

UNITED NATIONS DEVELOPMENT PROGRAMME
Project of the Governments of the Association
of South-East Asian Nations (ASEAN)
Brunei Darussalam, Indonesia, Malaysia, Philippines
Singapore and Thailand

PROJECT DOCUMENT

Title : Technical Cooperation in
Pharmaceuticals among ASEAN
Countries

Number : RAS/86/067/B/01/14

Duration : Five years (1987-1991)

Primary function : Direct support

Secondary function :

ACC programme classification :

Government implementing agencies : Ministries of Health

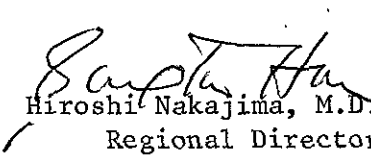
Executing agent : World Health Organization

Estimated starting date : January 1987

Government inputs :

UNDP inputs : US \$1 200 000

Signed:


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Regional Director

on behalf of the World Health Organization



Date: 25 JUL 1986


on behalf of the United Nations Development
Programme

Date:

09 FEB 1987


on behalf of ASEAN Governments

Date:

9/2/87

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PART I: LEGAL CONTEXT

This Project Document shall be the instrument referred to as such in Article I, paragraph 1, of the Assistance Agreement between the United Nations Development Programme (UNDP) and the governments of those participating countries which have signed such an Agreement.

Alternatively, for those participating countries which have not signed such an Agreement, this project document shall be the instrument referred to as a plan of operation envisaged in Article 1, paragraph 2 of the Agreement concerning assistance under the Special fund Sector of UNDP, between UNDP and the governments of those participating countries which have signed such latter Agreement.

PART II : The Project

This document describes continuing technical cooperation among ASEAN countries on pharmaceuticals consequent to earlier Phases I and II of the project (RAS/81/016) covering the period 1982-1986. The framework and activities of the project were discussed and accepted by ASEAN countries at the Sixth Meeting on Technical Cooperation among ASEAN Countries on Pharmaceuticals, held in Jakarta, Indonesia, in December 1985. The member countries are in agreement that the activities carried out under the project will not only strengthen national capabilities but also lead to the achievement of self-reliance in the training of manpower within the region in certain fields.

A. Development Objectives

The Development Objectives of the collaboration within the ASEAN countries are:

(i) to strengthen the pharmaceutical sector to meet the objective of the WHO Action Programme on Essential Drugs, which is to ensure regular supply of safe and effective drugs of acceptable quality at the lowest possible cost to all peoples and their rational use in order to reach the overall objective of health for all by the year 2000 through health systems based on primary health care; and

(ii) to achieve self-reliance in the training of manpower within the region in certain fields.

B. Immediate Objectives

in furtherance of two aspects of the development objectives,

(i) aspects of the pharmaceutical sector relating to hospital pharmacy management, drug management at the peripheral

levels, standardization, quality control and utilization of herbal medicine, and strengthening of communication, information and education on drugs to the community; and

(ii) establishment of regional training centres in ASEAN countries in certain areas where there is the capability to be self-reliant in the training of manpower,

the immediate objectives of this project are:

- (a) To upgrade capabilities within the region in the field of hospital pharmacy management
- (b) To upgrade capabilities within the region in the field of drug management at the peripheral level.
- (c) To strengthen communication, information and education on drugs to the community with the aim of rationalizing drug use
- (d) To strengthen the quality assurance system covering herbal medicine through standardization and common quality control procedures
- (e) To promote the cultivation, production and utilization of medicinal plants
- (f) To formulate an essential drug information manual for use by health providers thereby promoting wider acceptance of the essential drug concept
- (g) To establish regional training centres for:
 - good manufacturing practices (GMP)
 - drug information
 - drug evaluation
 - laboratory quality control
 - production and utilization of reference substances

C. Special Considerations

In addition to the existing close social and economic relations among ASEAN countries, a close professional rapport, a deeper understanding of each country's problems and priorities in the pharmaceutical sector, and a greater awareness of the underlying aim of self-reliance through technical cooperation have been developed during implementation of the earlier phases of the project from 1982 to 1986 and continue to develop through the communications, both official and unofficial, that take place between responsible officers in the countries on matters relating either to the project or to other professional matters. This is important in the project, where, in addition to exchange of expertise and group educational training in new aspects of the

pharmaceutical sector not covered previously, five regional training centres will be established to meet the needs for collective self-reliant training in specific fields where local ASEAN capability has been proved. All these activities continue to contribute to the promotion of technical cooperation among developing countries and to the organization and support of the subregional integration movement.

D. Background and Justification

This project was preceded by project RAS/81/016 - Technical Cooperation in Pharmaceuticals among ASEAN Countries, which was implemented in two phases, Phase I in 1982-83 and Phase II in 1984-86. Project RAS/81/016 undertook collaborative activities in six areas:

1. Exchange of information on drugs
2. Training and exchange of expertise in drug supply and management
3. Development, production and utilization of regional standards and reference substances
4. Development of practical guidelines for implementation of good manufacturing practices
5. Drug evaluation and control
6. Development of adequate quality control laboratories

The achievements of project RAS/81/016 were assessed at a December 1986 Terminal Tripartite Review. It was agreed that the formulation of the immediate objective ("to strengthen the quality assurance system") could be taken as having been achieved. Six specific results were identified that were attributed directly to the project:

1. Adoption of guidelines for good manufacturing practices by the five participating countries and practical implementation of the guidelines in inspection of manufacturing facilities.
2. Improved exchange of information on pharmaceuticals, using common hardware and software.
3. Establishment of a quality control laboratory in Malaysia, and collaboration between WHO and Indonesia and Thailand in quality control.
4. Simpler and more effective systems for drug evaluation and control in the five participating countries, a shorter time

for evaluation and registration of manufacturers in Indonesia and improved teaching of clinical pharmacology in Thailand.

5. Improved procurement and distribution of drugs in the five participating countries.
6. A total of 26 reference substances adopted by ASEAN.

Through this close collaboration, all countries have upgraded the technical capability of their personnel in those fields. Support has also been given to the upgrading of certain institutions by providing equipment for validation of reference substances. The adoption of twenty ASEAN reference substances through this collaboration has contributed to the strengthening of the quality assurance system in all countries.

The identification of and proposals for new activities were first discussed at the Fifth Meeting on Technical Cooperation among ASEAN Countries, held in Bangkok, Thailand, in December 1984. The areas of possible technical cooperation identified at the First Meeting held in Jakarta in 1979, which were not included for implementation in phases I and II of the project, were examined, and possible areas were singled out for further evaluation and consideration by a Task Force.

The Task Force comprised temporary advisers from ASEAN countries, who, after making country visits to discuss with governments the need for, and interest in, nine activity areas, concluded that these were feasible. The report of the Task Force as well as a draft project document were discussed by ASEAN delegates at the Sixth Meeting on Technical Cooperation among ASEAN Countries on Pharmaceuticals, held in December 1985, and the following areas of technical cooperation involving various activities were proposed and endorsed:

- (1) development of hospital pharmacy management;
- (2) training programme on drug management at the peripheral levels;
- (3) strengthening of communication, information and education on medicine in the community;
- (4) standardization, quality control and utilization of herbal medicine;
- (5) formulation of an essential drug information manual;
- (6) establishment of a regional training centre for Good Manufacturing Practices (GMP);
- (7) establishment of a regional training for drug information;
- (8) establishment of a regional training centre for drug evaluation;
- (9) establishment of a regional training centre for laboratory quality control; and

- (10) establishment of a regional training centre for the production and utilization of regional standards and reference substances.

In the ASEAN spirit of consensus, the responsibility for coordinating the activities, as well as for the establishment of the five regional training centres, has been shared out on an equitable basis among the countries, also taking into account the country situations and the rapid development in the various fields in the countries.

While the activities proposed under (1), (2), (3), (4) and (5) above are those new aspects which will contribute to the rational use of drugs, an important national objective in all ASEAN countries, the proposed establishment of regional training centres is a step forward in achieving self-reliance in the training of manpower in the region. All the activities are planned so that their outputs are linked directly to national programmes covering drug policies having similar development objectives to those of this project.

Establishment of regional training centres

Training of manpower within and outside the region has been a major component in previous ASEAN technical cooperation activities. There has been insufficient time and little or no emphasis has been given during these fellowships and training, to establish trainees to acquire expertise in carrying out training themselves, primarily because of the need to expose as many officers as possible to an experience and understanding of different country situations and various operating procedures relating to the activities covered, e.g. drug supply management, drug evaluation, laboratory quality control, drug information, outside their own country. This was essentially a learning process for those officers who could adapt any such procedures, if feasible, to the situation in their own countries. Guidelines on ASEAN good manufacturing practice and inspection have also been prepared which could be applied in the countries of the region. Technical cooperation in producing regional reference substances has been a feature of the activities.

By the final year of the plan period, ASEAN countries should collectively have the capability to conduct their own training in five specific fields utilizing their own resources.

In general, the plan for establishing these centres involves the choice and designation of a particular institution or department in an ASEAN country which could be developed (if necessary, with minimal support in the form of materials and manpower) to conduct training courses in its specific disciplines within the country during or near the end of the plan period. Government inputs at the country level will consist of provision of facili-

ties for training and also the resources for such training throughout the plan period. As and when trainers from ASEAN countries complete their training, their training functions in these centres will form part of their country's input into this project. The need for support in the early period of the project plan varies according to the present stage of development of the centre concerned but, under the plan, all five training centres will, after 1991, coordinate with the other countries to determine and meet their training needs on a continuing basis without further support and on a regional self-reliant basis. It is envisaged that such training could then still be carried on in the country where the training centre is located, incidental expenses being met and no charge being made for such training, while the country sending the trainees will provide transport expenses and per diem allowances.

The interest in, and the need for, such training centres in the region and their feasibility were considered and fully discussed in the country visits undertaken by the Task Force, culminating in a meeting held at the end of these country visits, at which a consensus was reached on the designation of institutions/departments in those ASEAN countries considered suitable for the purpose.

The names of the training centres are specified in Annexes 7 to 11. These are all well established existing agencies forming part of the Health Ministries of the individual countries. The training function of these institutions will be strengthened through this project, so that they can perform the functions of a training centre, but this does not necessarily imply that new organizations named "training centres" will be set up in these institutions. Currently, there are no full time employees exclusively engaged in training, though some in-service training is provided for newly recruited staff or local government staff.

More detailed background/justification, objectives, and linkage with national programmes on each individual proposed activity are contained in Annexes 2 to 11.

E. Outputs

The major outputs from the activities in the project are as follows:

(a) The organization of group training, including provision of fellowships within the region, as well as in certain developed countries, will permit the upgrading of technical and managerial capabilities and expertise in the three identified areas: hospital pharmacy management; strengthening of communication, information and education on medicine to the community; and standardization quality control and utilization of herbal medicine. The upgrading of such capabilities will also permit the establishment of

regional training centres in good manufacturing practice, drug information, drug evaluation and laboratory quality control.

(b) In the implementation of the training programme activity on drug management at the peripheral levels, only the organization of group training, as well as fellowships within the region, is planned. This is the first step towards reliance on ASEAN capabilities in those fields, reflecting partially the results of earlier technical cooperation activities in phases I and II of the project.

(c) Hospital pharmacy management, both in the urban and rural areas, will be improved thus contributing to a better level of patient care. A manual of good hospital pharmacy practice and management (GHPPM) will be established and disseminated, in which areas of responsibility of the hospital pharmacy are clearly defined, including new areas presently being developed, e.g. intravenous additives, etc. Basic facility requirements for hospital pharmacies will be included.

(d) Strengthening of drug management at the peripheral levels will directly improve the supply of essential drugs used in primary health care. A manual will also demarcate the areas of responsibility of various staff as well as indicate the requirements for an effective system.

(e) The public education programme on drugs and drug information for health personnel will be improved in furtherance of the objective of the rational use of drugs.

(f) The formulation of monographs laying down standard specifications and quality control procedures for medicinal plants, as well as the exchange of herbal materials used for reference purposes, will strengthen the efforts of countries in the field of quality assurance for herbal medicine. A manual on identification and proper use of herbal medicines for use by health workers at the rural level will be prepared and disseminated. Local cultivation of medicinal plants and also production and utilization of herbal medicines will be promoted.

(g) Expertise will be obtained in the establishment of, or the improvement in operating, drug information services, which are critical to effective drug management and control at the national level.

(h) The establishment of the five regional training centres, with their output of trained manpower in specific fields, will contribute to the effectiveness of all the country programmes covering drug management and control, drug evaluation, drug quality control and drug utilization, and will demonstrate the region's capability in regional self-reliance.

The specific outputs are as follows:

In relation to objective (a)

1. Cadre of trained hospital pharmacists in each ASEAN country
2. 5 to 30 middle level trained hospital pharmacists in each ASEAN country
3. Guidelines in good pharmacy practices

In relation to objective (b)

1. Manual of work procedures for drug supply management at the peripheral level.
2. Several specialist trainers in each ASEAN country except Singapore in peripheral drug supply management.

In relation to objective (c)

1. Information material including video tapes on proper use of medicine.
2. Concrete recommendations on effective means, methods and materials for public education programmes for ASEAN countries
3. A few specialists in each ASEAN country in communication, information and education on medicine to the community.

In relation to objective (d)

1. A list of commonly used medicinal plants and herbal medicines.
2. Standardization monographs of commonly used medicinal plants and herbal medicines.
3. Reference herbal materials (herbaria) from which commonly used herbal medicines are derived.
4. Trained personnel in ASEAN countries for the identification quality control of herbal medicines.

In relation to objective (e)

1. Manual on cultivation, production and utilization of commonly used herbal medicines.
2. 2 trainers each in Indonesia, Philippines and Thailand in the cultivation and use of medicinal plants.
3. 30 trained persons each in Indonesia, Philippines and Thailand for the promotion of cultivation and use of medicinal plants.

In relation to objective (f)

1. Essential drug information manual for ASEAN countries for use by health providers.

In relation to objective (g)

1. A cadre of national specialists in ASEAN countries in the areas of GMP, drug information, drug evaluation, laboratory quality control and the production and utilization of reference substances.
2. National agencies with expertise necessary for training personnel in their respective areas.

F. Activities

The major activity components of the project are:

1. Development of hospital pharmacy management (coordinated by Thailand), detailed in Annex 2, pages 32-50.
2. Training programme for drug management at the peripheral level (coordinated by Malaysia), detailed in Annex 3, pages 51-68.
3. Strengthening of communication, information and education on medicine to the community (coordinated by Singapore), detailed in Annex 4, pages 69-88.
4. Standardization, quality control and utilization of herbal medicine in ASEAN countries (coordinated by Indonesia, co-coordinated by Thailand), detailed in Annex 5, pages 89-120.
5. Formulation of an essential drug information manual (coordinated by Brunei Darussalam), detailed in Annex 6, pages 121-136.
6. Establishment of a regional training centre for good manufacturing practices (GMP) at the Directorate General of Drug and Food Control, Ministry of Health, Jakarta, detailed in Annex 7, pages 137-156.
7. Establishment of a Regional Training Centre for Drug Information at the Directorate General of Drug and Food Control, Ministry of Health, Jakarta, detailed in Annex 8, pages 157-176.
8. Establishment of a Regional Training Centre on Drug Evaluation at the Bureau of Food and Drugs, Ministry of Health, Manila, detailed in Annex 9, pages 177-194.
9. Establishment of a Regional Training Centre for Laboratory Quality Control at the National Pharmaceutical Control Laboratory, Ministry of Health, Petaling Jaya, Malaysia, detailed in Annex 10, pages 195-214.
10. Establishment of a Regional Training Centre for the Production and Utilization of Regional Standards and Reference Substances at the Department of Medical Sciences, Ministry of Public Health, Bangkok, detailed in Annex 11, pages 215-236.

