WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

REPORT

WORKING GROUP ON HERBAL MEDICINES

Manila, Philippines
8-12 December 1997

Manila, Philippines
March 1998

(WP)TRM/ICP/TRM/002/VD/96 English only
Report series number: RS/97/GE/36(PHL)

REPORT

WORKING GROUP ON HERBAL MEDICINES

Convened by:

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC
Manila, Philippines
8-12 December 1997

Not for sale

Printed and distributed by:
World Health Organization
Regional Office for the Western Pacific
Manila, Philippines
March 1998

NOTE

The views expressed in this report are those of the participants in the Working Group Meeting and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the Regional Office for the Western Pacific of the World Health Organization for governments of Member States in the Region and for the participants in the meeting of the Working Group on Herbal Medicines held in the Western Pacific Regional Office, Manila, Philippines, from 8 to 12 December 1997.

CONTENTS

Key words

Medicine, Herbal / Medicine, Traditional / Philippines

SUMMARY

The Working Group on Herbal Medicines met in Manila, Philippines, from 8 to 12 December 1997. The main objective of the meeting was to develop guidelines for the appropriate use of herbal medicines for interested countries in the Region which would assist in the development of national policies and programmes on herbal medicines.

The meeting was attended by 17 temporary advisers, two consultants, two secretariat staff from the WHO Regional Office for the Western Pacific and three observers. Dr Wong Kum Leng was elected Chairman, Mrs Napsah binti Mahmud, the Vice-Chairman and Dr Nelia Cortes-Maramba and Dr Boun Hoong Southavong were the two Rapporteurs.

The meeting commenced with presentations from the two consultants and one secretariat member. These presentations briefly summarized:

(1) the Regional growth of herbal medicine and relevant WHO policies and programmes;

(2) the regulation of herbal medicine in the Region; and

(3) progress in herbal medicine research.

Dr S.T. Han, WHO's Regional Director for the Western Pacific, delivered a speech during the opening ceremony. Country reports on the status and activity of herbal medicine were then presented by the temporary advisers.

On subsequent days, significant focus was given to identifying the essential principles behind the development of any national policy and programme in herbal medicine, and key issues relevant to the regulation of herbal medicines and herbal medicine practitioners. In the course of these discussions, the Working Group developed the guidelines for the appropriate use of herbal medicines.

A summary of the principal conclusions and recommendations follows:

(1) With the growing use of herbal medicines in the Region, it is becoming important for Member States to formulate their own national policy and programme on herbal medicine.

(2) The guidelines for the appropriate use of herbal medicines, developed by the Working Group, are to be utilized fully or partially by Member States, depending on each country's own situation and distinct needs.

(3) Herbal medicines, especially traditional herbal medicines, will increasingly need to meet basic standards of quality control and safety. Member States are encouraged to work towards this as part of their national programme on herbal medicine.

(4) Bilateral and multilateral cooperation among Member States and with WHO are essential to harmonize regulatory standards across Member States and to facilitate exchange of information.

1. INTRODUCTION

Herbal medicine in traditional medical practice is an important resource which can be mobilized for the attainment of the common goal of health for all. These herbal medicines have contributed significantly to man's struggle against diseases and maintenance of health. In recent years, interest in the use of herbal preparations has increased. Herbal medicines are used in most countries in the Region either within the state health care system or in communities and private practices outside the state system. The growing interest in, and the increased consumption of herbal preparations as herbal medicines have also raised considerations about the need for regulation. Special attention to the nature and characteristics of herbal medicines is warranted in forming regulatory provisions and procedures.

The consumption of herbal medicines is significant and appears to be steadily increasing for a number of countries in the Region. In rural China, 35% of outpatients and 22% of inpatients are treated with traditional medicines. Herbal medicine sales accounted for 33.1% of the drug market in 1995, and represented a greater than 200% increase on production levels of 1990. In Hong Kong, 60% of the population have consulted traditional medicine practitioners. Japan saw a 15-fold increase in herbal medicine sales between 1979 and 1989 in contrast to a 2.6 fold increase in sales of pharmaceutical drugs during the same period. In Australia, a recent survey identified 48.5% of Australians as using alternative medicines, including herbal medicine. The consumption of herbal medicines does not appear to be abating.

WHO's policy on herbal medicines acknowledges their important role for the health of a large number of people. For particular cultural and socioeconomic groups, they form a significant part of their health services. WHO promotes the safe and effective use of herbal medicines and encourages their integration, wherever possible, into the delivery of mainstream health care services.

1.1 Objectives

The objectives of the meeting were to:

(1) review the current status of the appropriate use of herbal medicines in the Region;

(2) present and discuss various issues and models for the appropriate use of herbal preparations as herbal medicines;

(3) develop draft guidelines for the appropriate use of herbal medicines; and

(4) recommend future directions for the implementation of these guidelines.

1.2 Participants

The Working Group was composed of 17 temporary advisers, two consultants, two secretariat staff from the WHO Regional Office for the Western Pacific and three observers. The list of participants is attached as Annex 1.

1.3 Organization

Dr Wong Kum Leng and Mrs Napsah binti Mahmud were elected Chairman and Vice-Chairman of the Working Group. Dr Nelia Cortes-Maramba and Dr Boun Hoong Southavong were the two Rapporteurs.

1.4 Opening ceremony

Dr S.T. Han, Regional Director for the Western Pacific, opened the meeting by pointing out that WHO recognizes the very significant contribution which traditional medicine, and in particular herbal medicine, can make to public health in the Region. He reported on the high usage figures for herbal medicines in the Region, the capacity of plant materials to offer new drugs and successful medical treatment, and the degree of integration into the official health care system of herbal medicine by some Member States. Dr Han indicated that WHO fully supports Member States in their efforts to integrate traditional medicine into their health care delivery systems. He noted that the Working Group, in preparing guidelines for the appropriate use of herbal medicines, should include technical suggestions for Member States interested in promoting the proper use of herbal medicine, which are flexible, feasible and practical.

Dr S.T. Han's opening speech is attached as Annex 2.

2. PROCEEDINGS

The agenda of the Working Group is shown in Annex 3.

2.1 Initial presentations

The meeting commenced with presentations from the two consultants and one secretariat member. These presentations briefly summarized:

- the Regional growth of herbal medicine and relevant WHO policies and programmes;
- the regulation of herbal medicine in the Region; and
- progress in herbal medicine research.

Dr Chen Ken, WHO Medical Officer for Traditional Medicine, outlined the current status of herbal medicines in the WHO Western Pacific Region and drew the Working Group's attention to growth statistics from a number of countries and areas. It was identified that:

- A great number of people in the Region still use herbal medicine for various reasons.
- A major part of traditional therapies involves the use of herbal medicines.
- Herbal medicines have a susbtantial share of the drug market.
- Medicinal plants are important sources of pharmaceutical products.
- Medicinal plants are important sources for the development of new drugs.

WHO's policy and programme on herbal medicines was also outlined. WHO's policy describes a high level of awareness of the importance of herbal medicines and the need to promote the proper use of medicinal substances. WHO's programme objectives are to:

- promote the safe and effective use of traditional medicine; and

- encourage the integration of traditional medicine into the general health services system, where applicable.

WHO will continue efforts to promote the proper use of herbal medicine through policy development, training, research and information exchange.

Mr Alan Bensoussan, Senior Lecturer, Faculty of Health, and Head, Research Unit for Complementary Medicine, University of Western Sydney, Campbelltown, Australia, summarized the essential policy elements and trends within a number of regional jurisdictions to do with the practice of herbal medicine. Legislative structures governing the practice of herbal medicine vary significantly between neighbouring jurisdictions. Regulatory approaches to herbal medicine in different countries may be seen as a continuum, from a highly regulated model where practitioners are licensed and supervising boards are established to maintain standards and oversee qualifications; to a virtual absence of regulation, where any person may set up in practice of herbal medicine, constrained only by the prospect of personal liability for negligence and breach of contract, and general provisions relating to poisons and therapeutic goods. More extreme legislation in some jurisdictions may result in the complete exclusion of herbal medicine practitioners from the health care marketplace.

Regional and overseas trends indicate that increasing numbers of jurisdictions are contemplating the introduction of occupational regulation of herbal medicine practitioners to supplement the various forms of regulation on the materials and the conduct of herbal practice.

Professor Il-Moo Chang, Director, Natural Products Research Institute, Seoul National University, Seoul, Republic of Korea, summarized herbal medicine research activities in the Region. The major areas of activity include the following:

- There is a significant current focus on quality control methods to achieve standardization. Where a herb has unknown active ingredients, indicative constituents and/or fingerprint analysis (usually high pressure liquid chromatography patterns) have been used for the purpose of standardization and quality control.

- Classical animal cell culture, as well as gene manipulation techniques, are being applied to produce active ingredients of CITES-subjected (Convention on International Trade in Endangered Species) animal species.

- Where it is not easy to understand the efficacy of herbal medicine in terms of modern pharmacology, animal models are being developed to test the efficacy of specific herbs.

- Because of the difficulty in assessing an extensive range of herbal prescriptions (est. 100 000), efforts have been made to establish minimum safety assessment requirements. These include assessment of acute toxicity and some systematic toxicity tests. If abnormalities arise then more detailed toxicological studies are undertaken.

- Information databases and exchange mechanisms are being established.

- A coding system for nomenclature of traditional Chinese medicine prescriptions is being established.

2.2 Country reports

Country reports on the status and activity of herbal medicine were presented by the temporary advisers and are summarized below.

Australia

Ms Laurayne Bowler communicated that responsibility for the regulation of medicine is split between States and Territories on the one hand, who deal with practitioners, and the Commonwealth on the other hand, with whom the responsibility for proprietary medicines largely lies. However, there is only limited control on the dispensing of raw herbal material. The Therapeutic Goods Act, which was passed in 1989, set out for the first time in Australia a system for the regulation of herbal proprietary medicines. Approximately 1500 herbal substances are contained in some of the medicinal products entered on the Australian Register of Therapeutic Goods. A recent government review of the Therapeutic Goods Act in 1997 has made a number of further recommendations to improve regulations on advertising, herbal standards, the regulatory process and the food/drug interface, while imposing the minimum regulatory burden on industry necessary to protect public health and safety.

The regulation of Chinese herbal medicine practitioners is due for consideration by State and Territory health ministers early in 1998.

Cambodia

Mr Seng Lim Neou reported that many valuable traditional medicine documents and skilled practitioners were lost during the time of Polpot-Khmer Rouge. In 1979, the Government officially integrated traditional medicine into the national health system and it has played a significant role in Cambodian health care. However, since 1990 and the Government's adoption of a free market policy, its importance has gradually diminished. Currently, approximately 230 traditional healers are registered with the Health Department of the Municipality of Phnom Penh. They all work in the private sector and perform all tasks - from manufacturing and sales to patient treatment. There is no quality control of their products.

The national policy on traditional medicine is to increase the importance of Cambodian traditional medicine and encourage traditional practice as a complement to modern medicine.

China

Mr Shen Yu Long indicated that the administration of Chinese herbal medicine in China has two important aspects. The first is the policy of government support, (mutual development and promotion of modern and traditional Chinese medicine), which is signified in China's constitution. The second consists of the substantial infrastructure of research, education and training in herbal medicine existent in China. There are 170 Chinese medicine research institutes with about 15 000 professional researchers. There are 30 universities and colleges with a total of 37 000 Chinese medicine students.

Both aspects are symbolic of the substantial degree of recognition, support and integration of Chinese herbal medicine as part of the mainstream health care system in China.

Hong Kong

Dr Ting-hung Leung reported that, although Chinese medicine is very much an integral part of the health care system in the Hong Kong Special Administrative Region (SAR), China, there has been no specific legal control and recognition of Chinese medicine practitioners or medicines. There are an estimated 7000 Chinese medicine practitioners in Hong Kong. Following recommendations of a Working Group report (1989), a Preparatory Committee on Chinese Medicine (PCCM) was appointed by the Secretary of Health and Welfare in 1995. Recent recommendations from the PCCM include the establishment of a statutory framework to regulate the practice, the use of and trading in Chinese medicine. The Hong Kong Government would commence statutory registration of Chinese medicine practitioners by the year 2000 and

regulation of Chinese medicines would occur in phases from that date. The Basic Law of the Hong Kong SAR provides that the Government shall formulate appropriate policies to develop both western and traditional Chinese medicine.

Japan

Dr Motoyoshi Satake stated that, in Japan, the practice of herbal medicine is restricted to western medicine doctors and pharmacists. In 1976, Kampo (traditional Chinese) medicines were introduced by the National Health Insurance System and have been used in hospitals and pharmacies. Herbal medicines sold in the market are estimated to be worth about US$1.5 billion, which is about 3.5% of the total medicine market. The Japanese pharmacopoeia contains over 100 monographs on traditional Chinese herbs.

A re-evaluation process is now occurring for some of the 210 Kampo products currently available under the Pharmaceutical Affairs Law. Some debate ensued as to what was driving this new evaluation of Kampo herbal formulae for which approval was already granted. The question was raised as to whether political, economic or social reasons were behind this re-evaluation.

Republic of Korea

Dr Soo-Myung Oh and Dr Dong-Suk Park reported that oriental medicine has a long history in the Republic of Korea and plays a significant role in the health care system. A particular form of traditional medicine developed from the combination of Korean and Chinese medicines. In 1952, a national medical law was passed establishing oriental medicine and modern medicine as parallels within the health care system. There are now 11 colleges providing six-year programmes in oriental medicine. There are now more than 9000 licensed oriental medicine doctors.

So far as herbal medicines are concerned, there are specialized guidelines for manufacturers and traders, and the Government is currently standardizing the commonly used proprietary herbal medicines. In 1996, the Department of Oriental Medicine within the Ministry of Health and Welfare was opened, employing experts in herbal medicine. Previously, western medicine pharmacists were readily permitted to dispense some herbal medicines, but now western pharmacists, in order to be authorized to dispense herbal medicines, are required to take a national examination spanning some 100 traditional Chinese prescriptions. A parallel system of oriental pharmacists is also being created which will provide experts capable of dispensing the full range of herbal prescriptions. The increasing public demand for herbal medicines requires further substantial national support at Government level.

