1998, it became clear and was agreed that some resources needed to be re-allocated within the NDP Programme, in favour of health system research activities and workshops, in 1999 and 2000. It was decided to re-allocate, within project no.5, over half a million Swedish crowns to the HSR; from cancelled or redirected activities (NDP management course), from savings in local costs and from activities which had been taken care of by others such as WHO paying for training in drug registration in the region.

To increase capacity for HSR, and to be able to monitor the NDP implementation and its effect, IHCAR held a two week introductory course in October 1998 and a follow up course in April 1999. In the first course the twenty four participants, from different institutions involved in NDP implementation, developed five research projects. These have relevance in that results from this research will measure impacts of NDP implementation including problems; in a few of the major NDP areas. These are quality assurance, rational use of drugs, traditional medicines and overall NDP monitoring.

The five research project teams also attended a course for data analysis of findings and are now in the process of finalising the results from the studies. These have already given important feed back for needed changes to be made in for example inspection and IEC work.

The five HSR research studies concern::

1. Effectiveness of "Feedback" for improving quality of treatment based on STG
2. Can health messages reduce irrational use of antibiotics?
3. Use of Traditional Medicine in Champasack province
4. Attitudes and beliefs about quality of drugs in Lao PDR
5. Towards an effective NDP in Lao PDR

Assessment

This is an important, innovative and recently introduced component with a systematised approach to health systems research in the pharmaceutical sector in Laos. Its purpose to obtain data towards an evident based National Drug Policy is highly relevant. The data from the five research projects conducted in 1999 are now being analysed. The results from these, and from the extensive and highly relevant Savannakhet research project, will serve as basis for this year's review of the 1993 National Drug Policy, and for introducing changes in the various projects under the whole NDP Programme. The Health Systems Research and its capacity building should continue. The methods, the experience gained and the application could be shared with others in a meeting or workshop with neighbouring countries, in the Region and elsewhere.

3.8 Project management including project 0

The overall responsibility for the management of the project has naturally rested with the Ministry of Health. The specific agreement of 21May 1993 between Lao PDR and Sweden for Phase I (1992/93–1994/95), and the one of 30 May 1996 for Phase II, specify obligations of the parties concerning reporting, other implementation co-operation procedures, and disbursement of funds. The provisions in the agreement follow the normal Sida standard. The second agreement differs from the first, as it includes new provisions for reporting according to Sida's Logical Framework Approach guidelines. The reporting period was also changed to align with the financial year of Lao PDR which is from October to September.

The MoH set up no formal project organisation during the first phase.

The project document for Phase II, approved by Sida in May 1997, does not include a description of the project management arrangements. A formal project organisation was, however, established. There was a project manager responsible for the day-to-day operations of the project, reporting to a project director, who also holds the position of deputy director of FDD. A FDD staff member was assigned to assist with project administration and accounting. Nine sub-project co-ordinators were appointed to lead the activities within the various projects/components. NDP co-ordinators were appointed in collaborating provinces and districts.

In order to strengthen the overall NDP Programme management within the MoH, a Steering Committee was established in1999. The committee consists of the vice-ministers and directors, and is chaired by the Minister.

A Management Committee of five persons was also formed for the NDP Programme implementation. The Management Committee is chaired by the National Programme Director. It further includes a representative from the Cabinet and the Curative department, apart from the Programme Manager, who is FDD Drug Control Chief. The fifth member is the assistant accountant from FDD, who acts as secretary.

The terms of reference of the consultant, IHCAR, for Phase II are set out in an appendix to the contract. The co-ordinating tasks of the consultant are described as "minimum required", and refer mainly to management of the Consultant's own activities in the whole Project. However, IHCAR is also to "assist the MoH in its development of work plans and reports to Sida". As discussed in chapter 1, a separate budget line, corresponding to Project 0, was created to facilitate IHCAR's support to project co-ordination

As explained in chapter 1, the second phase of the project started effectively in mid 1997 when the project document had been approved. The level of implementation of activities since then has been high. This fact points at a good capacity to actually get things done. However, project management has been a recurring issue in the annual review meetings between the MoH and Sida. Already in 1993, during the annual review, it was agreed that "IHCAR shall propose a format for a comprehensive budget". In the same meeting it was noted that "the format of plans and reports should be compiled in such a way that easy analytical and descriptive results of the project operations can be extracted". The parties agreed that "a standard format will be adopted". These statements do not seem to have led to any systematic action. IHCAR's 26 October 1995 final report from Phase I raised concern over budget reporting responsibility. The agreed minutes from April 1997, December 1997, April 1998 and December 1999 also express need for improved reporting.

Assessment

The Mission has found that the quality of progress reports has somewhat improved over the project period. However, the reports are excessively detailed and at the same time lacking in overview. The financial reporting does not give a comprehensive picture of the expenditures under each specific component under a project. Therefore, it is difficult to follow intended or unintended reallocations between projects and components over the project period. It is furthermore difficult to follow up the expenditure, in relation to the budget agreed upon in the project document. The progress reports only focus on the previous year, and the financial statements relate only to the previous year's budget. The overview of accumulated results and expenditure from the start of the project is therefore not seen.

The operational and budgetary implications of the extension of the project until the end of 2000, and the reallocation of funds from MoH to the consultant are difficult, or almost impossible, to find out from the submitted reports by MoH, IHCAR or from Agreed Minutes at the yearly reviews.

There may be several explanations to the continuous concern over progress- and financial reporting.

First, the project operates under complex conditions. Comprehensive financial reporting has to be based on three different accounts. The NDP Programme keeps account of advance disbursements by Sida to the Programme bank account. Sida keeps account of disbursements to the Programme through MoH, the consultant and direct procurement made by Sida. IHCAR keeps account of its expenditure. In order to report comprehensively, the Programme management needs to obtain information from both Sida and the Consultant. The whole NDP project also operates with three different currencies and two different financial years.

Second, the LFA planning system introduced in Phase II requires substantial induction to be understood, and training to be practised. There seem to have been minimal measures taken to facilitate learning of the new system. Furthermore, the NDP Programme and the Consultant have been required to submit separate reports, although the Consultant has assisted the NDP Programme in preparing the annual report and annual work plan.

The Mission has also noted that NDP project documents specify a detailed activity budget for each of the three years of implementation. Experience of development projects of this nature shows, that such detailed programming can be counterproductive in the sense that the overall objective is lost in favour of focusing on details.

Third, the size and complexity of the project, as outlined in the project document would have required an in-depth analysis of the implications for the management of the project. The experience from the first phase would probably, if analysed, have led to the conclusion, that initial measures should have been taken to raise competence of the staff and establish financial- and progress reporting formats and procedures. This was not done from the outset. A possible explanation may be that the MoH, Sida and the Consultant were not sufficiently aware of the requirements.

The awareness of the need to improve the project management seems to have grown during the implementation of the project. The management audit carried out in 1998 resulted in some improvement of financial reporting and streamlining of financial procedures within MoH. The financial procedures within MoH are, however, still centralised. The National Programme Director, and the programme manager do not have the powers to dispose of the funds within the approved budget. A motive for setting up a project organisation to handle development work is to create room for flexibility in project implementation. This requires delegation of financial responsibility to a project director, from the line organisation. Furthermore, the budget of a project has to be speci-

fied at such a level of detail, that a project leader can make reallocations without approval of higher levels in the organisation.

As implementation has gained momentum, the number of institutions outside FDD and the number of people involved in project activities has grown. The Programme Management has been successful in establishing working relationships with stakeholders in the Programme. This fact, plus the fact that the pace of implementation has increased should be kept in mind, when the capacity and quality of reporting is assessed.

The volume of technical assistance in the project has grown considerably during implementation of Phase II. In the original contract signed between IHCAR and Sida in November 1996, the total amount agreed was Msek 2. The amount set aside for technical assistance in the project document approved in May 1997 increased to Msek 2,7 million. The extension of the specific agreement until year 2000 led to an addendum (see sections 1.4 and 3.7.2) to the original contract between IHCAR and Sida, in May 1999. In this addendum the ceiling amount was set at Msek 3,75 million to cover the period from October 1998 to September 2000. IHCAR has reported expenditures up to September 1998 of Msek 2,1 million. A total of Msek 5,85 million has, thus, been allocated for technical assistance, as mentioned earlier in the report.

The results reported above indicate, that the technical assistance to the various sub projects has been effective. It is, however, obvious that the need for technical assistance to implement the programme was grossly underestimated, when the project was planned. The view of the mission is that the ambitious project document should have alerted the actors to question the amount allocated to technical assistance. As indicated in chapter 1, the comparatively (external versus local costs) high cost of technical assistance may explain the reluctance of MoH to request more technical assistance, than was done originally.

It is, however, more difficult to understand that Sida, at the outset of the project, accepted the low level of technical assistance planned for. Capacity-and institution building programmes typically have a large knowledge content. Some of this knowledge can be transferred through study tours and training courses, but some of the knowledge has to be developed on the spot as it has to be adapted to prevailing circumstances. The methods to develop this type of knowledge are typically provided by external consultants in all organisations, not only in development co-operation projects. To facilitate knowledge development and learning, substantial external inputs are required. In a situation where the recipient is unaware of those needs it would be up to the donor agency to insist on the need for considerable technical assistance. This might have been tried by Sida before the agreements for Phase II were signed, but without success. However, when the need for increased technical assistance became obvious to all, Sida responded effectively and with flexibility.

Another question that might be asked is whether the technical assistance provided has grown out of proportion to the objectives set out in the project document? The answer of the mission is no. The observation above, that the technical assistance provided has largely been effective supports this assessment. Capacity building programmes, without big investment components in buildings and equipment, typically have technical assistance component which is around two thirds of total costs.

3.9 Institutional capacity

In general terms, institutional capacity can be defined as the ability of an organisation to implement its mission. The mission of public service organisations e.g. ministries, ministerial departments or agencies is defined by the regulatory framework of the organisation. The ability or the institutional capacity is determined by factors such as organisational structures, production methods and operating procedures, physical, human and financial resources. All these are necessary prerequisites for the organisation to produce the desired outputs and outcomes.

When MoH and Sida started to discuss co-operation in the area of drug policy in 1991, only a few regulations had been adopted, defining certain desirable outputs such as licensing of pharmacies and import/export of drugs. The institutional capacity to implement the few regulations that existed was very weak. When the National Drug Policy was adopted in early 1993, a new basis for developing the institutional capacity was created.

The Pharmaceutical department, set up in 1988, was reorganised to become the Food and Drug Department in 1994. The quality control laboratory, built and equipped with Sida support, was inaugurated in 1995. Food and drug units were established in the provincial health departments and staff at district level was assigned to work with drug control and supply. Through these changes a structural basis was created for developing the institutional capacity to implement the NDP. The structure for drug management developed further through the establishment, in 1998, of the Medical Products Supply Centre. This centre is responsible for co-ordination and central procurement of i.a. drugs for the public health care system.

Structure and staffing
The structure and staffing of the three key organisations of the drug management system is shown in *Annexes 5, 7, and 8.*

The number of staff of the Food and Drug Department (FDD) *(Annex 5)* has grown slightly since 1994/95, from 35 to 40, mainly due to increase of administrative staff. Three divisions are responsible for implementation of the NDP. The drug control division is responsible for registration of drugs and licensing of manufacturers, importers and pharmacies. The inspection division is responsible for inspection of factories, imports and pharmacies, and the IEC division is responsible for drug information to the health care system and the general public. The department considers the staffing to be adequate in terms of numbers, except for the division for information, education and communication, which should have six staff members instead of the current two.

The staffs of the divisions have all participated in programme activities and in training provided under the project. The staffs are competent to operate the working methods and tools for registration, licensing and inspection introduced during last years. The competence is still regarded as inadequate, especially for capability to develop methods and tools for the work. The competence is also inadequate to utilise the information that the systems for registration, licensing and inspection are capable to provide for management and development purposes.

The Food and Drug Quality Control Centre *(Annex 7)* has increased its staff from 16 in 1994/95, to 32 at present. This is due to an increase in staff for drug analysis, establishment of a special food section and expansion of the narcotics and microbiological divisions. The FDQCC has equipment and staff capable of undertaking physico-chemical analyses. The capacity to carry out microbiological tests is not yet adequate.

The NDP programme has played a decisive role in establishing the capacity for drug testing. During Phase I, the laboratory building was built and equipped. Staff was trained in Thailand and on-the-job. Training has continued during Phase II, both in Thailand and in Sweden on new equipment and on-the-job.

The Medical Products Supply Centre *(Annex 8)* was created in 1998 out of the logistics division of FDD. The creation was a result of the technical assistance given under project 4 of the NDP Programme. The Centre has 33 staff members of whom 5 are responsible for procurement. ADB/ WB supports the MPSC in procurement of drugs. The MPSC has recently moved into a new building, built with Japanese support. Japan is supporting the Centre´s repair shop for medical equipment.

The NDP Programme technical assistance has resulted in an appropriate organisation, and in establishing the system for procurement and distribution of drugs, which is documented in a manual. A foundation has been laid, from which the system can be further improved and developed.

Outputs, operating procedures and standards
Institutional capacity is reflected in the ability of an organisation to produce the expected output according to set standards. Clear improvements have taken place in this respect since the start of Phase I and particularly during Phase II.

The computerised system based on MS Access software for licensing of manufacturers, importers and pharmacies is in full operation since 1999. Statistics can be produced and information of individual licensees is easily retrievable. A computerised system also based on MS Access software for drug registration is in operation since 1998.

Operating procedures and standards for inspection of manufacturers (GMP), importers (GWP) and pharmacies (GPP) have been adopted. Inspection of pharmacies is supposed to be done 4 times a year. All inspectors in the 5 pilot provinces, 15 at provincial level and 110 at district level, have been trained in the application of GPP. From reports by the pilot provinces, it is clear that the frequency of inspection is far below the set target. The Mission was unable to get statistics of the number of inspections carried out by type and by province. Planning and implementation of annual inspection of pharmacies is an area where improvements are required. Through inspection, drug samples are collected for post-marketing analysis by the FDQCC. The planning of inspection and the strategy for drug sampling is therefore of greatest importance for the planning of work at the laboratory.

FDQCC has increased the number of tests made every year since 1995 when 224 samples were analysed, to 1410 samples in 1999. This development indicates a growing production capacity. Of the samples tested in 1999, 826 were drug samples. According to an expert (Bremer) one analyst should be able to analyse about 100 samples per annum. If this assessment is correct the utilisation of staff of the drug section of the laboratory is good. The composition of drug samples has changed during Phase II. As mentioned earlier in the report, pre-marketing samples constituted the vast majority of samples tested in 1996 and 1997. The post-marketing samples have now taken over. They constituted 90% of samples tested in 1999. This reflects the fact, that the number of newly registered drugs has decreased. It also shows that inspections result in drug sampling for testing.

Financing
The state budget provides funds for current operations of the administrative departments, human resource development, funds for drugs and other medical supplies and for investment in buildings. The operative budget is divided into salaries and administrative expenditure (electricity, stationary, service travel etc.)

The management of the budget is centralised to the finance department of the MoH. The departmental directors have no budget for which they are responsible. The MoH recurrent budget can only meet costs of the most basic needs, such as salaries and minimal administrative expenditure. All development activities of administrative systems, staff, equipment etc. are funded by donors. The government has limited possibilities to provide funds to meet the recurrent funding implications of development activities.

MoH charges fees for licenses and registration of drugs. The revenue generated is, according to government financial regulations, transferred to the state treasury. Recently the MoH has been allowed to keep a small portion of the revenue collected. The fees have, however, not been adjusted to inflation and are to day very minimal. MoH is considering proposing higher fees to the Government. In 1998, the NDP Programme study on financing requirements of FDQCC (Bremer) provided options for changing the system. So far, MoH has as a whole not acted on the recommendations as discussed under section 3.3.3 and in Annex 11.

Implementation of the NDP and the maintenance of achievements made will require a higher level of recurrent funding than the state budget provides at present. Additional funding will be required for:

- maintenance and improvement of operating procedures and standards (MoH)
- extension of inspection to new provinces and maintaining a reasonable number of inspections (provinces, districts)
- maintenance and renewal of equipment i.e. vehicles, computers, lab (MoH, provinces)
- consumables for especially FDQCC
- upgrading of computer software (MoH, provinces)
- continuous training and up-grading of staff
- continuos IEC activities directed towards health system staff, private pharmacies and general public

Furthermore, the extension of the implementation of NDP to all provinces will require investments in equipment and training of at least the same level, that has been provided to the pilot provinces.