G. Inputs

i) Government Input

As practised during phases I and II of the project, each country will assume responsibility for the coordination of the implementation of one or more areas of TCDC in pharmaceuticals and/or for the establishment of regional training centres. Designated national agencies of ASEAN countries will coordinate and implement the activities in the programme or establish and operationalize the regional training centres. Staff from responsible national agencies involved in training activities either from within or outside the training centres, the facilities for each training, and the maintenance of such centres will form government inputs. The governments will review and select suitably qualified candidates for fellowships and receive trainees from other ASEAN countries, where appropriate.

ii) UNDP Inputs

UNDP inputs will provide the funds for short-term consultants, temporary advisers, fellowships, workshops, meetings, equipment, printing of documents etc. The budget for the period 1987 - 1991 amounts to US \$ 1,200,000

The UNDP inputs, for each planned output towards achievement of the objectives indicated, are as follows:

Objective (a)

Output:

1. Fellowships outside ASEAN in hospital pharmacy and management (6 m/m)
2. Group training at the national level for hospital pharmacists (240 m/2 wks)
3.
 - a. Experts to draft guidelines on good pharmacy practices (1 m/m)
 - b. Meeting to review and adopt the guidelines (6 m/5 days)
 - c. Publication materials for the guidelines

Objective (b)

Output:

1.
 - a. Experts to prepare manual of work procedures for drug supply management at the peripheral level (3.5 m/m)
 - b. Meeting to review and adopt the manual (6 m/3 days)
 - c. Publication materials for the manual
2. Training workshops on drug management at the peripheral level (30 m/5 days)

Objective (c)

Output:

1. a. Experts to aid in the preparation of information materials (2 m/m)
b. Equipment and materials needed to produce videotapes, slides, posters, etc.
2. Workshop on communication, information and education on medicines in the community (6 m/3 days)
3. Fellowships within and outside ASEAN countries in the field of communication, information and education on medicines in the community (12 m/m)

Objective (d)

Output:

1. Experts to identify and categorize commonly used medicinal plants and herbal medicines (4 m/2m)
2. a. Subcontract for preparation of draft standardization monographs
b. Meeting to evaluate and adopt standardization monographs (18 m/2 wks)
c. Equipment for preparation of monographs
3. a. Subcontract to prepare reference herbal materials
b. Meetings to evaluate and adopt reference herbal materials (together with the monographs, 18 m/2 wks)
c. Supplies for the preparation of reference herbal materials
4. Fellowships within and outside ASEAN countries in fields pertaining to quality control of herbal medicines (18 m/m)

Objective (e)

Output:

1. a. Experts to prepare the manual on cultivation, production and utilization of medicinal plants and herbal medicines (3 m/m)
b. Group training to evaluate and adopt the manual and to train trainers in its use (6 m/m)
c. Supplies for the printing of the manual
2. a. Fellowships inside and outside ASEAN countries in cultivation and utilization of medicinal plants (4 m/m)
b. Group training mentioned in (1.b.) above
3. Local costs for national level training.

Objective (f)

Output:

1. a. Experts to design the format and prepare the skeleton of drug information manual (2 m/m)
- b. Workshop to adopt the design format and skeleton of the manual including drugs to be covered (6 m/4 days)
- c. Experts to finalize the draft manual (5m)
- d. Workshop to study and adopt the draft manual (12 m/2 wks)
- e. Meeting to review field trial and finalize the manual (12 m/week)
- f. Supplies for printing of the manual for field trials and final distribution to each ASEAN country

Objective (g)

Output:

1. a. Group training courses in the areas of GMP, drug information, drug evaluation, laboratory quality control and reference substances (total duration: 246 m/wks)
- b. Experts to assist in the preparation and training activities (29 m/m)
- c. Supplies for preparation of course materials
2. a. Fellowships outside ASEAN countries to refresh trainers in their knowledge and skills (10 m/m)
- b. Seminar to review drug evaluation guidelines to be used for the training (6 m/3 days)
- c. Equipment and supplies for strengthening the teaching capability

iii) WHO inputs

As executing agency, WHO inputs will be as follows:

(a) collaborates in coordinating and providing administrative facilities for the implementation of the programme;

(b) collaborates in selecting competent consultants as and when required; and

(c) where extra budgetary resources are required, collaborates in coordinating and implementing the various activities, mobilize funds and provide WHO technical staff for undertaking specific country studies, preparing background documentation or providing resource persons.

H. Preparation of Work Plan

The work plans as proposed in Annexes 2 to 11 and showing also the budgetary implications were discussed and endorsed by the ASEAN delegates at the Sixth Meeting on Technical Cooperation on Pharmaceuticals, held in Jakarta in December 1985. A more detailed work plan will be jointly prepared by the executing agency and the coordinating ASEAN country at the start of the project and brought forward periodically.

I. Preparation of the Framework for the Effective Participation of National and International Staff in the Project

The activities to be undertaken to achieve the immediate objectives of the project will be carried out jointly or singly by the member countries of ASEAN under the auspices of the WHO Secretariat and with the financial support of UNDP. The respective roles of each country and the national and international staff assigned to carry out activities are indicated in the work plan. The respective roles of the national and international staff shall be in accordance with the established concept and specific purpose of technical cooperation.

J. Development Support Communication

Not applicable

K. Institutional Framework

The activities will primarily involve the departments dealing in drug control administration in the ministries of health and also in some countries in the relevant departments responsible for drug analysis.

The coordination required between the executing agency and the national agencies will be assured through a system of designated national coordinators in each ASEAN country responsible for the implementation of the particular activity components assigned to the ASEAN Member State.

Since the activities concern the countries of two WHO regions, the project will be administered by the WHO Regional Office for the Western Pacific, Manila, in collaboration with the WHO Regional Office for South-East Asia, New Delhi.

L. Prior Obligations and Prerequisites

Not applicable

M. Future UNDP Assistance

With a view to achieving a new higher level of existing objectives, a higher level of institutional capacity for the regional training centres and also to implementing related new activities consonant with the development objectives of the project, proposals for a successor phase of the project for UNDP funding will be forwarded after the Terminal Tripartite review.

PART III. SCHEDULE OF MONITORING, EVALUATION AND REPORTS

A. The project will be subject to periodic review in accordance with the policies and procedures established by UNDP for the monitoring of project and programme implementation.

B. This project will be subject to evaluation in accordance with the policies and procedures established for this purpose by UNDP. The organization, terms of reference and timing of the evaluation will be decided by consultation between the governments, UNDP and the executing agency concerned. It is anticipated that a joint evaluation will be undertaken in mid-1988.

C. Six monthly progress reports will be produced by the executing agency for submission to UNDP. A terminal report will be produced for the Terminal Tripartite Review in November 1991.

PART IV. BUDGETS

The project budget covering UNDP contribution totalling US\$1,200,000 is presented below:

Budgets for the individual activities are contained in Annexes 2 to 11. A table containing the project budget covering all activities (activities versus year) is given in Annex 13.

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating countries: BRUNEI DARUSSALAM, INDONESIA, MALAYSIA, PHILIPPINES, SINGAPORE, THAILAND

Project: Technical cooperation in pharmaceuticals among ASEAN countries

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
	11-60 Consultants	83 1/2	252 400	17 1/2	70 400	15 1/2	57 625	17 1/2	50 375	15	30 000	18	44 000
	11-99 Sub-total												
19	Component total	83 1/2	252 400	17 1/2	70 400	15 1/2	57 625	17 1/2	50 375	15	30 000	18	44 000
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
	21 Sub-contracts	12 000				6 000		3 000		3 000			
29	Component total	12 000				6 000		3 000		3 000			

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	272 200	174 900	53 500	31 000	6 400	6 400
32	Group training	432 480	8 800	67 200	130 280	114 800	111 400
33	Inservice training	35 000	-	-	-	13 000	22 000
39	Component total	739 680	183 700	120 700	161 280	134 200	139 800
40	<u>Equipment</u>						
41	Expendable equipment	57 000		-	28 000	18 000	11 000
42	Nonexpendable equipment	105 920	86 920	1 000	12 000	6 000	
49	Component total	162 920	86 920	1 000	40 000	24 000	11 000
50	<u>Miscellaneous</u>						
51	Miscellaneous	-	-	-	-	-	-
53	Sundry	33 000	-	13 000	18 000		2 000
59	Component total	33 000		13 000	18 000	-	2 000
99	<u>Project total</u>	1 200 000	341 020	198 325	272 655	191 200	196 800

ANNEX 1

MATRIX FOR WORKPLAN

Immediate objectives

<u>Project elements</u>	<u>Success criteria</u>	<u>Verifiers</u>	<u>External factors</u>
(a) To upgrade capabilities within the region in the field of hospital pharmacy management	<p>This objective will be considered successfully carried out if:</p> <p>(1) technical staff the hospital pharmacies have acquired improved knowledge and skills to deliver their services more efficiently;</p> <p>(2) appropriate guidelines/manuals to this end have been prepared and utilized; and</p> <p>(3) as a result of the above, hospital pharmacy practices and management have been improved.</p>	<p>With regard the to supervisor's report would be the verifier since the trainee's having improved their knowledge and skills could be evaluated by their supervisors</p> <p>(2) could be verified by the existence of the product (guidelines), an evaluation by an external expert of the technical content of the product and the supervisor's report on the extent to which the product is utilized. With regard to (3), periodic accomplishment reports of the hospital pharmacies indicating improvements in the range of services provided as well as a comparative survey of patient's compliance will be the verifiers where baseline data are available</p>	<p>(a) Change of policy brought about by change of government resulting in change in national priorities.</p> <p>(b) Availability of external collaboration in fellowship training and technical advice.</p> <p>(c) Change of national counterparts due to transfer, promotion or separation.</p> <p>(d) General socio-economic conditions.</p>
(b) To upgrade capabilities within the region in the field of drug management at the peripheral level	<p>This objective will be considered successfully carried out if:</p> <p>(1) staff of health centres and subcentres have acquired improved knowledge and skills</p>	<p>With regard to (1), supervisor's report would be the verifier. (2) can be verified by the existence of the product (manual), an</p>	<p>Except (b), all the external factors that apply to the preceding objective will also apply to objective (b).</p>

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to optimize drug distribution system; (2) an appropriate manual of work procedures to this end has been formulated and utilized; (3) as a result of the above, storage, distribution and quality assurance of drugs at the peripheral level have been improved

evaluation of the product by an external expert and by the supervisor's report on the extent to which the product is utilized. With respect to (3), the verifier would be a comparative survey on deterioration or loss of drugs due to poor storage and handling and distribution coverage in relation to manpower and if baseline data are available

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|---|--|---|---|
| (c) To strengthen communication, information and education on drugs to the community with the aim of rationalizing drug use | This objective will be considered successfully carried out if:
(1) the means, methods and materials for effective public education programmes have been determined;
(2) materials for public education programmes have been prepared; and (3), improved knowledge and skills have been acquired by the national staff about effective public education on drugs. | With regard to (1), the report of the workshop planned for 1990 will be the verifier. (2) can be verified by the information materials to be produced by the project in 1989. In respect to (3), the verifier would be the availability of plans of work and supervisor's report as the knowledge acquired by national staff through this activity will enable drug control agencies to draw up a public education plan and the staff's initiative would be reflected in the supervisor's report. | The same external factors as for objective (a) will apply |
| (d) To strengthen the quality assurance system covering herbal medicine through standardization and common quality control procedures | This objective will be considered successfully carried out if:
(1) commonly used medicinal plants and herbal medicines in ASEAN countries have been identified;
(2) standard specifications | With regard to (1) and (2), the existence of the product (monograph) that will appear as a report will be the verifier. With regard to (3), the herbal materials to be prepared will be the | The same external factors as for objective (a) will apply |

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and common quality control procedures for these plants and herbal medicines have been worked out; (3) reference herbal materials have been prepared and exchanged among ASEAN countries; (4) technical staff of quality control laboratories have acquired improved knowledge and skills to check the identity and quality of herbal medicines and medicinal plants. (5) as a result of the above, these monographs have been adopted by ASEAN countries as a common basis for quality assurance of herbal medicines.

verifier. With regard to (4), the supervisor's report on the performance of the trained staff as well as the periodic accomplishment report of the laboratory will be the verifier. (5) can be verified by the report from ASEAN coordinators

(e) To promote the cultivation, production and utilization of medicinal plants

This objective will be considered successfully carried out if:
(1) an appropriate manual on cultivation, production and utilization of commonly used herbal medicines has been prepared and used;
(2) cultivation and use of medicinal plants have been promoted particularly in pilot areas.

With regard to (1), the verifier will be existence of the product and its evaluation by an external expert.
(2) could be verified by the report of the pilot project indicating the scope of cultivation and utilization of medicinal plants in the area. A national survey could verify same on a broader scale.

The same external factors as for objective (a) will apply.

(f) To formulate an essential drug information manual for use by health providers thereby promoting wider acceptance of the essential drug concept

This objective will be considered successfully carried out if:
(1) a manual has been formulated which contains complete information on essential drugs; (2) the manual has been accepted by health authorities and health providers as a guide to the rational use of drugs.

With regard to (1), the manual itself and its content will be the verifier. In respect to (2), reports on field trials as well as information obtained from various health centres can be the verifier.

The same external factors as for objective (1) will apply.

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(g) To establish regional training centres for:	This objective will be considered successfully carried out if:	The verifiers will be the following: (1) the supervisor's report reflecting the trainee's knowledge in his field of speciality;	The same external factors as for objective (a) will apply
(a) good manufacturing practices (GMP)	(1) key personnel of national drug regulatory agencies have adequately been trained in the use of GMP guidelines/manuals;	(2) the teaching materials developed;	
(b) drug information	(2) key personnel of national drug regulatory agencies have been trained in the organization and function of drug information centres;	(3) report of the centres on the training conducted.	
(c) drug evaluation	(3) key personnel of national drug regulatory agencies has adequately been trained in drug evaluation procedures;		
(d) laboratory quality control	(4) key personnel of national quality control laboratories has been adequately trained in testing procedures and maintenance of equipment;		
(e) production and utilization of reference substances	(5) specialized national staff have acquired expertise in the production and utilization of chemical and microbiological reference substances; and (6) the centres have acquired expertise necessary for training personnel in their respective areas including the development of teaching materials.		

Outputs

<u>In relation to objective (a):</u>	(1) Pharmacists from core hospitals of ASEAN countries have improved their knowledge and skills for the management of hospital pharmacy	(1) Fellowship termination report to be prepared by the trainees and the report on the group training planned for 1989 as well as the hospital director's	As in the IMMEDIATE OBJECTIVES
(1) Cadre of trained hospital pharmacists in each ASEAN country.			