Dr Park Sang-Pyo also provided a paper entitled, "Current status of herbal medicine in Korea".

Lao People's Democratic Republic

Dr Boun Hoong Southavong reported that in rural areas, more than 90% of communities use traditional Lao medicine to prevent and cure disease. The Government of Laos has in place a national policy which actively promotes the use of traditional medicine and has set up the Research Institute of Medicinal Plants (RIMP). The development of Lao infrastructure for traditional medicine (including the RIMP) depends very much on WHO support and is currently quite fractured across the country. There is a significant effort in progress for the revival of traditional medicine. No clear regulatory mechanisms currently exist for traditional medicine practitioners or herbal medicines.

Macao

Dr Cheong Tai stated that the majority of Macao people believe in and rely on indigenous traditional medicines to satisfy their primary health care needs. In 1994, a law came into effect to ensure control of a number of aspects of traditional Chinese medicines, including their safety, efficacy and quality, and the regulation of trade and marketing. Importers, exporters and wholesalers and traditional Chinese pharmacies are required to hold licences. There are currently 100 licensed traditional Chinese medicine pharmacies in Macao. A form of defacto registration exists which requires that all products imported into Macao be registered and sold freely in their countries of origin. Where proprietary herbal medicines are exempt from registration controls in their own countries, then Macao importers are required to produce an analysis certificate for each individual batch. All traditional medicine products must comply with general labelling requirements. Over 400 herbs, including 31 classified as toxic herbs, are restricted for sale by licensed Chinese pharmacies. The list of toxic herbs is currently being updated and perfected.

Malaysia

Mrs Napsah binti Mahmud reported that implementation of registration and licensing of traditional medicines in 1992 marked the systematic regulatory control of traditional medicines in Malaysia. The registration exercise, while ensuring safety and quality of imported and locally manufactured traditional medicines, could also be considered a starting point for the upgrade of local herbal medicine manufacture. Manufacturing methods will need to comply with the basic elements of GMP by the end of 1997.

The Ministry of Health has recently set up committees to review the possibility of traditional medicines playing a formal role in the health care system. The three main areas of focus should be:

- registration of traditional medicine practitioners;
- education and training of practitioners; and
- the identification of products with proven safety, quality and efficacy.

A National Committee on Herbal Medicines was also established in 1995 to look into such aspects as research and development on herbal medicinal plants, the establishment of a series of Malaysian herbal monographs, and developing strategies to ensure conservation of medicinal plants and to promote the herbal medicines industry.

Mongolia

Dr Miaegombo Ambaga reported that Mongolia has an abundant diversity of plant species and a rich tradition of utilization. There have been recent increases in the usage of traditional medicine and in the number of new plant preparations. A government drug agency monitors quality control of herbal medicines. Full registration of herbal medicine practitioners includes reference to three groups: western medical practitioners with little traditional herbal training, graduates from the new schools of traditional medicine, and a number of older private practitioners for whom examinations are available.

New Zealand

Dr Paratene Ngata shared with the Working Group the distinct nature of the Maori indigenous traditional healing practices. So far as the regulation of herbal medicine practitioners is concerned, Common Law principals operate in New Zealand, as they do in

Australia. Herbal medicines are listable under New Zealand law (Medicines Act 1981 and Medicines Regulations 1984) and fall under the category of 'dietary supplements'. Dr Ngata indicated that the inclusion of traditional healing in the health system may occur through a system of Government 'purchasing' services for consumers. This would impose some formalization of healing activities to develop acceptable standards, which may in turn risk autonomy or compromise certain essential characteristics of healing.

Philippines

Dr Alfonso T. Lagaya summarized that the Philippine government is very supportive of activities related to the research, education and production of traditional herbal medicines and, for these purposes, has recently approved the establishment of the Philippine Institute of Traditional and Alternative Health Care.

There are two groups of practising herbalists in the Philippines - a handful of licensed modern medicine physicians and approximately 250 000 unregulated traditional herbalists. While the integration of traditional medicine into the current health care delivery system is intended, no plans exist for the future regulation of the large unregulated traditional medicine workforce.

The production and sale of herbal medicines are regulated by the Department of Health. A listing system is established for local herbal and traditional drugs but imported proprietary medicines are currently exempted. Government policy is that herbal medicines will be used nationwide within a primary health care context.

Professor Nelia Cortes-Maramba added that there are new and substantial levels of evaluation of herbal medicines commencing from point of growth to the provision of the finished product.

Singapore

Dr Wong Kum Leng stated that while western medicine is the main form of health care in Singapore, herbal medicine continues to enjoy considerable popularity. In 1994, the Ministry of Health appointed a committee to review the practice of Chinese medicine. The Committee advocated the need to regulate the more than 2000 Chinese medicine practitioners in Singapore and also recommended steps to upgrade the standard of training. In 1995, the Ministry established a departmental Chinese Medicine Unit.

Singapore has adopted a phased approach, initial self-regulation is to be followed by statutory regulation. Statutory regulation for acupuncturists will be implemented by the year 2000, while that for Chinese herbalists is intended to be in place several years later. At present, herbal medicines are exempted from product registration unless they contain controlled substances - essentially, no licences are required for their manufacture, sale or importation. However, various aspects of herbal medicines are required to comply with the various legislations. No product registration for Chinese proprietary medicines is anticipated although products will be listed by the Government. Manufacturers will be licensed on the basis of GMP standards.

There is a prohibition on labelling and advertising claims for 19 diseases. There was some discussion as to the basis upon which the 19 prescribed diseases were selected.

Viet Nam

Professor Le Van Truyen reported that, since 1955, traditional medicine has played a formal role in Viet Nam. This has involved the re-establishment of traditional medicine as a

component of public health care, the establishment of an appropriate network from central government to the local level, the training of traditional medical personnel, and the introduction of a programme of scientific research and international cooperation. A number of laws have been passed on the regulation of practitioners and medicines. The Vietnamese pharmacopoeia, which was compiled in the 1970s, is now being rewritten to include herbal medicine monographs.

However, despite these efforts, some problems still exist. There are two colleges in Viet Nam specializing in training personnel in traditional medicine, but the system of training needs reorganization. Nineteen out of 63 provinces are without traditional medicine hospitals and many other hospitals do not have traditional medicine departments. The demand for this form of medical care cannot currently be met. Presently, 30% of all patients are being treated by traditional medicine and an estimated 50% of the population want to be treated by traditional medicine.

2.3 Principles and format for the development of the guidelines

Dr Chen Ken led the Working Group discussion by clarifying the purposes of the guidelines and the context of their development. One role of WHO is to provide technical advice to Member States. Furthermore, WHO has already received requests from Member States for support in this area. In the context of herbal medicine practice, Member States generally face one of three difficulties: a lack of awareness within government of the role of herbal medicines; a gap between government interest and significant support; or, finally, a lack of relevant expertise in dealing with herbal medicines.

Many different countries and regional jurisdictions are grappling with a range of issues related to the practice of herbal medicine, its widespread and increasing usage and how best to ensure it is delivered safely and effectively to consumers. Preparing informed guidelines on the appropriate use of herbal medicine will support all nations in developing an appropriate national programme which reflects their specific requirements and cultural context. The guidelines are designed to act as foundation principles for all interested countries and jurisdictions.

These guidelines are designed to assist government determine policy and practice in herbal medicine. A series of principles for the formation of the guidelines emerged during discussion. These include that the guidelines:

- promote the practice and development of the appropriate use of herbal medicines;
- represent a set of generic principles able to be flexibly implemented by different jurisdictions according to their domestic contexts;
- are able to meet the needs and different situations of countries in the Region;
- support the harmonization of the promotion, management and regulation of herbal medicine without making significant impositions on individual countries;
- respect traditional knowledge in the formation of these guidelines;
- facilitate communication and information exchange between Member States, including the development of bilateral and regional cooperation;
- act as a reference point for government and health authorities; and
- may be used by manufacturers, researchers, academics and practitioners.

The Working Group was then organized into two discussion groups. The focus of the first discussion group was to develop draft guidelines on national policy and programme formation, and the regulation of herbal medicine practitioners. The second discussion group focused on issues related to the management and regulation of herbal medicines. These groups met independently for one and a half days each and developed draft guidelines which were then debated more comprehensively in plenary sessions.

2.4 Discussions on national policy and programme development

Discussion group members agreed unanimously that the formation of a national policy and programme for herbal medicine is a critical first step in giving support to and promoting the use of herbal medicine. A national policy will support the implementation of the practice of herbal medicine into the health care services of the country. It will also aid in the national and international coordination of regulatory structures, the establishment of suitable research programmes and the ability to undertake effective international collaboration.

2.5 Discussions on regulation of herbal medicines

The second discussion group focused on issues related to the regulation of herbal medicines. The group acknowledged that some form of regulation was required of manufacturers and distributors in that their products may be used widely by consumers. However, Good Manufacturing Practice (GMP) may not be able to be implemented in some developing nations that are heavily reliant on herbal medicines. The group agreed that phased implementation of regulatory requirements was important. The appropriate training of staff involved in regulatory matters was also raised and discussed. The WHO certification scheme on the qualify of pharmaceutical products was identified as a scheme that may be of help in small countries where there are no facilities or mechanisms for the systematic evaluation of the safety of herbal products.

During the one and a half days of discussion that followed, a number of areas were considered and debated, including:

- the distinct regulatory requirements for raw plant materials, processed plant materials, and medicinal herbal products;
- marketing, labelling and advertising issues;
- regulatory measures consistent with the conservation of species;
- general aspects of safety assessment (toxicity studies, safety based on experience);
- general aspects of assessment of efficacy and intended usage; and
- monitoring of adverse reactions to herbal medicines.

2.6 Final discussion on the guidelines

After one and a half days of group discussion, the Working Group resumed activity in a plenary session, providing opportunity for further discussion. One of the principal concerns was the way in which guidelines may be interpreted by regulatory authorities. The Working Group, while wishing to provide some direction on the kind of safety data that may be required of some herbal medicines, did not wish this to result in significant impositions for some countries who might have substantial difficulties in implementing stringent regulatory measures. Furthermore, there was a strong feeling among some members of the Working Group that regulatory guidelines with long lists of potential data requirements may inappropriately encourage

regulatory authorities to require more rather than less. This may overlook the fact that herbal medicines by definition have been used extensively and over long periods of time and that some modifications, such as dosage forms or indications, may not fundamentally affect the herb's safety. The history of use of a substance should in most cases be adequate evidence of its basic safety.

The regulation of practitioners was discussed at some length and it was agreed that only limited review of this area would be provided in the guidelines. Forms of professional regulation vary significantly within and between nations, reflecting the varying legislative structures, and the Working Group deemed it appropriate only to make general recommendations in this regard.

2.7 Closing ceremony

In his closing remarks, Dr S.T. Han, Regional Director of the WHO Regional Office for the Western Pacific, stated that he accepted the recommendations of the expert Working Group and that he would ask his operational staff to prepare a plan for their implementation. He commented that he was most impressed by the focused and detailed discussions and the productiveness of the Working Group in developing the guidelines. Dr Han communicated his reservations, however, that imposing GMP on the herbal medicines industry, particularly in developing countries, may not at this stage be a realistic goal. Each country will need to determine the appropriate times for the implementation of various parts of the guidelines. Dr Han expressed confidence that the final guidelines accurately reflected the substantial expertise contained within the membership of the Working Group.

On behalf of all participants, Dr Wong acknowledged the effort and support of the WHO Regional Office for the Western Pacific in holding the Working Group meeting and thanked all temporary advisers and the two consultants for their continued efforts throughout the week in devising the final guidelines based on the discussions of the Working Group.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The Working Group recognizes the significant growth that has occurred in the use of herbal medicines in the Region and the major health care role they play in many countries. Major advances have also occurred in research on herbal medicines, confirming their value and significant contribution to health care services. Their increasing use also raises the need for appropriate monitoring and evaluation of herbal medicines.

The Working Group recognizes that the work of WHO is important in providing direct guidance and support to countries and areas in the development of national herbal medicine policies and programmes. WHO can continue to make a major contribution to public health through supporting the development of policies that generate better access to quality herbal medicines.

The Working Group recommends that the WHO Regional Office for the Western Pacific continues to develop, expand and adjust as necessary the technical, managerial and administrative tools needed for the formulation and implementation of national herbal medicine policies in accordance with these proposed guidelines. It further recommends that WHO

continues to strengthen its support to countries in developing and implementing national herbal medicine policies.

It is highly desirable that the WHO Regional Office for the Western Pacific plays a role in stimulating collaboration among Member States for purposes such as general information exchange, standardizing nomenclatures, and sharing research knowledge and experience.

These guidelines, which were formally adopted by the Working Group, represent a milestone in that they signal a common direction for the appropriate use of herbal medicines that, in turn, can be either adopted or adapted by Member States in the Region.

One immediate outcome of this Working Group meeting is that the Working Group volunteers to form an informal network to facilitate information exchange on herbal medicines and to collaborate in other areas with a view to expanding the networking as appropriate. This reflects the priority given by members of the Working Group to these issues.

3.2 Recommendations

The Working Group's main recommendations are reflected in the Guidelines for the Appropriate Use of Herbal Medicines. In addition, the members of the Working Group provide the following recommendations which are focused on the implementation of the Guidelines:

(1) WHO should promote the use of the Guidelines for the Appropriate Use of Herbal Medicines among Member States by:

- reporting the contents of these Guidelines to Member States;
- helping Member States to organize training courses, seminars and national workshops on the appropriate use of herbal medicines;
- helping Member States to set up an action plan for the development of a national policy on the appropriate use of herbal medicines; and
- encouraging Member States to translate the Guidelines into national official languages.