For the foreseeable future, the government will not be able to fund these requirements from the state budget. Funding of the core system of quality assurance – registration, inspection and laboratory testing – poses the greatest threat to the sustainability of achievements made. Without a solution to the funding of quality assurance, the nation wide application will also be jeopardised.

Assessment of findings
Institutional development

In assessing the impact of the project on the institutional capacity for national drug policy implementation, the approach and concepts of the Staircase model for diagnosis of organisations in development co-operation has been applied*.

According to this model, an organisation can be viewed as a production system that receives inputs from the environment and transforms these inputs to outputs, with the aim to create benefits to the

* Göran Andersson and Peter Winai: Diagnosis of Organisations in Development Co-operation. Guidelines for application of the Staircase Model. Report to Sida, 1997.

customers or clients of the organisation. The purpose of a development project may be to assist the organisation to develop its capacity to create benefits to the client/customer system.

With such a purpose, interventions by a development co-operation project may be directed at defining appropriate outputs, improving quality of inputs and improving methods and ability to transform the inputs into the desired outputs for the customers or clients. The model distinguishes stages of development of an organisation.

At stage one, an organisation has been established, but output may not be clearly defined and/or output is unpredictable and of low quality.

At stage two, the organisation is able to deliver expected output with reasonable reliability and quality

At stage three, the organisation meets the performance standard for producing outputs. It is also capable to initiate and carry out changes on its own, regarding outputs, production methods and management systems.

At stage four, the organisation works actively with its client to increase the value of its outputs, products and services, in the client/customer system.

In assessing the stage that an organisation has reached, observations are made in two dimensions. One dimension covers the output. Is anything at all produced and if so, in which quantities and with what quality? Has the output been produced with reasonable input of resources? Is the output relevant and beneficial to the clients/customers? The second dimension covers what is accomplished within the organisation in terms of changes of produced outputs, production methods, administration and management. Changes in these respects reflect the development ability and capacity of the organisation.

The findings, accounted for above, indicate that the NDP Programme has been instrumental in building institutional capacity.

At the start of Phase I, the MoH did not have the organisational set up required to implement a drug policy. The policy, when adopted, defined the types of outputs that the organisational set up was supposed to produce. At that time, however, the existing organisation was not capable of producing the outputs. The methods and tools to implement the policy were not developed. The competence to identify and develop the required methods and tools was not sufficient within MoH. At this time, the drug administration operated on stage one of the model, in the areas where it operated.

Gradually the organisational set up was developed with concrete manifestation. The laboratory, the FDD as well as the provincial and district drug administration were created. Training created competence to carry out laboratory tests. The capacity of the laboratory to produce expected outputs has now reached stage two of the model. Methods and tools for the other parts of the drug administration has been developed and put in regular operation regarding licensing, drug registration and inspection. Regularity of inspection work has not yet reached an acceptable level and quality is not yet assessed. The quality assurance organisation is approaching stage 2 of the model with inspection lagging behind.

The organisational set up to promote rational use of drugs was practically non-existing during phase one of the project. Now there is a regular production of information through the Food and Drug Bulletin, radio spots and other means. The system of Standard Treatment Guidelines and Drug Therapeutic Committees and monitoring drug use through indicators is established and is

gradually becoming functional and spread to hospitals. The system for drug supply to public health institutions has changed through the establishment of drug revolving funds. A new central organisation, MPSC, has also been established and is becoming fully operational. The organisation for promotion of rational use of drugs can also be assessed to approach stage two of the model.

It should be noted that the analysis above refers to the drug administration at central level, and to the pilot provinces that have been involved in the programme.

The conclusion that can be drawn is, that the drug administration has reached a stage where it is capable of using methods and tools developed by the project and to produce the expected outputs with some predictability and reliability. The organisation is approaching stage two of the model, but has not yet firmly established itself at this level.

The competence to manage the whole system, identify needs for development, find new solutions and implement change is, however, weak. Improved managerial and professional competence is required for the drug administration to reach stage three of the model.

4. Overall assessment

4.1 The National Drug Policy

In the overall assessment of the National Drug Policy the questions raised in the beginning of the report need to be answered. For the first NDP question "Was the national drug policy relevant to the situation in Laos when it was adopted in 1993?", the answer is "yes". From the discussions in chapter 3, section 3.2, one can reiterate here and conclude, that Lao PDR got a National Drug Policy, which was appropriate for its needs, at the time when it was adopted. The 1993 NDP had "Lao ownership" and was not a document copied from other countries, although inspirations to develop the NDP had come from several sources and visits to other countries. Apart from some unrealistic goals included in a few of the elements, the NDP has been a useful guide for action, the purpose of a national drug policy.

To what extent has the policy been implemented? In what way and to what extent has the NDP Programme contributed to this? The detailed answers to these questions are also discussed in the assessment under 3.2 and in the following sections in chapter 3. In answer to the first question, the mission estimates that overall implementation of the 13 NDP elements taken together could be considered to be around 70%, based on information provided to the mission. The answer to the second question is, that the NDP Programme has contributed very largely to this. Without the contribution of the Programme and the continuous technical and financial support from Sida , it is very unlikely that the achievements seen today would have been possible. The political commitments on the part of the government and the stakeholders are of course vital ingredients for the achievements seen.

Is the policy still relevant? As mentioned earlier, with new developments having taken place since 1993 in overall national drug policy issues, the Lao NDP should, as already planned, be reviewed at a national seminar in 2000. Important new elements such as overall human resources development in the whole pharmaceutical sector, new economic strategies and management issues have to be added. The mission agrees with the Programme's already identified priorities among the 13 existing elements. Highest priority should rightly be given to support future activities under the current NDP elements of, drug legislation and regulation; financial resources; quality assurance; and rational use of drugs. All, including an enhanced human resources component, require continued support.

4.2 The Sida Supported Programme

The question referring to this section is "Were the project components relevant, adequate and sufficient to achieve the project objectives". Before answering this question one should follow up on he above discussions in 4.1 and ask "Were the five project areas the relevant ones?". The answer to that is "yes" in the technical areas, but "no" for not including from the start an overall management and co-ordination project in such a complex programme.

Some of the project objectives set will take a long time to achieve, for example in the case of the project quality of drugs (see Annex 4)and the one under the rational use of drugs which needs to be reviewed. However, the components selected towards reaching long-term objectives in all projects were, and still are relevant, and sound and should be continued, as they worked. Some components

such as inspection and IEC will need strengthening and the laws and regulation component will require substantial financial and technical support. Eventual nation wide application of all achievements reached and methods developed so far will pose a great problem in the present economic environment in Laos.

The overall assessment is that technical and financial Sida support is vital for a third and final phase. That should cover current components under the projects, quality of drugs, rational use of drugs and strengthening the institutional framework for the NDP. To these should be added projects and/or components of: general human resources development in the pharmaceutical sector; economic strategies and financing mechanisms, management and organisation in NDP development and co-operation. In the latter should be included a part on an integrated approach to both national and international technical and financial collaboration.

4.3 Sustainability

A sustainable organisation is an organisation that is capable of continuously producing utility for its clients or customers and its stakeholders at a cost that motivates them to supply the resources required to keep the production going.

Public, budget financed, organisations are highly dependent on policies and priorities of the Government. A high performing organisation may not survive because of changing political priorities at the same time as low performing organisations continue to exist.

The drug administration of Lao PDR has essentially been created during the last 10 years. As shown above it has reached a level of capacity where it is capable of performing certain essential functions of its mission. The question whether the drug administration today is sustainable in the sense defined above must, however, be answered by no. This answer has to be qualified.

As regards political relevance there are no signs of Government questioning the need for a drug policy and a drug administration capable of implementing that policy. The expected enactment of the proposed Law on Drugs, Pharmacy and Medical Products supports this assessment. The staircase model used to assess the level of institutional development also provides two criteria for assessing sustainability. The first criterion concerns the financial resources and the second concerns the competence of the organisation. By combining those two criteria with the two types of activities in which organisations are involved, current operations and development activities, a more qualified assessment can be made of sustainability.

Finance
i) Is the drug administration dependent on external financial support to sustain its regular and core operations?

To day, this question has to be answered by yes. The limited ability of the Government to finance necessary inputs and maintenance of equipment for the laboratory, fund costs of inspection, drug samples and IEC activities poses a real threat to achievements made.

ii) Is the drug administration dependent on external financial support for development and change?

The answer is yes. The Government does not seem to have the ability to fund the investments required to expand to new provinces. The same seems to be true for renewal of equipment, investment in new equipment and hiring of external expertise.

Competence
iii) Is the organisation now dependent on external technical assistance to carry out regular operations?

This question may be answered by a qualified no. Regular operations of quality assurance and RUD activities are carried out today as reported above. Capacity to monitor and analyse the operations in order to gradually improve quality and efficiency is, however, still weak and requires technical assistance.

iv) Is the drug administration dependent on external technical assistance for development and change?

The answer is yes. The technical assistance provided by the NDP Programme, WHO and other international donors has played a critical role in the development that has taken place. Further development of institutional capacity and consolidation of made achievements will require continued technical assistance.

4.4 Programme management and technical assistance

The management of the programme was not given the attention it would have required at the start of Phase II. Efforts have since been made by all parties – MoH, Sida, IHCAR – to make up for the initial neglect. Project 0 was added already in 1997 to enable IHCAR to assist more actively in co-ordination of the programme. In 1998, a financial audit was made of the programme which resulted in certain improvements of financial management procedures. This was followed up during 1999 with the installation of a new accounting system, designed by a local consulting company. In 1999, a programme management committee was formed to assist the National Programme Director and the Programme Manager.

The terms of reference for IHCAR in the contract signed 15 November 1996 includes only a minor role in management, outside its own sphere of technical assistance work. The ToR under Project 0: Co-ordination in the contract's Appendix B notes, "assist MoH in their development of work plans and reports to Sida". Gradually, however, IHCAR has influenced the management of the programme, evidenced by the growing emphasis of strengthened management capacity. The fact that the programme has gained momentum and implementation has proceeded well since 1998 indicates that IHCAR came to play an important role in management of activities. IHCAR project co-ordinators and core consultant were in Laos more often and were thus able to follow and be involved in the programme development more closely, because of some added consultant weeks under Project 0. However, IHCAR has been less instrumental in actually achieving substantial improvements in programme administration, which is in their ToR for planning and reporting, but not for accounting. Such required administrative support is nevertheless time consuming, and considering the still very limited time given under the co-ordination Project 0, IHCAR seemingly had to prioritise the professional issues.

In spite of weaknesses in project management, noted in chapter 3.8**,** the pace of implementation has been high, especially during the last year. This fact indicates a growing capacity to handle this rather complex programme.

The reluctance towards technical assistance seems to have disappeared as programme implementation progressed, as evidenced by the fact that the cost of technical assistance will more than double compared to the estimate made in the project document. The gradual recognition of the need for

increased technical assistance and the subsequent reallocation of funds to meet this need have played a decisive role in achieving the results.

The continued support by Sweden during a third phase, as recommended below, will require that due attention is given to the scope, content and issues of project management and administration, and the role of technical assistance, right from the start. It is important that the programme director is given the authority necessary to manage the programme. Sufficient training has to be provided for handling the accounts, financial and progress reporting. The Ministry and the Consultant should report jointly.

4.5 Cost effectiveness

The Mission has concluded that the programme, on the whole, has achieved its objectives. Largely the right things have been done. A prerequisite for assessing cost effectiveness is, that it should be possible to identify alternatives to the chosen strategy. That is, a strategy that would have achieved the same or better results. In assessing the implementation of the programme the mission has identified a number of related weaknesses in its initial design. The programme objectives were very ambitious requiring a high pace of implementation right from the start to be possible to complete within a three- year period for Phase II. The capacity of the MoH to implement the programme was overestimated and the need for technical assistance underestimated. The reality gradually corrected these weaknesses, through extension of the period of implementation and reallocation of funds in favour of technical assistance.

The question is whether it would have been possible to avoid the initial weaknesses, and if this would have led to a faster implementation and/or lower costs for implementation, with at least the same results as have actually been achieved?

A more realistic assessment of the implications for implementation of the project document would likely have led to reallocation of resources, in favour of more technical assistance from the start. If this would have led to speedier implementation and/or better results is impossible to have any firm view about. It might very well be the case that initial reluctance of MoH to accept high levels of technical assistance also reflected a low awareness of the needs for such assistance. The readiness to absorb higher level of technical assistance was therefore low, and the risk for ineffective support high. The gradually increasing awareness of technical assistance needs, and the subsequent reallocation of resources to technical assistance may very well have secured effective utilisation of the technical support.

Given the circumstances under which the second phase took off, it is difficult to construct an alternative strategy that would have been more cost effective. The parties showed a great deal of flexibility and ability to adjust as experience of implementation accumulated. This is exactly what is required of programmes aiming at institutional development.

A broader question can be raised. Why has it then been good to support the NDP Programme? The reply to this is that any country, poor or rich, has a responsibility to safe guard their citizens against dangerous drugs and to ensure that the needed drugs are available, that they are of good quality and that proper information for their use are provided to consumers and health professionals. Poor countries need development support for this and to build up their regulatory control systems. Needed medicines safe lives, prevent and cure diseases. To weigh health matters against other matters such as education is like asking "which comes first? – the chicken or the egg?". Both are and must be there. In the case of Laos both health and education require support.

4.6 Co-ordination with other programmes

The National Drug Policy Programme has collaborated with WHO/HQ in early NDP development, with WHO/WPRO in quality assurance issues and the registration system. FDD, being the centre of all NDP activities, has worked and works with UNICEF, national and international NGO's, Japan and Germany in setting up drug revolving funds in different provinces. MPSC works with the World Bank and the Asian Development Bank in the primary health care project including a part of drug supply management (*Annex 12* lists major organisations involved in the NDP Programme).There seems however to have been limited formal efforts for co-ordination on the part of FDD, or the Consultant, to get all major actors together "into" the NDP Programme and all its activities. The revision of the NDP later this year will provide a good opportunity to do so. Although FDD and other staff involved in the NDP Programme has been on WHO fellowships and received financial support to attend important courses in quality assurance and rational dug use, new and recent important WHO material on drugs and drug policies was not well known or familiar to the staff. All technical consultants to the NDP Programme should make it a regular feature to update the Lao staff on recent important publications of relevance to the NDP activities. Lao staffs should also make sure that they are listed on core address list s to receive such material.

4.7 Programme's importance for the poor

Being one of the poorest countries in the world, Lao PDR has, as mentioned in the beginning of this report, social and health indicators that are among the worst in the world. The poor and those living in rural areas , which in Laos is 80% of the population, generally bear the burden of such illnesses as tuberculosis, pneumonia, diarrhoea and malaria. Although socio-economic factors play a major part in eliminating these and other diseases affecting the poor, access to health services and access to essential drugs of assured quality can help prevent and cure some of these and other illnesses. The Lao National Drug Policy Programme overall objective for Phase II is precisely to contribute to good health through the availability of good quality drugs at low cost and used rationally. All Laotians shall of course be able to benefit when this objective is fulfilled, but it is the poorest part of the population that is the most affected by illnesses.

The Lao National Drug Policy called for the establishment of revolving funds. Availability and access to essential drugs for the rural population has therefore lately improved thanks to the setting up of such funds not yet countrywide, but in many villages, in district and in provincial hospitals. The income from the funds has meant, that the very limited government money allocated to hospitals for purchasing of drugs, can be used for the part of the population that is not able to pay for its medicines.

The various measures to attain the goal of good quality medicines, not only for the poor but for the whole Lao population, have been discussed in detail earlier in the report.

Accessibility to drugs in Laos also means that essential drugs available in the private sector must be of low cost. The cost and price of drugs in the private pharmacies is, however, still a matter which the government has to address and resolve. Drug prices are not controlled or monitored in Lao PDR. According to one recent research study in Savannakhet province (Stenson et al. 1999) there was considerable inter-pharmacy variation for the four drugs studied. The study also found that drug prices had a general tendency to increase with the distance from the provincial capital thus affecting the poorer population.-

Several specific examples can be mentioned to illustrate the importance of the NDP Programme for the poorer part of the population, i.e. the people mostly affected by common and serious illnesses:

- The Lao national standard treatment guidelines for the seven most common illnesses give information on how to diagnose and treat these correctly. The 11 STG indicators, and the 10 RUD indicators were introduced to monitor diagnosis and quality of treatment by health professionals (see section 3.4.1).
- Another example is among the GPP indicators (section 3.3.2) where e.g. indicators 6 (correct dispensing) and 7 (knowledge of drugs for diarrhoea and malaria) are directed towards attaining good dispensing and advising practice in pharmacies, where the majority of Laotians go to seek health care.
- Adult literacy rate is only 60% in Laos. It is again the poor that are the disadvantaged. The IEC activities in the NDP Programme have been sensitive to this by holding village focus groups discussions, before developing radio programmes and game plays on health care and medicines suitable for an illiterate population.