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(2) 5 to 30 middle level trained hospital pharmacists in each ASEAN country	(2) 5 to 30 middle level hospital pharmacy staff have been well trained to perform their duties more efficiently in each of the ASEAN countries.	report on the management of the pharmacy.
(3) Guidelines in good pharmacy practices	(3) Useful guidelines on hospital pharmacy practices have been formulated and printed.	(2) Supervisor's report on the trainee's performance
		(3) Evaluation by an external expert of the technical content of the guidelines and the pharmacy director's report on the extent to which guidelines are being utilized.

In relation to objective (b):

(1) Manual of work procedures for drug supply management at the peripheral level.

(2) Several specialist trainers in each ASEAN country except Singapore in peripheral drug supply management

(1) Useful manuals on drug supply management at the peripheral level have been formulated and printed.

(2) Several trainers have been adequately trained in all aspects of peripheral drug management from each ASEAN country except Singapore so that they can train other staff in proper handling of drugs at the periphery.

(1) Evaluation by an external expert of the technical content of the manual and the report by the directors of health centres or sub-centres on the extent to which the manual is utilized.

(2) If baseline data are available, a comparable survey on drug wastage before and after the training of trainers and the report by the national project coordinator on national training the programmes utilizing trainer's expertise.

As in the IMMEDIATE OBJECTIVES.

In relation to objective (c):

(1) Information material including video tapes on proper use of medicine.

(2) Concrete recommendations on effective means, methods and materials for public education programmes for ASEAN countries.

(1) Useful slides, video tapes, posters and other information material on proper use of medicine have been produced and distributed to ASEAN countries

(2) Practical recommendations for the formulation of public education programmes for ASEAN countries have been worked out and put into practice.

(1) The education materials produced as well as the evaluation by an external expert of these will be the verifier.

(2) Workshop report expected in 1990 with recommendations as well as national project coordinator's report on the use of this will be the verifier.

As in the IMMEDIATE OBJECTIVES.

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(3) A few specialists in each ASEAN country in communication, information and education on medicine to the community.

(3) A few specialists in each ASEAN country have been trained adequately in the art of public education on proper use of medicine.

(3) Fellowship termination report and the trainee's supervisor's report will be the verifier.

In relation to objective (d):

(1) A list of commonly used medicinal plants and herbal medicines.

(1) A reasonable number of commonly used medicinal plants and herbal medicines have been identified.

(1) Consultant's report As in the IMMEDIATE to be prepared in 1987. OBJECTIVE.

(2) Standardization monographs of commonly used medicinal plants and herbal medicines.

(2) Monographs giving specifications and test methods of commonly used medicinal plants and herbal medicines have been prepared and utilized in quality control laboratories of ASEAN countries.

(2) Standardization monographs to be prepared and adopted by 1990 and national project coordinator's report on the use of these monographs.

(3) Reference herbal materials (herbaria) from which commonly used herbal medicines are derived.

(3) Reference herbal materials have been prepared and exchanged among ASEAN countries.

(3) Report on reference herbal materials prepared and adopted, expected by 1991, and project coordinator's report on the exchange of these materials among ASEAN countries.

(4) Trained personnel in ASEAN countries for the identification quality control of herbal medicines.

(4) A few specialists in each ASEAN country have been trained adequately in taxonomy, phytochemistry and other disciplines used for the quality control of medicinal plants and herbal medicines.

(4) Fellowship termination report and report on group training as well as their supervisor's report.

In relation to objective (e):

(1) Manual on cultivation, production and utilization of commonly used herbal medicines.

(1) A practical manual on the cultivation, production and utilization of commonly used herbal medicines have been prepared and utilized.

(1) The manual itself and its evaluation by external experts would be the verifier. The report on national in-service training would verify the use of the manual.

As in the IMMEDIATE OBJECTIVES.

(2) 2 specialists each from Indonesia, Philippines and

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(2) 2 trainers each in Indonesia, Philippines and Thailand in the cultivation and use of medicinal plants.

(3) 30 trained persons each in Indonesia, Philippines and Thailand for the promotion of cultivation and use of medicinal plants.

Thailand have been adequately trained all important aspects of the cultivation, production and utilization of medicinal plants to be able to teach these techniques to others at the country level.

(3) 30 persons in each of the three countries have acquired sufficient knowledge to promote cultivation and utilization of medicinal plants in pilot areas.

(2) The report on the training course planned for 1990 as well as the report of the national in-service training planned for 1991 would be the verifier of output (2).

(3) The report of the national in-service training planned for 1991 would be the verifier.

In relation to objective (f):

(1) Essential drug information manual for ASEAN countries for use by health providers.

(1) A manual containing complete and unbiased information on drugs has been prepared, field-tested and adopted by ASEAN countries.

(1) The verifier will be the report of the workshop planned for 1991 to finalize the manual and the evaluation of the manual, if needed, by an external expert.

As in the IMMEDIATE OBJECTIVE.

In relation to objective (g):

(1) A cadre of national specialists in ASEAN countries in the areas of GMP, drug information, drug evaluation, laboratory quality control and the production and utilization of reference substances.

(2) National agencies with expertise necessary for training personnel in their respective areas.

(1) Several specialists have been adequately trained in each ASEAN country in the five disciplines to be able to play a leading role in their respective countries.

(2) The national agencies designated as the training centre in each respective area have acquired necessary expertise and capability of conducting training course in their own country, and, if needed, for trainees from other ASEAN countries.

(1) The verifier will be the supervisor's report reflecting the expertise acquired by the trainees and the report of the centres on the training given. As in the IMMEDIATE OBJECTIVE.

(2) A survey after completion of the project would be needed to verify that the national agencies have actually acquired the capability of conducting training in their specific disciplines.

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Inputs

Objective (a):

Output (1)

Fellowships outside ASEAN in hospital pharmacy and management (6 m/m)	(1) Placement of the fellows are timely, and the programmes are correlated to the fellows' needs.	(1) Fellowship terminal reports	Same as IMMEDIATE OBJECTIVES.
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Output (2)

Group training at the national level for hospital pharmacists (240 m/2 wks)	(2) Objectives and expected outcome of the courses are clearly established; logistics are set ahead of time.	(2) Working documents for the courses and organizer's reports on the courses
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Output (3)

(a) Experts to draft guidelines on good pharmacy practices (1 m/m)	(3) (a) The expert has experience of undertaking similar assignments and shows a good sense of judgement.	(3) (a) Personal history of the candidate and his assignment report.
(b) Meeting to review and adopt the guidelines (6 m/5 days)	(b) Objectives and expected outcome of the meeting are clearly established: logistics are set ahead of time.	(b) Working documents for the meeting and organizer's report on the meeting.
(c) Publication materials for the guidelines	(c) Materials are sufficient in amount, available on time and appropriate for the designated purpose.	(c) Reports/comments by the party using the materials.

Objective (b):

Output (1)

(a) Experts to prepare manual of work procedures for drug supply management at the peripheral level (3.5 m/m)	(1) (a) the Experts have extensive experience of undertaking similar assignments and show a good sense of group cooperation.	(1) a) Personal history of the candidates and their assignment reports. (b) Working documents for the meeting and organizer's
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| (b) Meeting to review and adopt the manual (6 m/3 days) | (b) Objectives and expected outcome of the meeting are clearly established; logistics are set ahead of time | report on the meeting. |
| (c) Publication materials for the manual | (c) The materials are sufficient in amount, available in time and appropriate for the designated purpose. | (c) Reports/comments by the party using the materials. |

Output (2)

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|---|---|--|
| Training workshops on drug management at the peripheral level (30 m/5 days) | (2) Objectives and expected outcome of each workshop are clearly established; logistics are well organized ahead of time. | (2) Training materials for the workshops and organizer's reports on the workshops. |
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Objective (c):

Output (1)

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|---|---|--|
| (a) Experts to aid in the preparation of information materials (2 m/m) | (1) (a) The experts have substantial experience of similar assignments and show a good sense of creativity. | (1) (a) Personal history of the candidates and their assignment reports. |
| (b) Equipment and materials needed to produce videotapes, slides, posters, etc. | (b) The equipment and materials are properly chosen and available on time. | (b) Reports/comments by the party using the equipment. |

Output (2)

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|---|---|--|
| Workshop on communication, information and education on medicines in the community (6 m/3 days) | (2) Objectives and expected outcome of the workshop are clearly established; logistics are set ahead of time. | (2) Working documents for the workshop and organizer's report on the workshop. |
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Output (3)

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|--|--|-------------------------------------|
| Fellowships within and outside ASEAN countries in the field of communication, information and education on medicines in the community (12 m/m) | (3) Placement of the fellows is timely, and the programmes are correlated to the fellows' needs. | (3) Fellowship termination reports. |
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Objective (d):

Output (1)

Experts to identify and categorize commonly used medicinal plants and herbal medicines (4 m/2m)	(1) The experts have substantial experience of similar assignment and show a good sense of judgement.	(1) Personal history and their assignment reports.	Same as IMMEDIATE OBJECTIVES.
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Output (2)

(a) Subcontract for preparation of draft standardization monographs	(2) (a) Subcontractors are qualified for the task and efficient in producing draft monographs.	(2) (a) Personal history of the contractors and the draft monographs produced by them.
(b) Meeting to evaluate and adopt draft standardization monographs (18 m/2 wks)	(b) Objectives and logistics of the meeting are clear cut and catered to the standard of the participants' expertise.	(b) Working documents for the meeting and the report of the meeting.
(c) Equipment for preparation of monographs	(c) The equipment is delivered on time in good condition.	(c) Reports/comments by the party using the equipment.

Output 3

(a) Subcontract to prepare reference herbal materials.	(3) (a) Subcontractors are qualified for the task and efficient in collecting and preparing reference herbal materials.	(3) (a) Herbal materials prepared and the report of the meeting.
(b) Meetings to evaluate and adopt reference herbal materials (together with the monographs, 18 m/2 wks)	(b) Objectives and expected outcome of the meetings are clear and logistics are set well ahead of time.	(b) Working documents for the meeting and organizer's report on the meeting.
(c) Supplies for the preparation of reference herbal materials.	(c) The materials are procured on time and in good condition.	(c) Reports/comments by the party using the materials.

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Output (4)

Fellowships within and outside ASEAN countries in fields pertaining to quality control of herbal medicines (18 m/m)	(4) Placement of the fellows are timely, and the programmes are correlated to the fellows' needs.	(4) Fellowship terminal reports and the organizer's report in the case of placement in ASEAN countries
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Objective (e):

Output (1)

(a) Experts to prepare the manual on cultivation, production and utilization of medicinal plants and herbal medicines (3 m/m)	(1) (a) The experts are qualified for the task and efficient in preparing the manual.	(1) (a) Personal history of candidates and the manual to be prepared by them.
(b) Group training to evaluate and adopt the manual and to train trainers in its use (6 m/m)	(b) Objectives and expected outcome are clearly identified and logistics are set well in advance. The participants are properly selected.	(b) Organizer's report on the group training.
(c) Supplies for the printing of the manual	(c) The supplies are received on time in good condition.	(c) Reports/comments by the party using the manual.

Output (2)

(a) Fellowships inside and outside ASEAN countries in cultivation and utilization of medicinal plants (4 m/m)	(2) (a) The placement is made without delay and the programme meets the fellows' needs.	(2) (a) Fellowship termination reports.
(b) Group training mentioned in b) above		

Output (3)

Local costs for national level training.	(3) Funds are released without delay based on adequate planning.	(3) The plan from the national organizer and the report on the national in-service training course.
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Objective (f):

Output (1)

a) Experts to design the format and prepare the skeleton of drug information manual (2 m/m)	(1) (a) The experts are qualified for the task and available when required.	(1) (a) Personal history of the candidates and their assignment report.	Same as IMMEDIATE OBJECTIVES.
b) Workshop to adopt the design format and skeleton of the manual including drugs to be covered (6 m/4 days)	(b) Objectives and expected outcome of the workshop are clearly defined; logistics set well in advance.	b) Report of the workshop.	
c) Experts to finalize the draft manual (5m)	(c) The experts are well informed of the current situation in ASEAN countries as well as the shop pharmacological nature of drugs.	(c) Personal history of the candidates and their assignment report including the draft manual.	
d) Workshop to study and adopt the draft manual (12 m/2 wks)	(d) Planning is done on clearly defined objectives; logistics are set well in advance. Participants are selected to effectively meet the objectives.	(d) Report of the workshop.	
e) Meeting to review field trial and finalize the manual (12 m/week)	(e) Planning is based on clearly defined objectives; logistics are set well in advance and the participants are selected to ensure the wide acceptance of the manual in each ASEAN country.	(e) Report of the meeting.	
f) Supplies for printing of the manual for field trials and final distribution to each SEAN country.	(f) the supplies are received on time in good condition.	(f) Reports/comments by the party using the manual.	

Objective (g):

Output (1)

a) Group training courses in the areas of GMP, drug information, drug evaluation,	(1) (a) The courses are planned on clearly defined objectives, organized as planned and attended by	(1) (a) Organizer's reports and the reports or comments by the participants.	Same as IMMEDIATE OBJECTIVES.
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laboratory quality control and reference substances (total duration: 246 m/wks)

appropriate national staff

(b) The experts, both international and local, are qualified for the task and show a good sense of cooperation.

(b) The personal history of the candidate and his assignment report as well as the organizer's report on the training course.

(b) Experts to assist in the preparation and training activities (29 m/m)

(c) The supplies are received on time and in good condition.

(c) Reports/comments of the party using the supplies.

(c) Supplies for preparation of course materials

Output 2

(a) Fellowships outside ASEAN countries to refresh trainers in their knowledge and skills (10 m/m)

(2) (a) Fellows are placed as scheduled and the programmes are suitable for fellows' needs.

(2) (a) Fellowship termination reports.

(b) Seminar to review drug evaluation guidelines to be used for the training (6 m/3 days)

(b) The updated guidelines are suitable for use in training in drug evaluation in ASEAN countries.

(b) Reports/comments by the trainees on the experience of using these guidelines.

(c) Equipment and supplies for strengthening the teaching capability.

(c) The equipment and supplies are received on time in good condition.

(c) Comments of the users as reflected in the training centres' reports.

ACTIVITY: DEVELOPMENT OF HOSPITAL PHARMACY MANAGEMENT COORDINATED BY THAILAND

1. BACKGROUND/JUSTIFICATION

1.1 The role of hospital pharmacy

The hospital pharmacy and its services play an integral role in the delivery of medical care by the hospital. In rural hospitals, there have also been successful country experiences in the integration of preventive health programmes with additional responsibilities for pharmacy in drug supply management.

1.2 Functions of the hospital pharmacy

The practice of pharmacy in hospitals at all levels continues to undergo evolutionary changes to become more responsible for assuring appropriate functioning by the hospital. In general, the following functions are undertaken:

- (a) effective and efficient management of the Department;
- (b) provision of drug information;
- (c) management of product formulation and packaging;
- (d) drug supply management;
- (e) patient-oriented service, e.g. patient counselling;
- (f) quality assurance programme; and
- (g) educational activities;

1.3 Aspects of hospital pharmacy

Two major aspects of hospital pharmacy management are professional and the administrative aspects.