(2) Member States should be urged to develop national policies and programmes to promote the appropriate use of herbal medicines as part of the national health care services. WHO Guidelines for the Appropriate Use of Herbal Medicines could be used as a basis for developing a national policy and programme on herbal medicines. As an initial step, each Member State should assess the need and extent of regulatory mechanisms required to promote safe and effective use of herbal medicines. Attention should be directed to the regulation of herbal medicine practitioners and related workers, regulatory provisions related to manufacturing and distribution, and evaluation mechanisms for herbal medicines.

A collaborative framework among countries and areas in the Region to support the appropriate use of herbal medicines should be established. The framework should include mechanisms to facilitate the exchange of information, the preparation of monographs on medicinal plants and the development of training and education resources and programmes. The WHO Regional Office for the Western Pacific should coordinate the development of the collaborative framework. To facilitate this activity, Member States should advise WHO of:

- progress on implementation of their national policies and provide copies to WHO for distribution, including regulating structures that have been adopted;

- proposals to develop resources, such as monographs and training programmes and provide to WHO copies of these resources; and

- adverse effects or particular problems which may be of importance or interest to Member States.

The WHO Collaborating Centres for Traditional Medicine and other interested institutions could play an active role in supporting the coordinating activities of WHO. Members of the Working Group will form an informal network to facilitate information exchange and collaboration on herbal medicine matters among them and to support WHO programme activities in the area of herbal medicines.

(3) Medicinal plants represent valuable natural resources. There is an increasing concern surrounding the issue of endangered species of plants with significant therapeutic benefits. Member States are therefore urged to:

- document endangered species in their countries;

- develop a sustainable conservation plan which may include ex-situ, in-situ and on-farm conservation, natural parks, botanical gardens, and seed banks for medicinal plants; and

- implement appropriate regulation for the sustainable development and management of these endangered species.

(4) In consultation with indigenous people and with their involvement, Member States should actively encourage.

- the identification of indigenous plants with significant therapeutic activity;

- research into their safety and efficacy; and

- applied research on their use.

The private sector and industry should be encouraged to participate in these efforts.

(5) The Working Group notes the recommendations made by the WHO Working Group on the Safety and Efficacy of Herbal Medicines in 1992 encouraging research on herbal medicine. The Working Group reaffirms these recommendations and encourages WHO and Member States to maintain their efforts in promoting scientific research on herbal medicine.

(6) It is noted that several computer databases on medicinal plants and herbal medicines are available and a new database on toxicity of herbal medicines will be developed. An active programme of promotion and education should be developed to ensure that existing databases are used and information from these databases is disseminated.

ANNEX 1

LIST OF TEMPORARY ADVISERS, CONSULTANTS, OBSERVERS AND SECRETARIAT

1. TEMPORARY ADVISERS

Dr Miaegombo Ambaga
Scientific Secretary of
Medical Research Institute and
Director of Centre of Clinical Medicine
Ministry of Health
Ulaanbaatar
Mongolia
Tel. no. (976) 1 300945

Dr Boun Hoong Southavong
Programme Manager
Research Institute of Medicinal Plants
Ministry of Public Health
Vientiane
Lao People's Democratic Republic
Tel. no. (856-21) 312-354
FAX: (856-21) 312-354

Ms Laurayne Bowler
Acting Director
Chemicals and Non Prescription Drugs Branch
Therapeutic Goods Administration
Department of Health and Family Services
Canberra
Australia
Tel. no. (02) 6232 8660
FAX: (02) 6232 8659

Dr Cheong Tai
Coordinator
Traditional Chinese Medicine
Division of Pharmaceutical Affairs
Macao Medical and Health Department
Macao
Tel. no. (853) 598 3527
FAX: (853) 524 016

Annex 1

Professor Jiang Tingliang
Director of WHO Collaborating Centre for
Traditional Medicine
Institute of Chinese Materia Medica
Beijing
China
Tel. no. (8610) 6 401 3996
FAX: (8610) 6 401 3996

Dr Alfonso T. Lagaya
National Programme Manager
Traditional Medicine Unit
Department of Health
Manila
Philippines
Tel. no. (063-2) 7438301 local 2502
FAX: (063-2) 7115266

Dr Leung Ting-hung
Assistant Director of Health
Traditional Chinese Medicine
Department of Health
Hong Kong
Tel. no. 2961 8880
FAX: 2836 0071

Dr Nelia P. Cortes-Maramba
Professor
Department of Pharmacology
College of Medicine
University of the Philippines
Manila
Philippines
Tel. no. (632) 526-40-48
FAX: (632) 5218251

Mrs Napsah binti Mahmud
Head, Traditional Medicine Registration Unit
National Pharmaceutical Control Bureau
Ministry of Health
Kuala Lumpur
Malaysia
Tel. no. 603-753611
FAX: 603-7562924

Annex 1

Mr Seng Lim Neou
Director of Pharmacy
Ministry of Health
Phnom Penh
Cambodia
Tel. no. 855-23-366572
FAX: 855-23-724595

Dr Paratene Ngata
Medical Officer
Rural Health Services
Tairawhiti Healthkare Ltd.
Te Puia Springs Hospital
Te Puia Springs
East Coast
New Zealand
Tel. no. (06) 8626658 (res.)
FAX: (06) 8626500 (res.)

Professor Oh Soo-Myung
Director
East-West Medical Research Institute
Kyung Hee University
Seoul
Republic of Korea
Tel. no. (82-2) 958-8263
FAX: (82-2) 958-9083

Dr Park Sang-Pyo
Deputy Director
Division of Oriental Medicine
Ministry of Health and Welfare
Seoul
Republic of Korea
Tel. no. (82-2) 503-7524
FAX: (82-2) 504-6418

Dr Motoyoshi Satake
Director
Pharmacognosy and Phytochemistry Division
National Institute of Health Sciences
Tokyo
Japan
Tel. no. 3-3700-1141
FAX: 3-3707-6950
E-mail: satake@nihs.go.jp

Annex 1

Mr Shen YuLong
Vice Director-General
China International Centre for
Traditional Chinese Medicine
State Administration of Traditional
Chinese Medicine
Beijing
China
Tel. no. 0086-10-64025673
FAX: 0086-10-64025674

Professor Lê Van Truyen
Vice Minister of Public Health
Ministry of Health
Hanoi
Viet Nam
Tel. no. (844) 845-3303
FAX: (844) 846-4051

Dr Wong Kum Leng
Deputy Director of Medical Services and
Director, Traditional Chinese Medicine
Ministry of Health
Singapore
Tel. no. 325 9220
FAX: 224 1677

2. CONSULTANTS

Mr Alan Bensoussan
Senior Lecturer, Faculty of Health
Head, Research Unit for Complementary Medicine
University of Western Sydney
PO Box 555
Campbelltown
Australia
Tel. no.: 61-2-97729363
FAX: (612) 9773 0998
E-mail: a.bensoussan@uws.edu.au

Annex 1

Professor Il-Moo Chang
Director
Natural Products Research Institute
Seoul National University
Seoul
Republic of Korea
Tel. no.: (82-2) 762 8320
FAX: (82-2) 742 9951
E-mail: changim@plaza.snu.ac.kr

3. OBSERVERS

Dr Cho Dong Wuk
Principal Research Scientist
Korea Institute of Oriental Medicine
Seoul
Republic of Korea
Tel. no. (02) 3442 0514
FAX: (02) 3442 0515

Dr Alan Feranil
Officer-in-Charge
Research Management and Development Division
Philippine Council for Health Research
and Development (PCHRD)
Department of Science and Technology
Bicutan, Taguig
Metro Manila
Tel. no. 837-75-35
FAX: 837-29-24
E-mail: alan@health.pchrd.dost.gov.ph

Dr Park Dong-Seok
Deputy Director
East-West Medical Research Institute
Kyung Hee University
Seoul
Republic of Korea
Tel. no. (82-2) 958-9080
FAX: (82-2) 958-9083

Annex 1

4. SECRETARIAT

Dr N.V.K. Nair
Director, Health Infrastructure
WHO Western Pacific Regional Office
U.N. Avenue, Ermita
Manila
Philippines
Tel. no.: (63 2) 528-9951
FAX: (63 2) 521-1036
E-mail: nairn@who.org.ph

Dr Chen Ken (Operational Officer)
Medical Officer
Traditional Medicine
WHO Western Pacific Regional Office
U.N. Avenue, Ermita
Manila
Philippines
Tel. no.: (63 2) 528-9948
FAX: (63 2) 521-1036
E-mail: chenk@who.org.ph

ANNEX 2

OPENING SPEECH OF DR S.T. HAN, WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC REGION

WORKING GROUP ON HERBAL MEDICINES
8 December 199[illegible], Manila, Philippines

DISTINGUISHED PARTICIPANTS, COLLEAGUES, LADIES AND GENTLEMEN,

I am very pleased to welcome you all to this meeting.

Herbal medicine is the main component of the traditional system of medicine. It has been used for thousands of years and has made a significant contribution to human health. Today, people still attach considerable importance to herbal medicine, particularly in this Region.

For its part, WHO recognizes the very significant contribution which traditional medicine can make to public health in the Region. We fully support Member States in their efforts to integrate traditional medicine into their health delivery systems, particularly in extending the coverage of primary health care.

Accurate figures on regional expenditure on herbal medicine are not available. However, in Australia for example, expenditure on alternative medicine, including herbal medicine, is estimated at about US$438 million annually. In China, herbal medicine represents about one-third of the drug market. In Hong Kong, herbal medicines worth over US$260 million are imported annually and over 900 raw and processed herbal medicines are generally available in herbal shops. In Malaysia, sales of traditional medicines are estimated at about US$315 million annually.

Herbal medicine holds great but still largely unexplored potential for the development of new drugs to combat major health problems. Artemisinin and its derivatives, for example, extracted from *Artemisia annua,* have become the most effective remedy for multi-drug-resistant malaria cases.

In China, Japan, the Republic of Korea and Viet Nam, the use of herbal medicine is an integral part of the formal health service system. In other countries, herbal medicine is usually used only in the community or in private practice. However, increasing public interest, as demonstrated by herbal medicine's share of the drug market, has raised government awareness in the Region. Health authorities in several countries and areas are reviewing the current status of herbal medicine and the possibility of bringing it into the mainstream of the health service.

Mechanisms for ensuring the safety and control of herbal medicine need to be introduced as part of its formal incorporation into the health service system. In Australia, Macao and Malaysia, for example, systems for the registration of herbal medicine products have been implemented. The regulation of the use of herbal medicine in medical practice is being considered in Australia, Hong Kong, Malaysia and Singapore.

Recognition of the value of herbal medicine is not always accompanied by strong support and the development of vigorous programmes at national level and below. Implementation of government policy is often slowed down by the lack of experience of health authorities. The different philosophical backgrounds of traditional and modern medicine make it difficult for one system to judge the other. Despite these difficulties, there have recently

Annex 2

been some significant developments regarding the promotion of traditional medicine in the Region. For example, the meeting of the Ministers of Health of the Pacific island countries in Rarotonga in August 1997 agreed that the use of traditional medicine, including herbal medicine, should be encouraged where appropriate, and steps should be taken to incorporate its use in the health care system. At the forty-eighth session of the WHO Regional Committee for the Western Pacific it was decided that a technical briefing on traditional medicine should be included during the forty-ninth session of the Regional Committee in 1998.

The major task of this Working Group is to prepare guidelines for the appropriate use of herbal medicine. These guidelines will include technical suggestions for Member States interested in promoting the proper use of herbal medicine. They will include recommendations on how to develop a comprehensive national programme, regulate the practice of herbal medicines and introduce measures for registration. Guidelines on education and research and information exchange will also be prepared.

There is no single model for promoting the proper use of herbal medicine. The guidelines you recommend should be flexible enough to provide various options to Member States to enable them to identify the most appropriate approach to suit their own needs. The guidelines you provide should be both feasible and practical.

I am fully aware that it will not be an easy task to prepare such guidelines. This will be a challenge to all of you. The Working Group is a good mixture of policy-makers, administrators, researchers and practitioners. With your broad experience of herbal medicine, I am sure that you will be able to provide extremely valuable recommendations for further steps to promote the proper use of herbal medicine in the Region. I look forward very much to hearing the outcome of your deliberations.

I like to inform you that the meeting is held with support from the Republic of Korea Government.

I wish you a successful and fruitful meeting and an enjoyable stay in Manila.

ANNEX 3

AGENDA

1. Opening ceremony
2. Herbal medicines in the Western Pacific Region and the WHO programme on herbal medicines
3. Regulation of herbal medicine - a regional review
4. A review of herbal medicine research in the Region
5. Country reports
6. Introduction: Preparation of guidelines for the appropriate use of herbal medicine
7. Discussion: Principles and format for the development of guidelines
8. Group I discussion: National policy and programme development (including utilization, research, education and other programme areas)
9. Group II discussion: Regulation and registration of herbal medicine
10. Plenary session: Reports and comments on group discussions
11. Group preparation of draft guidelines
12. Plenary session: Presentation and discussions on the draft guidelines prepared by the groups
13. Discussion: Recommendations of the Working Group
14. Final discussions on the guidelines
15. Adoption of guidelines
16. Final discussions on the recommendations of the Working Group
17. Adoption of the recommendations of the Working Group
18. Closing ceremony

ANNEX 4

CLOSING REMARKS OF DR S.T. HAN, WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC

WORKING GROUP ON HERBAL MEDICINES
12 December 1997, Manila, Philippines

THANK YOU MR CHAIRMAN AND DISTINGUISHED DELEGATES,

Traditional medicine, including herbal medicine, is a very important area that may need to be more exploited in future. The Western Pacific Region has established a lead in the theory and practice of herbal medicine and we intend to consolidate it. For example, only two days ago in the Philippines, the President signed the alternative medicine act, "R.A. 8423 - an act creating the Philippine Institute of Traditional and Alternative Health Care to accelerate the development of traditional and alternative health care in the Philippines, providing for a traditional and alternative health care development fund and for other purposes". This working group is a good example of how seriously traditional medicine is taken in the Region. In fact, I think this was one of the liveliest and most productive meetings we have ever held in the Regional Office, and I congratulate you for that.