While strategies and activities in the NDP Programme has given importance and emphasis to the poorer part of the population in Laos, past and present health systems research conducted in Laos under the Programme is revealing that theory in many areas does not match practice. Both final and preliminary results from the HSR reveal among others that improvements are needed to reduce for example irrational use of antibiotics, particularly in self-medication which is widely practised in Laos. Consumers and drug sellers also need to better informed about quality of drugs and the latter must generally improve dispensing practices in their pharmacies, as demonstrated in the Savannakhet study.

4.8 Gender

Since several decades the Lao Women's Union (LWU) is the advocate for women's rights and gender concerns. According to the 1997 AusAid funded Health Sector Report, LWU has the largest mass organisation in the country with almost 20.000 women working in the organisation at different levels. The Union has, over half a million members, an extensive grassroots network, access to government and political authorities at all levels, and has more staff in integrated village development than any other institution and government office. The Lao Women Union has been involved in the NDP Programme since its inception in 1992. Representatives took part in the preparatory NDP work, in the implementation planning meeting in Thailand in 1993 and has ever since been an active participant in NDP Programme development.

The mission visited the Lao Women Union and learned of its central role in promoting and running drug revolving funds at village levels, and its organisation to support this at central, provincial, district and village health levels. LWU has taken an active part in focus discussions and development of IEC material under the NDP Programme, in collaboration with among others, UNICEF. LWU works closely with the NDP management committee, and in particular with FDD and its IEC department.

Laos has one of the highest maternal mortality rates in the world, 656 per 100.000. This enormous problem is of course not within the scope of the NDP Programme. However, it is concerned with providing correct information to pregnant women, when they come to the pharmacies to buy drugs. "What do you recommend to a pregnant women?" is one of the questions pharmacy owners are

asked by inspectors under GPP indicator No. 7, knowledge about drugs. On the spot, and organised training courses have served to reinforce the correct answers.

One of the recent health systems research studies carried out under the NDP Programme concerns self-medication of antibiotics among children, the dangers of this with regard to antibiotic resistance, other side effects, allergic reactions and toxic poisoning. The study, which is not yet published, interviewed mothers being the general care takers of the children. It also explored the mother's own use of antibiotics, their beliefs, knowledge and attitudes regarding the use of antibiotics and self-medication. Recommendations will now follow for a more effective mass media information strategy to promote the rational use of drugs.

Managers and co-ordinators of the NDP projects and components of the NDP Programme have given attention to gender issues. Equal gender distribution for staff attending workshops, meetings and training is regularly considered, and number of males and females are generally recorded and provided for review.

Some examples will illustrate the development with regards to gender awareness in Lao NDP implementation.

The Food and Drug Quality Control Center (FDQCC) had a staff of 20 in 1994–95, ten males and 10 females. In 1998–99 with a staff of 32, twenty two were females and ten males. One observation is that laboratory work seems to attract females, also that more women than men seem drawn to study pharmacy and laboratory technology. The Director of the FDQCC is a woman and so are two of the four chiefs of divisions.

Other examples are from Project 2, Rational Use of Drugs. Many meetings and workshops took place in the development of the Standard Treatment Guidelines (STG), the STG and RUD indicators, and the Drug Therapeutic Committee work. Generally one could say, that about half of the participants in these activities were women. For example; in the eight meetings it took to develop the first seven STGs, a total of 101 persons participated. Forty four were women. The indicator development required nine meetings with a total of 94 participants, 48 of whom were women. At the five workshops to introduce the STGs and the indicators at the provincial hospitals 123 women took part, out of a total 293 persons. Now when the second set of standard treatment guidelines is being produced, at a recent meeting of 69 professionals, 26 were females.

Among the 30 participants in the Health Systems Research training 14 are women. Moreover, all research projects (not only the one on self-medications mentioned above) have designs that take care of gender aspects by e.g. conducting focus group discussions with both men and women groups.

Finally it can be added, that the first Phase II NDP Programme manager was a women, who now is studying towards her Masters Degree in Sweden.

4.9 The Programme in the international and regional context

The NDP Programme collaborated with WHO/DAP/HQ in Phase I, in the

preparation of Phase II document and in the FDCQC financial and management study for the Center. The WHO Regional Office for the Western Pacific (WPRO) in Manila has now taken over some of this collaboration in specific technical areas. Section 3 in the Lao-WHO Co-operation plan and budget for 2000–2001 is relevant to the NDP Programme as it concerns drug management.

A budget of USD 91.000 is earmarked for local costs of for example a national seminar on management of drug supply in the provinces, on fellowships in quality assurance and national drug policies, on technical support (consultant) in reviewing and revising the NDP, on a local workshop to develop implementation plans for guidelines, and some supplies and equipment (computer and printer). Close collaboration with the WHO office in Laos in planning Sida future support and in implementing activities in the final year of Phase II is advised not only in technical co-operation, but also in the joining of financial resources. Additional resources outside the regular WHO budget could also be sought from the WHO headquarters. Particularly so in the case of the mission on the mechanisms for the MoH retention of fees for quality assurance matters, discussed elsewhere in the report and in Annex 11.

Lao PDR has benefited from the closeness to Thailand and its support, but also from collaboration with other countries in the region, i.e. the Philippines, Malaysia, Indonesia and Vietnam, under the ASEAN pharmaceutical scheme in areas of drug registration, drug evaluation, drug information etc., co-ordinated by the WHO Manila office. It is very important that this support continues and that it is well integrated with the objectives and goals of the Lao National Drug Policy.

Earlier has been mentioned the drug seller training in Nepal. This is an area in which Lao PDR and Nepal could exchange experiences. Other areas for collaboration and exchange in the regional context are those concerning counterfeit and substandard drugs. Studies on this have been carried out by WHO and others (Japan support) in Lao neighbouring countries.

In the Lao NDP Programme there are some unique features such as the well co-ordinated and carried out health systems research towards an evidence based NDP. This could be shared in workshops with neighbouring countries, and at broader international meetings on a topic of common concern, such as quality assurance and/or rational drug use.

5. Recommendations

5.1 Need for continued support

The Mission has found that implementation of the NDP will continue to need financial and technical support. The achievements made in the different areas reported above are commendable and were attained through Lao hard work plus a combination of technical and financial support. The technical support through IHCAR has been crucial for the development and implementation of new methods, tools and approaches. The technical competence of the FDD and other Government actors involved in NDP implementation is, however, not yet sufficient to improve and further develop the methods and tools. Neither is the capability to manage and develop the whole system and its components. Technical and financial assistance should therefore be provided in certain key areas over a final phase.

The Mission has concluded that the comparative advantage of continued Swedish support to traditional medicine is little and that the continued need for support to drug supply management could preferably be handled within the co-operation with ADB/WB and the WHO. The Mission therefore recommends that those component are excluded from support during the recommended final phase.

5.2 Seamless transition to Phase III

The transition from Phase I to Phase II was characterised by interruption of implementation activities and uncertainty. At this stage of implementation a similar delay in transition from Phase II to a final phase should be avoided. The mission recommends that there should be a seamless transition from the current phase to Phase III, in order not to jeopardise the momentum now obtained in implementation of the NDP.

5.3 Financial sustainability of current operations

In the medium term, the MoH will have to find ways to ascertain financial sustainability of the regular activities supporting quality and rational use of drugs. Unless this can be obtained, the achievements in building institutional capacity is highly threatened.

The major problem facing the core function of quality assurance is the financing of current operations, of inspection, and of FDQCC. Fees charged for registration of drugs, licensing of drug manufacturers, wholesalers and pharmacies have not been adjusted to compensate for the fall of the value of the KIP. The fees, when set, were not based on the condition that they would fund the operations of the quality assurance system. FDD has proposed certain revision of fees based on a comparison of fees charged in neighbouring countries. The financial regulations governing the determination and use of fees do not now allow MoH to retain the revenue to finance current operations.

The Mission strongly recommends that the Government of Lao PDR (MoH/MoF) carries out a thorough study, with external assistance. This study is recommended to be a follow up and an extension of the 1998 financial and managerial study (Bremer), which included the feasibility of funding the quality assurance system from fees. The new study should thus expand on the previous

findings and outline and discuss modalities and requirements for implementing such a "retention of fees system". This work will require analyses and collaboration with the Ministry of Health and the Ministry of Finance. Retention of collected fees in drug regulatory control is current practice in most countries today. Such practice would be in line with the Lao Government policy on drug revolving funds.

In order not to loose time it is important that such a study (see basis for ToR in *Annex 11*) is carried out as soon as possible in order to be ready before a specific agreement for a final phase is agreed between the governments. A firm commitment on the part of the government of Lao PDR to find a solution to the recurrent cost funding of the quality assurance system should be made before the final phase is entered into.

In view of the Mission, it should be possible to implement a new funding mechanism from fiscal year 2001/2002.

5.4 Management and organisational development of core functions

A new financing mechanism would require development of new management tools for planning, implementation, follow-up and evaluation of quality assurance activities. There will also be a need to establish mechanisms for co-ordination of actors involved (FDD, FDQCC and Provincial health departments). The system for financial management – including budgeting, accounting, cash management and financial decision making – will need to be developed to match the new requirements. The leadership of MoH, managers and staff of the concerned organisations will need to acquire new managerial and technical skills. Technical assistance will be required for this development.

The Mission recommends that one component of the final phase should be directed towards development and implementation of the new tools and procedures required to manage the new financing system. This would also include training of the managerial staff of the concerned organisations.

5.5 Support to core functions

The mission recommends that Sida continues to support a number of core technical and managerial functions in a final phase of NDP Programme. These include the National Drug Policy review and monitoring with health systems research and indicators; the quality assurance including enforcement mechanisms for the new drug law, stepped up inspection activities both in the field and with the FDQCC; the rational use of drugs with expansion of STG and DTC applications and indictor use, and IEC. Part of these core functions should be human resources development, including both university and continuous education in the whole pharmaceutical sector, and management training with an integrated approach to national and international technical and financial collaboration.

5.6 International, Regional and National Co-ordination with donors and international organisations and NGO's

The mission recommends that representatives from national, regional and international organisations take part in the national NDP review seminar planned for the end of this year. This will provide an excellent opportunity to share the Lao NDP implementation experience and to plan for

future needs and co-ordination in major areas of common concern to all involved in enhancing a revised Lao National Drug Policy – the Lao 2000 NDP.

5.7 Sida support during a third and final phase

The Sida support required for the final phase would consist of a mix of technical assistance and financial support to meet local costs for programme implementation.

Technical assistance will be needed to meet the requirement of long-term financial sustainability. In the short term, this includes support to develop the new financing system for quality assurance. In the medium term, support has to be provided to develop and implement the management system required to manage the new financing system.

Technical assistance will also be required in building capacity and competence for policy review and monitoring, as well as for consolidating achievements made in quality assurance and rational use of drugs.

The Mission recommends that a team is appointed, as soon as possible, to prepare a project document for a third and final phase for 3 years. The team should also review and establish the modalities of project management.

5.8 Next steps

The Mission recommends that the following steps are taken before the final annual review of Phase II:

a) Seminar with MoH, Sida and IHCAR to agree on a joint strategy for continued support during a third phase

b) Study of financing operations of the quality assurance system

6. Lessons learned

In this chapter we would like to provide some observations of the development process that the NDP Programme has spearheaded. The observations concern the awareness of development needs among the actors involved, the transition from development activities to regular operations, and the roles the actors are given or taking.

Awareness of development needs
Institutional development is characterised by addressing open ended problems. They are open ended in the sense that no given solutions are available. Different solutions may be found as well as different ways to arrive at and to implement a solution. The process can be described as a sequence of learning cycles, where the first cycle is one where the awareness of development needs is raised among the actors or concerned stakeholders. For example, in the end of the 1980s the problems of drug quality started to emerge. The problems were recognised by some actors and through a dialogue with i.a. Sida and IHCAR the needs to address the problems were articulated.

Not until needs are articulated is it likely that action is taken. And the needs have to be articulated by those who have power to trigger off action. In an organisational context, a sufficient number of influential actors must be capable of articulating the needs for action to be taken. The awareness raising learning cycle is followed by learning cycles required to find solutions and learning cycles to implement and sustain solutions.

The art of institutional development is to facilitate for the learning cycles to take place. In this process the technical assistance is supposed to play an active role. The common perception of the role of technical assistance is to assist in developing solutions and to assist in implementation of those solutions. What is often forgotten is the critical importance of the awareness raising learning cycle. The time it takes to raise awareness of development needs varies a lot depending on many factors. But the time it takes is very often underestimated. If stakeholders who are supposed to act are provided with a ready project plan, they may not share the level of awareness that is required for action to take place. This may delay or even stop implementation.

The NDP Programme provides several illustrations of the importance of the awareness raising learning cycle. The conference in Sri Lanka in 1992 and the study tour to Uong Bi hospital were critical events for the NDP to be formulated, and for the system of STG monitoring through DTCs. Another important example is the whole HSR training process, which is based on using the awareness raising learning cycle to improve capacity and performance among participants. On the other hand, the non-take off of the originally planned Management and Planning component could perhaps be explained by wrong timing and low level of awareness of development needs in this area. The slow response to the emerging need of securing financial sustainability of regular operations in the quality assurance system can also be interpreted as lack of sufficient awareness of the critical actors capable of addressing this problem.

Transition from development activities to regular operations
It is often difficult to distinguish between development activities and regular operation. The result of development activities are gradually incorporated in the line organisation. Implementation of the NDP is a typical example of this process where the centre and selected provinces have participated in the development activities and gradually tested the solutions.

As reported above, a number of systems and operating procedures have now been tested and are in regular use. At this stage new issues emerge. First, there is the issue of extending the systems to the whole country, and second to establish the management systems required to operate the systems. The need for management development is rarely in focus when organisations operate at stage one of the staircase model discussed in chapter 3.8. At this stage the focus is on establishing the production system required to fulfil the mission of the organisation. This is also what has been in focus of the NDP Programme. Now when the organisation is reaching stage two – several key production systems have been developed and are ready for regular application – management development emerge as a key area in order to plan extension to other provinces and to secure regular operations and quality of work.

It is a well known experience that human beings are subjected to selective perception. Depending on professional background and position in an organisation we tend to focus on different issues. Professional organisations, like FDD, have a tendency to focus on the professional content of work. The limited managerial autonomy of FDD reinforces the professional focus. The professional and technical nature of the consultancy support, as determined in the terms of reference, has not induced IHCAR to focus on management development. However, until now management development has not been a major issue but has to be placed in focus during the final phase.

Roles

Three main actors appear on the NDP Programme scene, MoH, Sida and IHCAR. Which roles have those actors played? What significance for the result of the programme has the role distribution had?

At the start of the process, IHCAR played a *visionary*[6] role which broadened the scope of the approach the MoH had chosen, to encompass the whole range of issues relevant to a national drug policy. Both MoH and Sida endorsed the vision and made it their own, which eventually led to the adoption of the NDP. Parallel to this, IHCAR and a few officials of the MoH acted as *network builders*, in the sense that they pulled together the local resources necessary for programme implementation. At this early stage IHCAR also acted as a *contact broker* especially with Thailand. Those latter two roles have been maintained by IHCAR, but increasingly the MoH has taken over these roles.

Sida has, as expected, played a major role as *financier* of the programme, whereas the *operational role* has been played by MoH and IHCAR. The financing arrangement, where Sida advances funds to MoH and provides direct procurement services and IHCAR operates on its own budget together with the weaknesses in programme management reported above, made Sida to take a role as *operational controller*. Sida has spent considerable efforts in monitoring the programme and also taken several initiatives to reduce its engagement in this role. The reporting system, operated by the MoH and IHCAR, is supposed to provide the actors with information in order for them to play the role of *tactical controller*, that is to control achievement of programme objectives. As observed by the Mission, Sida has felt uneasy in this role due to the difficulties to interpret the progress reports.

It is interesting to note that Sida decided to eventually phase out the support to the health sector, before the NDP Programme was comprehensively evaluated. In this case, Sida exercised a role as *strategic controller*. The decision to phase out the support to the health sector was obviously not based on results achieved by the NDP Programme. It was rather based on internal administrative considerations and possibly on an assessment of the relevance of Swedish support to the health sector in a

[6] For a definition and explanation of the role concepts used see: Bra Beslut. Om effektivitet och utvärdering I biståndet. Ds 1991:63 (Only in Swedish)

wider development context. If internal administrative considerations influenced the decision, the conclusion is that the actors that operate the project have to assume the roles of operational and tactical controllers and perform them well.