1.3.1 Professional aspect

In the professional field, it is clear that the person responsible for the management of the pharmacy department should be a professionally qualified pharmacist. However, the paramedical supportive staff utilized in such departments vary in countries from trained assistant pharmacists, dispensing or pharmacy assistants to nurses' aides or attendants. Moreover, in some very small rural hospitals, no pharmacists are posted, and pharmacies in such hospitals are managed by untrained staff supervised by the doctor in charge of the hospital. Whilst such staffing practices may be the result of a national policy on manpower production and

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utilization, nevertheless it is fully recognized that for an effective and efficient basic pharmacy service, trained and experienced manpower is of utmost importance. In the hospital in the urban setting, with the development in some countries of more specialized pharmacy services, e.g. patient counselling, intravenous additive programme, parenteral nutrition solution preparation and individualized inpatient dispensing, the interaction between the pharmacy and the other medical staff requires that the management of a hospital pharmacy should be in capable professional hands. Hospital pharmacy practice is now universally recognized as a definite specialized discipline in the pharmacy curriculum in teaching institutions both in developed as well as in developing countries.

1.3.2 Administrative aspect

On the administrative aspect, because the hospital pharmacy in some ASEAN countries is concerned with the medical supply management function, the department is loaded with the management of surgical and other hospital supplies. In such cases, the professionally trained pharmacist has to devote a considerable portion of his time to supply management duties which are not directly related to his training. The use of full-time supply officers to assist the pharmacist in supply management has been found effective in some country situations. Where computerization is being considered both in the hospital drug store as well as in the wards, supportive computer staff are required. The need for a more efficient method of collection of charges for drugs has also been a felt need in countries.

1.4 Contribution to patient care

Generally, there are hospitals operating at various levels ranging from the urban, highly specialized hospital delivering tertiary health care to the smaller hospitals outside of the large cities, where only general curative care is provided (in some cases, in addition to preventive health care). In all these situations, there is a felt need for the hospital pharmacy to contribute more effectively to patient care in the ASEAN countries in the following ways:

(a) Define the responsibilities of the pharmacy department and the pharmacist in the delivery of health care to all patients;

(b) Delineate new aspects of pharmacy practices, e.g. unit dose systems and define the professional relationships between the pharmacy and its staff vis-à-vis the other medical staff, as well as its medico-legal implications;

(c) Delineate the area of supply management that should be within the purview of the hospital pharmacist;

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(d) Propose the organizational structure of the pharmacy within the hospital with clearly defined roles and responsibilities consonant with the present development in pharmacy practice and management now taking place at different levels and at different paces in the countries;

(e) Define the responsibilities of the pharmacist and the pharmacy department in hospitals where there is integration of curative and preventive health services;

(f) Propose the necessary basic facilities and procedures required for the discharge of the responsibilities of the hospital pharmacy; and

(g) Propose procedures used in the production of extemporaneous and other pharmaceutical preparations.

The programme activities do not attempt to be a substitute for specialized postgraduate training in hospital pharmacy needed by countries in the region, such training being a national responsibility. With the training of the hospital pharmacy personnel and the development and application of guidelines as stated above, hospital pharmacy management practices and standards will improve thereby contributing to the improvement of the standards of the country's health care delivery. Inservice training courses at the national level will be conducted by local Temporary Advisers for pharmacists serving in hospitals.

2. ACTIVITY OBJECTIVES

The objectives of the activity are as follows:

(a) To improve and strengthen hospital pharmacy practices and management and their development as appropriate and efficient components in health care delivery;

(b) To train technical personnel in hospital pharmacy practices in general, district and peripheral hospitals in order to improve patient compliance and rational utilization of drugs; and

(c) To prepare guidelines/manuals.

Annex 2

3. MAJOR ACTIVITY COMPONENTS

<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i) Fellowship training in hospital pharmacy practices and management	United States of America/	1 month	1987
	Canada United Kingdom/ Nordic Country	1 month	1987
(ii) Preparation of guidelines/manual for good hospital pharmacy practices and management and publication in national languages	Brunei	1 month	1988
	Darussalam Indonesia Malaysia Philippines Singapore Thailand		1989
(iii) Intercountry meeting to review and adopt guidelines/manual	Thailand	5 days	1989
(iv) National level inservice training course for hospital pharmacists	Brunei	2 weeks	1990
	Darussalam Indonesia Malaysia Philippines Singapore Thailand		1991

4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

The activity will enable the development of new pharmacy activities in hospitals, strengthen the management of hospital pharmacies thus directly contributing to a higher standard of patient care. Identification of basic requirements for facilities, operational procedures and manpower for hospital pharmacy will assure a proper development of hospital pharmacy throughout the region within the context of national health development plans and their priorities.

WORKPLAN

Annex 2

Coordinating country : THAILAND

Activity: Development of hospital pharmacy management

Components	1987	1988	1989	1990	1991
1. Consultants					
(1) Field/duration (m/m)		Drafting of guidelines/ manual for good hospital pharmacy practices and management 1 m/m	For meeting to review and adopt guidelines/ manual for good hospital pharmacy practice and management 1 m/m		
(2) Estimated cost		\$ 6 500	\$ 6 500		
2. Temporary advisers					
(1) Field/duration (m/m)		Drafting of guidelines/manual for good hospital pharmacy practices and management 1 m/m	For meeting to review and adopt guidelines/manual for good hospital pharmacy practice and management 1 m/m	Organization and conduct of national level inservice training course 1 country	Organization and conduct of national level inservice training course 1 country
				Total 6 x 3 wks	Total 6 x 3 wks
(2) Estimated cost		\$ 2 000	\$ 2 000	\$ 9 000	\$ 9 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration					
(4) Fellowship countries					
(5) Estimated cost					

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
4. <u>Fellowships</u> (outside of ASEAN)						
(1) Field of study	Hospital pharmacy practices and management					
(2) Place of study	A United States of America/Canada					
	B United Kingdom/Nordic Country					
(3) Duration (man/months)	A 3 m/m					
	B 3 m/m					
(4) Fellowship countries	A 1 each from Indonesia, Philippines, Singapore					
	B 1 each from Brunei Darussalam, Malaysia, Thailand					
(5) Estimated cost	\$51 000					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title			Review and adoption of guidelines/ manual for good hospital practices and management	Training of hospital pharmacists in national inservice training course	Training of hospital pharmacists in national inservice training course
(2) Duration			5 days	2 weeks	2 weeks
(3) Venue			Thailand	each country	each country
(4) Participants/ cost			1 per country/ \$8 280	30 for Indonesia, the Philippines, Thailand 20 for Malaysia 5 for Brunei Darussalam and Singapore	30 for Indonesia, the Philippines, Thailand 20 for Malaysia 5 for Brunei Darussalam and Singapore
(5) Local cost			\$1 000	\$ 3 000 x 3 \$ 2 000 x 1 \$ 1 000 x 2	\$ 3 000 x 3 \$ 2 000 x 1 \$ 1 000 x 2
(6) Estimated cost			\$9 280	\$13 000	\$13 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(a) <u>Expendable equipment</u>					
(1) Description of items			Publication of guidelines/manual for good hospital pharmacy practices and management		
(2) Purpose			For dissemination and application		
(3) Estimated cost			US\$ 1 000 for printing of guidelines US\$12 000 - \$2 000 each country for translation/printing in national/local language		

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(b) <u>Non-expendable equipment</u>					
(1) Description of items					
(2) Purpose					
(3) Estimated cost					
• <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$51 000	\$ 8 500	\$30 780	\$22 000	\$22 000

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: THAILAND

Activity: Development of hospital pharmacy management

		Total		1987		1988		1989		1990		1991	
		m/m	\$	m/m	\$	m/m	\$	m/m	\$	m/m	\$	m/m	\$
10	<u>Project personnel</u>												
	11-60 Consultants	13	35 000			2	8 500	2	8 500	4 1/2	9 000	4 1/2	9 000
19	Component total	13	35 000			2	8 500	2	8 500	4 1/2	9 000	4 1/2	9 000
		Total (\$)		1987		1988		1989		1990		1991	
20	<u>Sub-contract</u>												
	21 Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	51 000	51 000				
32	Group training	9 280			9 280		
33	Inservice training	26 000				13 000	13 000
39	Component total	86 280	51 000		9 280	13 000	13 000
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment						
49	Component total						
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry	13 000			13 000		
59	Component total	13 000			13 000		
	Total for activity	134 280	51 000	8 500	30 780	22 000	22 000

ACTIVITY: TRAINING PROGRAMME FOR DRUG MANAGEMENT AT THE PERIPHERAL LEVEL
COORDINATED BY MALAYSIA

1. BACKGROUND/JUSTIFICATION

1.1 Scope of previous training activities

The activity in Phases I and II on "Training and exchange of expertise in drug supply and management" had as its objective the strengthening of manpower capabilities in drug supply and management in order to optimize and improve the drug distribution system in the ASEAN countries. From the training programme implemented, it is evident that the attachment training for the fellows, both within as well as outside of the ASEAN countries, had been mainly confined to the system of centralized procurement and inventory control at the central medical store level and distribution up to only the state/provincial medical store/general hospital. In this respect, the programme has achieved its objective as can be seen from the reports submitted by the fellows who have undergone such attachment training.

1.2 Problems of drug management at the peripheral level

There still leaves, therefore, a section of the supply chain that has not been covered and, that is, the drug management at the peripheral level. At the peripheral level which cover health centres/health sub-centres, rural and other static clinics where drug stocks are kept,

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drug management and maintenance of vaccine cold chain present even more urgent problems to be looked into and improved upon. A chain is only as strong as its weakest link. So in the case of drug management at the peripheral level, it is found that the weakest link is the storage and distribution at the peripheral level owing to untrained manpower or inappropriate facilities or inoperative logistic systems. The category of staff responsible for drug management at the peripheral level varies substantially among the ASEAN countries, from trained health workers such as nurses, nursing aides, dispensers/pharmacy assistants, storekeepers to primary health care and community workers to even completely untrained staff. There is, therefore, an urgent need to improve drug management at this level through the implementation of an appropriately planned training programme which should take into consideration an efficient supply system ensuring the availability and quality of drugs while at the same time preventing overstocking and wastage. The training will also cover basic requirements for facilities and logistic systems at that level.

2. ACTIVITY OBJECTIVE

This activity is aimed at strengthening the capabilities of ASEAN countries in drug management at the peripheral level covering health centres/health sub-centres, rural and other static clinics where drug stocks are kept in order to optimize and improve drug distribution system, drug availability and drug quality assurance at this level through manpower training and the formulation of manual of work procedures for the supply system.

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3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Preparation of a manual of work procedures for drug supply management at the peripheral level in the ASEAN countries and publication in national languages	Indonesia Malaysia Philippines Thailand	2 months	1987
(ii)	Intercountry meeting to review the manual for publication and distribution to all participating countries	Malaysia	3 days	1988
(iii)	Intercountry training workshop on drug management at the peripheral level	Malaysia	5 days	1989 1990
(iv)	Fellowship in the field of drug management at the peripheral level	Indonesia Malaysia Thailand	2 weeks	1989 1990 1991
(v)	Workshop to review manual of work procedures based on implementation experience at national level	Malaysia	5 days	1991

4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

The activity is closely linked with the objective of sensible management of drug storage and distribution at the peripheral level with its direct bearing on primary health care programmes. In cases where the drugs are handled by manpower not specifically trained for the task, there is a very urgent need to ensure proper storage and distribution, including quality assurance at these levels. The trainees who attend these courses

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can be utilized as trainers on their return. National programmes, whether these refer to the plans for integrated district medical stores or to district pharmaceutical warehouses to serve the rural health units, will be strengthened with additional manpower training.

WORKPLAN

Coordinating country : MALAYSIA

Activity: Training programme for drug management at the peripheral levels

Components	1987	1988	1989	1990	1991
1. <u>Consultants</u>					
(1) Field/duration (m/m)					
(2) Estimated cost					
2. <u>Temporary advisers</u> (local)					
(1) Field/duration m/m	Preparation of a manual of work procedures for supply systems at the peripheral levels 2 m/ m (Malaysia) 3 x 2 wks (Indonesia, Philippines, Thailand)	Organization and conduct of meeting to review the manual of work procedures 1 m/2 weeks	Organization and conduct of a training workshop 1 m/2 weeks	Organization and conduct of a training workshop 1 m/2 weeks	Organization and conduct of a training workshop 1 m/2 weeks
(2) Estimated cost	\$ 7 000	\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. Fellowships (within ASEAN)					
(1) Field of study	Drug management at peripheral levels		Drug management at the peripheral levels	Drug management at the peripheral levels	Drug management at the peripheral levels
(2) Place of study	Indonesia, Philippines, Thailand		Malaysia	Thailand	Indonesia
(3) Duration (man/months)	1m/2 wks		4 m/2 weeks	4 m/2 weeks	4 m/2 weeks
(4) Fellowship countries	Malaysia		1 each from Brunei Darussalam, Indonesia, Philippines, Thailand	1 each from Brunei Darussalam, Indonesia, Malaysia, Philippines	1 each from Brunei Darussalam, Malaysia, Philippines, Thailand
(5) Estimated cost	\$ 2 000		\$ 6 400	\$ 6 400	\$ 6 400
4. Fellowships (outside of ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration (man/months)					
(4) Fellowship countries					
(5) Estimated cost					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title	Meeting to review and adopt a manual of work procedures for supply system at the peripheral levels	Training workshop on drug management at the peripheral levels	Training workshop on drug management at the peripheral levels	Workshop to review manual of work procedures based on implementation experiences at national level	
(2) Duration	3 days	5 days	5 days	5 days	
(3) Venue	Malaysia	Malaysia	Malaysia	Malaysia	
(4) Participants/ cost	1 per country, except Singapore \$ 6 000	2 per country, except Singapore \$ 13 800	2 per country, except Singapore \$ 13 800	2 per country, except Singapore \$ 13 800	
(5) Local cost	\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000	
(6) Estimated cost	\$ 7 000	\$ 14 800	\$ 14 800	\$ 14 800	

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(A) <u>Expendable equipment</u>					
(1) Description of items		Publication of a manual of work procedures for supply systems at the peripheral levels			
(2) Purpose		For dissemination and application			
(3) Estimated cost		\$ 1 000 for printing of guidelines \$10 000 - \$2 000 each country (except Singapore) for translation/ printing in national/local language			

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(B) <u>Non-expendable equipment</u>					
(1) Description of item					
(2) Purpose					
(3) Estimated cost					
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$ 9 000	\$ 19 000	\$ 22 200	\$ 22 200	\$ 22 200

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: MALAYSIA

Activity: Training programme for drug management at the peripheral levels

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
11-60	Consultants	5 1/2	11 000	3 1/2	7 000	1/2	1 000	1/2	1 000	1/2	1 000	1/2	1 000
19	Component total	5 1/2	11 000	3 1/2	7 000	1/2	1 000	1/2	1 000	1/2	1 000	1/2	1 000
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
21	Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	21 200	2 000	-	6 400	6 400	6 400
32	Group training	51 400		7 000	14 800	14 800	14 800
33	Inservice training						
39	Component total	72 600	2 000	7 000	21 200	21 200	21 200
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment						
49	Component total						
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry	11 000		11 000			
59	Component total	11 000		11 000			
	Total for activity	94 600	9 000	19 000	22 200	22 200	22 200

ANNEX 4

ACTIVITY: STRENGTHENING OF COMMUNICATION, INFORMATION AND EDUCATION ON
MEDICINE TO THE COMMUNITY COORDINATED BY SINGAPORE

1. BACKGROUND/JUSTIFICATION

1.1 Importance of public education on drugs

ASEAN countries are making every effort to meet the need of essential drugs in their health care programmes. It is realized that in order to obtain the desired therapeutic effect of medicines supplied, to minimize wastage and to prevent misuse with its possible adverse effects on the patients, there is a need to educate the general public on the rational use of medicines. Member Countries on their own effort have initiated programmes in these areas, the scope and depth of the activity varying from country to country. For example, in some countries, advertisement of over-the-counter drugs in the mass media has to be approved by regulatory bodies prior to publication. Consumer organizations are also active in some countries although most of their efforts have been directed against marketing of certain drugs.