Although I can assure you that we shall continue to pay serious attention to traditional medicine, I do not think we should attempt to cover all aspects. I would like to focus our efforts on two areas: medicinal plants or herbal medicine and acupuncture. We have already been very active in these two areas. For example, I have just signed the preface of *Medicinal plants in the Republic of Korea*, which will be published next year. This is the fourth in a series of books. *Medicinal plants in China* and *Medicinal plants in Viet Nam* have already been published and *Medicinal plants in the South Pacific* is being printed.

During your discussions you have discussed policy development with regard to herbal medicine. You have drawn up some draft guidelines for Member States which I think are excellent, as good if not better than those governing pharmaceutical management in Western medicine. Of course these are guidelines and it is up to governments whether they adopt or adapt them, according to their needs. For example, I am a little concerned that some countries may not be able to implement GMP, good manufacturing practice, in herbal medicine when they already have problems implementing GMP with regard to Western medicine. Nevertheless, I think the guidelines are very important because they enable Member States to see what can be done at the national level. Here at WHO we shall do our best to implement those parts of the guidelines that relate to the work of WHO.

Please allow me to make some specific points about the guidelines. First of all, let me assure you that they will be widely disseminated and that we shall be promoting their use. Second, using these guidelines I shall try to ensure that all countries will be able to develop their own national policies and programmes in the field of herbal medicine. Third, I would like to emphasize the importance of the networking aspect, in particular making use of collaborating centres within and outside the Region. This is in conformity with one of the 47 recommendations made to the Executive Board with regard to reforming the work of WHO. This recommendation advocated that greater use be made of WHO collaborating centres. Fourth, the issue of endangered species was mentioned frequently in your discussions. I think we have to preserve as many species of plants as possible. Fifth, we need better databases, they should be expanded and the information they contain analysed closely. In particular, databases

Annex 4

should record not only the beneficial effects and availability of herbal medicinal plants but also the toxicity and adverse effects of certain herbal medicines.

With regard to following-up this meeting, I would like to suggest that the next meeting on this subject be held in about three years. We have to give Member States time to implement the recommendations. If we are to have a meeting annually, we shall simply repeat what was said at this meeting.

In closing, let me thank you Mr Chairman and also the Vice-Chairman and two rapporteurs who must have worked very hard to write these excellent guidelines. I would like to thank the temporary advisers and others who have also guided or helped guide the meeting, especially Professor Il-Moo Chang and Mr Alan Bensoussan.

With these few words, I would like to wish you a pleasant journey back home. I am sure we shall meet again sometime in the future. Thank you very much.

ANNEX 5

GUIDELINES FOR THE APPROPRIATE USE OF HERBAL MEDICINES

1. INTRODUCTION

1.1 The role of herbal medicines

Plants have been used for health and medical purposes for several thousands of years. The number of higher plant species on earth is about 250 000. It is estimated that 35 000 to 70 000 species have, at one time or another, been used in some cultures for medicinal purposes. A majority of the world's population in developing countries still relies on herbal medicines to meet its health needs. Herbal medicines are often used to provide first-line and basic health service, both to people living in remote areas where it is the only available health service, and to people living in poor areas where it offers the only affordable remedy. Even in areas where modern medicine is available, the interest on herbal medicines and their utilization have been increasing rapidly in recent years.

Medicinal plants are important sources for pharmaceutical manufacturing. Medicinal plants and herbal medicines account for a significant percentage of the pharmaceutical market. For example, in China, medicinal plants and their products had a 33.1% share of the pharmaceutical market in 1995. In the Republic of Korea, herbal medicine constituted about 28% of the total national expenditure on drugs in 1996.

1.2 WHO's policy on herbal medicines

The World Health Organization is fully aware of the importance of herbal medicines to many of its Member States and supports the use of medicinal plants and their products. In early 1978, the World Health Assembly, the WHO governing body, adopted a resolution on drug policies and management of medicinal plants, which recognized the importance of medicinal plants in the health care system. The World Health Assembly proposed coordinating efforts through the preparation of an inventory of medicinal plants, the development of criteria and methods for proving the safety and efficacy of medicinal plant products, and the dissemination of relevant information. In 1987, 1988 and 1989, three more resolutions were adopted covering the identification, evaluation, preparation, cultivation, utilization, regulation and conservation of medicinal plants.

Based on those resolutions, WHO's policy on herbal medicine may be summarized as follows:

(1) WHO is fully aware of the importance of herbal medicines for the health of a large number of the population in today's world. Herbal medicines are recognized as valuable and readily available resources, and their appropriate use is encouraged;

(2) To promote the proper use of medicinal plants, a comprehensive programme for their identification, evaluation, preparation, cultivation, recognition as valuable and readily available resources, and their appropriate use is encouraged;

(3) It is necessary to make a systematic inventory and assessment (pre-clinical and clinical) of medicinal plants; to introduce measures on the regulation of herbal medicines to ensure quality control of herbal products by using modern techniques, applying suitable standards and good manufacturing practices; and to include herbal medicines in the national standard or pharmacopoeia.

Annex 5

(4) As many of the plants that provide traditional and modern drugs are threatened with extinction, WHO endorses the call for international cooperation and coordination to establish programmes for the conservation of medicinal plants, to ensure that adequate quantities are available for future generations.

1.3 The need for the guidelines on appropriate use of herbal medicines

Herbal medicines, particularly those applied by traditional systems of medicine, have been used for thousands of years. Clinical experience built over many centuries provides a substantial basis for the safe and effective use of herbal medicines, not just as a main form of therapy, but as a complement to the main stream of Western medical treatment in certain diseases. In developing countries, herbal medicines are considered to be more readily available, accessible, affordable, culturally acceptable and sustainable than Western medicines. In developed countries, the popularity of herbal medicines is continuing to grow, particularly for the treatment of certain categories of disease.

Herbal medicines, however, are not necessarily always safe simply because they are natural. Some have given rise to serious adverse reactions and some contain chemicals that may produce long-term side effects such as carcinogenicity and hepatotoxicity. Herbal medicines will only benefit the health of human beings when they are used appropriately. Thus, good quality control and standardization of herbal medicines are essential. Furthermore, with the increased use of both herbal medicines and modern western pharmaceutical drugs, there is a need to monitor interactions.

With the growing popularity of herbal medicines worldwide, many countries will be interested in receiving technical support and guidance in developing a framework for the promotion, development and regulation of herbal medicines. This framework will lay a strong foundation for the future development of herbal medicines in the health care systems of individual countries.

The management of herbal medicine practices and the use of herbal medicinal plants differ from country to country and are at different stages of development. These guidelines for the appropriate use of herbal medicines, general enough to be comprehensive and yet flexible enough to be modified for each individual country's needs, will, therefore, be helpful.

2. GOALS AND OBJECTIVES OF THE GUIDELINES

2.1 Goals:

- To promote the appropriate use of herbal medicines; and
- to encourage the integration of herbal medicines into the mainstream health service delivery system.

2.2 Objectives:

- To provide basic principles and applicable standards for interested countries and areas in the Region to develop a national policy and programmes on herbal medicines;
- to guide interested countries and areas in the Region to develop measures for promoting the appropriate use of herbal medicines, appropriate to their own situations;

- to facilitate information exchange on the appropriate use of herbal medicines among policy-makers, researchers and drug administrators; and

- to ensure the safe and effective use of herbal medicines by practitioners and consumers.

3. DEFINITIONS

The following terms are used as working definitions in this document:

Characterizing compound or marker - a natural constituent of a plant part that may be used to assure the identity or quality of a plant material or preparation, but is not necessarily responsible for the plant's biological or therapeutic activity.

Herbal medicines - plant-derived materials or products with therapeutic or other human health benefits which contain either raw or processed ingredients from one or more plants. In some traditions, materials of inorganic or animal origin may also be present, although for the purpose of this document, the focus will be on plant materials only.

Under this definition, there are three kinds of herbal medicines: raw plant materials, processed plant materials and medicinal herbal products. The definition does not apply where the active component has been identified, and either isolated or synthesized as a chemical component of a drug product.

Ingredient - the substance in the herbal formulation which may not be a purified chemical component.

Medicinal herbal products - finished, labelled pharmaceutical products in dosage forms that contain one or more of the following: powdered plant materials, extracts, purified extracts, or partially purified active substances isolated from plant materials. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines.

Medicinal plant - a plant which has been used for medical purposes at one time or another, and which, although not necessarily a product or available for marketing, is the original material of herbal medicines.

Processed plant materials - plant materials treated according to traditional procedures to improve their safety and efficacy, to facilitate their clinical use, or to make medicinal preparations.

Raw plant materials - fresh or dry plant materials which are marketed whole or simply cut into small pieces.

Therapeutic compound - a constituent which is responsible for the intervention of a plant, that results in the amelioration of the manifestations of human disease.

Traditional use - the use of herbal medicines by practitioners of a traditional system of medicine, where:

(a) the use is well-established and widely acknowledged, i.e., the use represents the accumulated experience of many practitioners over an extended period of time;

Annex 5

(b) the use of the herbal medicine, including dosage, indication, and administration route is well-established and documented; and

(c) the use is generally and currently regarded as safe.

4. NATIONAL POLICY DEVELOPMENT

A national policy is a statement of the Government. It should clearly indicate the view of the Government on the role of herbal medicines in promoting and maintaining health and the Government's position on their development, appropriate use and relationship to the national drug policy.

4.1 Process for the development of a policy on herbal medicine

A systematic review of the current status of herbal medicine in individual countries and its role in maintaining health will be necessary for policy development.

The national health authority is the most appropriate body to take the lead in developing the national policy. It can be assisted by a national advisory committee, supported by subcommittees to advise on specific aspects, if required. Where necessary, expert opinions can be obtained from international agencies and other countries. In formulating the policy, consideration should be given to the existing health care system, socioeconomic situation, local tradition and culture. The approach should be practical.

A strategic plan should be developed as part of overall planning. Following identification of problems and benefits, priorities can be set and objectives better defined. The adoption of a strategy is very important as it may involve a choice between several approaches to address the issues. Consultation with the communities and interested parties concerned is essential.

The contents of the draft policy document should be discussed with institutions within and outside government and with the private sector before it is finalized and submitted for formal endorsement.

4.2 Issues to be included in the policy

A number of components will be important in the development of an effective policy on herbal medicine. The policy should recognise the contribution herbal medicine can make to the overall health care system of the country.

4.2.1 Recognizing the role of herbal medicine in the health care system

It is noted that herbal medicine has been used by traditional systems of medicine for a long time. Prolonged and apparently uneventful use of herbal medicine is highly suggestive of its safety and efficacy. Traditional use of herbal medicine is usually an integral part of the culture, which developed within an ethnic group before the spread of modern science. The principles of the traditional system of medicine must be respected when a policy on herbal medicine is prepared. As a general rule, traditional experience should be taken into account along with the medical, historical and ethnological background of the medicine.

4.2.2 Supporting the appropriate use of herbal medicine

The policy should address the importance of herbal medicines in the health care system by identifying the health, economic, social and other benefits of their use. The policy may need to make reference to specific strategies for promoting and incorporating the use of herbal medicines.

4.2.3 Developing appropriate human resources

To ensure the safe and effective use of herbal medicines, the training requirements of practitioners and regulators need to be addressed. This should include reference to quality training programmes for practitioners, and consideration of the educational requirements of regulatory and other personnel.

The policy should also address the education of medical practitioners, pharmacists and the community to facilitate the safe and effective use of herbal medicines as an integral part of the total health care system.

4.2.4 Establishing suitable management and regulatory measures

The needs of consumers and industry, the role of practitioners, and the responsibilities of government should be clearly established in this regard. Policies should be responsive to these identified needs and be designed to ensure they best serve the public in terms of the delivery of safe and effective herbal medicines. The policy should consider the regulatory framework necessary to oversee the manufacture, processing, storage, distribution, sale, import, export and use of these products.

4.2.5 Planning for research and development

The direction and priorities for research and development should be identified. These should take into account such matters as the nature of the country's health care system, the economic and social situation, the availability of health and research personnel, and the degree of access to orthodox and herbal medicines. Account should also be taken of associated research activities occurring in the Region and globally.

4.2.6 Supply of herbal medicines

Where appropriate, the policy should address the need for, and mechanisms to ensure reliable supply of quality herbal medicines. These measures may include policies to manage the utilization of local natural resources, and cultivation and trading with attention to minimizing contamination.

4.2.7 Subscribing to the conservation of medicinal plants

The policy should address the need to preserve endangered species, particularly those identified as requiring conservation nationally and internationally. Practical measures for conservation may need to be identified, particularly for those plants identified as having significant therapeutic use and other benefits to the country.

4.2.8 Provisions of funds

For a national policy to be realised, the policy should identify the costs associated with any national programme and the expected sources of funding. The cost-benefit of the national herbal medicine policy and programme may need to be identified.

Annex 5

4.2.9 Technical cooperation among countries

The importance and benefits of cooperation with other countries, particularly on technical issues, should be recognized. Mechanisms to facilitate this cooperation should be included in the policy.

4.2.10 Monitoring and evaluation of national herbal medicine policies

A process for monitoring and evaluating of the progress and success of the policy should be an integral part of the herbal medicine policy. This will provide the basis for any adjustment to the policy as it evolves, and support for ongoing funding.

5. DEVELOPMENT OF A NATIONAL PROGRAMME ON HERBAL MEDICINES

During the forty-second World Health Assembly, Member States were urged to initiate comprehensive programmes on medicinal plants used in traditional medicine for their identification, evaluation, preparation, cultivation and conservation. The approach to the adoption and development of these programmes should take into consideration the socioeconomic situation of the country and availability of resources to support these programmes. The countries should take a phased approach taking into consideration the priorities of each country.