The Mission has arrived at the conclusion, that the programme has been successful in achieving its objectives as stated in the project document, and that IHCAR has played a very important role for this to happen. Which consulting roles have IHCAR used?

Apart from a general facilitating and counselling role much of the consulting work has concerned professional and technical issues. Professional knowledge, technical solutions, methods and tools in drug administration and management are well established on the international scene. What IHCAR has done well is to bring in this body of knowledge to MoH, develop it further and facilitate acceptance and willingness to adapt and deploy the knowledge in the Lao environment.

The role as "teacher", i.e. " here are some principles you can use to solve problems of this type", seems to have been extensively applied. In some interventions a more hands-on type of expert role, "I will do it for you; I will tell you what to do", has been used for example in setting up and equipping the laboratory. In some areas such as the development of guidelines and indicators and health systems research these roles have been combined with a partner role characterised by " We will do it together and learn from each other".

A development programme of this complexity naturally requires the consultant to exercise different roles and shift the combination of roles depending on the circumstances. It seems as if IHCAR has been sensitive for this requirement, especially in areas where IHCAR has extensive experience and expertise.

The challenging task ahead, to address the management issues on a broader basis will require much sensitivity on the part of the actors. A partnership role seems to be best suited for this challenge and requires adoption, not only by the consultant, but also by the MoH.

Annex 1

Terms of Reference

Terms of Reference for Evaluation of the Implementation of the Lao National Drug Policy Programme

I. Background

Lao PDR approved in 1993 a National Drug Policy (NDP) in order to promote a rational use of safe drugs and to control and safe-guard the quality of drugs available in Laos. Since 1992 Sida has supported the Ministry of Health in Implementing the Policy, during the first phase from July 1992–December 1995 with Msek4 and during the second phase January 1996–December 2000 with Msek15.

During the first phase the NDP Implementation Programme primarily focussed on analytical activities for planning the implementation programme, on training of inspectors, and on the establishment of a drug control laboratory. There was an interim period of preparations between the first and second phase of the programme mainly due to the processing of the project document and the extended process for procuring the Technical Assistance Services.The second phase of the implementation programme is spelt out in the agreed project document of April 1997. It contains the following six 'projects' and components:

- Project 1 for safe-guarding the quality of drugs, including components on legislation, drug inspection and the drug laboratory;
- Project 2 for promoting the rational use of drugs, including components on standard treatment guidelines, IEC (information, education and communication) addressing health staff, pharmacies, factories as well as the general public, and a component on development of indicators for monitoring progress;
- Project 3 on traditional medicine, mainly a mapping and documentation of traditional plants;
- Project 4 on management of drug supply, focusing on the establishment of a unit within the MoH for supply of drugs;
- Project 5 on strengthening the capacity of the MoH to implement the Policy.
- Project 0 was added to cover the coordination by IHCAR.

The major aim of the Swedish support to the Programme has been to promote the buidling up of Lao competence and institutional capacity to develop and sustain the implementation of the Policy.

IHCAR, a department of the Karolinska Institute, was comissioned to advise and assist the MoH by providing consulting services to the Programme mainly by means of short term consultants.

As mentioned above the start of the second phase was delayed by over 15 months, which was the main reason for extending the initial three year agreement period with another two years, i e ending 31 December 2000.

II. Reasons for the Evaluation

The Implementation of the NDP has been going on for more than seven years and so has the Swedish support to the Programme. It is therefore natural to make an external evaluation of achievements and performance in order to learn from experiences. However, Sweden has also decided in its country strategy for Laos that the support to the health sector should be phased out in favour of support to other sectors. In order to consolidate the NDP Programme, Sweden is prepared to consider a final period of support to cruicial activities necessary to sustain the achievements gained so far in the Programme.

The report and its recommendations will be used by Sida and the Ministry of Health in discussing and preparing the content of such a final support agreement. The report will also be a useful instrument for the MoH to discuss and review the future direction of the NDP implementation programme.

III. Scope and Focus of the Evaluation

The Evaluation Team shall make

1. An overall assessment of National Drug Policy (NDP), the implementation of which is the development goal of the Sida-supported NDP Programme. Does the Policy still seem relevant and adequate for Laos when taking into consideration the experiences gained during the implementation phase so far, and considering recent international thinking on the subject? Has the Policy lead to any changes or had any practical implications as yet?
2. An evaluation of the NDP Implementation Programme during the period 1992–2000 with emphasis on the period 1996–2000, and thereby especially
   - assess the relevance of the project objectives with regard to the fulfillment of the development goal of sustainable implementation of the Policy. Was the selection of project objectives the most adequate?
   - assess the relevance and adequacy of the project components, sub-components and activities in relation to the project objectives. Were these components etc adequate and suffcient to achieve the project objectives?
   - assess achievements in relation to the set objectives and targets and make a problembased analysis of the results.
3. An assessment and analysis of the prerequisites for long term sustainability of achievements. The major aim of the Lao-Swedish cooperation is to build sustainable competence and institutional capacity for development work within the area of drug control and rational use of drugs. It is therefore important to analyse the achievements of the Project in this respect and identify crucial requirements for a final phase of the programme.
4. An assessment of the Programme Organisation and Technical Assistance for Implementation.
   - a description and critical analysis of the project organisation, specifically with regard to management, coordination and cooperation between departments and units
   - an analysis of pros and cons with regard to the Technical Assistance provided by IHCAR, including IHCAR's role as management adviser to the Lao project management and its role as coordinator and provider of short term consultants. To what extent and how has IHCAR worked to secure development of Laotian competence and institutional capacity? Has this particular way of providing technical assistance lead to any sustainable institutional development at various levels?

5. An assessment of the cost efficiency of the programme; would there have been alternative ways of obtaining same, or better results at lower costs;
6. An assessment of the extent of coordination beetween the NDP Programme and other ongoing development programmes incl those of WHO, UNICEF, WB and Asian Development Bank.
7. An assessment of the importance of the programme for the poor part of the population, particularly those in the rural areas.
8. An assessment of gender aspects of the NDP. To what extent does the programme contribute to increased gender equality in Laos.
9. An assessment of any regional and global aspects of the programme.
10. Recommendations with regard to support from Sida for a final phasing out period. What further actions are absolutely crucial for Lao PDR to be able to maintain and continue implementation and development of the National Drug Policy? Views on organizational forms should be included.

IV. Methodology, Evaluation Team and Time Schedule

The Evaluation team will be composed of:

- Mrs. Margareta Helling- Borda, Team Leader. Former Director of WHO Action Programme on Essential Drugs, pharmacist with post graduate specialization in publich health and executive management;
- Mr Göran Andersson, M.A (business admin), expert on public sector management and institutional development.

The team should work approx. three weeks in Laos (17 Jan–4 Febr 2000).

Before leaving for Laos, programme documents and reports available in Sweden shall be studied. Interviews will be carried out with relevant Swedish consultants who have been involved in the programme (November/December).

In Laos relevant project sites will be visited. In-depth interviews will be carried out with project staff both with regard to technical issues as well as on management, and building of capacity and competence. In-depth discussions will be held with the management of the MoH.

While in Laos, the MoH will provide the team with access to transport and to a resource person who can facilitate programme arrangements.

V. Reporting

The report shall be written in English. The final report will be translated into Lao. The main report shall not contain more than approximately 30 pages. Additional information shall be annexed. Format and outline of the report shall follow the guidelines in "Sida Evaluation Report – a Standardized Format (see annexe 1).

Prior to the departure from Laos, the Team shall present the major findings of the evaluation in a meeting with the Ministry of Health and the Embassy of Sweden in Vientiane.

In Sweden, the Team shall present the major findings of the Evaluation in a meeting with the Health Division, Sida.

A draft report shall be submitted before 21 February 2000 to Sida for comments. Sida and the MoH will meet to discuss the recommendations of the draft report.

A final report shall be submitted to Sida within four weeks after receiving Sida's comments on the draft report. In addition, the report shall be submitted to Sida and the Swedish Embassy in Vientiane by e-mail in Word 6.0 format. The report should be presented in a way that enables publication without further editing. Subject to decision by Sida, the report will be published and distributed as a publication within the Sida Evaluations series.

The evaluation assignment includes the production of a Newsletter summary following the guidelines in Sida Evaluations Newsletter – Guidelines for Evaluation Managers and Consultants (Annex 2) and also the completion of Sida Evaluations Data Work Sheet (Annex 3). The separate summary and a completed data work sheet shall be submitted not later than four weeks after submission of the final report.

- The main report should focus on the problem oriented assessments and analysis of relevance and sustainability on the one hand and on the implementation, organisation, performance, technical assistance and cost efficiency on the other hand.
- A summarized description of the project should be annexed which will allow persons not previously involved in the Programme to understand the objectives, main features and achievements of the programme.
- A summary of programme costs shall be annexed showing costs for local expenditures, training abroad and equipment as well as the technical assistance provided through IHCAR. The TA-cost should be shown for each Project component, also showing the number of visits and number of TA-weeks.
- A list of the main steering documents and reports concerning the project shall be annexed.
- If possible, a summary of Lao PDR earnings and public spendings on health over the last decade shall be annexed (eg 1990, 1993, 1996 and 1999).

Annex 2 (i)
Schedule for evaluation in Stockholm December 1999, Lao NDP Programme

Monday 13/12.	**Tuesday 14/12**	**Wednesday 15/12**	**Thursday 16/12**	**Friday 17/12**
Ann-Marie Steinmann Ann Sophi Eriksson	Ann-Marie Steinmann	Ann Sophi Eriksson	Ann-Marie Steinmann	Ann Sophi Eriksson
9.15-10.00 Introduction Bengt Höjer Head of IHCAR IHCAR documents Ann-Marie Steinman**n**, Ann Sophi Eriksson	9.00-1200 IHCAR Göran Tomson Rolf Wahlström Torkel Falkenberg - First phase of the project and introduction to phase II. (GT) - First part of phase II (TF)	9.15-10.30 David Finer Holger Nilén P2 C2: Rational use of drugs - Information, Education, Communication		9.30-10.30 Gösta Surén P1 C2: Quality of Drugs - Inspections
10.00-11.00 Coffee-break with Lucia	10.00 Coffee-break			
11.00-12.00 Introduction Göran Tomson Project Leader Introduction of the week. Comments/ revisions related to the schedule	10.15 - Second part of phase II, including budget (RW) - Capacity and institutional building (RW) -Towards an Evidence Based NDP (GT)		11.00-12.00 Göran Tomson	11.00-12.30 Wrap-up meeting Göran Tomson Torkel Falkenberg Bengt Höjer Ann Sophi Eriksson
		Lunch		
13.30-17.00 Anders Nordström Ulla Edström and Gunilla Essner at Sida Health Division	13.00-15.00 Lamphone Syhakhang Lao NDP Programme Manager 1996-99	(14.25-14.55 HSP-External Evaluation of research group)	Ulla Edström, Sida	Ervor Edman, Sida
	15.00-16.00 The Lao NDP project and IHCAR Bengt Höjer Head of IHCAR			Göran Tomson
	16.00-17.00 Björn Lindgren P1 C3: Quality of Drugs - Food and Drug Quality Control Centre			

Annex 2 (ii)

Agenda of Sida Evaluation Team in Lao[7] PDR From January 18 – February 4, 2000.

First Week

Tuesday 18 Jan.	11.00 – 12.00	Swedish Embassy, Mr. Klass Rasmusson
	13.00 – 15.00	Meeting with the NDP Director, Manager, team, head of components
	15.00 – 16.00	Background/history of NDP Programme by Dr. Kongkeo Ch.
	16.00 – 17.30	Meeting with Long Term Advisor, Dr. Bernard Osmond
Wednesday 19	8.30 – 12.00	Contin. of Background/history of NDP Programme by Dr. Kongkeo Project 1/ Component 1 Drug Law (Dr. Thanom Insal)
	13.30 – 16.00	Project 1/ Component 2 Inspection (Dr. Soulithon Vongdamith) Project 1/ Component 3 FDQCC (Dr. Ot Manoline)
Thursday 20	8.30 – 9.20	WHO (Dr. Giovanni Deodato)
	9.30 – 12.00	Project 2/ Component 1 STG (Dr. Bouathong + Dr. Amphayvanh) Project 2/ Component 2 IEC (Dr. Khampheng Kh. + Dr. Mayphet) Project 2/ Component 3 Monitoring and Supervision of RUD (Dr. Bouathong Sisounthone)
	13.30 – 16.00	Project No 3: Traditional Medicine (TM) (Dr. Kongmany Sidara) Project No 4: Managing Drug Supply (Dr. Thanom Insal) Project No 5/ Component 1 Strengthening NDP in general (Dr. Sivong Sengaloundeth) Project No 5/ Component 2 Health System Research (Dr. Chanhthakath Paphatsalang)
	16.00 – 16.30	Project No 0: Coordination (Dr. Sivong Sengaloundeth)
Friday 21	8.30 – 12.00	Visit to the FDQCC & MPSC (Dr. Latsamy Vongsack + Dr. Thanom)
	13.30 – 16.00	Visit to the CD Dr Sommone PHOUNSAVATH, Director of Curative Department & Traditional Medicine (Dr. Kongmany).

Second Week Interview sessions

Monday 24	8.30 – 10.00	Dr. Vilayvang Phimmasone, Director of FDD.
	10.00 – 12.00	Dr Vanhliam, Friendship Hospital
	13.30 – 16.00	NDP Financial (Dr. Sivong + Dr. Bounxou) Visit to Director FDD
Tuesday 25	8.30 – 12.00	UNICEF Representative in Lao PDR (Mr. Rafael + Dr. Intong)
	13.30 – 16.00	Drug Registration (Dr. Vilayvang Phimmasone + Dr. Sivong) Private Pharmacy visits (5) in Vientiane Visit to MPSC
Wednesday 26	8.30 – 10.00	Drug registration Computerized System (Dr. Boun xou)
	10.00 – 12.00	Dr Khamphay RATSAMY, Vice Minister of Labour, Social and Welfare,
	13.30 – 16.00	Dr Bounkong Sihavong, Deputy Director, Mahosot Hospital, DTC

[7] For agenda and itinerary in Stockholm and Bangkok, see Annex 3 (i) Persons met in these places

Thursday 27 – Friday 28		Visit to Louang Prabang Province (Provincial Health Department Dr. Khampheng & FD unit, The Provincial Health office, Provincial Hospital & the DTC; District hospital, Dispensaries, PrivatePharmacy visits in LP (5 in LP) Discussions with Mr Klas Rasmusson in Luang Brabang
Saturday 29		Visit to Swiss Red Cross Representative in LP and Return to Vientiane

Third Week

Monday 31 Jan.	8.30 – 10.00	Dr S. Saramany , President of Lao Red Cross
	14.00 – 15.20	Mrs Onesy Sengmouang, Director Lao Women Union Dr. Kaysamy
	15.30 – 16.30	Dr Prasongsith BOUPHA, Director of ADB II
Tuesday 1/2/00	11.00 – 12.00	Meeting with Minister of Health, Dr. Ponemek Dalaloy.
	13.30 – 16.00	Data review and drafting of findings & recommendations, at hotel
Wednesday 2/2/00	8.30 – 12.00	Preparation for presentation of prelim. Findings & Rec.
	13.30 – 16.30	Presentation of Draft Findings and Preliminary Recommendations to the Minister and NDP Steering Committee, senior MoH officials, the Embassy of Sweden, and Project/components responsible persons
Thursday 3/2/00		Data review and verifications at FDD and elsewhere.
Friday 4/2/00	8.30 9.30	Meeting with WHO
	10.00	Meeting and Debriefing at Swedish Embassy
	14.00	Meeting with Auditor (Mr. Goran Andersson) (did not take place)
	14.00 – 16.00	Meeting with FDD people on Quality assurance and Drug Reg. Control,Review and application of relevant WHO material (Mrs.Margaretha Helling Borda)

Saturday 5/2/00 Return to Geneva and Stockholm

Annex 3 (i)

Persons met at visit to Stockholm, December 1999

IHCAR staff or consultants for Lao NDP:

Name	Project	Abbreviation
Bengt Höjer	Project-group	
Göran Tomson	All	
Rolf Wahlström Co-ordinator	Co-ordination, Strengthening the institutional framework for the National Drug Policy	P0, P5
Torkel Falkenberg Co ordinator	Co-ordination, Strengthening the institutional framework for the National Drug Policy	P0, P5
Lamphone Syhakhang Lao Programme Manager	All	
Graham Dukes STC, Professor Emeritus	Quality of Drugs, Establishment of Law and Regulations	P1 C1
Gösta Surén Pharmacist Medical Products Agency, Uppsala	Quality of Drugs Inspection	P1 C2
Rolf Johansson Medical Doctor, LTC(**see below**)	1. Quality of Drugs, Inspection 2. RUD, Development of Standard Treatment, Information, Education and Community 3. Strengthening the institutional framework for the NDP	1. P1 C2 2. P2 C1+C2, 3. P5
Bernhard Osmond (**see below**) Pharmacist, LTC, Manager of Drug Supply	Managing Drug Supply	P4
Björn Lindgren Pharmacist Medical Products Agency, Uppsala	Quality of Drugs, Food and Drug Quality Control Centre	P1 C3
John Flensburg Pharmacist Medical Products Agency	Quality of Drugs, Food and Drug Quality Control Centre	P1 C3
David Finer Medical Journalist	Rational Use of Drugs, Information, Education and Communication	P2 C2
Holger Nilén Medical Journalist	Rational Use of Drugs, Information, Education and Communication	P2 C2
Marianne Warsame Medical Doctor	Rational Use of Drugs, Information, Education and Communication	P2 C2

Stig Lövgren STC	Managing Drug Supply	P4
Solveig Freudenthal IHCAR	HSD-course in Laos	P5 C2
Bo Eriksson Nordic School of Public Health	HSD-Course in Laos	P5 C2

Consultants interviewed: in Geneva (MHB), December 1999; by e-mail (MHB) in January 2000 (MHB); in Bangkok (MHB and GA) January 17, 2000; and in Vientiane (MHB and GA)

Kari Bremer, Pharmacist, WHO EDV, Geneva	Quality of Drugs: Financial and managerial plan (FDQCC)	P1 C3
Bo Stenson (in Geneva)	Phase I and Health Systems Research	Phase I and Phase II Research
Graham Dukes (in Bangkok)	Establishment of law and regulations	P 1 C1
Rolf Johansson (in Bangkok and Vientiane)	Rational Use of Drugs and other areas – general technical follow-upl	P1 C2 and P2 C1 + C3
Bernard Osmond (in Vientiane)	Managing Drug Supply	P4
Stig Lövgren (by e-mail)	Managing Drug Supply	P4
Wiyanda Akarawut, Medical Science Department, MoH, Thailand	Quality of Drugs, Food and Dug Quality Control Center	P1 C3
Arunee Poompnich, see above	see above	see above

Persons met at Sida, Stockholm, December 1999 and Sida, Laos january 2000

Anders Nordström,	Head Health Division	
Ulla Edström	Senior Programme Officer, Health division	Responsible for Lao NDP Project, April 1997 to end 1999
Gunilla Essner	Senior Programme Officeer, Health divison	Responsible for Lao NDP Project from end December 1999
Ervor Edman	Senior Project Manager (transport)	Sida responsible in Laos 1993-September 1999
Klas Rasmusson	First Secretary, Swedish embassy, Laos	Sida responsible in Laos since end 1999
Jörgen Schönning	Economist, Asia Department	Responsible for Lao PDR

Annex 3 (ii)

List of persons met in Lao PDR for the NDP Evaluation

No.	Name	Agency	Position
1.	Dr. Ponemek Dalaloy	MoH	Minister
2.	Dr. Daovone Vonsack	MoH	Vice Minister
3.	Dr. Bounkouang Phichith	MoH	Vice Minister
4.	Dr. Vilayvang Phimmasone	FDD	Director of FDD
5.	Dr. Kongkeo Chounlamountry	FDD	Deputy Director of FDD,NDP Director)
6.	Dr. Sivong Sengaloundeth	FDD	Chief of Drug Control Div, NDP Manager
7.	Dr.Soulithon Vongdamith	FDD	Chief of Inspection Div.
8.	Dr. Khampheng Khotsay	FDD	Chief of IEC Div.
9.	Dr. Thanom Insal	MPSC	Director of MPSC
10.	Dr. Chanthakhat Paphatsalang	NIOPH	Health Legislation Unit
11.	Dr. Chansamone	NIOPH	Technical staff
12.	Dr. Kongmany Sidara	TMRC	Deputy Director of TMRC
13.	Dr. Latsamy Vongsack	FDQCC	Director of FDQCC
14.	Dr. Ot Manolin	FDQCC	Chief of Physico-Chemical
15.	Dr. Thavy	FDD	Technical Staff
16.	Dr. Bouathong Sisounthone	Curative Depart.	Chief of Drug & Equipment (NDP Management Committee)
17.	Dr. Amphayvanh		Curative Depart. Technical Staff
18.	Dr. Bounfeng Phoummalaysith	MoH	Technical Staff (NDP Manag. Committee)
19.	Dr. Bounkong Sihavong	Mahosot Hosp.	Deputy Director of Mahosot
20.	Dr. Bounkhong Sisonethone	Mahosot Hosp.	Chief Pharmacy section
21.	Dr. Seun Soukkaserm	Mahosot Hosp.	Deputy Chief
22.	Dr. Mayphet Phonsyma	FDD	Staff
23.	Dr. Chittavong Syviengxay	FDQCC	Deputy Director of FDQCC
24.	Dr. Vongsavanh Insixiengmay	FDQCC	Chief of Administration
25.	Dr. Douangchay Malyvanh	FDQCC	Staff
26.	Dr. Vongmany	FDQCC	Chief of Narcotic Div.
27.	Dr. Vanhliam	Friendship Hosp.	Head of Department
28.	Dr. Bouaphat	Friendship Hosp.	Head of Department
29.	Dr. Boun xou Keohavong	FDD	Technical Staff (NDP accountant)
30.	Mr. Klas Rasmusson	Swedish Embassy, First Secretary of SE,	
31.	Mr. Rafael Diaz Diaz	UNICEF	Project Officer
32.	Dr. Inthong	UNICEF	Associate professional Officer, Health&Nut.
33.	Dr. Giovanni Deodato	WHO	WHO Representative in Laos
34.	Dr. Khamphay Rasmy	Min. LW	Vice Minister
35.	Dr. Bounsouan	PCU	Director
36.	Dr. Pasongsith	ADB II	Director
37.	Dr. Sommone	Curative Depart.	Director of CD
38.	Mrs. Onesy	LWU	Deputy Director of Lao Women Union
39.	Dr. Viengxay Keobounthanh	MoH	Director of P&B Depart.
40.	Mrs. Chanhthanom Manotham	MoH	Director of Cabinet
41.	Dr. Phoukhong Chommala	MoH	Chief of Foreign Relationship Division

42.	Dr. Kotsaythoun Phimmasone	MoH	Technical Staff of (Planning &Budget)
43.	Dr. Manisone	MPSC	Staff
44.	Dr. Chanhthone Vichit	LP Hosp.	Deputy Director
45.	Dr. Sommay Lattanavong	LP Hosp.	Deputy Chief of Pharmacy
46.	Mr. Chanthon Vilaylack	LP Hosp.	Deputy Director
47.	Dr. Sichanh Himpapat	LP Hosp.	Director
48.	Dr. Khampheng Yeaveu	LP PHD	Chief of PHD
49.	Dr. Thongdee	LP	PHDChief of Food and Drug Unit
50.	Dr. Thanakhanh	Mahosot Hospital	Staff
52.	Dr. Laouane	Mahosot Hospital	Deputy Chief of Pharmacy
53.	Dr. Vilayvanh	Mahosot Hospital	Statistics Unit
54.	Dr. Oudayvone	Mahosot Hospital	Staff of International Clinic

Annex 4

Project component results/indicators at Evaluation in Jan-Feb 2000 compared with original (April 97) LFA matrix project and component objectives, indicators and results planned for Phase II

Project 1 Quality of drugs	***Component 1 Establishment of law and regulations***
Objective: -Drugs used by the population will be safe, effective and of good quality Indicator:% of drugs that are safe, effective and of good quality	Objective:-To have in place an appropriate legal framework for the drug sector Indicator: Drug law and regulations
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. Drug legislation committee established/Decree of Minister of Health	FDD working group established in 1997. First meeting of expanded drug law committee in 1998
B. Drug law adopted/Decree of the President of Laos	Final drug law draft "Law on Pharmacy, Drugs and Medical Products" to be submitted to National Assembly for adoption, March 2000
C. Set of new regulations available/5 new regulations	3 issued: drug advertisement(No.853,1997); procurement (3174, 1998) and GMP; 2 new planned (drug donations and drug prescribing)
D. Existing regulations updated/5 updated regulations	2 existing (pharmacy from 1988and sanctions from 1994) under revision; 2 others (drug import-export and manufacturing) to be updated
E. The drug law translated and printed/Policy documents	The drug law draft is in Lao and English
F. -An information seminar on the drug law/Reports from the seminar	Local seminar for about 70 persons for 3 days planned in 2000, after expected March adoption
(result of adoption of drug law depends on the functioning of the National Assembly)	(the National Assembly is to meet in March 2000 and the Drug law is on the agenda)

Project 1 Quality of drugs	***Component 2 Inspections***
Objective:-Drugs used by the population will be safe, effective and of good quality Indicator:% of drugs that are safe, effective and of good quality	Objective:-To have an inspection which will ensure that drugs available in the country are safe, effective and of good quality and are dispensed according to good practices Indicator: At least 50% of the pharmacies in the 5 provinces should be inspected once a year/Inspection reports
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. A functional inspectorate at central level and in 5 provinces/Registration records B. 10 trainers for training drug inspectors/Staff records C. 40 trained inspectors in good inspection practices/40 trained inspectors in place	A. Both levels need strengthening and reinforcement .—B. A total of 13 trainers (MoH 5 and the five pilot provinces 8). –C.23inspectors (MoH and pilot provinces) trained at least twice in GMP, GPP and GWP. More than 100 from 55 districts in pilot provinces trained once in GPP.—Total of 154 trained on GPP, 22 on GWP and 9 on GMP
D. A reliable system for sampling drugs in the market in order to carry out post marketing surveillance for a number of problem drugs/70% of drugs at the point of sale will be within expire date	Not fully operational – Feedback and financing for payment of samples and for inspection activities problematic.—GPP indicators include expired drugs which are reported to be much less frequent now.

E. Guidelines for inspection including tested indicators/A manual for inspection available	Manual for Drug Inspectors published by FDD Inspectorate Division 1998. The ten GPP indicators used country wide since 1995 are in process of revision "Lao GPP-2000 Indicators"
F. Evaluation and Monitoring System established/Monitoring system in place and evaluation report available	Pharmacies in pilot provinces inspected about once a year /Evaluation and Record books produced and available in a sample of pharmacies visited during evaluation. -Computer monitoring system in process
G. Equipment and vehicles procured/equipment and vehicles installed	Five Toyota Hilux Double Cab, 45 motorbikes to 5 provinces and districts, four computers
H. Logos for vehicles and equipment published and used/Vehicles and equipment with logos stamped	Logos published and used on vehicles and equipment and printed on publications
Project 1 Quality of drugs	***Component 3 Food and Drug Quality Control Center (FDQCC)***
Objective:-Drugs used by the population will be safe, effective and of good quality Indicator:% of drugs that are safe, effective and of good quality	Objective:-To have a functioning laboratory which will contribute to the improvement of the quality of drugs available in the country Indicator: The number of samples which have successfully passed quality control have increased by 50%
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. Capacity to test at least all the ED in the market according to GLP/Number of samples tested	Total analysed samples were 224 in 1995 and 1410 in 1999 (629% increase).- Drug samples (67% of all samples) were 150 in 1995 and 826 in 1999 (551% increase). – Total pre- and post marketing drug samples were 490 in 1997 and 826 in 1999. Of these, post marketing drug samples increased from 152 to 746.
B. 10 staff trained in laboratory techniques/10 people trained and in place and performing acceptable standard	30 staff (of total 32) trained at the FDQCC in GLP and SOP.- 4 senior staff had more specific laboratory technique training in Bangkok and Sweden
C. 2 staff trained in management/2 staff trained and in place	2 staff trained in administration and regulation aspects in Thailand in February 1999 and in place.
D. Operational standard procedures completed/Operational standard procedures available	Manual for Drug Analysis available. Further SOPs are in process in one or two areas; needed in others such as management and co-ordination with FDD inspectorate
E. Equipment, spare parts, chemicals procured/Equipment installed	HPLC, UV spectrophotometer and other equipment installed but no local access to spare parts and maintenance. Chemicals procured and reference substances received through WHO support. -One Toyota, 2 motorbikes and one computer received.
F. An implementation plan for cost recovery and sustainability of FDQCC/Plan available	Consultant report of 1998 (K. Bremer) analysed situation and proposed alternatives. A follow up study with external help is now urgently needed.
G. Confirm the quality of work/Staff trained and in place and performing acceptable standard	International proficiency testing (Sweden, Thailand) done in 1995.-Staff increased from 8 persons in 1993 to 32 in 1999. -The component indicator could not be reliably measured from the available data.

Project 2 Rational Use of Drugs (RUD)	***Component 1 Development of Standard Treatment Guidelines***
Objective:-People after 3 years will use drugs more rationally Indicator: 50% increase in ORS use in children under five with diarrhoea	Objective:-To have STGs for 50% of the most common diseases after 3 years Indicator: STGs available for 3-4 of the seven most common diseases
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. STGs developed. Adopted, printed, disseminated and used/No. of copies printed of the STGs, distribution and hospital prescription records	3000 copies of STGs for 7 most common diseases (malaria, diarrhoea, parasites, pneumonia, dengue fever, tuberculosis, leprosy) printed, distributed and introduced in 1998. -STG volume II for emergency in surgery, gynaecology-obstetrics and internal medicine now under preparation.
B. Functioning STGs Committee/Number of meetings and minutes with important issues	STG Committee established in 1995 (MoH decree 1270/95) with Minister as chairman.7 subcommittees (58 persons) developed draft STGs for wide consultation. Important meeting reports exist.
C. 9 workshops for promoting the STGs to the health personnel/Reports from workshops	5 workshops held in 5 pilot provincial hospitals and 2 in Mahosot and Friendship hospitals in Vientiane
D. A set of indicators for monitoring the adherence to STG/Indicators available	11 STG indicators for measuring quality of treatment available
E. Monitoring (Refer to project 2 Component 3)	(Refer to project 2 component 3)

Project 2 Rational Use of Drugs (RUD	***Component 2 Information Education and Communication (IEC)***
Objective:-People after 3 years will use drugs more rationally Indicator: 50% increase in ORS use in children under five with diarrhoea	Objective:-Health personnel and the public will be better informed about drug use Indicator: Information material available
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. IEC strategy/ IEC strategy report available	Reports (Finer May 97, Remstrand September 97) exist. Clear and more focused strategy yet to be developed.
B. 10 health messages related to drug use communicated through radio, other mass media and IEC channels to be developed and transmitted/Health message report and transmission report	a) One page handout for consumers, 7 health and drug related messages, 15000 copies b) Calendar 1998 and 2000 (1000 and 2000 copies) c) T-shirt (FDB reader response) NDP logo, 80 printed in 1999 d) Radio spots 1996-99; 18 topics (5 selected), Drama on Rational Use of antibiotics, also on TV e) TV 1997-99 disease oriented; doctor interviews f) Newspaper articles, 3 times g) Manual produced and used for 2 day workshop on simplest of communication on drug use (RUD) h) 19 ADR from WHO published and disseminated by News
C. To produce and disseminate a relevant Food and Drug Bulletin (FDB)/At least 3 issues per year of the FDB and 12000 copies for each year	1 to 2 issues per year produced. FDB No. 10 just published in 3000 copies

D. Revised curricula adopted for doctors, pharmacists, pharmacy assistants and nurses/Curricula for the target groups	Curricula Revision Committee formed: five members visited Philippines to study curricula development. RUD curriculum for health science students in process
E. Guidelines for training drug sellers/Guidelines available	First edition of Guidelines (Drug seller Manual) for training of trainers, published in 1999, 3000 copies
F. 10 trainers for drug sellers training/10 trainers in place	25 trainees from the five pilot provinces trained for 2 weeks, June 1999. Organised by Curricula Committee
G. 10 workshops at district level for the health personnel on rational use of drugs/Reports of workshops	Workshops just starting at district level. But 2 days workshop on training of trainers from the five pilot provinces held in December 1998. At provincial levels also held a 2 day workshop for district health staff, drug sellers, monks, village leaders, teachers, LWU, journalists, TV and radio
H. 9 MoH staff trained at INRUD courses/Report from courses	3 attended INRUD course in Nepal in 1998 and 3 in Thailand in 1999. Reports available
Equipment for UHS and CHT/Equipment installed	Two sets of computers and other equipment installed
J. Knowledge on drug use for health staff/Data collection and analysis report from the previous survey	Data collected from provincial hospitals and a few district hospitals using the 10 RUD indicators. Improvement seen in use of ORS.
K. Training sessions carried out by Provincial Health personnel at district level with drug sellers/Report from training sessions	See above under G and under Project 1 Component 2 Inspection.