1.2 Scope for self-medication

In all countries, the need for a measure of self-medication by the population is acknowledged as being able to reduce the pressure and demands placed on overloaded health care systems. Public education programmes on

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the utilization of safe and efficacious drugs which can be used in such self-medication are, therefore, important components in national drug policies.

1.3 Consumer protection

Consumer education forms part of the consumer protection process for promoting the rational use of drugs and is also critical in improving patient compliance. Tailoured information may be required for various groups, e.g. the elderly, women, etc. One of the main target groups is the youth group where drug education information properly presented will be a preventive against drug abuse.

1.4 Mass communications

With the increase in literacy rate in the ASEAN countries, there is a need to adopt more modern and sophisticated means of communication in order to achieve effective interactions. The subject of mass communication in the present day context has developed to become a professional course in the universities. It is opportune that ASEAN countries should review and upgrade the educational programmes on medicine planned for patients and the community.

1.5 Multisectoral cooperation

The rapid advancement of medical sciences and the aggressive marketing of many drugs have made rationalization of drug usage a very difficult task for both the health personnel and the national authorities. It has been recognized that "the production of public education programme to foster reasonable expectations concerning the benefits to be derived from the rational use of drugs" could be one of the means of cooperation among ASEAN countries. In this instance, cooperation should be multisectoral in nature and involve not only drug regulatory agencies but the health professions, the pharmaceutical industry and consumer groups as well.

2. ACTIVITY OBJECTIVES

The objectives of the activity is to improve patient compliance in drug therapy and to educate the community on the proper use of medicine by determining the means, methods and materials for effective public education programmes and effectively disseminating such information.

3. MAJOR ACTIVITY COMPONENTS

<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(1) Fellowship training in the communication, information and education on medicine to the community	Brunei Darussalam Indonesia Malaysia	1 month	1987

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	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(ii)	Fellowship training in the communication, information and education on medicine to the community	Philippines Singapore Thailand	1 month	1988
(iii)	Fellowship training in the communication, information and education on medicine to the community	Australia	1 month	1989
(iv)	Preparation of information material including production of video tapes on proper use of medicine	Singapore		1989
(v)	Intercountry workshop on communication, information and education on medicine in the community	Singapore	3 days	1990

4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

The output from these activities will directly contribute to national programmes covering the promotion of rational use of drugs as well and national efforts in countries which are currently revising and upgrading their materials used in public drug education activities. The knowledge and experience gained in fellowship attachment can be used in strengthening and improving current and future national programmes.

WORKPLAN

Coordinating country : SINGAPORE

Activity: Strengthening of communication, information and education on medicine to the community

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
<hr/>					
1. <u>Consultants</u>					
(1) Field/duration m/m	Planning activities on communication, information and education on medicine to the community 1 m/m				
<hr/>					
(2) Estimated cost	\$ 6 000				
<hr/>					
2. <u>Temporary advisers</u>					
(1) Field/duration m/m	To provide technical expertise for the preparation of information material including the production of video tapes on "Proper use of medicine" 1 m/m		For organizing and conducting a workshop on communication information and education on medicine 2 m/2 weeks		
<hr/>					
(2) Estimated cost	\$ 2 000		\$ 2 000		

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study	Communication, information and education on medicine to the community	Communication, information and education on medicine to the community			
(2) Place of study	Brunei Darussalam Indonesia, Malaysia	Singapore, Philippines Thailand			
(3) Duration (man/months)	3 m/1 m	3 m/1 m			
(4) Fellowship countries	1 each from the Philippines, Singapore, Thailand	1 each from Brunei Darussalam, Indonesia, Malaysia			
(5) Estimated cost	\$ 9 600	\$ 9 600			

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
4. <u>Fellowships</u> (outside of ASEAN)					
(1) Field of study			Communication, information and education on medicine to the community		
(2) Place of study			Australia		
(3) Duration (man/months)			2 groups of 3 m/1 m 1/country		
(4) Fellowship countries			All ASEAN countries		
(5) Estimated cost			\$ 24 600		

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title				Workshop on communication, information and education on medicine to the community	
(2) Duration				3 days	
(3) Venue				Singapore	
(4) Participants/ cost				1/country \$ 7 200	
(5) Local cost				\$ 1 000	
(6) Estimated cost				\$ 8 200	

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(a) <u>Expendable equipment</u>					
(1) Description of items		Preparation of information material including the production of video tapes on "Proper use of medicines" for all Member Countries	(a) Material for workshop US\$ 1 000 (b) Preparation of slides, printing of posters and other information materials on "proper use of medicine" for all member countries Printing of materials and posters for all member countries US\$ 10 000		
(2) Purpose		To educate the public on the use of medicine	For dissemination to member countries		
(3) Estimated cost		US\$ 20 000	US\$ 11 000		

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(b) <u>Non-expendable equipment</u>					
(1) Description of items			Slide projector, overhead projector, screen and other communication equipment	Books on public education on medicine for all member countries	
(2) Purpose			Implementation of communication, information and education activities in member countries		
(3) Estimated cost			\$12 000	\$ 6 000	
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$15 600	\$ 9 600	\$58 600	\$ 27 200	

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: SINGAPORE

Activity: Strengthening of communication information and education on medicine in the community

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
	11-60 Consultants	3	10 000	1	6 000			1	2 000	1	2 000		
19	Component total	3	10 000	1	6 000			1	2 000	1	2 000		
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
	21 Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	43 800	9 600	9 600	24 600		
32	Group training	8 200				8 200	
33	Inservice training						
39	Component total	52 000	9 600	9 600	24 600	8 200	
40	<u>Equipment</u>						
41	Expendable equipment	31 000			20 000	11 000	
42	Nonexpendable equipment	18 000			12 000	6 000	
49	Component total	49 000			32 000	17 000	
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	111 000	15 600	9 600	58 600	27 200	

ACTIVITY: STANDARDIZATION, QUALITY CONTROL AND UTILIZATION OF HERBAL
MEDICINE IN ASEAN COUNTRIES COORDINATED BY INDONESIA
CO-COORDINATED BY THAILAND

1. BACKGROUND/JUSTIFICATION

1.1 Increased use of herbal medicine

The use of herbal medicine is increasing in all countries in the region, stimulated by the need to increase health care coverage, the need to utilize local natural resources and, in some cases, a rebound effect from the various reports of various adverse reactions with the use of drugs of chemical origin. Due to ethnic diversity found among the populations in ASEAN countries, there is also diversity in the systems of traditional medicine. In some countries, patients view the various medical systems, including "modern" medicine, as complementary rather than antagonistic and move freely from one to the other in search for relief and cure, more so for those suffering from severe or chronic illness regardless of ethnic origin. There is considerable trade in herbal medicine among the ASEAN countries. Some ASEAN countries have initiated programmes to promote the use of herbal medicines in primary health care.

1.2 Organizational relationships

Four different types of organizational relationships between official allopathic and the traditional health care services have been defined, i.e. the monopolistic, the tolerant, the parallel and the integrated. In the

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ASEAN region, there are countries where the tolerant relationship exists and also those where there are measures taken by governments to introduce certain herbal medicines into organized health care on a pilot project basis. (These medicines are manufactured with modern pharmaceutical packaging equipment.).

1.3 Quality assurance and regulatory control problems

Because the use of herbal medicines is more often derived from empirical experience and also owing to the lack of standardization and quality control in its preparation, efforts in increasing the utilization of such medicines are hampered. Identification and study of pharmacologically active components of such medicines is ongoing in some countries at different investigative levels. Among the problems are:

(a) Imitation preparations of popular brands;

(b) Plants of different origin sold under the popular names of another plant, e.g. in Thailand, whole roots of ophipogon intermedius fam. liliaceae are sold as "fakhom" which is actually the rhizome vetiveria zizanioides fam. gramineae;

(c) Because of shortage of supply or strong market demand, medicinal plants are harvested prematurely with lower level of active ingredients resulting in a "substandard" herbal medicine;

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(d) Deliberate "adulteration" of herbal medicines with chemical substances like prednisolone (without declaration of the substances on the label), which, when "prescribed" by the herbalist, gives rise to adverse drug reaction; and

(e) Contamination and impurities found in herbal medicine.

1.4 Approach to standardization and quality control

To overcome the above-mentioned problems, standard specifications, quality control procedures for these medicine are required by producers, as well as the regulatory agencies, to check their authenticity, quality and purity. Some countries have individually established some general specifications for some medicinal plants and herbal medicine. The approach can be in determining the plants used in the production of commonly used herbal medicines in the region and as a first phase, undertaking joint activities in developing and setting up standards and quality control procedures for those plants, as well as in the preparation and exchange of herbal material used for reference purposes.

1.5 Approach to the utilization of herbal medicine

A list of commonly used herbal medicines in each country will be prepared. A manual will be required describing identification and proper therapeutic uses of such herbal medicines. Community health

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workers/village health volunteers will then be trained in the use of herbal medicine in a pilot project area. They will also receive training in the local cultivation of commonly used medicinal plants so that some herbal medicines can be prepared locally. Country capability for production of herbal medicines will be strengthened and transfer of technology will be encouraged.

2. ACTIVITY OBJECTIVE

The objective of the activity is to assure the quality of herbal medicine, particularly the ones widely and commonly used by the people in the ASEAN countries and to promote their utilization in primary health care programmes by:

(a) setting up of standards and quality control procedures for medicinal plants used in the production of these medicines;

(b) preparing and exchanging herbal materials used for reference purposes.

(c) preparing a manual on cultivation, production and utilization of herbal medicines commonly used in primary health care in ASEAN countries and training community health workers/village health volunteers in the use of the manual in a pilot project area.

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(d) promoting cultivation of medicinal plants and production of herbal medicines commonly used in primary health care, particularly in the project areas.

3. MAJOR ACTIVITY COMPONENTS

<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i) Identification and inventory commonly used medicinal plants and herbal medicine used in primary health care. Planning of standardization activity and preparation of herbaria	Indonesia	2 months	1987
(ii) Group training on the field of taxonomy and pharmacognosy, phytochemistry and herbaria	Indonesia Philippines Thailand	1 month	1987
(iii) Group training in the field of taxonomy and pharmacognosy, phytochemistry and herbaria	China Germany	1 month	1988
(iv) Preparation of draft standardization monographs and herbaria	Indonesia	1 month	1988 1989 1990
(v) Intercountry meeting to evaluate, validate and adopt draft standardization monographs and herbaria	Indonesia	2 weeks	1989 1990 1991

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<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(vi) Provision of camera lucida for the preparation of draft monographs	Indonesia Philippines Thailand		1987
(vii) Group training in the field of cultivation production and utilization of herbal medicines in primary health care (co coordinated by Thailand)	Indonesia Philippines Thailand	1 month	1987
(viii) Group training in the field of cultivation production and utilization of herbal medicines in primary health care (co coordinated by Thailand)	China/India	1 month	1988
(ix) Preparation of draft manual on cultivation production and utilization of herbal medicines used in primary health care (co coordinated by Thailand)	Thailand	1 month	1989
(x) Intercountry course to evaluate and adopt manual and to train trainers in its use (co-coordinated by Thailand)	Thailand	1 month	1990
(xi) National level in service course for training of nationals in use of manual (co-coordinated by Thailand)	Indonesia Philippines Thailand	1 month	1991

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4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

Although there are marked differences in country situations, activity outputs such as trained manpower, standardization and quality control procedures and monographs will have a direct bearing on improving the quality assurance of medicine used in all ASEAN countries, assist the countries in their regulatory efforts, as well as stimulate intra-ASEAN trade in herbal medicines. The manual on cultivation, production and utilization of herbal medicines used in primary health care will promote utilization of herbal medicines in rural areas and thereby increase health coverage. The group educational experiences will become more meaningful and beneficial as governments intensify their interest in making full use of herbal medicine proven to be safe and efficacious.

WORKPLAN

Coordinating country : INDONESIA, THAILAND (CO-COORDINATOR)

Activity: Standardization, quality control and utilization of herbal medicines

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
1. <u>Consultants</u>					
(1) Field	Identification and inventory of commonly used medicinal plants and herbal medicines in primary health care				
	Identification and inventory of existing herbaria				
	Planning of standardization activity, preparation of herbal materials				
	Collection of existing standardization monographs of medicinal plants				
	Allocation of tasks for drafting standardization monographs				
(2) Duration	1 m/2 m				
(3) Estimated cost	\$12 000				

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
2. <u>Temporary advisers</u> (local)						
(1) Field	<p>Identification and inventory of commonly used medicinal plants and herbal medicines in primary health care</p> <p>Identification and inventory of existing herbaria</p> <p>Planning of standardization activity, preparation of herbal materials</p> <p>Collection of existing standardization monographs of medicinal plants</p> <p>Allocation of tasks for drafting standardization monographs</p>			<p>To attend meeting to evaluate, validate and adopt validated draft standardization monographs as resource persons (Indonesia)</p>	<p>To attend meeting to evaluate, validate and adopt validated draft standardization monographs as resource persons (Indonesia)</p>	<p>To attend meeting to evaluate, validate and adopt validated draft standardization monographs as resource persons (Indonesia)</p>
(2) Duration	3 m/2 m (from Indonesia, the Philippines and Thailand)			3 m/3 weeks	3 m/3 weeks	3 m/3 weeks
(3) Estimated cost	\$23 400			\$ 4 500	\$ 4 500	\$ 4 500

Components	1987	1988	1989	1990	1991
(1) Field			Preparation of training programme and manual for cultivation, production and utilization of herbal medicines in primary health care (co-coordinated by Thailand)	Organizing and conducting training course for trainers (co-coordinated by Thailand)	Organizing and conducting national level in service courses (co-coordinated by Thailand)
(2) Duration			3 x 1 m/m (from Thailand)	1 m/m	3 x 1m/m
(3) Estimated cost			\$6 000	\$2 000	\$6 000
3. Fellowships (within ASEAN)					
(1) Field of study	Group A - Taxonomy and pharmacognosy Group B - Phytochemistry Group C - Herbaria				
(2) Place of study	Grp A Indonesia, Grp B the Philippines, Grp C Thailand, respectively				
(3) Duration (man/months)	4 m/1 m (for each group)				
(4) Fellowship countries	1/country each group, except Singapore, Brunei				
(5) Estimated cost	\$38 400				