5.1 National management body for the herbal medicine programme

A national body of appropriate size to coordinate the development of the herbal medicine programme should be established. This body should be responsible for defining the national policy and strategy and translating them into an action plan. It should work closely with other related agencies such as the national drug policy body.

The national management body for herbal medicine should coordinate the implementation of multisectoral and interdisciplinary activities related to herbal medicine. It should also provide advice, suggestions and references to policy-makers. It should ensure that the adopted policy, strategy and action plans are translated into operational activities at different levels.

Advisory committees should be set up to provide suggestions and recommendations to the national body. A national network for implementation of the national herbal medicine programme should be established to support the work of the national body.

5.2 Use of herbal medicines in health care

In many communities and families in the Region, herbal medicine is an available, affordable, effective and culturally-acceptable health care modality. The use of herbal medicine can meet certain primary health care requirements of the people, particularly in less developed, rural and remote areas. The existing community-based traditional medicine projects in several countries have demonstrated the vital role that can be played by herbal medicine in primary health care. In more developed countries, it can complement modern pharmaceutical medicines.

The knowledge available in communities about the use of medicinal plants should be collected and collated, preferably with the participation of the communities themselves. Medicinal plants commonly used in the communities should be selected. The basic criteria in the selection of plants should be: (1) locally available; (2) useful for common health problems; and (3) availability of references on their safety and efficacy. Educational and training materials on these selected plants should be prepared and disseminated. Community health workers should be trained in the

identification, collection, processing, storage and utilization of the plants. Villagers should be encouraged to plant medicinal plants in their gardens or backyards.

The herbal medicine practices should be coordinated and integrated into the country's health care system. They can be components of health care establishments at the primary, secondary and tertiary levels or can stand alone. Countries are encouraged to be aware of recent developments in herbal medicine throughout the world and to adopt such treatments into their health care services as and when appropriate if it is beneficial to the community.

5.3 Research on herbal medicines

Although herbal medicines used by traditional systems of medicine have been tested through long historical practice, scientific research on herbal medicines will provide additional evidence of their safety and efficacy. Research will also provide data on herbal medicines to meet regulatory requirements. However, respect of the principles of the traditional system of medicine under study must be an important consideration when the research project is prepared, conducted and evaluated. The *Research guidelines for evaluating the safety and efficacy of herbal medicines*, prepared by the WHO Regional Office for the Western Pacific, provide suggestions and guidance on research methodology on pharmacodynamic and general pharmacological studies, toxicity investigations and clinical trials.

Efforts should be made to upgrade research capability in the field of herbal medicines. Research should initially be utilization-based and preferably include the participation of practitioners and consumers to ensure maximum support from the community.

Whenever necessary, research projects should be conducted in collaboration, involving various research agencies.

5.4 Preparation of information on medicinal plants

A monograph on medicinal plants is a technical document which provides scientific information on the safety, efficacy and quality control of medicinal plants to promote their proper use as herbal medicines. It can serve as a document for official endorsement as well as assist the appropriate use of herbal medicine. It will also facilitate information exchange among Member States.

The information contained in the monographs includes botanical features, quality control standard and test methods, major chemical constituents, clinical applications, pharmacology, posology and possible contraindications and precautions. The format of monographs for medicinal plants, prepared by a WHO collaborating centre for traditional medicine at the University of Illinois in Chicago, United States of America, could be used as a model for interested countries.

Each country should prepare informative publications from the monographs as a reference for the health care workers and the public.

5.5 Conservation of medicinal plants

The use of plants as medicines has been taken for granted on the assumption that the plants will be available on a continuing basis. However, many medicinal plants face extinction or severe genetic loss. The forty-first World Health Assembly (1988) adopted a resolution which endorsed the call for international cooperation and coordination to establish a basis for the conservation of medicinal plants to ensure that adequate quantities are available for future generations. Each individual country is encouraged to develop programmes to preserve the continuing existence of local medicinal plants and, if applicable, to introduce additional plants through appropriate processes.

Annex 5

Guidelines on the conservation of medicinal plants prepared by WHO, IUCN (The World Conservation Union) and WWF (World Wide Fund for Nature) should be followed by Member States when a national programme on herbal medicine is prepared.

Medicinal plants are valuable natural and genetic resources and an inventory and survey of medicinal plants should be conducted in each country regularly. A list of endangered species of medicinal plant in each country should be prepared and actions for their protection and conservation should be taken, preferably by the Government, including the establishment of seed banks.

The cultivation of plants needed for medicinal purposes should be encouraged to ensure adequate local supply. Incentive schemes could be devised to support this.

5.6 Training and education

Proper plans should be made concerning the education and training of practitioners and related health workers, and, where appropriate, examination, continuing education, and registration or licensing of the appropriate groups.

A human resource development plan should also be prepared to ensure that there will be adequate types and numbers of health care personnel to support this programme. External support and expertise may be required at various stages.

It is desirable to include knowledge on traditional and herbal medicine in the curricula for students in medical and pharmaceutical schools.

5.7 Collection and exchange of information on herbal medicines

Collection and exchange of information on herbal medicines, including the preparation of monographs on medicinal plants and evaluation of their safety, efficacy and quality, should be encouraged. For collected information, the construction of various databases is desirable to promote information exchange. Utilization of available databases and distribution of information from existing databases should be given high priority.

6. REGULATION OF PRACTITIONERS

Herbal medicines may be used as self-medication for many conditions. However, in most cases, the use of herbal medicines needs to be guided by qualified practitioners.

The type of regulatory framework deemed appropriate for herbal medicine will thus depend on the nature of the problems identified as arising from its practice.

Regulation of practitioners who provide service to others, particularly practitioners whose practice brings economic benefit, should ensure quality of herbal medicine services and thus protect the public. The regulation of herbal medicine practitioners may also protect the qualified practitioners.

6.1 Options

There are many regulatory options which can be adopted. These range from professional organizations imposing standards on their own members, to a recognition of these standards, either directly or indirectly, by the government, including statutory support for bodies which impose standards or formal government registration of practitioners by law.

6.2 Examination

To facilitate the process for registration of practitioners, a national examination system could be created. The examination could be organized by health authorities or an independent body under the supervision of the Government. The establishment of a national examination system will promote efforts in upgrading the training on herbal medicine and ensuring that certain standards of practice are met.

7. REGULATION OF THE MANUFACTURE AND DISTRIBUTION OF MEDICINAL HERBAL PRODUCTS

7.1 General considerations

Medicinal herbal products are prepared from material of plant origin which may be subject to contamination and deterioration, and may vary in composition and properties. This is in contrast to conventional pharmaceutical products, which are usually prepared from synthetic materials by means of reproducible manufacturing techniques and procedures. Furthermore, in the manufacture and quality control of medicinal herbal products, procedures and techniques are often used which are substantially different from those employed for conventional pharmaceutical products and from traditional methods of preparation.

The control of the starting materials, storage and processing assumes particular importance because of the complexity, variability and perishable natures of any medicinal herbal products and the number of potentially active ingredients present in small quantities. It is advisable that medicinal herbal products that may be widely used in the marketplace are adequately regulated so as to ensure quality, efficacy and safety of the products.

In recognition of the various legislative, socioeconomic and cultural contexts, the degree and form of management or regulation should be consistent with the specific circumstances of that country, yet adequate to ensure safety and quality of herbal medicines. In some countries different regulatory requirements for herbal medicines have been applied. The WHO *Guidelines for the assessment of herbal medicines* should be consulted when assessment processes for herbal medicines are being prepared.

A regulatory system should be developed for manufacturers and distributors of medicinal herbal products at all levels including importers, exporters, wholesalers or retailers by licensing, registration or other means. The system should allow for periodic review.

7.2 Good manufacturing practices (GMP)

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to quality standards appropriate to their intended use and as required by the marketing authority. GMP rules are directed primarily at diminishing the risks inherent in any pharmaceutical production that cannot be prevented completely through the testing of final products.

All procedures for the manufacture of herbal medicine under regulation should be in accordance with GMP. WHO *Good manufacturing practices for pharmaceutical products* and *Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicinal products* may be consulted when the GMP for an individual country is prepared.

Annex 5

A phased approach to the implementation of GMP may be required.

7.3 Training of regulatory staff

The agency administering the regulatory system should develop appropriately qualified staff resources, capable of making informed decisions in the area of herbal medicines. This may involve the provision of specific training programmes.

7.4 WHO certification scheme on the quality of pharmaceutical products moving in international commerce

Countries that do not have professional staff or laboratories to evaluate and handle extensive documentation for registration, may wish to take into account regulatory decisions made in other countries. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce could be applied.

The aim of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce is to assure the quality of imported drugs, especially in small countries that have no drug registration system or no facilities for the systematic evaluation of the quality, efficacy and safety of pharmaceutical products.

A certificate is issued by drug regulatory authorities in exporting countries on request from drug regulatory authorities in importing countries. The certificate issued under the scheme confirms that:

(1) the pharmaceutical product mentioned in the certificate has been: evaluated for quality, safety and efficacy; registered in the country of origin; and approved for sale in that country. An explanation is required if any of these three criteria are not met;

(2) the pharmaceutical product has been manufactured according to Good Manufacturing Practices and that the manufacturing plant in the country of origin has been regularly inspected by the drug regulatory authorities to confirm compliance with GMP;

(3) the labelling and any other written information accompanying the product has been approved by the drug regulatory authority in the country of origin.

A similar system could be used for herbal medicines available for the international market.

8. REGULATION OF HERBAL MEDICINES

8.1 General considerations

8.1.1 Each country or area should adopt a regulatory system to manage the appropriate use of herbal medicines. Adopting a regulatory mechanism will help ensure that herbal medicines have acceptable quality, safety and efficacy.

Legislation should act as clear guidelines to industry and in its formation should draw on the expertise of a wide range of stakeholders (industry, consumers, practitioners, etc).

Legislation on herbal medicines should also recognise specific issues such as traditional history of use and/or level of current (unregulated) usage in the community.

8.1.2 Characteristics of herbal medicines

Herbal medicines have several attributes which differ from chemical synthetic drugs.

Herbal medicines are major remedies used by traditional systems of medicine which were developed based on different concepts from those of modern medicine.

Herbal medicines, as defined above, are usually mixed chemical compounds. Often not all active components of herbal medicines have been isolated, characterized or quantified. Efficacy is a result of the summation of pharmacological activity of an undefined blend of active components from one or more species of herb. Even a single plant material is not a purified single chemical compound. Standard techniques for the control of individual purified components may not be applicable for evaluating the quality of herbal medicines. In most cases it may not be appropriate to transfer the existing controls on chemical drugs to herbal medicines.

Where herbal medicines are not prepared by traditional methods it would need to be established that the processes have not changed the safety and therapeutic activity of the herbal medicines.

8.1.3 The regulatory process is a mechanism for evaluating the safety, efficacy and quality of medicinal products. The levels of evaluation may vary depending on the product. A comprehensive regulatory system for pharmaceutical products would require adequate data on pharmaceutical chemistry, pharmacological and toxicological studies, clinical investigations and therapeutic applications. However, for herbal medicines some modifications to the regulatory system are necessary. The registration requirement for herbal medicines would most likely be different from that for purified chemical drugs.

8.1.4 Various assessment procedures can be established with consideration of the categories of herbal medicine and different country situations.

(a) Notification procedure (listing): This involves obtaining information on herbal medicines which are being sold in a certain country. The amount of information requested in a notification may vary. It may initially be restricted to the names of herbal medicines and of manufacturers or importers if the medicine is imported from other countries. It may then be expanded to require notification of the composition, the pharmacological action, and the therapeutic classification. The assessment of listed herbal medicines may focus solely on the safety and quality for each intended use.

The listed herbal medicines may include those used traditionally, which are well-established, and those only used for simple, self-limiting conditions, without therapeutic claims having been assessed.

(b) Registration procedure (licensing): This comprises detailed evaluation of data submitted in support of the safety, efficacy, and quality of pharmaceutical products. It also determines the indications for its use. The procedure includes an assessment of both the herbal medicinal product, manufacturing procedures and facilities.

8.1.5 All manufacturing procedures should be in accordance with Good Manufacturing Practices (GMP). However, for many developing countries, medicinal herbal products are manufactured by factories, small workshops or traditional medical practitioners which may not meet GMP requirements. Countries should establish a process for manufacturers to acquire GMP status within an established timeframe.

Annex 5

8.1.6 Different regulatory procedures may be applied to raw plant materials, processed plant materials and medicinal herbal products. In some countries, raw plant materials may not be required to be regulated.

8.1.7 For toxic plant materials, the regulatory authority may issue a list of controlled toxic plant materials to guide manufacturers, wholesalers or importers and the public. The use of listed toxic medicinal substances may need special regulations.

8.1.8 For countries where a mechanism for the regulation of herbal medicines has not yet been established, the regulation procedure could be initiated step by step. A first stage notification (listing) procedure will provide useful data on medicinal herbal products available on the market. Depending on human resource and laboratory facilities, more comprehensive regulatory procedures could be implemented in order to achieve an acceptable level of safety, quality and efficacy.

8.2 Requirements for raw plant materials

While a regulatory system for raw plant materials used in individual dispensing would be difficult and impractical to implement, plant materials identified as toxic should be subjected to specific regulatory procedures. Plant materials classified as toxic should be dispensed only by appropriately qualified practitioners.

At all levels of handling of raw plant materials, clear and accurate identification and labelling is paramount. Countries should also give consideration to mechanisms for controlling contamination of raw plant materials with pests, microorganisms, aflatoxins and other mycotoxins, pesticides, heavy metals and other foreign matters.