Project 2 Rational Use of Drugs (RUD	***Component 3 Monitoring and supervision in RUD***
Objective:-People after 3 years will use drugs more rationally Indicator: 50% increase in ORS use in children under five with diarrhoea	Objective:-Increased capacity of MoH and health facilities to monitor and improve drug use Indicator: Set of RUD indicators
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. Increased capacity of CD staff to supervise the health facilities in relation to drug use/Number of supervisory reports, set indicators A.1. CD staff trained in supervision/CD staff trained in place A.2. Office equipment procurement/Equipment installed	Reports available in hospitals, in Curative Department (CD) and in FDD.–10 RUD indicators to measure rational use of drugs in prescriptions developed and introduced together with STG, and STG indicators (see Project 2 component 1) in major hospitals (Vientiane and 5 provincial hospitals).-CD staff trained and in place.-Equipment installed.
B. ADR monitoring system in place/Document available on the design and functions of the ADRM system	Not yet implemented. On advice from IHCAR decided to wait with this complex activity and put efforts into IEC for the public instead
C. 6 staff trained in Adverse Drug Reaction Monitoring/Training reports	See above
D. 6 study tours to assist organising Drug Therapeutic Committees (DTC)/Study tour reports	Study tour to Uong Bi hospital in Vietnam in January 1998 greatly influenced the nine key MOH persons to develop DTCs in Laos, also making Mahosot a model hospital in DTC development.
E. Monitoring system in place in central and 5 province hospitals/Report documents	DTC monitoring system introduced and developing in 2 central and 13 provincial hospitals using STGs and STG indicators to measure quality of treatment, and RUD indicators to measure rational use of drugs in prescribing.

F. Functioning Drug Therapeutic Committees in place in 5 provinces/Meeting reports with important issues	DTCs organised and developing in 13 provincial and 2 major hospitals (Mahosot and Friendship) in Vientiane.

Project 3 Traditional Medicines	
Objective: Increased knowledge of traditional medicines and increased rational use of TM Indicator: Increased rational use of traditional medicines	
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. A map of available traditional medicines completed/Map available	Survey in four provinces of 648 plant species, 105 herbarium and 50 recipes completed; map from the four surveys of medicinal plants produced in 50 copies in 1999. Survey reports (2 in 1998, 1in 1997 and 1 in 1997) available.-Publishing of books (600 copies) on traditional prescriptions (recipes) planned.
B. 4 completed studies on 4 different traditional medicines/Reports from 4 studies	Study on traditional medicine in treatment of malaria conducted in 1996. Planned studies or clinical trials on anti-hyperglycaemic and anti-inflammatory remedies not carried out. Pilot study on remedy for skin disease under consideration in three major hospitals.
C. Increased knowledge of other regional and country policies related to TM/Reports from study visits to countries in the region	6 persons study tour to Uong Bi Hospital in Vietnam undertaken in 1997.
D. Book on "Medicinal Plants of Lao" printed in 1000 copies/Number of copies printed and disseminated	First book "Pharmacognosia" of medicinal plants of Laos available in 1998: 600 copies in two volumes printed and disseminated for use by students and others to promote traditional medicines use.
Equipment procured/Equipment installed	One computer installed in 1997.

Project 4 Managing Drug Supply	
Objective: -Improve the drug supply system in the public sector Indicator: Steps taken to improve the drug supply sector	
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. A plan for drug procurement and distribution in the public sector/Plan available	Plan prepared and included in "Procedure Manual for the Procurement and Distribution of Essential drugs and Basic Medical supplies", finalised by Long term adviser in January 2000
B. Increased awareness of policy makers on issues related to drug procurement and distribution through study tours in the region/Study tours for 5 policy makers. Policy makers approved legal documents	Study tours partly replaced by recruitment of Long term adviser: -Medical Product Supply Centre (MPSC) created in 1998 (MoH decree No. 3174 of 14.12.98) to plan and co-ordinate central and provincial level estimation of drug needs, drug procurement, distribution, ordering, storing and dispensing.

C. A study on the feasibility for the government company to import drugs in bulk and repack them/Study available	Consultant study on overall drug supply organisation, in 1996 and 1997 (proposed creation of a separate Drug Supply Unit) led to creation of MPSC in 1998.
D. 5 trained procurement officers in commercial English/5 staff trained and in place	5 staff of FDD and former Logistics Division trained in commercial English at Unity School. Course focused on management of business, marketing and international procurement system. Some staff in place in MPSC.
E. 2 trained staff in international procurement procedures /2 staff trained and in place	See above
F. Logistics Division reformed/Organisation report	Logistics division at FDD disestablished; replaced by MPSC in 1998 (see above under B and C).
G. Procurement Committee established/Committee decree	Procurement Committee established. Chairman Director of Cabinet of MoH
H. Drug supply management established /Drug supply management in place	MPSC with help of Long term Adviser (end 1998-Jan 2000) on its way towards improved drug supply management through training of provincial FDD staff
I An improved planning system for drug requirement/Relevant ED available in hospitals	System for assessing continuous availability of ED not yet in place. -Study on "the Availability and distribution of basic drugs and medical supplies in the Lao PDR:" prepared by Long term adviser in 1999 under WHO – Government of Lao PDR agreement

Project 5 Strengthening the NDP (original title) **Project 5 Strengthening the institutional framework for the National Drug Policy (current title used)**	***Component 1 Strengthening the NDP in general***
Objective:-Improve the capacity and knowledge of FDD to implement and monitor all the components of the NDP Indicator: Review and evaluation reports	Objective: Improve the capacity and the knowledge of FDD to implement and monitor all the components of NDP
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
A. Increased knowledge and skills on specific issues for the NDP implementers through training, study tours, attendance at international meeting (20 persons)/Training and study tours reports and supervision reports	1 FDD staff for course in epidemiology and Field Research Methods in Umeå, 1997. -1 FDD staff for Master Degree, Sweden from 1999.- IEC study tour on control of drug promotion in Thailand replaced by Health Technology Assessment studies in 1999 and 2000, requested by Minister of Health
B. Increased knowledge in English (30 persons)/Training certificates	More than 40 persons from central and provincial levels trained in English/No need for interpreters
C. Established and used functioning monitoring of the NDP: development of indicators, setting of a computerised monitoring system/Systems for monitoring NDP in place, report evaluation	System for monitoring NDP under development. Indicators from HSR courses in October 98 and April 99 used by 5 project teams in 5 pilot provinces for evaluation. Analysis of data in process

Project 5 Strengthening the NDP (original title) **Project 5 Strengthening the institutional framework for the National Drug Policy (current title used)**	***Component 2 Health Systems Research for implementing NDP (component added in 1998)***
Objective:-Improve the capacity and knowledge of FDD to implement and monitor all the components of the NDP	Objective: Strengthen the national capacity and the knowledge through HSR for implementing all components of NDP Planned output: Increased capacity building on HSR in support of NDP
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
D. Strengthened MoH capacity to conduct operational research through support to a number of limited research studies (drug use, antibiotic resistance, impact of interventions etc....)/Number of operational research studies undertaken in relation to drug use, antibiotic resistance...) (Original text)	HSR workshops held in October 98 and April 99. Five research projects finalised. Research conducted, workshop on data analysis methods held in October 99 and data now being analysed. Five studies cover: *1. Effectiveness of "Feedback" for improving quality of treatment based on STG; 2. Can health messages reduce irrational use of antibiotics?; 3. Use of Traditional Medicine in Champsack province; 4. Attitudes and beliefs about quality of drugs in Lao PDR; 5. Towards an effective NDP in Lao PDR*
E. Review and evaluation carried out/Review and evaluation reports	Reviews included in MoH and IHCAR annual progress reports. External evaluation in process

Project 0 Co-ordination	
Objective: To assist the food and Drug Department in implementing the second phase of NDP Programme by providing STCs, drafting terms of references, reports to Sida and to monitor progress of NDP Programme	
Results/Indicators planned for Phase II	**Results/Indicators at evaluation in 2000**
Minimum tasks of the project co-ordination set out in 15 November 1996 signed contract between IHCAR and Sida: **9 mweeks** divided between the project group (1nmw), the project leader (5mw), and the project co-ordinator 3 mw, with 2 trips to Laos during year 1	Time for co-ordination, support and management grossly underestimated from the start for a Program of such complexity.
April 1997 Annual Review between LAO PDR and Sida agreed that two additional weeks proposed for project 0 should be used for the work of consultant for assessment of financial situation of FDQCC	Important study and proposal for MoH fee retention resulted after January 1998 consultancy. Government still to address, examine and follow-up on this important and crucial question towards sustainability.
At November 1998 Annual Review NDP programme management requested further support to overall and inter-management issues. Agreed to an increase of a few extra weeks for IHCAR for management support to the Programme.	Management and reporting improved and better co-ordination between sub-projects and components resulted.

Annex 5

Chart: Organisational structure of the Food and Drug Department

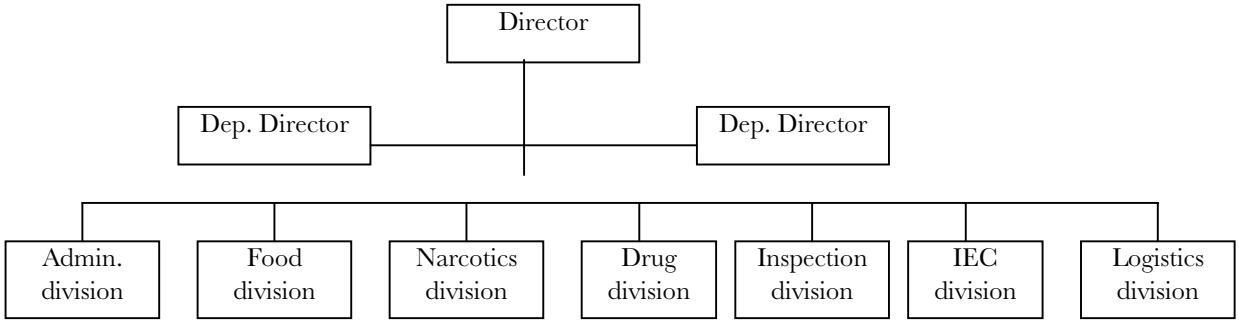


Table 5.1: FDD staff 1994/95 and 1999/00

Unit	1994/95			1999/00		
	M	F	Total	M	F	Total
Director				1		1
Deputy Director	2		2	2		2
Admin. division	4	3	7	6	6	12
Food division	4	2	6	2	3	5
Narcotics division	3	0	3	2	1	3
Drug division	4	2	6	4	3	7
Inspection division	5	2	7	6	2	8
IEC division	2	2	4	1	1	2
Logistics division*	5	1	6	-	–	-
Total	29	12	41	24	16	40

* The logistics division formed the core of the new Medical Products Supply Centre established in 1998/99

Annex 6

FDQCC production statistics

Test samples received and analysed 1995 and 1999

Table Annex 6.1

Test samples	1995	%	1999	%	% Increase
Received	250	100	1596	100	638
Analysed	224	90	1410	88	629

Composition of analysed samples 1995 and 1999

Table Annex 6.2

Analysed samples	1995	Relative share%	1999	Relative share%	% Increase
Food	71	32	316	22	445
Drugs	150	67	826	59	551
Susp. Narcotics	0	0	104	7	
Other	3	1	164	12	5467
Total	224	100	1410	100	629

Analysed pre- and post marketing drug samples 1995,1997 and 1999

Table Annex 6.3

Type of analysis	1995 Number	1997 Number	Relative share%	1999 Number	Relative share%
Pre-marketing		338	69	80	10
Post-marketing		152	31	746	90
Total	150*	490	100	826	100

* No differentiation was made in the statistics

Number of drugs registered at FDD between 1991 and 1999 (includes new and re-registered drugs)

Table Annex 6.4

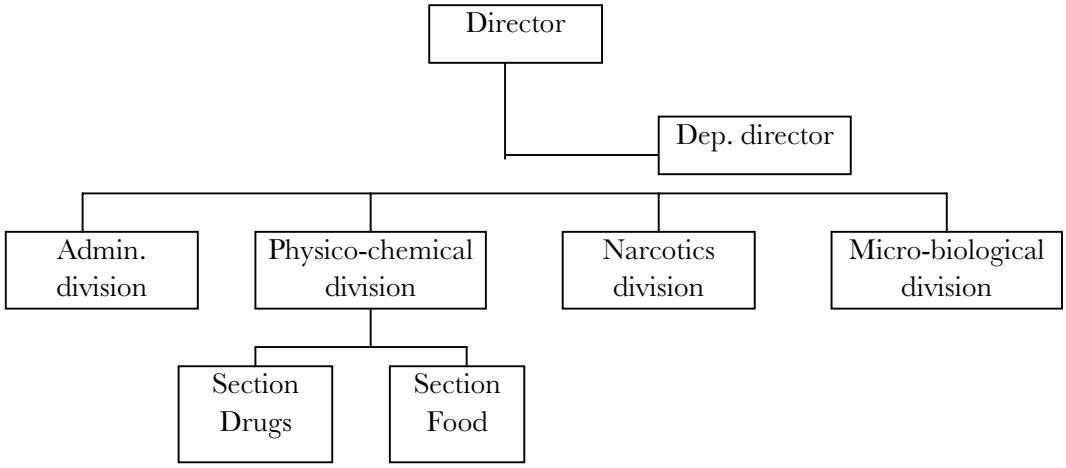
1991	1992	1993	1994	1995	1996	1997	1998	1999
9	138	68	186	100	648	505	308	137

Total: 2099 of which 297 locally produced and 1793 imported medical products
Registration started already in 1991 but not based on issued regulation. Such a regulation was issued in 1995.

Annex 7

Food and Drug Quality Control Centre (FDQCC)

Chart Annex 7.1



Staff of FDQCC

Table Annex 7.1

Unit	1994/95			1999/00		
	M	F	Total	M	F	Total
Director		1	1		1	1
Dep. Director	1		1	1		1
Admin. Division	1	2	3	1	4	5
Physico-chemical division						
- Chief	1		1	1		1
- Deputy chief		1			1	1
- Drug section	3	2	5	2	5	7
- Food section	*4*	*3*	*7**	2	3	5
(Sub-total				*5*	*9*	*14)*
Narcotics division	1	1	2	1	3	4
Microbiological division	2		2	2	5	7
TOTAL	9	7	16	10	22	32

* In 1994/95 drug and food sections had not been established.