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(1) Field	Group D - Cultivation, production and utilization of herbal medicines (co-coordinated by Thailand)					
(2) Place of study	Indonesia, Philippines,					
(3) Duration (man/months)	2 m/m					
(4) Fellowship countries	2 from Thailand					
(5) Estimated cost	\$ 8 600					
<hr/>						
4. <u>Fellowships</u> (outside of ASEAN)						
(1) Field of study	Group A - taxonomy pharmacognosy Group B - phytochemistry					
(2) Place of study	Group A - China Group B - Germany					
(3) Duration (man/months)	3 m/m (for each group)					
(4) Fellowship countries	1 each from Indonesia, the Philippines, Thailand (for each group)					
(5) Estimated cost	\$37 500					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(1) Field of study		Group C - Cultivation, production and utilization of herbal medicines (Co-coordinated by Thailand)			
(2) Place of study		China/India			
(3) Duration (man/months)		2 m/m			
(4) Fellowship countries		2 from Thailand			
(5) Estimated cost		\$ 6 400			

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title			Meeting to evaluate, validate and adopt draft standardization monographs and herbaria and prepare a plan for further development	Meeting to evaluate, validate and adopt draft standardization monographs and herbaria and prepare a plan for further development	meeting to evaluate, validate and adopt draft standardization monographs and herbaria and prepare a plan for further development
(2) Duration			2 weeks	2 weeks	2 weeks
(3) Venue			Indonesia	Indonesia	Indonesia
(4) Participant/ cost			2 each from Indonesia, the Philippines, Thailand	2 each from Indonesia, the Philippines, Thailand	2 each from Indonesia, the Philippines, Thailand
			\$ 9 600	\$ 9 600	\$ 9 600
(5) Local cost			\$ 1 000	\$ 1 000	\$ 1 000
(6) Estimated cost			\$10 600	\$10 600	\$10 600

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(1) Title				Training course for trainers in use of manual in training in cultivation, production and utilization of herbal medicines in primary health care (co-coordinated by Thailand)	National level in service course in cultivation, production and utilization of herbal medicines in primary health care (co-coordinated by Thailand)
(2) Duration				1 month	1 month
(2) Venue				Thailand	Indonesia, the Philippines, Thailand
(4) Participants/ cost				2 each from Indonesia, the Philippines	30 each from Indonesia, the Philippines, Thailand
(5) Local cost				\$ 1 000	\$ 3 000 x 3
(6) Estimated cost				\$12 800	\$ 9 000

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Annex 5

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(A) <u>Expendable equipment</u>					
(1) Description of items			Materials for the preparation of herbaria for distribution \$ 6 000	Materials for the preparation of herbaria for distribution \$ 6 000	Materials for the preparation of herbaria for distribution \$ 6 000
			Printing of manuals for cultivation, production and utilization of herbal medicines in primary health care for use in training course (co-coordinated by Thailand) \$ 2 000	Training material for training course (co-coordinated by Thailand) \$ 1 000	Printing of monographs \$ 5 000
(2) Purpose					For dissemination and implementation
(3) Estimated cost			\$ 8 000	\$ 7 000	\$11 000

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(B) <u>Nonexpendable equipment</u>						
(1) Description of items	3 cameras (camera lucida)					
(2) Purpose	For the preparation of standardization monograph specifications in Indonesia, the Philippines, Thailand					
(3) Estimated cost	\$ 3 000					
7. <u>Sub-contract</u>						
(1) Description of items	Development of standard and quality control procedures and preparation of standardization monographs (Indonesia)	Development of standard and quality control procedures and preparation of standardization monographs (Indonesia)	Development of standard and quality control procedures and preparation of standardization monographs (Indonesia)	Development of standard and quality control procedures and preparation of standardization monographs (Indonesia)		
	Preparation of herbaria (Indonesia)	Preparation of herbaria (Indonesia)	Preparation of herbaria (Indonesia)	Preparation of herbaria (Indonesia)		
(2) Estimated cost	\$ 6 000	\$ 3 000	\$ 3 000	\$ 3 000		

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(1) Description of items					
(2) Estimated cost					
TOTAL	\$ 85 400	\$ 49 900	\$32 100	\$39 900	\$41 100

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: INDONESIA

Activity: Standardization, quality control and utilization of herbal medicine

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
11-60	Consultants	21	62 900	8	35 400			5 1/4	10 500	3 1/4	6 500	5	10 500
19	Component total	21 1/2	62 900	8	35 400			5 1/4	10 500	3 1/4	6 500	5	10 500
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
21	Sub-contracts		12 000			6 000		3 000		3 000			
29	Component total		12 000			6 000		3 000		3 000			

		Total (\$)	1987	1988	1989	1990	1991
30	<u>Training</u>						
31	Fellowships	90 900	47 000	43 900			
32	Group training	44 600			10 600	23 400	10 600
33	Inservice training	9 000					9 000
39	Component total	144 500	47 000	43 900	10 600	23 400	19 600
40	<u>Equipment</u>						
41	Expendable equipment	26 000			8 000	7 000	11 000
42	Nonexpendable equipment	3 000	3 000				
49	Component total	29 000	3 000		8 000	7 000	11 000
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	248 400	85 400	49 900	32 100	39 900	41 100

ACTIVITY: FORMULATION OF AN ESSENTIAL DRUG INFORMATION MANUAL COORDINATED
BY BRUNEI DARUSSALAM

1. BACKGROUND/JUSTIFICATION

1.1 The implementation of the essential drug concept

The essential drug concept, with its main objective of rationalizing the use of drugs and optimizing the use of available funds has been adopted in the ASEAN countries with different levels of implementation. The slow and unsatisfactory acceptance of the concept is partly due to the lack of adequate and sufficient information on essential drugs.

1.2 Essential drug information manual

Health providers in both public and private sectors are generally supplied information by pharmaceutical companies which is not always objective, complete and sufficient. For successful implementation of the concept, an Essential Drug Information Manual is needed to guide the health provider in the rational use of drugs. This manual will contain unbiased and complete information on essential drugs including pharmacological, clinical and pharmaceutical information as well as the rationale of selection. It is envisaged that the manual will contribute to a wider acceptance of the essential drug concept.

Annex 6

A comparative ASEAN Essential Drug List has been prepared in Phase II of technical cooperation and it is planned that information as indicated above on the most commonly used essential drugs be provided in the Manual. When accepted and used widely, it would enable Governments of ASEAN countries to fulfil one of the basic objectives of their drug policies concerning the use of essential drugs.

2. ACTIVITY OBJECTIVES

The objectives of the activity are to ensure the rational use of drugs at every level of health care services and to strengthen the implementation of the essential drug concept by formulating source material on essential drugs in the form of a manual containing information needed by health providers.

3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Formulation, design, format and content list of a draft essential drug information manual		1 month	1987
(ii)	Workshop to adopt design format and contents list of manual	Brunei Darussalam	4 days	1987
(iii)	Drafting of manual	-	1 month	1988

Annex 6

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(iv)	workshop to consider and adopt the draft essential drug information manual and printing of the manual	Brunei Darussalam	2 weeks	1989
(v)	National level field trial implementation of the manual	Brunei Darussalam Indonesia Malaysia Philippines Singapore Thailand	12 months	1990
(vi)	Workshop on field trial implementation of the manual and for finalization for printing of the manual	Brunei Darussalam	1 week	1991

4. LINKAGE WITH NATIONAL PROGRAMMES/PLAN FOR UTILIZING OUTPUT

The activity will contribute to the strengthening of national programmes for the implementation of the essential drug concept.

WORKPLAN

Coordinating country : BRUNEI DARUSSALAM

Activity: Formulation of an essential drug information manual

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
1. <u>Consultants</u>					
(1) Field (m/m)	Preparation of design, contents and format of essential drug information manual and a tentative list of essential drugs to be included in the manual for approval of ASEAN countries		Organize and conduct workshop and serve as resource person		Organize and conduct review meetings and finalization of manual
(2) Duration	2 x 1 m/m		3 x 3 weeks		3 x 3 weeks
(3) Estimated cost	\$12 000		\$12 000		\$12 000
2. <u>Temporary advisers</u> (local)					
(1) Field	Preparing and finalizing draft manual				
(2) Duration	5 m/m				
(2) Estimated cost	\$22 500				

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration					
(4) Fellowship countries					
(5) Estimated cost					
4. <u>Fellowships</u> (outside of ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration (man/months)					
(4) Fellowship countries					
(5) Estimated cost					

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)						
(1) Title	Workshop on design, contents and format of essential drug information manual and list of essential drugs for the manual			Workshop to consider and adopt the manual	National field trial implementation in pilot areas	Review meeting on field trial implementation and finalization of the manual
(2) Duration	4 days			2 weeks		1 week
(3) Venue	Brunei Darussalam			Brunei Darussalam		Brunei Darussalam
(4) Participants/ cost	1/country \$ 7 800			2/country \$19 200		2/country \$ 9 600
(5) local cost	\$ 1 000			\$ 1 000		\$ 1 000
(6) Estimated cost	\$ 8 800			\$20 200		\$10 600
6. <u>Supplies and equipment</u>						
(A) <u>Expendable equipment</u>						
(1) Description		Printing of manual for workshop		Printing of manual for field trial implementation		Printing of the manual for dissemination
(2) Purpose						
(3) Estimated cost		\$ 2 000		\$ 5 000		\$ 2 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(B) <u>Nonexpendable equipment</u>					
Estimated cost					
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$20 800	\$24 500	\$37 200		\$24 600

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: BRUNEI DARUSSALAM

Activity: Formulation of an essential drug information manual

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
	11-60 Consultants	11 1/2	58 500	2	12 000	5	22 500	2 1/4	12 000			2 1/4	12 000
	11-99 Sub-total												
19	Component total	11 1/2	58 500	2	12 000	5	22 500	2 1/4	12 000			2 1/4	12 000
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
	21 Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships						
32	Group training	39 600	8 800		20 200		10 600
33	Inservice training						
39	Component total	39 600	8 800		20 200		10 600
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment						
49	Component total						
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry	9 000		2 000	5 000		2 000
59	Component total	9 000		2 000	5 000		2 000
99	Project total	107 100	20 800	24 500	37 200	-	24 600

ACTIVITY: ESTABLISHMENT OF A REGIONAL TRAINING CENTRE FOR GOOD
MANUFACTURING PRACTICES (GMP) AT THE DIRECTORATE-GENERAL OF DRUG
AND FOOD CONTROL, MINISTRY OF HEALTH, JAKARTA

1. BACKGROUND/JUSTIFICATION

1.1 Adoption of GMP

The requirements for "good practices in the manufacture and quality control of drugs" (or GMP) as formulated by WHO had been generally accepted since the Twenty-eighth World Health Assembly. Adherence to these practices (which emphasize proper responsibility for, and execution of, the complete manufacturing process), complementing the various control tests followed from the beginning to the end of the manufacturing cycle, contributes substantially to the manufacture of consistently uniform batches of high quality drugs. These requirements are considered as general guides which, whenever necessary, may be adapted to individual country needs, provided the established standards of drug quality are still achieved.

1.2 GMP and quality assurance

In the developing countries of the ASEAN region, local production and formulation of pharmaceutical preparations are undertaken and encouraged as part of the objective of attaining self-reliance, but such local production should not be at the expense of quality. While the local associates of

Annex 7

multinational pharmaceutical firms follow GMP guidelines as laid down by their parent companies and also campaign for strict observance of GMP to its fullest extent, the local manufacturer needs to be guided in its implementation which could be in phases. At the present moment, the pharmaceutical industry in most ASEAN countries, especially the small and medium-sized companies, has not yet implemented acceptable good manufacturing practices. ASEAN GMP Guidelines and Manual for inspection of GMP had been formulated and adopted, and operational guidelines are being formulated. Implementation of these guidelines and manuals, however, can be effectively carried out by adequately trained staff from both the producing plants and the regulatory agencies. The decision on implementation in phases should be a national decision bearing in mind the country situation and not compromising or sacrificing the quality of the products of the local national pharmaceutical manufacturer. In the ASEAN countries, implementation of GMP is not only in ensuring compliance but more important in giving guidance and advice to local manufacturers in order that the standards and quality of their products are up to standard. This is important as the association of drug quality (seen as the healing potential of the drug) with drug price is still being actively promoted by multinational companies using smart packaging reinforced with extensive promotional campaigns.

1.3 GMP implementation

In the ASEAN countries, GMP implementation is now at different levels but with two guidelines and manuals adopted for use, the first step is now achieved, and the subsequent step would be in the training of manpower in effectively using these guidelines and operational manuals.

2. ACTIVITY OBJECTIVES

The objectives of the activity are as follows:

(a) To achieve a satisfactory level of quality assurance in the local production of pharmaceuticals in ASEAN countries, thereby contributing to its development;

(b) To improve the situation of the ASEAN pharmaceutical industry both within and outside the region; and

(c) To guide and advise local manufacturers on the correct implementation of GMP.

Annex 7

3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Training of trainers on general aspects of GMP, sterile and non-sterile production	United States of America/ Japan	1 month	1987
(ii)	Intercountry training course (including field training) on GMP inspection	Indonesia	3 weeks	1988 1989 1990 1991

4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

Local production of pharmaceuticals, where feasible, is one of the components of a rational national drug policy and is one of the main lines of action under the WHO Action Programme on Essential Drugs. Apart from this, the achievement of self-reliance is important to countries from the economic point of view. By ensuring that there is compliance with GMP in local pharmaceutical industry, the products of local as well as regional manufacturers will gain wider acceptance and contribute to national development and intra-ASEAN trade in pharmaceuticals.