8.3 Requirements for processed plant materials

8.3.1 Processed plant materials may be supplied as ingredients to practitioners or as starting materials to product manufacturers. In these cases, the following information should be supplied:

(a) taxonomical classification of the plant including genus, species and family;

(b) common names;

(c) expected countries of origin;

(d) part of the plant used and its condition (such as fresh aerial part; dried root and rhizome, sliced or decorticated);

(e) year, season, preliminary preparation and drying and methods of collection, if necessary;

(f) the method of preparation, including details of new processing techniques; and

(g) the excipients used (where relevant) for commercial reasons.

8.3.2 Where, for commercial reasons, the supplier/manufacturer of processed medicinal materials does not wish to provide details of the extraction methodology or excipients used to the manufacturer or practitioner, a notification (listing) or registration procedure could be implemented. In this case, particularly if using new processing methods, in addition to the information required under 8.3.1, the following information, may also be required, if relevant:

(h) characterizing compounds of the processed medicinal material and the chromatogram of the characterizing compounds;

(i) data on long-term toxicity tests, if appropriate;

(j) data on mutagenicity tests;

(k) data on carcinogenicity tests, if appropriate;

(k) data on reproductive and developmental toxicity tests when necessary;

(l) stability tests;

(m) quality standard, including the assay or limit of toxic ingredients, microorganisms, mycotoxins, heavy metals and pesticide, insecticide and herbicide residues; and

(n) reports on clinical trials, when necessary.

8.4 Requirements for medicinal herbal products

For medicinal herbal products a notification (listing) or registration procedure should be used in most cases. The manufacturers, distributors or importers should provide information on items listed below in relation to the product. In general, the requirements for medicinal herbal products would be pertaining to the product, however, data on individual components may in some circumstances be required. Efforts should be made to achieve high standards of practice in this area wherever possible.

(1) For traditionally used medicinal herbal products the following are needed:

(a) name of the product;

(b) list of ingredient(s) (active and inactive) of the product with scientific name(s), part of the plant used, and quantity; and with reference to the source text for the prescription, if available;

(c) the list of plant ingredient(s) of the product with taxonomic classification, including species, genus, and family;

(d) methods and technology used in manufacture;

(e) physical and chemical identification tests;

(f) quality standards for the ingredients when necessary (which may include the limit of residue of heavy metals and pesticides, insecticide and herbicide);

(g) quality standards for the products;

(h) stability tests;

Annex 5

(i) therapeutic uses and dosage;

(j) evidence of traditional use or recent clinical experience with the product in the form proposed, to support the safety and efficacy of the product;

(k) package and packaging materials; and

(l) content on label or package insert.

For those traditionally used herbal medicines with new dosage forms or new administration routes, the following additional data may be needed:

(m) comparative data on bioavailability.

For special dosage forms, such as injections and nebulisers, additional data may be required.

For those traditionally used herbal medicines with new indications, the following data, additional to items (a) to (l) may be needed:

(n) reports on clinical trials.

(2) For new medicinal herbal products which contain herbs with no traditional history of use, the following data should be submitted, in addition to the data on items (a) to (l) listed above:

(a) data on pharmacodynamic, bioavailability tests, and general pharmacological studies;

(b) data on acute toxicity tests;

(c) data on long-term toxicity tests, if necessary;

(d) data on mutagenicity tests, if necessary;

(e) data on carcinogenicity tests, if necessary;

(f) data on reproductive and developmental toxicity tests, if necessary; and

(g) reports on clinical trials.

(3) For importing countries, confirmation of the regulatory status in the country of origin should be required. Countries should consider extending the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce to cover medicinal herbal products. Where countries and areas have not yet adopted this scheme, the importers should submit a certificate of free sale and certificates of Good Manufacturing Practice (GMP) for the country of origin. Those certificates should be issued by the drug regulatory authority of the country of origin. After reviewing all the documents, a registration or notification (listing) may be given to medicinal herbal products imported by individual importers and the registration or listing number must appear on the labels of medicine.

8.5 Label requirements

It is recommended that the following is printed on the product label in the official language(s) used by the countries or areas:

(a) name of product;

(b) name and quantity (in dry weight when relevant) of active ingredient(s);

(c) dosage form;

(d) directions for use including indications, dosage, mode of administration, duration of use, age group limitations, and use during pregnancy and lactation;

(e) warning statements and relevant contraindications, adverse effects, if any, and overdose information when relevant;

(f) batch number;

(g) expiry date;

(h) storage conditions;

(i) name and address of manufacturers and/or importers; and

(j) registration or notification (listing) number.

The scientific name of active ingredient(s), in addition to the common name in the language of preference of the national regulatory authority, should be used.

The label and package insert should be "user-friendly". Easy and understandable information should be provided.

The drug regulatory authority may provide to industry directions on labelling and on allowable indications and claims.

8.6 Responsible government agency for regulation

The responsible government agency could be the Drug Regulatory Authority or other government agencies with similar responsibilities. It is recommended that a special unit for herbal medicines should be created under the responsible agency for the regulation of medicines.

The responsible agency should review and evaluate all the data received from manufacturers or wholesalers. The applicants should be informed on time whether or not their products have been accepted for notification (listing) or registration.

The responsible agency should keep all the records for registration or notification of herbal medicines.

A registration or notification number should be given when an herbal medicine has been accepted with the drug regulatory authority. A certificate of registration or notification will be issued to each herbal medicine accepted by the relevant authority.

Annex 5

The regulatory authority should provide information to medical practitioners, pharmacists, owners of herbal drug stores and the public on the regulatory process and should have available a list of accepted medicinal herbal products.

8.7 Promotion and advertisement of herbal medicines

Advertisements and other promotional activities aimed at health personnel and the public should be fully consistent with the accepted product information. Restrictions may be placed on some advertising claims consistent with public health and safety.

8.8 Monitoring of adverse reactions to herbal medicines

The regulatory authority should establish a system for monitoring or surveillance of adverse reactions to herbal medicine. In the first instance, manufacturers should be encouraged to submit reports of adverse reactions. Ultimately, post-marketing surveillance should be required for medicinal herbal products which contain either toxic ingredients or present with new indications, new processing methods or routes of administration. Practitioners and consumers should be encouraged to report any adverse effects related to the use of medicinal herbal products. The regulatory authorities should investigate reported cases of adverse effects and, if necessary, issue relevant warnings or impose further restrictions on the use of the medicinal herbal product. Regulatory authorities are encouraged to maintain accurate records of reported adverse reactions to herbal medicines and to make available that information to other Member States on request.

9. USE OF THE GUIDELINES

These guidelines for the appropriate use of herbal medicines are intended to facilitate the work of national health authorities. It is hoped that they can cover a wide range of issues and meet the different situations of countries and areas in the Region. These guidelines can be modified by each Member State to suit their own specific needs. It is hoped that each interested country will eventually develop its own management and regulatory system for herbal medicine which will best suit its own situation. A phased approach to the adoption of the guidelines should be considered by Member States.

These guidelines also provide reference points for researchers, manufacturers and traders.

Annex 5

REFERENCES

1. *Guidelines for the assessment of herbal medicines*, programme on traditional medicine, Geneva: World Health Organization, document, 1991 (WHO/TRM/91.4).

2. *Research Guidelines for evaluating the safety and efficacy of herbal medicines*, World Health Organization, Regional Office for the Western Pacific, Manila, 1993 (ISBN92 9061 110 3).

3. *Guidelines for developing national drug policies*, World Health Organization, Geneva, 1988 (ISBN92 4 154230 6).

4. *Good manufacturing practices for pharmaceutical products,* Annex 1, WHO expert committee on specifications for pharmaceutical preparations, WHO Technical Report Series 823.

5. *Good manufacturing practices: supplementary guidelines for the manufacture of herbal medicinal products, A*nnex 8 , WHO expert committee on specifications for pharmaceutical preparations, WHO Technical Report Series 863.

6. *Therapeutic Goods Act* 1989, Australia.

7. *Guidelines for the registration of non-prescription drugs-appendix on herbal products,* Therapeutic Goods administration, Commonwealth Department of Health, Housing and Community Services, Australia, December 1991.

8. *Guidelines for the classification of dried herbs as therapeutic or nontherapeutic goods,* Therapeutic Goods Administration, Commonwealth Department of Health, Housing and Community Services, Australia, September 1991.

9. *Guidelines for the application of GMP to the manufacture of herbal medicinal products.* Therapeutic Goods Administration, Commonwealth Department of Health, Housing and Community Services, Australia, May 1991.

10. *Evidence of standard of overseas manufacturers,* Therapeutic Goods Administration, Commonwealth Department of Health, Housing and Community Services, Australia, July 1991.

11. *Guidelines to the expression of herbal ingredients in ARTG applications and on labels (herbal ingredient expression guidelines),* Therapeutic Goods Administration, Commonwealth Department of Health, Housing and Community Service, Australia, September 1992.

12. *Provisions for new drugs approval,* Beijing, China: Ministry of Public Health, 1988.

13. *Provisions for new drugs approval: supplementary stipulations and revision of issues related to traditional Chinese Medicine*, Beijing, China: Ministry of Public Health, 1992.

14. *Guiding principles for clinical research on new drugs (traditional Chinese medicine).* Beijing China: Bureau of Drug Policy and Administration, Ministry of Public Health, 1989.

15. *Quality control methods for medicinal plant material,* WHO/PHARM/92.559.

Annex 5

16. *ASEAN Good manufacturing practices guidelines*, Third edition, 1996.

17. *Towards a Safer Choice: the practice of traditional Chinese medicine in Australia*, Alan Bensoussan and Stephen P. Myers, Australia, 1996.

18. *Report: Regional Workshop on Traditional Medicine*, 13-15 November 1995, Hong Kong.

19. *Report of the Working Party of Chinese Medicine*, Hong Kong, October 1994.

20. *Traditional Chinese Medicine: a report by the committee on traditional Chinese medicine*, Singapore, October 1995.

21. *Anthology of policies, regulations and laws of the People's Republic of China on traditional Chinese Medicine*, the State Administration of Traditional Chinese Medicine, China, 1997.

ANNEX 6

COUNTRY REPORTS

Australia

Cambodia

China

Hong Kong

Japan

Republic of Korea

Lao People's Democratic Republic

Macao

Malaysia

Mongolia

New Zealand

Philippines

Singapore

Viet Nam

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./1
8 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

AUSTRALIA

by

Ms Laurayne Bowler
Acting Director
Chemicals and Non Prescription Drugs Branch
Therapeutic Goods Administration
Department of Health and Family Services
Canberra

Annex 6

REGULATION OF HERBAL MEDICINES IN AUSTRALIA

BACKGROUND

Australia is a country of 19 000 000 people. It is federation where the powers of the national government are proscribed by the Constitution. The considerable residual powers rest with the States and Territories. The Commonwealth's powers include control over import, export, quarantine, corporations and interstate trade. The Commonwealth is also a purchaser of some health services such as pharmaceutical benefits and medical services such as doctors and so indirectly exercises some additional controls in these areas.

Until 1989 domestic control of therapeutic goods had largely been exercised by State and Territory Governments through drugs and poisons legislation as well as some regulation of therapeutic goods. The passing of the *Therapeutic Goods Act 1989* improved the Commonwealth's ability to protect public health and safety. The Act introduced a range of controls over therapeutic goods. The purpose of the Act is, as the object of Act states:

> '.... to promote the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia.....' [1]

This objective was supported by State and Territory Health Ministers who agreed to introduce complementary legislation to bring those areas not covered by Commonwealth powers (primarily sole traders and intrastate trade) within this system. Two States have already done this and it is hoped that the remaining jurisdictions will do so before too long.

The *Therapeutic Goods Act 1989* adopts a risk based approach tailoring the level of regulation to the level of risk. Thus the regulations require a high level of intervention and a very high level of scrutiny for high risk products while the weight of regulatory intervention is less for low risk products about which the safety concerns are not so great. The Act is administered by Therapeutic Goods Administration (TGA), a Division of the Department of Health and Family Services.

While the *Therapeutic Goods Act 1989* introduces a system of control on the safety, quality and efficacy of therapeutic goods, matters such as access, labelling and packaging remain the responsibility of the States and Territories. These controls are exercised through the relevant drugs and poisons legislation of each jurisdiction. Despite this there is considerable uniformity in the level of control exercised by the various jurisdictions. This has largely been achieved as a result of the development of a Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The SUSDP is amended and maintained by the National Drugs and Poisons Schedule Committee (NDPSC) which comprises representatives of the Commonwealth, all Australian States and Territories and New Zealand as well as a number of experts and representatives of various government bodies, industry and consumer organisations. To date neither the SUSDP or the NDPSC have had any legal status. Following agreement by all State and Territory Health Ministers in August 1997 it is anticipated that both the NDPSC and the SUSDP will be given legislative underpinning under Commonwealth legislation in 1998.

---

[1] *Therapeutic Goods Act 1989*, Section 4

Annex 6

Prior to the introduction of the *Therapeutic Goods Act 1989* the regulation of herbal medicines was undertaken by the various States an Territories and, apart from controls on herbs regarded as toxic were largely unregulated, and what regulation there was varied considerably from one jurisdiction to another.

CURRENT CONTROLS

With the passing of the *Therapeutic Goods Act* 1989 many herbal medicines were regulated for the first time.

The Therapeutic Goods Act 1989 defines a 'therapeutic good' as goods:

> '(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
>
> (i) for therapeutic use; or
>
> (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or .....

but does not include:

> .....(e) foods.[2]

'Therapeutic use' is defined as:

> '(a) preventing, diagnosing, curing or alleviating diseases, ailment, defect or injury in persons or animals: or
>
> (b) influencing, inhibiting or modifying a physiological process in persons or animals: or.....[3]

The Act requires all therapeutic goods (unless specifically exempted) to be entered on the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia, imported or exported. There are two levels of entry to the ARTG - Registered and Listed. Listed products are those which contain substances where the public health and safety risks are minimal. All products must comply with the quality and safety standards set out by the Act. However, only registered products are evaluated for efficacy before being entered on the ARTG. Listed products are required to hold data to support the efficacy of the claims being made. These products are restricted to indications for temporary relief of minor self-limiting

---

2 *Therapeutic Goods Act 1989*, Section 3

3 Ibid

conditions. Sponsors cannot make claims to the public for any condition prohibited under the *Therapeutic Goods Advertising Code*. To assist sponsors applying to have their products listed on the ARTG Australia has developed an electronic lodgement facility (ELF). This has led to considerable improvement in the processing electronic applications from approximately 5 months to a target of 10 working days, with a further 10 days for verification of eligibility.