Annex 8

Chart Annex 8. Organisation of Medical Products Supply Centre (MPSC)

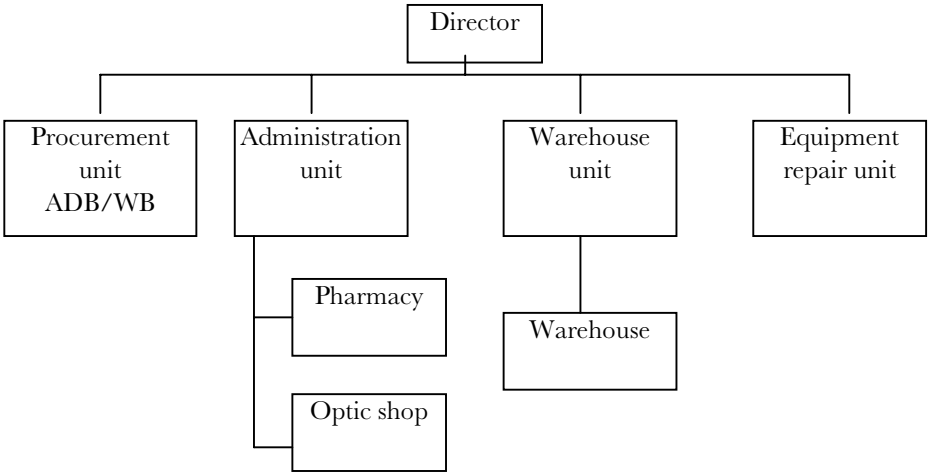


Table 8.1 Staff of MPSC

Unit	1998	1999
Administration incl. director	2	7
Procurement	1	5
Warehouse	4	7
Repair	1	5
Pharmacy	-	3
Optic shop	6	6
Total	14	33

Annex 9

Major Preparatory documents; Project documents; Agreements; Contracts; Annual reviews and Work plans etc., from 1992 to 1999
Table with annotations

Lao National Drug Policy Project and Programme

Category of document	Title or subject of document	Author of document or mission	Date of document or mission	IHCAR ref. or date, and Comments
Phase I: NDP process	1.Towards a National Drug Policy: **IHCAR Review mission** of the essential drugs sector in Lao PDR, (37 pages plus 20 annexes)	Kiatying-Angsulee, Paphassarang, Tomson, Wibulpolprasert	Date of report is May 1992 Mission took place in March 1992	Consultants Report; Lao Dept. of Pharmacy, IHCAR and consultants
	2.Towards a National Drug Policy: **Report from the National Drug Seminar** "Towards a NDP" in Lao PDR, Vientiane November 16-18, 1992, (53 pages and 11 annexes)	A team from Dept. of Pharmacy, MOH Lao PDR, lead by Dr Chanthakhath Paphassarang assisted by Dr Chanpen Choprapawon NEBT and Dr Göran Tomson IHCAR	November 16-18 1992	IHCAR ref. date of report, 1993 ***Pages 36-53 includes the actual Lao NDP***; decree signed by the Lao Prime Minister March 13,1993
***Phase I Sida; MoH, IHCAR minutes, TOR*, etc.**	3. **Progress report** from Lao PDR (1 page)	Not stated	1993	
	4. Uppdrag till Chefen for Hälsobyrån att **uphandla konsult**(1page)	John Olof Johansson, Sida	8 June 1993	
	5. **Draft TOR for IHCAR** including budget (6 pages)	Health Division Eva Nordenskjöld, Sida	21 April 1993	includes budget
	6. Bilateralt stöd till Laos 92/-94/95 **Promemoria** och regeringsbeslut av 31 maj 1991 (12 pages)	Eva Nordenskjöld, Sida	26 -April 1993	includes budgets
	7. **Lao/Sweden agreement**		21 May 1993 for 92/-94/95	Valid for 1 July 92-30 June 95 - 4..050.000 Sek
	8. **Scientific agreement** between the governments of Sweden and Laos on Health support 92/93-94/95 (9 pages)	Signed by Rolf Carlman and Dr Ratsamy Khamphay, Vice Minister	8 June 1993	Summary budget per year
	9. **Avtal med IHCAR** konsult 92/93 -94/95 (12 pages)	Hans Ehrenstråhle	17 September 1993	Budget for MAP and NDP

Category of document	Title or subject of document	Author of document or mission	Date of document or mission	IHCAR ref. or date, and Comments
Phase I **cont.**	10. **Agreed minutes** from the Review of the **Lao Swedish Co-operation** Programme (7 pages)	Signed in Vietiane by Dr Champone Mongkhonvilay and RC	17 December 1993 -to Sida 10.1.94	Listing of 10 appendices
	11. **Lao Health Project:-Final Report from IHCAR** (9 pages)	Bengt Höjer and Bo Stenson	26 October 1995; to Sida Nov. 95	Notes on complexity of budget follow-
	12. **TOR for independent Review** of the Sida supported National Drug Policy Project of the Lao PDR (2 pages) = .	Hans Ehrenstråhle, Sida Health Division	14 July 1995	
	13. **Review of Sida Support Drug Policy and Control Project** Report on Vientiane Visit : (27 pages)	. Prof. Prof. Prof.ChitrSitthiamorn, Chulalongkorn University/Bangkok	August 2-13, August 2-13 1995 (Revised report to Sida Feb. 1996)	
Phase II preparation for ***Project proposal, project document and agreement***	14. The Lao National Drug Policy Programme: **Report on the assistance to the Lao Ministry of Health** in preparing a plan for Swedish support (24 pages and 4 Annexes)	Pascale Brudon, WHO/DAP and Ulf Rundin, SPM consultants	November 1995 (covering letter to Hans Troedsson Sida 17 November 95)	LFA matrix and indicators in Annex 2 and Plan of Action inn Annex 3; Tentative budget in Annex 4
	15. Project: National Drug Policy Programme: **Contract for consulting Services between Sida and IHCAR** (7 pages and A to G Appendices) (Project Leader G. Tomson and Project co-ordinator T. Falkenberg-Annex G)	Signed Hans Troedsson, Deputy Head of Health Division, Bengt Höjer IHCAR Deputy Director, Rune Fransson Head of Adm. IHCAR	November 15 1996	Annex E Manning schedule; Annex F Total and Project budgets; Annex G Project Organisation
	16. **IHCAR report: Revision of the Lao Drug Policy Programme Phase II 1996-1998**: Report from a mission to Lao PDR, January 18-31,1997(around a total of 140 pages)	Torkel Falkenberg and Göran Tomson, IHCAR	January 18-31,1997	IHCAR ref. 97/01 -March 1997; Includes LFA revised and several consultants' TOR
	17. **Agreed Project Document: Sida support :The National Drug Policy Progr.Supp. for 1996-98**	Food and Drug (FDD) and IHCAR	April 1997	Project Document; includes LFA

Category of document	Title or subject of document	Author of document or mission	Date of document or mission	IHCAR ref. or date, and Comments
	18. **Minutes of Understanding** regarding the Annual Progress Report and Annual Work Plan & Budget 1997/98 (3 pages)	Signed in Vietiane 7 April 1998 by Dr Somthavy Changvisommid and Olof Milton	7 April 1998 (earlier meeting FDD and Sida(Embassy) 23 January 98	Sida Health Div. could not attend – Note increase 27 to 72 weeks IHCAR
	19. **Addendum to contract between Sida and IHCAR** on consulting services to the National Drug Policy (NDP) Programme, Laos (5 pages)	Signed in Stockhom 10 and 30 May 1999,by Anders Nordström Sida and Bengt Höjer IHCAR, Folke Meijer June 10 1998	10 and 30 May 1999 and 10 June 1999	Addendum to contract = Revision of original budget Appendix E and F for budget years 1998-2000
Phase II ***Annual Work Plans and Progress reports***	20. Ministry of Health Food and Drug Department: **The Annual Work Plan** of National Drug Policy Programme: Sida Support for 1998-99 and 1999-00 (total of 37 pages)	Lamphone Syhakhang, Manivone Sayamongkhonh and Kongkeo Chounlamountry, assted by T. Falkenberg, G. Tomson and Rolf Wahlstroöm	December 1998	Annexes 1=Documents listing 2=Expenditure 3= LFA Matrices 4=Manning schedule
	21. Draft 3:Ministry of Health Food and Drug Department: **The Annual Work Plan** of National Drug Policy Programme: Sida support for 1999-00 (total of 51 pages)	Lamphone Syhakhang, Sivong Sengaoundet, Manivone Sayyamongkhonh, Bounxou Keohavong assisted by G. Tomson and R. Whalström	November 1999	Annexes: 1=Documents listing 2=Expenditure 3=LFA Matrices 4=Manning schedule
Phase II ***Annual Progress Reports by FDD***	22. **Annual Progress Report** of the Lao national Drug Policy Programme from October 1996 to September 1997 (total of 56 pages)	Lamphone Syhakhang, Manivone Sayamongkhonh, Vilayvang Phimmasone, Kongkeo et al.	22 November 1997	Annexes 1=Org. 2=Achievements 3=Expenditure 4= Tentative Plan of
	23. **Annual Progress Report** of the Lao National Drug Policy Programme from *January to September 1997* (total of 30 pages)	same as above	October 1997	2 reports so close in dates because of adjustment to Lao fiscal year

Category of document	Title or subject of document	Author of document or mission	Date of document or mission	IHCAR ref. or date, and Comments
	24. **Annual Progress Report** of the Lao National Drug Policy Programme from October 1997 to September 1998 (total of 66 pages)	same as above except for V. P from FDD and added Rolf Wahlström from IHCAR	December 1998 (22 December 1998 approved by Director FDD)	
	25. Draft 4: **Annual Progress Report** of the Lao National Drug Policy Programme from October 1998 to September 1999 (total of 65 pages)	same as above but added Sivong Aloundeth to FDD	November 1999	
Phase II ***Progress Review by Sida***	26. **Årsgenomgång** av stödet till Laos National Drug Policy (NDP) Programme: Travel Report (8 pages)	Ulla Edström, Sida	23 November 1998	Includes minutes from Annual review 1998
Phase II ***Progress reviews and other reviews by IHCAR -I***	27. The Lao National Drug Policy Project Phase II 1996-1998 – **Progress report** Oct 1996-Dec 1997 (14 pages)	Torkel Falkenberg and Göran Tomson, IHCAR	February 1998	
	28. The Lao National Drug Policy Project Phase II 1996-1998 **Progress Report** (Jan-Sept 1998) Including Comments on Work Plan (Oct 1998-Sept 1999 (2000) (total of 20 pages)	IHCAR	October 1998	This is the revised plan of the above
	29. **Letter from IHCAR to Sida**, Laos: RE: Reallocation of resources for Health System Research in National Drug Policy Implementation (8 pages)	Signed Göran Tomson Project leader; Torkel Falkenberg Co-ordinator and Rolf Wahlström Co-ordinator	7 December 1998	Addressed to Ervor Edman Includes descriptions of Research projects
	30. **Progress report**:Towards an Evidence-Based National Drug Policy in Lao PDR -The Lao National Drug Policy Project Phase II 1996-1998 with prolongation to 1999-2000 – Final Progress Report October 1998-September 1999 (18 pages)	Göran Tomson and Rolf Wahlström, IHCAR	October 1999	Annexes 1=Consultancy visits 98-99 2=Reports written 1998-1999 3=Techn.assistance by IHCAR 98-99 Expend. Versus Budget

Annex 10

Consultant reports[8] and other references

I. Major IHCAR technical reports from pre- and during Phase I, and start Phase II implementation:

- *Towards a National Drug Policy:* Review mission of the essential drugs sector in Lao PDR, May 1992, by Kiatying-Angsulee, Paphassarang, Tomson, Wibulpolprasert
- *Towards a National Drug Policy:* Report from the National Drug Seminar "Towards a NDP" in Lao PDR, November 16–18, 1992, issued from IHCAR1993 (this report includes the National Drug Policy)
- Lao National Drug Policy (NDP), Lao RUD VII, towards Quality of Care; *Standard Treatment guidelines; Indicators for Inspection and Supervision*, Pharmacies, primary health Care and hospitals, , October 15-November 12, 1995, by Rolf Johansson, IHCAR, (La015/96, Report issued December 1995).
- *Revision of the Lao National Drug Policy Programme*: Phase II, 1996 -1998, January 18–31, 1997, by Torkel Falkenberg and Göran Tomson, (97/01, Report issued March 1997)

II. Consultant reports, IHCAR, from Phase II: grouped and listed under project and component

Project 1 Quality of drugs (law and regulation; Inspections; Food and Drug Quality Control Center)
Project 2 Rational Use of Drugs (Development of Standard Treatment Guidelines; IEC, and Monitoring and supervision)
Project 3 Traditional medicines
Project 4 Managing Drug supply.
Project 5 Strengthening the Institutional Framework for the national Drug Policy (Strengthening the NDP in general; Health systems Research for implementing NDP)
Project 0 Project 0 Co-ordination by IHCAR _

Project 1 Quality of Drugs:

Component 1 Establishment of law and regulations (C1)

- *Summary Report* on a visit to LAO PDR February 8–21, 1997, *P1: Quality of Drugs, C:1 Establishment of law and regulations* by M.N. Graham Dukes (97/03, Report issued October 1997)
- *Pharmaceutical Legislation and Regulation*: A brief report on a visit to LAO PDR, May 28 – June 12, 1998 by M.N. Dukes (98/13, Report issued June 1998)
- *Pharmaceutical Legislation and Regulation*: Report on a visit to LAO PDR, January 10–22, 1999, Project 1: Quality of Drugs, component 1: Establishment of law and regulation by M.N. Dukes (99/20, Report issued February 1999)
- *Status of Pharmaceutical Legislation and Regulation in Lao PDR as of January 2000*, Mission January 10–17, 2000, 16 January Draft report by M.N. Dukes

Component 2: Inspection (C2)

- *Quality of Drugs Component 2: Inspection* and Rational Use of Drugs (RUD), Component 1: Standard Treatment Guidelines and Component 3: Supervision-Rational Use of Drugs, March 2–28, 1997 by Rolf Johansson (Lao 97/02, Report issued May 1997
- *Inspection Seminar*, *Project 1: Quality of Drugs*, November 27 – December 19, 1997 by Rolf Johansson and Gösta Surén (97/10, Report issued January 1998)

[8] Annual Review Reports and Work plans are found in Annex 9.

- *Inspection Seminar,* Project 1, Quality of Drugs, October 26 – November 5, 1998 by Gösta Surén (98/15, Report issued November 1998)

- *Project No. 1: Quality of Drugs, Component 2: Inspection Seminar* and –Project No. 2: Rational use of Drugs, Component 1: Standard Treatment Guidelines and Component 3: Supervision- Rational Use of Drugs, December 5–19, 1998 by Rolf Johansson (99/21, Report issued February 1999)

- *Lao GPP-2000 Indicators*, Lao RUD, Drug Therapeutic Committees, Draft report from missions 7–20 November 1999 and 5–12 December 1999, by Rolf Johansson

Component 3: Food and Drug Quality Control Center (FDQCC) (C 3)

- *Assessment* of the situation at the FDQCC of Lao PDR, FDQCC *Project 1 Component 3.* May 3-10,1997, by Björn H Lindgren (97/04 IHCAR ref.)
- Refreshment *training* at the FDQCC in Lao PDR, FDQCC, *Project 1, Component 3*, September 7 – October 3, 1997 by Björn H Lindgren (97/08, Report issued November 1997)
- *Training* course at the FDQCC Vientiane Lao PDR, *Project 1,* Quality of Drugs, *Component 3*: FDQCC, October 19 – November 6, 1998 by Björn H Lindgren (98/18, Report issued December 1998)
- *Refreshment training* at the FDQCC in Lao PDR, Part II, *Project 1* Quality of Drugs, *Component 3*: FDQCC, October 1-25, 1997 by Wiyada Akawarut (97/11, Report issued January 1998)
- The 2nd *Refreshment Course* on Drug Quality Control: HPLC analysis of Multicomponent Preparations, *Project 1 C 3*: FDQCC, January 11 -16, 1999 by Wiyada Akarawut (99/25, Report issued May 1999)
- *Financial and managerial plan* for the FDQCC of Lao PDR, *Project 1*, *Component 3*, January 7-17 1998 by Kari Bremer DAP/WHO (98/14, Report issued October 1998) – (a copy of this report from WHO where there is, in addition, a summary cover sheets of recommendations and follow-up needed-- retrieved from WHO).

Project 2 Rational Use of Drugs

Components 1: Standard treatment guidelines and component 3: Indicators for Monitoring and Supervision

- Towards Quality of Care: *Standard Treatment Guidelines, Indicators* for *Inspection and Supervision*, Pharmacies, Primary health Care and Hospitals PHASE 1, October 15 – November 12, 1995 by Rolf Johansson (Lao 15/96, Report issued December 1995)
- Quality of Drugs Component 2: Inspection and *Rational Use of Drugs (RUD), Component 1: Standard Treatment Guidelines and Component* 3: Supervision-*Rational Use of Drugs*, March 2-28, 1997 by Rolf Johansson (Lao 97/02, Report issued May 1997)
- Rational Use of Drugs, Project no.2, component 1: *Standard Treatment Guidelines* and Component 3: *Supervision – RUD*, November 27 – December 19, 1997 by Rolf Johansson (97/09, Report issued January 1998)
- Rational Use of Drugs, Component 1: *Standard Treatment Guidelines* , Component 3: *Supervision – Rational Use of Drugs*, October 17–29,1998 by Rolf Johansson (98/16, Report issued December 1998)
- (1996–2000) Project No. 1: Quality of Drugs, Component 2: Inspection Seminar and – Project No. 2: *Rational use of Drugs, Component 1: Standard Treatment Guidelines and Component 3: Supervision- Rational Use of Drugs*, December 5–19, 1998 by Rolf Johansson (99/21, Report issued February 1999)
- (1996-2000) Project No. 2: Rational Use of Drugs (RUD) Component 1: *Standard Treatment Guidelines, Indicators – RUD and Component 3: Drug Therapeutic Committee*, January 6–25, 1999 by Rolf Johansson
- (1996-2000) Rational Use of Drugs, *Drug Therapeutic committee*, *Standard Treatment guidelines – Indicators* Lao Rud Indicators, April 16–24, 1999 by Rolf Johansson (99/27, Report issued June 1999)
- Lao GPP-2000 Indicators, *Lao RUD, Drug Therapeutic Committees*, Draft report from missions 7–20 November 1999 and 5–12 December 1999, by Rolf Johansson

Component 2: Information, Education and Communication

- Review of *baseline studies and mass media strategy of NDP*, LAO PDR, Project No. 2, Rational Use of Drugs, April 27 – May 9 1997 by David Finer and Marian Warsame (97/05, Report issued September 1997)
- The *Information, Education and Communication strategy on the NDP* in LAO PDR, P2: Rational Use of Drugs, C2: Information, Education and Communication, September 15–27, 1997 by Lars Gunnar Remstrand (97/07, Report issued November 1999)
- *Development of mass media strategy Part 2*, Project No. 2, Rational use of Drugs, Information, Education and Communication, February 19 – March 6, 1998 by David Finer (98/12, Report issued April 1998)
- *Development of Mass Media Strategy Part 3*, Project No.2: Rational use of Drugs, Component 2: Information, Education and Communication, December 1–12, 1998 by Holger Nilén (99/19, Report issued January 1999)

Project 3 Traditional Medicine

- Project 3 Traditional medicine, March 11-20, 1999 by Rolf Johansson (99/24, Report issued April 1999)
- Report by T. Falkenberg , Title and Year-?