WORKPLAN

Coordinating country : INDONESIA

Activity: Establishment of a regional training centre for Good Manufacturing Practices (GMP)

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
1. <u>Consultants</u>					
(1) Field/duration m/m					
(2) Estimated cost					
2. <u>Temporary advisers (local)</u>					
(1) Field/duration	For a course and field training on GMP inspection 3 m/m	For a course and field training on GMP inspection 3 m/m	For a course and field training on GMP inspection 3 m/m	For a course and field training on GMP inspection 3 m/m	For a course and field training on GMP inspection 3 m/m
(2) Estimated cost	\$ 6 000	\$ 6 000	\$ 6 000	\$ 6 000	\$ 6 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration (man/months)					
(4) Fellowship countries					
(5) Estimated cost					

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
4. <u>Fellowships</u> (outside of ASEAN)						
	Trainers from Indonesia					
(1) Field	(a) General aspects of GMP, including premises, personnel and documentation (b) Biological production and sterile production on sterile and non-sterile products					
(2) Place of study	(a) Japan (b) United States of America					
(3) Duration	(a) 1 m/m (b) 1 m/m					
(4) Fellowship countries	Indonesia					
(5) Estimated cost	\$ 10 900					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title	Course and field training on GMP inspection	Course and field training on GMP inspection	Course and field training on GMP inspection	Course and field training on GMP inspection	Course and field training on GMP inspection
(2) Duration	3 weeks	3 weeks	3 weeks	3 weeks	3 weeks
(3) Venue	Jakarta	Jakarta	Jakarta	Jakarta	Jakarta
(4) Participants/ costs	1 per country \$ 12 300	1 per country \$ 12 300	1 per country \$ 12 300	1 per country \$ 12 300	1 per country \$ 12 300
(5) Local cost	\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(6) Estimated cost	\$ 13 300	\$ 13 300	\$ 13 300	\$ 13 300	\$ 13 300

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>						
(A) Expendable equipment						
(1) Description of items			Training material for course	Training material for course	Training material for course	Training material for course
(2) Purpose						
(3) Estimated cost			\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(B) Non-expendable equipment						
(1) Description of items	Overhead projector Slide projector Screen					
(2) Purpose	For training course					
(3) Estimated cost	\$ 1 000					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$ 89 100	\$ 19 300	\$ 19 300	\$ 19 300	\$ 19 300

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: INDONESIA

Activity: Establishment of a regional training centre for good manufacturing practices (GMP)

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
	11-60 Consultants	12	24 000			3	6 000	3	6 000	3	6 000	3	6 000
19	Component total	12	24 000			3	6 000	3	6 000	3	6 000	3	6 000
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
	21 Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	10 900	10 900				
32	Group training	53 200		13 300	13 300	13 300	13 300
33	Inservice training						
39	Component total	64 100	10 900	13 300	13 300	13 300	13 300
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment	1 000	1 000				
49	Component total	1 000	1 000				
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	89 100	11 900	19 300	19 300	19 300	19 300

ACTIVITY: ESTABLISHMENT OF A REGIONAL TRAINING CENTRE FOR DRUG INFORMATION
AT THE DIRECTORATE-GENERAL OF DRUG AND FOOD CONTROL, MINISTRY OF
HEALTH, JAKARTA

1. BACKGROUND/JUSTIFICATION

1.1 Drug information for drug management and control

One of the main lines of action under the WHO Action Programme on Essential Drugs has been the development of national drug policies to improve the national drug management and control system. All levels in the supply chain require expertise and, therefore, require information. Since drug information is an important requirement for effective and efficient drug management and control, and there is no such efficient centralized system to support drug management and control efforts in the ASEAN countries, establishment of drug information resource centres or strengthening of existing centres as in the case of certain ASEAN countries is urgently needed. The following information could be handled by such centres:

- (a) Registration and control status
- (b) Regulatory action, including withdrawal and/or restrictions
- (c) Monitoring of adverse drug reaction
- (d) Status within the health care system
- (e) Utilization patterns

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- (f) Prescription patterns
- (g) Supplier performance, prices
- (h) Quality control standards and techniques
- (i) Small-scale local production of herbal medicine

1.2 Scope of drug information centres

In the ASEAN countries, there are varied systems for storage, dissemination and utilization of such information. In the case of local information on drug usage in the public sector, this is incorporated into the government drug management and inventory control system in one country. In another country, pre-existing information from overseas, e.g. the Iowa drug information service is now available centrally together with local information on drugs which are registered for marketing. In the same system, there is collaboration as one of the 23 centres participating in the WHO Scheme for Monitoring Adverse Drug Reactions, and regular bulletins on such topics are issued in the local national language. Drug management and control to be truly effective on a national scale must cover both the public and private sectors, in the same way that regulatory control through drug registration is effected. The need for ASEAN countries to set up such centres is, therefore, urgently felt, and a centre for training of manpower in this field will improve drug management and control in the countries in the region.

2. ACTIVITY OBJECTIVE

The objective of the activity is to enhance the effectiveness and efficiency of national drug management and control by providing accurate and up-to-date information necessary for such tasks through manpower training in the system, organization, responsibilities and management of drug information centres.

3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Training of trainers on the organization and management of drug information centres, drug utilization audit, including adverse drug reaction monitoring	Switzerland	1 month	1987
		Sweden	1 month	1987
(ii)	Intercountry training course on system organization and function of drug information centres (including exercise on management)	Indonesia	2 weeks	1988
				1989
				1990
				1991

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3. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

The provision of trained manpower is essential for the establishment or development of information centres required for national drug management and control. There is a direct linkage between the activity output and the development of national drug policies in the area of effective supply systems as well as regulatory systems in the countries.

WORKPLAN

Coordinating country : INDONESIA

Activity: Establishment of a regional training centre for drug information

Components	1987	1988	1989	1990	1991
<u>1. Consultants</u>					
(1) Field/duration (m/m)					
(2) Estimated cost					
<u>2. Temporary advisers (local)</u>					
(1) Field/duration (m/m)	Preparation of computer programs for drug information 1 m/2 m	For a course on system, organization, function and management of drug information 1 m/3 weeks	For a course on system, organization, function and management of drug information 1 m/3 weeks	For a course on system, organization, function and management of drug information 1 m/3 weeks	For a course on system, organization, function and management of drug information 1 m/3 weeks
(2) Estimated cost	\$ 4 000	\$ 1 500	\$ 1 500	\$ 1 500	\$ 1 500

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration (man/months)					
(4) Fellowship countries					
(5) Estimated cost					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
4. <u>Fellowships</u> (outside of ASEAN)					
	Trainers from Indonesia				
(1) Field of study	(a) Organization and management of drug information centres				
	(b) Drug utilization audit, including adverse drug reaction monitoring				
(2) Place of study	(a) Australia				
	(b) Sweden				
(3) Duration	(a) 1 m/m				
	(b) 1 m/m				
(4) Fellowship countries	Indonesia				
(5) Estimated cost	\$ 13 400				

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title	Course on system, organization and function of drug information centres Exercise on management of a drug information centre	Course on system, organization and function of drug information centres Exercise on management of a drug information centre	Course on system, organization and function of drug information centres Exercise on management of a drug information centre	Course on system, organization and function of drug information centres Exercise on management of a drug information centre	Course on system, organization and function of drug information centres Exercise on management of a drug information centre
(2) Duration	2 weeks	2 weeks	2 weeks	2 weeks	2 weeks
(3) Venue	Jakarta	Jakarta	Jakarta	Jakarta	Jakarta
(4) Participants/ cost	1 per country \$ 9 600	1 per country \$ 9 600	1 per country \$ 9 600	1 per country \$ 9 600	1 per country \$ 9 600
(5) Local cost	\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(6) Estimated cost	\$ 10 600	\$ 10 600	\$ 10 600	\$ 10 600	\$ 10 600

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(A) <u>Expendable equipment</u>					
(1) Description of items		Training material for course	Training material for course	Training material for course	Training material for course
(2) Purpose					
(3) Estimated cost		\$ 1 500	\$ 1 500	\$ 1 500	\$ 1 500
(B) <u>Non-expendable equipment</u>					
(1) Description of items					
(2) Purpose					
(3) Estimated cost					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$ 17 400	\$ 13 600	\$ 13 600	\$ 13 600	\$ 13 600

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: INDONESIA

Activity: Establishment of a regional training centre for drug information

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
	11-60 Consultants	5	10 000	2	4 000	3/4	1 500	3/4	1 500	3/4	1 500	3/4	1 500
19	Component total	5	10 000	2	4 000	3/4	1 500	3/4	1 500	3/4	1 500	3/4	1 500
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
21	Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	13 400	13 400				
32	Group training	48 400		12 100	12 100	12 100	12 100
33	Inservice training						
39	Component total	61 800	13 400	12 100	12 100	12 100	12 100
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment						
49	Component total						
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	71 800	17 400	13 600	13 600	13 600	13 600

ACTIVITY: ESTABLISHMENT OF A REGIONAL TRAINING CENTRE ON DRUG EVALUATION
AT THE BUREAU OF FOOD AND DRUGS, MINISTRY OF HEALTH, MANILA

1. BACKGROUND/JUSTIFICATION

1.1 Diversity of evaluation requirements and procedures

In order to ensure that drugs used in the ASEAN countries are safe and efficacious, certain countries have introduced legislation to require the assessment or evaluation of drugs prior to marketing and also of those already on the market at the time of such legislation. Apart from the considerable diversity in requirements for registration, there is also diversity in institutional structures, operative procedures and also in the objectives of such requirements. There is legislation in the ASEAN countries which only allows import and registration of only those drugs which are technically not possible and economically not feasible to be locally produced. With such procedures, there also has been price control placed on the drug at the time of registration. In others, where there are defined institutional structures and operative procedures, owing to insufficient resources, the problem is one of making a choice between sacrificing standards and intolerable delays in the processing of applications. Some countries, whose policy differs, do not operate a direct system of drug registration requirement but have bodies or committees that are responsible for ensuring the use of safe and efficacious drugs. In all cases, decisions made by reputable bodies outside the country are partially or fully accepted depending on the circumstances of each case.

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1.2 Need for improved capability in drug evaluation

Whatever the country situation, all ASEAN countries have an urgent need to improve their drug evaluation procedures both in cases of new drugs as well as those already in the market, although different country situations may affect the priorities and aims of such an exercise. The task of evaluation should be reduced for individual countries if they could have well-trained staff responsible for such an evaluation and if such a process were carried out with a full knowledge and understanding of similar processes carried out in the neighbouring ASEAN countries. The proposal for a common ASEAN regulatory agency, whilst simple and logical in concept, is not feasible in view of the diversity of country situations and policies.

1.3 Training approach

The training of national staff responsible for such procedures is, therefore, essential to the utilization of safe efficacious drugs in all ASEAN countries, and such training could develop and emphasize common criteria and operative procedures.

2. ACTIVITY OBJECTIVE

The objective of the activity is to improve and strengthen drug evaluation systems and procedures through:

- (a) manpower resources development; and
- (b) formulation and adoption of operational guidelines.

3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Training of trainers on drug evaluation procedures	United States of America	2 months	1987
(ii)	Intercountry seminar to review drug evaluation manuals or guidelines and to formulate operational guidelines	Philippines	3 days	1988
(iii)	Intercountry training course on drug evaluation	Philippines	3 weeks	1989 1990 1991

4. LINKAGE WITH THE NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

The aim of ensuring the availability of safe and efficacious drugs in the promotion of health care is a common objective in ASEAN countries health programmes. In upgrading the capabilities of staff in the area of drug evaluation as well as in the training of new staff required for the

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new activity of drug registration, the training centre will facilitate the transfer of technology among ASEAN countries. Trained staff will be contributing directly to each country's health programme, both in the curative as well as in the preventive fields, by ensuring the safety and efficacy of drugs being marketed in the country.

WORKPLAN

Coordinating country : PHILIPPINES

Activity: Establishment of regional training centre on drug evaluation

Components	1987	1988	1989	1990	1991
1. Consultant					
(1) Field/duration (m/m)	To evaluate drug evaluation guidelines and to prepare draft operational manual	Organization and conduct of a seminar to review drug evaluation guidelines and to finalize operational manual			
	1 m/1 m	1 m/2 wks			
(2) Estimated cost	\$ 6 000	\$ 3 250			
2. Temporary advisers (local)					
(1) Field/duration (m/m)		For Seminar to review drug evaluation guidelines and to finalize operational manual	Course in drug evaluation	Course in drug evaluation	Course in drug evaluation
		1 m/2 weeks	1 m/2 weeks	1 m/2 weeks	1 m/2 weeks
(2) Estimated cost		\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)						
(1)	Field of study					
(2)	Place of study					
(3)	Duration (man/months)					
(4)	Fellowship countries					
(5)	Estimated cost					
4. <u>Fellowships</u> (outside of ASEAN)		Trainers from the Philippines				
(1)	Field of study	Drug evaluation procedures				
(2)	Place of study	United States of America/Europe				
(3)	Duration (man/months)	1m/2m				
(4)	Fellowship countries					
(5)	Estimated cost	\$ 10 600				

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title		Seminar to review drug evaluation guidelines and to finalize operational manual	Course on drug evaluation	Course on drug evaluation	Course on drug evaluation
(2) Duration		3 days	3 weeks	3 weeks	3 weeks
(3) Venue		Manila	Manila	Manila	Manila
(4) Participants/ cost		1/country \$ 7 200	1/country \$ 14 400	1/country \$ 14 400	1/country \$ 14 400
(5) Local cost		\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(6) Estimated cost		\$ 8 200	\$ 15 400	\$ 15 400	\$ 15 400

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(A) <u>Expendable equipment</u>					
(1) Description of items			Training material for use in the course	Training material for use in the course	Training material for use in the course
(2) Purpose					
(3) Estimated cost			\$ 1 000	\$ 1 000	\$ 1 000
(B) <u>Non-expendable equipment</u>					
(1) Description of items		Overhead projector, Slide projector, Screen			
(2) Purpose		For training course			
(3) Estimated cost		\$ 1 000			

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$ 16 600	\$ 13 450	\$ 17 400	\$ 17 400	\$ 17 400

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: PHILIPPINES

Activity: Establishment of a regional training centre on drug evaluation

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
11-60	Consultants	3 1/2	13 250	1	6 000	1	4 250	1/2	1 000	1/2	1 000	1/2	1 000
19	Component total	3 1/2	13 250	1	6 000	1	4 250	1/2	1 000	1/2	1 000	1/2	1 000
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
21	Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	10 600	10 600				
32	Group training	57 400		8 200	16 400	16 400	16 400
33	Inservice training						
39	Component total	68 000	10 600	8 200	16 400	16 400	16 400
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment	1 000		1 000			
49	Component total	1 000		1 000			
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	82 250	16 600	13 450	17 400	17 400	17 400

ACTIVITY: ESTABLISHMENT OF A REGIONAL TRAINING CENTRE FOR LABORATORY QUALITY CONTROL AT THE NATIONAL PHARMACEUTICAL CONTROL LABORATORY, MINISTRY OF HEALTH, PETALING JAYA, MALAYSIA

1. BACKGROUND/JUSTIFICATION

1.1 Role of national drug control laboratories

National drug control laboratories function as effective agents in ensuring that only safe and efficacious drugs are marketed and also in carrying out proper drug surveillance. It has been stated that even a modest investment in laboratory facilities can be cost-effective and a strong deterrent against marketing malpractices. Capabilities of drug control laboratories vary in the countries of the region depending on national health priorities and the responsibilities of these laboratories under the regulatory mechanism in force.

1.2 Need for trained manpower

The need for strengthening manpower expertise and capabilities among ASEAN countries has been achieved in earlier phases of the project in the provision of individual fellowships for attachment training in advanced quality control techniques in the control laboratories of developed countries, supplemented by group training of officers from the ASEAN countries in a control laboratory in a developed country and a workshop/seminar on quality control procedures for drugs with no official

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methods of analysis. Such training so far has benefitted professional staff of national control laboratories in their daily work. A logical follow-up of the development of adequate quality control laboratories is to promote ASEAN training capability to increase trained manpower in laboratory drug quality control, manpower with such expertise being required in greater number as countries step up implementation of the quality assurance components in their national drug policies. The testing of dosage forms and pharmaceuticals at the periphery under the WHO Basic Test Scheme also increases the workload on national drug control laboratories which function as collaborating laboratories under the Scheme.

1.3 Problem of equipment maintenance

An area of concern in some countries relates to problems in the maintenance of equipment used in drug quality control work. There is a need to develop within the staff of these laboratories a capability in simple preventive maintenance and repair of equipment as such maintenance services sometimes cannot be obtained or can only be obtained at a very high cost. The training centre should have a module in its training programme on this subject.

2. ACTIVITY OBJECTIVE

The objective of the activity is to further strengthen the national drug quality assurance system through the provision of training to increase the number of trained personnel in the field of laboratory quality control techniques, analytical methods, testing procedures and maintenance of equipment.

3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Training of trainers in chemical, physical, microbiological, biological, toxicological aspects of quality control of drugs	United States of America/ Australia	1 month	1987
(ii)	Intercountry training course on laboratory quality control of drugs	Malaysia	2 weeks	1988 1989 1990 1991
(iii)	Provision of equipment for "hands on" experience in training	Malaysia		1987

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4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

Trained manpower for the back-up laboratories of regulatory agencies is the basis of enforcement responsibilities of these agencies. The trained manpower, when utilized in such laboratories, will enable more effective enforcement of laws relating to drug registration and post-marketing surveillance in the ASEAN countries. Drug quality assurance programmes are major components of the national drug policies of all ASEAN countries.