Herbal medicines range from the very toxic to the relatively safe. In Australia, the majority of herbal medicines which are used, because of the claims being made and their low toxicity, fall into the 'Listed' category. A herbal substance is defined as:

> '...all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin);
>
> (a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or other herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and
>
> (b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.[4]

Currently there are some 17 000 products listed on the ARTG of which a large proportion are herbals or combination of herbals with other substances such as vitamins. These products included approximately 1 500 herbal substances. These herbal substances were assessed by an expert Committee - the Traditional Medicine Evaluation Committee (TMEC) to establish whether their safety profile was such that they could be included in listable products on the ARTG.

Sponsors applying to have a herbal product included on the ARTG must supply details of all the herbs used - species, the plant part and the method of preparation including details of any solvent used.

As part of Australia's quality controls sponsors are required to use an approved name for all ingredients or components in products on the ARTG. Australia has prepared an extensive list of approved names to assist sponsors in making their applications. Wherever possible these names are taken from internationally recognised references such as the British Herbal Pharmacopoeia. These names are included in drop down tables in the ELF program to further assist sponsors. The botanical names and plant part must also be included on the label of all products. Common names may be used but cannot replace the approved botanical names.

Where sponsors wish to include a new herbal substance in their product an application to have their product registered must be submitted. In this case sponsors have been required to provide evidence which will enable the safety, quality and efficacy of the herb to be evaluated.

---

[4] *(Therapeutic Goods Regulation 2)*

Annex 6

These products were then referred to TMEC for advice. Following evaluation TMEC could recommend that the safety profile of a herb was such that it could be included in Listable products.

FUTURE DIRECTIONS

In April 1997 the Government set out a program for improving some aspects of the regulation of therapeutic goods in Australia. These changes arose out of a Review of the Therapeutic Goods Administration . The primary purpose of the Review was to ensure the appropriateness of the regulations and to remove any unnecessary impediments to industry and consumer access commensurate with the Government's obligations to public health and safety. The review looked a range of issues - many of which affect the regulation of herbal medicine .

Advertising

In its response to the Review *Medicinal Product: Standards Safety and Security* the Government stated that it:

> " regulates advertising of medicinal products because health outcomes can be seriously compromised when consumers take unnecessary, inappropriate or ineffective medicinal products, or by pass the advice of a professional..... [5]
>
> "The Government does not accept the view that advertising is simply a mechanism for informing consumers about the availability and benefits of a specific product. Industry largely accepts that where products have a restricted availability or the efficacy of the claims are unproven, the Government has a responsibility to ensure that consumers are appropriately protected despite the restrictions this imposes on business.[6]

The Government also recognised that there may be some scope for reviewing the current *Therapeutic Goods Advertising Code* as it is:

> " difficult to apply to preventive medicinal products, or those which promote general health and well being."[7]

However in evaluating preventive claims due consideration will need to be given to balancing the potential risks associated with continuous or long term use against the uncertainty of benefit; ie in a group of people, many may not suffer the untoward outcome that the product aims to prevent.

---

5 *Medicinal Product: Standards Safety and Security*, page 4

6 Ibid

7 *Medicinal Product: Standards Safety and Security*, page 5

Annex 6

Herbal Standards

While all therapeutic goods, including herbal products, must be manufactured in accordance with Code of Good Manufacturing Practice. The Government response to the Review recognised that there is currently no assurance that herbal products are produced to a consistent standard. The Government also directed that general standards be developed in relation to contamination with heavy metals, pesticides, other poisons and infectious agents such as bacteria. Australia is looking at developments in this area in other countries, particularly Europe, with a view to harmonising our standards wherever possible.

The Review highlighted developments in the area of herbal medicines and the need to assess the safety implications of these developments. In particular the trend towards highly concentrated extract of some herbs. In Australia evidence of traditional use is included in the evaluation of herbals products. However traditional use may be of limited value when highly concentrated extracts are used as these products can be very different from those on which the history of such use was based. Consequently the Government has also directed that the safety of these concentrated extracts be reviewed.[8]

Regulatory Processes

Flowing from the Review the Government is implementing a number of measures to improve the regulation of complementary medicines including herbal medicines. A new, broader based advisory committee has been established. The Complementary Medicines Evaluation Committee (CMEC), which replaces TMEC comprises a broad range of experts in the area of complementary medicine. It will advise the Minister and the Therapeutic Goods Administration on matters related to the safety, efficacy and quality of complementary medicines and assist in the preparation of standards and guidelines. CMEC will work closely with the other committees which provide advice to the Minister and the Therapeutic Goods Administration on other classes of therapeutic goods to ensure a consistent approach to the regulation of all therapeutic goods.[9] These Committees include the Australian Drug Evaluation Committee which provides advice primarily in relation to prescription drugs and the Medicine Evaluation Committee which advises on nonprescription medicines.

Administrative changes within the TGA will also be changed to enable appropriate evaluation of products. Legislative amendments will be made to reflect these arrangements.

Food/Drug Interface

The nature and philosophy behind complementary medicines (including Herbals) means that many of these products are used as both foods and drugs. This creates difficulties and uncertainties for regulators and industry and confusion for consumers. The Review highlighted these problems and directed that action be taken to clarify the issues while maintaining an appropriate level of regulation to protect public health and safety.

---

[8] *Medicinal Product: Standards Safety and Security*, page 11

[9] Ibid

Annex 6

For Australia, the difficulties in implementing appropriate regulation of products at the food/drug interface to protect public health and safety are complicated by the range of regulatory controls of such products around the world. In some cases these products are regulated as prescription products, while in many countries they are classified as dietary supplements and subject to only minimal regulation and limited enforcement.

SUMMARY

The last decade has seen a considerable increase in the use of herbal medicines in Australia. This reflects the influence of various cultural communities within Australia, particularly the Chinese community, a more informed consumer market, an increased desire on the part of consumers to take responsibility for their own health, a trend away from 'chemicalisation' of medical treatment and improved technologies.

In this climate Australia's *Therapeutic Goods Act 1989* was an important and significant step in recognising the community's need for access to a wide choice of safe and efficacious products of high quality. The recent Review has led to a reassessment of the current appropriateness of the regulation and changes are being made to ensure that the level of regulation is commensurate with the need to maintain a high level of public health and safety while improving the choice for consumers.

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./2
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

CAMBODIA

by

Mr Seng Lim Neou
Director of Pharmacy
Ministry of Health
Phnom Penh

Annex 6

TRADITIONAL MEDICINE IN CAMBODIA

by: Mr Seng Lim Neou

For several hundred years, especially during the Angkor era and the apogee under the reign of King Jayavarman VII in the 12th century, traditional medicine and remedies were used to prevent and cure disease among the Cambodian people. Natural products of plant, animal and mineral origin were part of the medical compendium.

The practice of Cambodian traditional medicine slowly decreased in line with the slow decline of the Angkor civilization, mainly due to the disappearance of most of the eminent experts on the field of TRM and the loss or concealment of valuable documents.

However, in spite of the influx of modern medicine, traditional medicine and herbal remedies still remained the primary support for maintaining the health of Cambodians.

During the time of the Polpot-Khmer Rouge, most of the remaining Pali books, together with the written expertise of the most gifted intellectuals and monks, were destroyed or lost. In 1979, the Government officially integrated TRM into the national health system and it continued to play a very useful role in Cambodian health care. However, since 1990, and the Government's adoption of a free market policy, its importance has gradually diminished.

The Khmer traditional medicine is now only being practised by healers called "Krou Khmer" who guard their traditional secrets to attract clients. Two hundred and thirty of these healers, who survived the Khmer Rouge regime, have been registered and trained in basic scientific knowledge by the Health Department of the Municipality of Phnom Penh. They are all working in the private sector. They perform all tasks in TRM: manufacture, wholesale, retail and patient treatment. There is no quality control of their products.

Annex 6

National Policy on Traditional Medicine

Objective: To increase the importance of Cambodian traditional medicine and encourage traditional practice as a complement to modern medicine.

(1) Fundamental applied research on traditional remedies will be pursued.

(2) Diseases which are to be treated effectively by traditional medicine will be identified.

(3) Efforts will be made to establish necessary methods and technologies to identify and develop traditional remedies.

(4) A means of regulation and control, adapted to the specific characteristics of traditional medicine, will be established under the authority of the Ministry of Health.

Regulatory situation of herbal medicine

The Drug Authority has submitted a proposed decree on traditional medicine to the Council of Ministers in an attempt to regulate private practice and to promote the safe and effective use of traditional drugs. The decree is intended to differentiate and separate the role of manufacturers, retailers and healers in TRM activities.

Government's future plans:

(1) To consolidate the Direction of Drugs under the Ministry of Health to be able to:

- control traditional medicine practice in the private sector;
- ensure the quality and safety of traditional remedies; and
- impose their registration.

(2) To strengthen the Research Centre of TRM to be able to:

- carry out an inventory and survey of medicinal plants to ascertain their uses;
- find out what diseases can be treated with efficacy by traditional remedies; and
- collect, collate and catalogue various specimens and documents currently distributed in the country.

(3) To train staff in the identification of plants such as:

- the physical and chemical assays; and
- documentation of information.

(4) To provide basic laboratory equipment to the Research Centre.

(5) To list the most common and reliable plants for use in primary health care.

(6) To prepare the National Traditional Pharmacopoeia.

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./3
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

PEOPLE'S REPUBLIC OF CHINA

by

Mr Shen Yulong
Vice Director-General
China International Centre for
Traditional Chinese Medicine
State Administration of Traditional Chinese Medicine
Beijing

Annex 6

ADMINISTRATION OF TRADITIONAL CHINESE DRUGS IN CHINA

by: Mr Shen Yulong

Traditional Chinese medicine (TCM) is an excellent and important aspect of Chinese traditional culture. It is the accumulation of experiences and theories in the course of a long-term struggle against diseases by the Chinese. It has made a remarkable contribution to the prosperity of the Chinese nation and it is still playing an important role in the health care services of China.

The Chinese Government has fully assured the social and scientific position of TCM and has included the development of traditional medicine in the Constitution. The official document of the Government further explains: "laying equal stress both on TCM and western medicine and modernization of the Chinese medicine industry". The development of TCM is guaranteed and supported by the Government.

I. Laws and regulations for traditional Chinese drugs (TCD)

I.1 Administration of new traditional Chinese drugs

Following the development in medical science and health care work, a series of laws and regulations on new drug approval have been formulated and adopted.

The Drug Administration Law of the People's Republic of China was issued and has been in force since 1985. The Provisions for Approval of New Drug Application (1985.7) and The Supplementary Regulations for Revision of New Drug Approval Relating to Traditional Chinese Drugs (1988.1) have been published. In 1992, several documents were drawn up including: the Guidance to new drug development of TCD; Guidelines for pre-clinical study of new TCD; Guiding principle for the development of injection of TCD; and Guiding principle for clinical study of new TCD and clinical pharmacology.

Based on these regulations, a new drug is defined as that which has not been manufactured in China or a drug already in the market but with new therapeutic claims, a different route of administration or different dosage form.

Annex 6

New drugs are classified into five categories:

(1) Class I of new TCD includes man-made products from Chinese herbal drugs, newly discovered Chinese herbal drugs and their products, the active compound extracted from Chinese herbal drugs and their products.

(2) Class II of new TCD includes injection from Chinese herbal drugs, newly discovered medicinal parts of Chinese herbal drugs and their products, the effective fraction extracted from Chinese herbal drugs and natural drugs and their products, Chinese herbal drugs from domestically-bred animals and their products.

(3) Class III of new TCD includes new Chinese medicine products, Chinese and western medicine complex products with Chinese medicine as the main ingredient, domestically cultivated and bred folk herbal drugs introduced from abroad and their products.

(4) Class IV of new TCD includes drugs with a new dosage form or different route of administration, herbal and animal drugs that are introduced from other regions and domestically cultivated or bred herbal and drugs from animals that used to be wild.

(5) Class V of new TCD includes drugs with new therapeutic claims.

The development of a new drug may be divided into two phases, the pre-clinical study and clinical investigation. The contents of each phase vary in different classes of new drugs.

Data in pre-clinical studies should be provided as follows:

Raw materials and their control:

Description: Official name in TCM and name of variety, species, genus, family; morphological and anatomical description; geographical distribution and current sources of the plant or other materials.

Processing: A description of the preparation of the botanical raw materials, including collection, washing, drying, cutting and/or detoxification procedures.

Chemical characterization: The chemical identify of the active constituent or characteristic marker in the material.

Annex 6

Assay: Assay for active constituent or characteristic marker, or biological assay, if available.

Storage conditions

Prescription: Its components and composition, historical experience and current use. Manufacturing process and its research data.

Quality control

Research data on its physical and chemical properties

Nature and appearance: colour, appearance and flavours of the drug.

Identification by microscopic, ordinary physical and chemical, and/or chromatographic method.

Examinations: Strength by weight, water content, residual solvents, microbial contaminants, and heavy metals, arsenic limit, if necessary.

Assay for active constituent or characteristic marker, if available.

Stability of the drug

Pharmacological studies: Main pharmacological actions and general pharmacological tests.

Safety studies: Acute, and repeat dose general toxicity studies. Mutagenic, teratogenic or carcinogenic studies only for specific drugs.