Project 4 Managing Drug Supply

- *Special Drug Procurement Consultancy*, Report for Ministry of Health, Food and Drug Department LAO PDR, Stig Lövgren, Senior Procurement consultant, December 1996 (mission for Sida with letter submitted to Hans Troedsson 20.12.96)
- *Managing Drug Supply*, Project No.4 , July 27 – August 8, 1997 by Stig Lövgren (97/06, Report issued September 1997)
- (1999 – 2000) *Managing Drug supply*, March 29 – April 9, 1999 by Stig Lövgren (99/26, Report issued June 1999)
- Ministry of Health LAO PDR, *Medical products Supply Centre Vientiane*, Drug Supply Management, Inception Report, September 1998 by Long Term Adviser (Bernard Osmund)
- Ministry of Health LAO PDR, *Medical Products Supply Centre* Vientiane, National Drug Policy Programme, Drug Supply Management (Project 4), November 1998, *Progress Report No.1* by Long Term Adviser
- Ministry of Health LAO PDR, Drug supply Management, Report on *GMP/Quality Assurance Audit, Factory Number 2*, 2–3 November 1998 by Long Term Adviser
- Ministry of Health LAO PDR, National Drug Policy programme, *Progress Report Number 3 (March – September 1999)*, *Medical Products Supply Centre* Vientiane, September 1999
- *Procedure Manual for the Procurement and Distribution of Essential Drugs and Basic Medical Supplies in the Lao Peoples Democratic Republic,* produced by Bernard Osmund. Long-term IHCAR consultant under the NDP Programme. (IHCAR consultant for about 1 year and then for WHO)

Project 5: Strengthening the Institutional Framework for the National Drug Policy

Component 1: Strengthening the NDP in general:

- The Lao National Drug Policy Project: Phase II 1996-2000 NDP Review and *Capacity Building* Mission report, August 16-22,1999 by Göran Tomson and Rolf Johansson (99/29, Report issued September 1999)

Component 2: Health Systems Research for implementing NDP

- *"Learning – Understanding – Applying", Health Systems Research course* for National Drug Policy implementation, October 5–16, 1998, Vientiane, Report and Recommendations by Rolf Wahlström (in consultation with Solveig Freudenthal, Bo Eriksson and Göran Tomson), (98/17, Report issued November 1998)
- Project co-ordination and management, *Health* Systems *Research Projects for NDP* Implementation January 10–21 (RW) and January 18–25 (GT) 1999 by Göran Tomson and Rolf Wahlström (99/23, Report issued February 1999)

– *Practice – Theory – Practice* , 2nd *Training course on Health Systems Research* for National Drug Policy Implementation, *Data Processing and analysis* , April 19-29, 1999 by Rolf Wahlström (99/28, Report issued June 1999)

Project 0 Coordination by IHCAR

– *Project co-ordination and management,* Health Systems Research Projects for NDP Implementation January 10–21 (RW) and January 18–25 (GT) 1999 by Göran Tomson and Rolf Wahlström (99/23, Report issued February 1999)

– Towards an evidence-based national Drug Policy in Lao PDR; The lao National Drug Policy Project, Phase II 1996–1998 with prolongation to 1999–2000: final Progress Report (october 1998 – 1September 1999) by Göran Tomson and Rolf Wahlström, IHCAR. October 1999

III. Scientific Publication-list of Lao NDP Programme

– Paphassarang C, Tomson G, Choprapawon C, Weerasuriya K, 1995 The Lao national drug policy: lessons along the journey; The Lancet Saturday 18, 1995 Vol.345 No.8947 433–435

– Stenson B, Tomson G, Syhakhang L, 1997 Pharmaceutical regulation in context: the case of Lao People's Democratic Republic. Health Policy and Planning; 12(4): 329–340

– Stenson B, Lindgren B.H, Syhakhang L, Tomson G,1998 The quality of drugs in private pharmacies in the Lao People´s Democratic Republic; International Journal of Risk & Safety in Medicine 11 (1998) 243-249

– Stenson B, Syhakhang L, Eriksson B, Tomson G; Real World Pharmacy: Assessing the Quality of Private Pharmacy Practice in the Lao People´s Democratic Republic (Private pharmacy practice in Laos) 1999 Accepted Social Science Medicine

IV. Other Reports:

Selected World Health Organisation documents concerning Laos

– DAP/WHO (now called EDM/WHO) *listing of documents in LAO "country box"*

– Report of mission to Phuket Thailand for "Technical Workshop on Drug *management"* for LAO, 24 July to 6 August 1993 by K. Weerasuriya (DAP) and co-traveller J. Norbhu from Bhutan, Temporary Adviser to WHO for the workshop

– Report on assisting the MOH of Laos in *reviewing procedures for registration* of pharmaceuticals and in *revising the EDL*, 2 – 13 April 1994 by K. Weerasuriya (DAP/WHO HQ)

– *Drug Supply Management through the Revolving Drug Fund Mechanisms*, 31 January – 6 February 1997 by Truls Eriksen, Scientist, Pharmaceuticals, Regional Office for the Western Pacific, World Health Organisation

– Report by Pascale Brudon DAP/WHO with Ulf Rundin Sida, consultant on preparation of the *LFA* in November 1995

– *Technical documents* regarding *drug policy*, *quality assurance, drug legislation and drug regulations, rational use of drugs, financing of drugs, IEC etc. from WHO* EDV and former Action Programme on Essential *Drugs*

– *Training package for Practitioners of Traditional Medicine,* World Health Organisation, Regional Office for the Western Pacific, Manila

– WHO Proposed Programme Budget 2000-2001 for Lao PDR with detailed programme of action for WHO/Lao co-operation

– WHO fellowship list for Laos (as of Jan 2000) and WHO short term consultants in Lao PDR July – December 1999

– Copies of correspondence on fake anti malaria drugs

– WHO-Lao PDR government Co-operation in Reproductive Health

Sida

- *Landanalys* LAOS , October 1998
- Förslag till *landstrategi for utvecklingssamarbetet med Laos* 1999 01 01 till 2003 12 31, Oktober 1998
- *Example of a Sida evaluation* (99/10) Working with Nutrition: A comparative study of the Tanzania food and Nutrition Centre and the national Nutrition Unit of Zimbabwe by Jerker Carlsson, Suraiya Ismail, Jessica Jitta and Estifanos Tekle, Department for Democracy and Social Development, Sida
- The *Staircase Model in Brief*, by Göran Andersson, Sipu International and Peter Winal InterManage, Sida
- *Diagnosis of Organisations in Development co-operation*, prepared by Göran Andersson Sipu International, Peter Winai InterManage, Report to Sida 1997

Published and unpublished other articles

- *Winds of change in Laos* , Article in the Le Monde January 1993
- *Diary*, by Victor Mallet in London Review of Books, 16 December 1993
- Summaries of Lao NDP Health Research studies, to be published in 2000
- Report on the *Health Sector and Donor participation in the LAO PDR*, prepared by Dr. Khampiou Syhakhang, Dr Khamla Chanthavong, Ms Mmargaret Gosling and Dr, Quentin Reilly, May 1997 (Lao year 2540) , funded by AusAID

Annex 11

Financial sustainability of core functions in quality assurance, in Lao PDR

Outline and basis for preparation of Terms of References for Follow up and Extension of the 1998 Study[9]

1. Background:

January 1998 study and consultancy
The objective of the 7–17 January 1998 study and consultancy by K. Bremer was to develop "a financial and managerial plan for the drug quality control laboratory (FDQCC) in Vientiane, in Lao PDR, in order to ensure cost-effective and sustainable operation within the drug management system". The consultant assessed the financial and managerial situation at the laboratory, examined registration fees at the Food and Drug Department (FDD) and presented options for a cost-recovery scheme towards sustainability of FDQCC.

The consultant recommended:

1. Design a cost-recovery scheme for FDQCC based on fees from the private sector
2. Change financial system and law to allow FDD and FDQCC to retain fees. If this is not feasible, find ways to increase their government budgets according to the sum of money collected in fees.
3. Find out if it is feasible to require suppliers to reimburse pharmacies for samples taken by inspectors.
4. Implement simple screening methods, first in the FDQCC laboratory, then by FDQCC staff in field conditions, eventually consider if is feasible to use the methods in the provinces.
5. Revise procedures for analysis in connection with registration.
6. Improve follow-up of substandard samples by FDD and provincial authorities
7. Revise terms of reference for FDD and FDQCC and identify areas for closer co-operation

Jan.-Feb. 2000 Evaluation of the Implementation of the Lao National Drug Policy Programme
In January – February 2000, Lao National Drug Policy Programme was evaluated. FDQCC establishment was found to be a major achievement, but financial sustainability of current laboratory activities are still unresolved and are of great future concern for the drug laboratory.

Other quality assurance matters, still unresolved are the financing of inspection activities and the creation of an effective manual and computerised system for tracking drug samples from provinces and districts through FDQCC analyses and corrective measures, when appropriate. The cycle of planning, monitoring, analysis of findings and their follow-up is weak in both FDQCC and in FDD. As a result of this, the necessary institutional co-operation is also weak. The staff needs to be exposed to and learn modern management methods and techniques.

2. Follow-up and extension of the 1998 study

The Lao PDR Ministry of Health partly pursued a few of the 1998 recommendations. For example, FDD has been allowed to keep a small portion of the revenue collected from drug registration fees. The department has also with varied degrees of success got manufacturers and importers to pay for

[9] – *Financial and managerial plan* for the FDQCC of Lao PDR, *Project 1*, *Component 3*, January 7–17 1998 by Kari Bremer DAP/WHO (98/14, Report issued October 1998)

drug samples taken during inspections. But these and a few other isolated actions such as shortening the registration period from 5 to 2 years represent only marginal financial contributions. The recommendations from the 1998 "Bremer report" are, however, often referred to in discussions with MoH officials, but in general terms the seven recommendations listed above have not been tackled. The reasons for this may be several, among others the complexity and sensitivity of the subjects, inexperience in planning and management, the organisational set up of the FDD and the FDQCC etc.

Updated, expanded, detailed financial and managerial analysis, operational plan and procedures for retention of fees in Ministry of Health towards sustainability:
It is now time to address, in depth, the more complex but urgent matters concerning future sustainability of core FDQCC and FDD activities. This means that the Ministry of Health must get formal approval from the overall government financing system to retain fees from drug registration, also from other suitable and acceptable sources of income such as licensing fees and penalties,. An updated, expanded and detailed financial and managerial analysis is needed. Further required as major output is an operational plan, and procedures for how the fee retention system shall function.

Analysis and plan to be carried out by MoH and MoF with external assistance:
The new study shall be carried out by the Lao Ministry of Health and the Ministry of Finance with external assistance. It shall update and expand on previous findings, outline and discuss modalities and requirements for implementing a "retention fee system", which is now common practice in many countries.

Institutional and departmental responsibilities should be indicated and a realistic time schedule for full operation should be included in the operational plan. This work will primarily require analyses and collaboration between the Ministry of Health and the Ministry of Finance and Trade, but other institutions such as the Customs and the Ministry of Justice also need to be consulted in view of the new Lao drug law. The views of those paying fees for drug registration, for licenses of premises etc. are also necessary, particularly when it comes to raising current fees, which will be necessary.

Time for completion of study and firm Lao government commitment before final Swedish NDP support is signed:
In order not to loose time, it is important that this study is carried out by September 2000, to be ready before a specific agreement for a final phase for Swedish support to Lao NDP implementation is agreed upon by the two governments. A firm commitment on the part of the government of Lao PDR to find a solution to the recurrent cost funding of the quality assurance system should be made before a final phase is entered into.

3. Examples of information and specific data needed in preparation for analysis and operational plan

The study shall cover general and specific policy, legal, financial, administrative and managerial matters with regard to MoH retention of fees.

Statistics from 1995 to mid 2000 must be provided by FDD and FDQCC. Apart from budgetary and staff information, these should include yearly data on category, cost and fees of drug registrations, re-registrations, licensing of premises , different drug quality control tests and inspection activities. Magnitude and scope of future drug regulatory control fees and costs shall then be estimated after review and analysis of the past years, and with a view to possible changes that will be introduced with the new drug law.

The Ministry of Finance shall provide input on the requirements, steps and procedures needed for retention of fees from drug registration, in the Ministry of Health.

4. Work schedule and Composition of study team

Work schedule of team:
The team that shall prepare the study and the operational plan and procedures will consist of a local group, and two external consultants. The local Lao group shall gather data and collect other information as indicated above and send this to the consultants a couple of weeks before their arrival in Laos. This will give the consultants a chance to request more information if needed, and help reducing the time it takes to search for such information while they are in Laos. At the arrival of the consultants in Laos they should have an initial two day (or more) meeting with the local group to review and discuss the data and the schedule of work, and the appointments set up by the local group. A seminar or workshop could be scheduled, mid-mission, to give a chance for those involved to comment on the proposals in the draft operational plan, put forward by the team (the local group and the consultants).

Composition of team:
Local team:
Four senior officers from the Ministry of Health (FDD, FDQCC, Cabinet) and two senior officers from the Ministry of Finance. (Others as needed, suggested to be decided by the NDP Steering Committee). A team co-ordinator should be appointed. It is suggested that the team meets at least once a week, starting as soon as the terms of reference have been finalised.

External consultants:
A pharmacist with postgraduate qualifications and at least 10 years experience in a senior position in drug registration and quality assurance administration in a well developed national drug regulatory control authority. Extensive experience from international work, such as WHO, is also needed. The work in Lao PDR requires technical, administrative, managerial and financial knowledge of national and international drug regulatory control functions. It would be an advantage to have the same person that undertook the 1998 consultancy (K. Bremer) as she is already familiar with the Lao environment and its drug regulatory control activities.

The second person needed for the mission is an economist and general management person with extensive experience in planning, budgeting, financing and general management in the public sector in developing and developed countries. Recent experience in health sector reform work in public/private sector mix would be a great advantage.

Length and timing of mission:
The length of the mission is estimated to three to four weeks but may well require longer time. It may also be necessary to split the mission into an initial, and a follow-up mission, depending on the progress of the preparatory work and negotiations and decision making in Laos regarding MoH retention of fees. Before Sida Stockholm finalises the terms of references, it is advisable that Sida Laos is asked to discuss with the Laotian MoH and the Government Administration, how a matter like this should be handled i.e., basis for and steps in decision making, parties and institutions needed to be involved in decision making, time urgency on the part of both parties (the Swedish and the Lao Government towards approval of a final NDP implementation phase) etc.

It is foreseen that the external mission will take place in the summer of 2000.

Annex 12

Current* or potential Donor Organisations, NGO's or others in the Lao National Drug Policy Programme

ADB*	Asian Development Bank
AusAID	Australian Agency for International Development
CARE	Care International
EU	European Union
GTZ*	Deutsche Gesellschaft für Technische Zusammenarbeit
IDA	International Development Association
IFRC	International Federation of Red Cross and Red Crescent Societies
JICA*	Japan International Co-operation Agency
JOCV	Japan Overseas Co-operation Volunteers
LWU*	Lao Women's Union
LRC*	Lao Red Cross
MDM	Médecins du Monde
MSF*	Médecins Sans Frontières
SCFUK	Save the children Fund UK
Sida**	Swedish International Development Agency
SRC*	Swiss Red Cross
UNDP	United Nations Development Program
UNHCR	United Nations Commissioner for Refugees
UNICEF*	United Nations Children Fund
USAID	United States Agency for International Development
VSO	Voluntary Service overseas
WB*	World Bank
WHO*	World health Organisation
WVL	World Vision Laos

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