WORKPLAN

Coordinating country : MALAYSIA

Activity: Establishment of a regional training centre for laboratory quality control

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
<u>1. Consultants</u>					
(1) Field/duration (m/m)		Planning and organizing course structure and materials 1 m/1 m			
(2) Estimated cost		\$ 6 000			
<u>2. Temporary advisers</u> (local)					
(1) Field/duration (/m/m)		Course in laboratory quality control of drugs 1 m/3 weeks	Course in laboratory quality control of drugs 1 m/3 weeks	Course in laboratory quality control of drugs 1 m/3 weeks	Course in laboratory quality control of drugs 1 m/3 weeks
(2) Estimated cost		\$ 1 500	\$ 1 500	\$ 1 500	\$ 1 500

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration (man/months)					
(4) Fellowship countries					
(5) Estimated cost					

<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
4. <u>Fellowships</u>						
(outside of ASEAN) Trainers from Malaysia						
(1) Field of study	(a) Chemical and physical aspects of quality control of drugs					
	(b) Microbiological and biological aspects of quality control of drugs					
(2) Place of study	(a) United States of America					
	(b) Australia					
(3) Duration (man/months)	(a) 1 m/m					
	(b) 1 m/m					
(4) Fellowship countries	Malaysia					
(5) Estimated cost	\$11 800					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. Group training (meeting/seminar/ workshop)					
(1) Title		Course on laboratory quality control of drugs	Course on laboratory quality control of drugs	Course on laboratory quality control of drugs	Course on laboratory quality control of drugs
(2) Duration		2 weeks	2 weeks	2 weeks	2 weeks
(3) Venue		Kuala Lumpur	Kuala Lumpur	Kuala Lumpur	Kuala Lumpur
(4) Participants/ cost		1/country \$ 9 600	1/country \$ 9 600	1/country \$ 9 600	1/country \$ 9 600
(5) Local cost		\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(6) Estimated cost		\$10 600	\$10 600	\$10 600	\$10 600

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<u>Components</u>		<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>						
(A) <u>Expendable equipment</u>						
(1) Description of items			Training materials, including reagents for the course	Training materials, including reagents for the course	Training materials, including reagents for the course	Training materials, including reagents for the course
(2) Purpose						
(3) Estimated cost			\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(B) <u>Non-expendable equipment</u>						
(1) Description of items	1 x each HPLC equipment 1 x each UV spectrophotometer					
(2) Purpose	To supplement existing equipment to provide "hands-on" experience and training					
(3) Estimated cost	\$50 000					

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
7. <u>Sub-contract</u>					
(1) Description					
(2) Estimated cost					
TOTAL	\$65 900	\$19 100	\$13 100	\$13 100	\$13 100

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: MALAYSIA

Activity: Establishment of a regional training centre for laboratory quality control

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
	11-60 Consultants	4	12 000			1 3/4	7 500	3/4	1 500	3/4	1 500	3/4	1 500
	19 Component total	4	12 000			1 3/4	7 500	3/4	1 500	3/4	1 500	3/4	1 500
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
	21 Sub-contracts												
	29 Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	11 800	11 800				
32	Group training	46 400		11 600	11 600	11 600	11 600
33	Inservice training						
39	Component total	58 200	11 800	11 600	11 600	11 600	11 600
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment	50 000	50 000				
49	Component total	50 000	50 000				
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	120 200	61 800	19 100	13 100	13 100	13 100

ACTIVITY: ESTABLISHMENT OF A REGIONAL TRAINING CENTRE FOR THE PRODUCTION AND UTILIZATION OF REGIONAL STANDARDS AND REFERENCE SUBSTANCES AT THE DEPARTMENT OF MEDICAL SCIENCES, MINISTRY OF PUBLIC HEALTH, BANGKOK

1. BACKGROUND/JUSTIFICATION

1.1 Scope of the past cooperation

The need for reference material used in daily quality control work had been felt by ASEAN countries from the commencement of planning for TCDC due to various reasons, e.g. cost, restricted supply and long delivery time for primary standards (e.g. International Biological Standards, USP, BP and EP Chemical Reference Standards). Whilst there were some ongoing activities in producing inhouse standards by countries individually, these were, however, hampered by difficulties in obtaining sufficient quantity and quality of bulk material, untrained manpower and lack of expertise and knowledge of specific techniques applied in that field. The economic and other benefits achieved with the establishment of secondary ASEAN standards on a collaborative basis have been realized. In some countries, this activity has, however, been limited to the public sector regulatory control agencies, and the extension should be made to cover the private sector laboratories as well as those in the universities undertaking quality control work using such materials.

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1.2 Continuing cooperation in production

TCDC activities had in the earlier phase covered chemical reference substances and later the biological substances. The necessary equipment had also been supplied to the laboratories concerned. Although the capability of the laboratories in the ASEAN countries has been established for this collaborative work and a total of 20 ASEAN reference substances adopted, a system and procedure has now been set up for continuing cooperation in this field to increase the number of reference substances for use in the countries of the region.

1.3 Need for trained manpower

The use of reference materials in pharmacopoeial assays is increasing rapidly. As more monographs covering standards of new drugs are established, reference substances needed in tests in these monographs also increase. However, the need for more types of such substances is also matched with the need for more trained manpower in the specific techniques used in the field of production and utilization of reference substances (including the private sector and universities which use these substances in their teaching or in research). The problem of existing manpower shortages required for such work in individual countries must be tackled first at the national level as provision of additional training opportunities for scarce and overloaded staff would not be an effective solution.

2. ACTIVITY OBJECTIVE

The objective of the activity is to strengthen the capabilities in the production and utilization of reference substances through manpower training to increase the number of ASEAN reference substances available for use in the region.

3. MAJOR ACTIVITY COMPONENTS

	<u>Description</u>	<u>Location</u>	<u>Duration</u>	<u>Year</u>
(i)	Training of trainers in the production and utilization of chemical and microbiological reference substances	Europe	2 months	1987
(ii)	Training courses (chemical and microbiological) on the production and utilization of reference substances	Thailand	2 weeks	1988 1989 1990 1991
(iii)	Meetings to review the programme and the data from collaborating laboratories for adoption	Thailand	3 days	1989 1991
(iv)	Supply of equipment (differential scanning colorimeter) for use in determining impurities in reference substances and upgrading capability of training centre	Thailand		1987

Annex 11

4. LINKAGE WITH NATIONAL PROGRAMME/PLAN FOR UTILIZING OUTPUT

The output from this activity will enable countries to reap the economic benefit with the establishment of secondary reference substances carried out collaboratively on a regional basis and to upgrade the standard of general quality control work in this area. The use of identical reference material would contribute to any future desirable harmonization of quality requirements for drugs in commerce within the region and also for the development of self-reliance.

WORKPLAN

Coordinating country : THAILAND

Activity: Establishment of a regional training centre for the production and utilization of regional standards and reference substances

Components	1987	1988	1989	1990	1991
1. Consultants					
(1) Field/duration (m/m)		To advise on the organization and conduct of training courses (chemical) 1 m/3 wks	To advise on the organization and conduct of training courses (microbiological) 1 m/3 wks		
(2) Estimated cost		\$ 4 875	\$ 4 875		
2. Temporary advisers (local)					
(1) Field/duration (m/m)		Course (chemical) on the production and utilization of reference substances 1 m/3 wks	Course (microbio- logical) on the production and utilization of reference substances 1 m/3 wks	Course (chemical) on the production and utilization of reference substances 1 m/3 wks	Course (microbio- logical) on the production and utilization of reference substances 1 m/3 wks
(2) Estimated cost		\$ 1 500	\$ 1 500	\$ 1 500	\$ 1 500

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
3. <u>Fellowships</u> (within ASEAN)					
(1) Field of study					
(2) Place of study					
(3) Duration (man/months)					
(4) Fellowship countries					
Estimated cost					
4. Fellowship (outside of ASEAN)	Trainers from Thailand				
(1) Field of study	Production and utilization of reference substances (chemical)				
(2) Place of study	Europe				
(3) Duration	1 m/1 m				
(4) Fellowship countries	Thailand				
(5) Estimated cost	\$ 9 300				

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(1) Field of study	Production and utilization of reference substances (microbiological)				
(2) Place of study	Europe				
(3) Duration	1 m/1 m				
(4) Fellowship countries	Thailand				
(5) Estimated cost	\$ 9 300				

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
5. <u>Group training</u> (meeting/seminar/ workshop)					
(1) Title		Course (chemical) on the production and utilization of reference substances	Course (microbio- logical) on the production and utilization of reference substances	Course (chemical) on the production and utilization of reference substances	Course (microbio- logical) on the production and utilization of reference substances
(2) Duration		2 wks	2 wks	2 wks	2 wks
(3) Venue		Bangkok	Bangkok	Bangkok	Bangkok
(4) Participants/ cost		1/country except Brunei Darussalam \$ 8 000	1/country except Brunei Darussalam \$ 8 000	1/country except Brunei Darussalam \$ 8 000	1/country except Brunei Darussalam \$ 8 000
(5) Local cost		\$ 1 000	\$ 1 000	\$ 1 000	\$ 1 000
(6) Estimated cost		\$ 9 000	\$ 9 000	\$ 9 000	\$ 9 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
(1) Title			Meeting to review programme and data from collaborating laboratories for adoption		Meeting to review programme and data from collaborating laboratories for adoption
(2) Duration			3 days		3 days
(3) Venue			Thailand		Thailand
(4) Participants/ cost			1/country except Brunei Darussalam \$ 6 000		1/country except Brunei Darussalam \$ 6 000
(5) Local costs			\$ 1 000		\$ 1 000
(6) Estimated cost			\$ 7 000		\$ 7 000

<u>Components</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
6. <u>Supplies and equipment</u>					
(A) <u>Expendable equipment</u>					
(1) Description of items		(a) Reagents, training materials, bulk substances and primary standards	(a) Reagents, training materials, bulk substances and primary standards	(a) Reagents, training materials, bulk substances and primary standards	(a) Reagents, training materials, bulk substances and primary standards
		(b) Reagents, bulk substances and primary standards	(b) Reagents, bulk substances and primary standards	(b) Reagents, bulk substances and primary standards	(b) Reagents, bulk substances and primary standards
(2) Purpose		(a) For the training course	(a) For the training course	(a) For the training course	(a) For the training course
		(b) For use in collaborating laboratories	(b) For use in collaborating laboratories	(a) For use in collaborating laboratories	(b) For use in collaborating laboratories
(3) Estimated cost		(a) \$1 000 (b) \$1 000x5 = \$ 5 000	(a) \$1 000 (b) \$1 000x5 = \$ 5 000	(a) \$1 000 (b) \$1 000x5 = \$ 5 000	(a) \$1 000 (b) \$1 000x5 = \$ 5 000
Sub-total		\$6 000	\$6 000	\$6 000	\$6 000

Components	1987	1988	1989	1990	1991
<hr/>					
(B) <u>Non-expendable equipment</u>					
(1) Description of items	Differential scanning colorimeter (DSC) (For Thailand)				
(2) Purpose	To determine the impurity of reference substances and for use in training				
<hr/>					
(3) Estimated cost	\$32 900				
<hr/>					
7. <u>Sub-contract</u>					
(1) Description					
<hr/>					
(2) Estimated cost					
<hr/>					
TOTAL	\$51 520	\$21 375	\$28 375	\$16 500	\$23 500

PROJECT BUDGET COVERING UNDP CONTRIBUTION
(in US Dollars)

Coordinating country: THAILAND

Activity: Establishment of a regional training centre for the production and utilization of regional standards and reference substances

		<u>Total</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
		<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>	<u>m/m</u>	<u>\$</u>
10	<u>Project personnel</u>												
11-60	Consultants	4 1/2	15 750			1 1/2	6 375	1 1/2	6 375	3/4	1 500	3/4	1 500
19	Component total	4 1/2	15 750			1 1/2	6 375	1 1/2	6 375	3/4	1 500	3/4	1 500
		<u>Total (\$)</u>		<u>1987</u>		<u>1988</u>		<u>1989</u>		<u>1990</u>		<u>1991</u>	
20	<u>Sub-contract</u>												
21	Sub-contracts												
29	Component total												

		<u>Total (\$)</u>	<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>
30	<u>Training</u>						
31	Fellowships	18 600	18 600				
32	Group training	74 000		15 000	22 000	15 000	22 000
33	Inservice training						
39	Component total	92 600	18 600	15 000	22 000	15 000	16 000
40	<u>Equipment</u>						
41	Expendable equipment						
42	Nonexpendable equipment	32 920	32 920				
49	Component total	32 920	32 920				
50	<u>Miscellaneous</u>						
51	Miscellaneous						
53	Sundry						
59	Component total						
	Total for activity	141 270	51 520	21 375	28 375	16 500	23 500

ASEAN PHARMACEUTICALS PROJECT
BUDGET ADJUSTMENT
(1987 - 1991)

<u>I. CUTS BY ACTIVITY (in US Dollars)</u>		
1. Development of hospital pharmacy management	163 260	134 280
2. Training programme for drug management at the peripheral level	94 600	94 600
3. Strengthening of communication, information and education on medicine to the community	154 400	111 000
4. Standardization, quality control and utilization of herbal medicine	348 600	248 400
5. Formulation of essential drug information manual	129 100	107 100
6. Training centre on Good Manufacturing Practices	138 900	89 100
7. Training centre on drug information	83 000	71 800
8. Training centre on drug evaluation	95 650	82 250
9. Training centre on laboratory quality control	178 600	120 200
10. Training centre on production and utilization of regional standards and reference substances	268 350	141 270
Grand total	1 654 460	1 200 000
<u>II. CUTS BY BUDGET LINE</u>		
Consultants/temp. ad	296 900	252 400
Sub-contracts	24 000	12 000
Fellowships	391 800	272 200
Group training	569 760	432 480
Inservice training	35 000	35 000
S/E	297 000	162 920
Miscellaneous	40 000	33 000
Grand total	1 654 460	1 200 000

TOTAL PROJECT BUDGET (US\$ x 1000)
(Activity vs Year)

No.	Coordination of activity	Establishment of training centre	1987	1988	1989	1990	1991	TOTAL
1	Development of hospital pharmacy management		51.0	8.5	30.78	22.0	22.0	134.28
2	Training programme for drug management at the peripheral level		9.0	19.0	22.2	22.2	22.2	94.6
3	Strengthening of communication, information and education on medicine to the community		15.6	9.6	58.6	27.2	-	111.0
4	Standardization, quality control and utilization of herbal medicine		85.4	49.9	32.1	39.9	41.1	248.4
5	Formulation of essential drug information manual		20.8	24.5	37.2	-	24.6	107.1
6		Training centre on good manufacturing practices	11.9	19.3	19.3	19.3	19.3	89.1
7		Training centre on drug information	17.4	13.6	13.6	13.6	13.6	71.8
8		Training centre on drug evaluation	16.6	13.45	17.4	17.4	17.4	82.25
9		Training centre on laboratory quality control	61.8	19.1	13.1	13.1	13.1	120.2
10		Training centre on production and utilization of regional standards and reference substances	51.52	21.375	28.375	16.5	23.5	141.27
Total			341.02	198.325	272.655	191.2	196.8	1200.0