Data in clinical studies should be provided as follows:

Results from clinical trial phase I on 10-30 cases, phase II on not less than 300 cases in the treated group with another 100 cases in the control group, and not less than 1000 cases for contraceptives. For new drugs of Class III, only phase II clinical study is required. For new drugs of Classes IV and V, only phase II study is required with not less than 100 cases and a control group.

Phase III for investigating new Chinese drugs, the number of cases is decided in accordance with its indication, generally not less than 300.

Annex 6

Study designs should be sanctioned by authorities. Clinical studies should be conducted in hospitals appointed by the Ministry of Public Health.

The Drug Administration Law of the People's Republic of China and Provisions for New Drug Approval became effective on 1 July 1985. From the first traditional Chinese drug approved in 1987 until the end of 1996, the number of applications for new TCDs has increased every year and a total of 699 approvals have been issued by the Ministry of Public Health. When the number of repeated approvals for some drugs is subtracted from this number, the number of new TCDs is 546. Of these, there are 20 of Class I, 21 of Class II, 229 of Class III, 270 of Class IV and 5 of Class V.

I.2 Re-evaluation of marketed traditional Chinese drugs

Before 1 July 1985, there were about 9000 TCDs on the market. These drugs were approved by provincial health agencies. Every province approves with different standards and a low level repetition existed. Some of them exhibited uncertain efficacy or adverse reactions, deficiencies in quality control, or confusion in their names. Re-evaluation of marketed TCD is necessary.

Under the guidance of the Drug Administration Law of the People's Republic of China, re-evaluation principles for marketed TCD, were worked out, as follows: (1) one drug with one prescription and one name; (2) the drugs to be of reasonable prescription, confirmed efficacy and stable quality. The approval for the drug that cannot meet these criteria will be cancelled and production suspended.

At the end of 1995, 4454 marketed TCDs passed the re-evaluation, 338 of them were eliminated. Quality control standards have improved significantly. Two thousand and seventy TCDs have been collected in the Ministerial Drug Standard and draft standards for another 4400 have been completed.

Annex 6

I.3 Protection of traditional Chinese drugs

In order to encourage the production of high quality TCDs and restrain a low level of repetition, the Regulation for Protection of Chinese Drug Products was issued in 1993. According to the regulation, a TCD produced by a certain manufacturing enterprise is protected and other enterprises have to stop production of the same product. This protection lasts for at least seven years.

Application for protection of a TCD is submitted voluntarily by the manufacturer. The provincial health agency is responsible for the initial review. The Office of the Chinese Product Protection Committee accepts the initial review report together with the application, organizes evaluation and sets forth opinions and suggestions for improvement. The committee submits the report to the Ministry of Public Health for sanction. One hundred and forty-nine TCDs obtained this right in 1996.

I.4 Certificate for GMP

The rule of Good Manufacturing Practices was announced in 1988 and revised in 1992. A committee for certification of GMP was set up The committee has received the application for certification of GMP from manufacturing enterprises since 1 October 1995. A newly established manufacturing enterprise is required to meet GMP standards. After 30 June 1998, no new drug will be allowed to be manufactured unless the enterprise is GMP certified.

II. Manufacture and Marketing of Traditional Chinese Drugs in China

There are over 1020 TCD manufacturing factories and more than 4000 pharmaceutical factories producing TCD apart from chemical drugs in China. Over 500 000 people are engaged in the manufacture and sale of TCDs.

After the re-evaluation of TCDs, there are approximately 5000 TCDs on the market with a 37% share of the total drug market. One thousand seven hundred TCDs are listed in the national basic drug catalogue while the rest are sold in drug stores.

The technical renovation in the Chinese drug industry has been supported by the State special fund. Over the past ten years, a large sum of money has been invested in technology renovation. This support has enabled most large and medium-sized TCD pharmaceutical factories to be modernized in terms of technology and equipment. Some technical equipment in

these factories is imported but most is manufactured locally. The quality and properties of locally manufactured equipment also meet the demands of TCD production.

To ensure the quality of TCDs, emphasis has been placed on the improvement of the processing technology, including extraction, concentration, drying and granulation, characteristic of TCD production, and the selection of the best processing procedure, technology and equipment to ensure a high standard.

There are more than 12 000 kinds of raw herbal materials in China. One thousand four hundred are available on the market. Among the commonly used herbs, over 140 are locally cultivated, throughout an area covering 16 600 000 square metres.

In order to ensure the quality of TCDs, the Government encourages enterprises to establish a raw materials base in the good quality herbal plantation areas with the aim of guaranteeing the quality of raw materials.

III. Scientific research on traditional Chinese drugs

There are approximately 15 000 professionals involved in scientific research on TCM in China, working in either research institutes or colleges and universities. Some scholars from comprehensive universities also participate in studies related to TCM. Since 1985, the research on Chinese materia medica has been listed as the state's key scientific project.

In recent years, the main research direction on Chinese materia medica was as follows:

- research on survey of Chinese materia medica resources;
- research on standardization and quality control of commonly-used raw materials;
- research on the cultivation of herbs and non-polluted green raw material; and
- research on biotechnology, preparation and processing methods of herbal drugs, new drug study, new excipients and technology study and quality control of Chinese patent medicine.

Notable progress has been achieved in all these studies. For instance, the study on quality control and reorganization of 200 similar herbs has been conducted. It includes the study of historical documentation, a resources survey, systematic identification, morphological identification, micro identification and physio-chemical quality analysis, etc. This shows that,

aside from the traditional quality analysis method, there is also a modern quality control standard for Chinese raw materials that are used in Chinese medicine.

In order to enable more people in the world to understand and use Chinese medicine, researchers have emphasized the research on the standardization of quality control so as to set up its own testing and identification method.

Emphasis is also laid on systematic research on complex prescriptions, specifically on the identification, pharmadynamics, pharmacology, quality control and evaluation of safety. A state research project called "Modernization of Chinese Medicine" has been designed.

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./4
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

HONG KONG

by

Dr Ting-hung Leung
Assistant Director of Health
The Government of the Hong Kong
Special Administrative Region
Wan Chai
Hong Kong

Annex 6

TRADITIONAL MEDICINE
IN
HONG KONG, CHINA

by: Dr Ting-hung Leung

1. Background

1.1 Hong Kong, after one and a half centuries of British administration, became a Special Administrative Region (SAR) of China on 1 July 1997. It is estimated that this fast growing city, with a total area of just under 1100 square kilometres, is inhabited by a population of 6.5 million, mostly of Chinese origin. Over the years, the health status of Hong Kong people has attained a very acceptable level. In 1996, the infant mortality rate was 4.1 per 1000 live births and the maternal mortality ratio was as low as 1.5 per 100 000 total births.

1.2 Practitioners of western medicine are the main health care providers in Hong Kong. This western influence, however, does not in any way tarnish the strong heritage of Chinese culture in Hong Kong and the faith of her people in the efficacy of traditional Chinese medicine (TCM). In a General Household Survey conducted in 1996 by the Census and Statistics Department, it was noted that 10.5% of the medical consultations used by the subjects under survey were with herbalists, bone-setters and acupuncturists. An earlier survey also showed that up to 60% of Hong Kong people had used TCM either for treatment of diseases or health maintenance.

1.3 Although TCM is very much an integral part of the health care system in Hong Kong, there has been no specific legal control and recognition of TCM practitioners and Chinese medicine for historical reasons. The Medical Registration Ordinance, Chapter 161 of the Laws of Hong Kong, explicitly exempts any person of Chinese race who practises medicine according to purely Chinese methods from the requirement to be registered. The Pharmacy and Poisons Ordinance also exempts proprietary Chinese medicines made from Chinese Herbal Materia Medica or from herbs customarily used by Chinese people from statutory control in respect of their sale, manufacturing, dispensing and compounding.

Annex 6

1.4 There is nonetheless incidental control of TCM in Hong Kong. The Public Health and Municipal Services Ordinance and the Pharmacy and Poisons Ordinance prohibit, respectively, the sale of drugs unfit for human consumption, and the adulteration of Chinese medicine with western medicine without prior registration. The Undesirable Medical Advertisement Ordinance provides that it is illegal to advertise in respect of diseases specified in the Ordinance.

2. Preparatory Committee on Chinese Medicine

2.1 In 1989, the Secretary for Health and Welfare appointed a Working Party on Chinese Medicine to review and make recommendations on the use and practice of TCM in Hong Kong. Following extensive discussion and public consultation, the Working Party recommended in its final report published in October 1994, among others, the setting up of a preparatory committee, comprising principally of members of the TCM profession, to advise on the future statutory framework for the promotion, development and regulation of TCM in Hong Kong.

2.2 On this recommendation, the Secretary of Health and Welfare appointed a Preparatory Committee on Chinese Medicine (PCCM) to take forward the recommendations of the report published by the Working Party of Chinese Medicine. Dr Daniel Tse, the Vice Chancellor of Hong Kong Baptist University, chaired the PCCM, with members comprising principally TCM practitioners, traders in herbal and proprietary Chinese medicine, university academics, Government representatives and lay members of the public to represent consumer interest. The Department of Health of the Hong Kong Government provided secretariat and support services tot he PCCM. In the first two years of its appointment, the PCCM, amongst others:

- conducted a general assessment of the TCM trade in Hong Kong;
- drew up a list of potent/toxic herbs available in Hong Kong;
- conducted a census on TCM practitioners; and
- submitted a report to the Secretary for Health and Welfare with recommendations on the way forward for TCM in Hong Kong.

Annex 6

3. TCM Trade in Hong Kong

3.1 The PCCM estimates that, based on information provided by traders of Chinese herbs, there are about 2000 types of Chinese herb on the market. It is also estimated that about 80% to 90% of these herbs are imported from Mainland China. There are abut 3300 brands of proprietary Chinese medicine on the market. Of these, only 500 brands are manufactured locally; the rest comprising medicines manufactured in China. Information provided by the Census and Statistics Department shows that in 1994 the number of organizations involved in the importation, wholesale distribution and retail of TCM added up to 5860, with about 27 000 employees.

3.2 The Department of Health of the Hong Kong SAR Government regularly samples Chinese medicine at the point of importation and at retail outlets to test for contamination with heavy metals and for adulteration with western medicine. Since 1977, a computer database has been established to facilitate the sampling process.

3.3 Importers and wholesalers are required to recall from the market products that are found to have been contaminated.

4. Potent and Toxic Chinese Herbs

4.1 The PCCM recognizes that, while Chinese herbs are generally safe, it is nonetheless necessary to educate the public and members of the TCM trade and profession to pay special attention to the proper use of certain Chinese herbs or medicinal materials which:

- have a narrow therapeutic to safety margin;
- are toxic without proper prior processing; and
- are primarily intended for external use only and are toxic on ingestion.

4.2 The PCCM has drawn up a list of 31 potent and toxic Chinese herbs and medicinal materials (Annex). It has also published a health education pamphlet for the general public to give a positive perspective on the efficacy of Chinese herbs and medicinal materials, and to advise on the proper use and preparation of herbal infusions or concoctions in accordance with prescriptions from herbalists.

Annex 6

4.3 The PCCM further published a pictorial guide to these toxic potent herbs and medicinal materials for members of the TCM trade and profession, particularly the TCM dispensers. The pictorial guide sets out the nomenclature, source, handing, nature, application, contraindication and signs and symptoms of poisoning. The guide also contains a set of guiding principles for Chinese herbal retailers, targeting mainly TCM dispensers. The guiding principles set out the basic dispensing knowledge and responsibility expected of TCM dispensers, proper storage methods, packaging, and labelling of Chinese herbs. The pictorial guides are given free of charge to all TCM dispensers and interested members of the public.

5. Census of TCM Practitioners in Hong Kong

5.1 In late 1995, the PCCM conducted a census on all TCM practitioners who were Hong Kong residents and who were either practising the TCM profession or had graduate diplomas in Chinese medicine. The aim of the census, officially announced as an enrolment exercise, was to solicit the support of TCM practitioners in providing the necessary information on their practice profile, in order that a long-term strategy for legal recognition of the profession could be formulated.

5.2 Of the 6890 TCM practitioners under survey, 4315 (62.6%) were herbalists, 1596 (23.2%) were bone-setters, 473 (6.9%) were acupuncturists and 33 (0.5%) were educators. Four hundred and seventy three respondents were practising the profession part-time. Other observations included:

- a male to female ratio of 7 to 2;
- 60% of the respondents were aged 40 to 59;
- 3026 (43.9%) had received university or tertiary education, 3484 (50.6%) had secondary school education and 380 (5.5%) had only primary school education;
- 894 (13%) had received full time university education in TCM; 1994 (28.9%) had received part-time TCM education;
- apprenticeship was common amongst the respondents (49.2%);
- 617 (9%) had little formal education in TCM and had acquired TCM knowledge through self-study;

- 23% of the respondents had more than ten years experience whereas 42.3% had 5 to 10 years of practical experience. 2379 (34.5%) had less than 5 years experience;
- 54.1% were trained in Hong Kong, and 3063 (44.5%) in China;
- 51% were self-employed and the rest were employed at herbal shops or clinics, charitable organizations or engaged in providing TCM courses; and
- 66% were full time practitioners, the rest being either part-time practitioners or not practising the profession at all.

5.3 The enrolment exercise provided valuable information to enable the PCCM to draw up recommendations on future registration criteria and training needs of TCM practitioners in Hong Kong.

6. Training in TCM

6.1 In the course of its deliberation the PCCM also noted that there were 17 organizations providing more than sixty part-time courses, of varying duration and depth, in Chinese medicine, acupuncture and Chinese herbs. These organizations included extramural departments of universities, non-profit making associations and professional unions of TCM practitioners. There is, as yet, no full-time university course in TCM.

7. Recommendations of PCCM

7.1 At the end of the first two-year appointment in March 1997, the PCCM submitted a report to the Secretary for Heath and Welfare on the way forward for the regulation and development of TCM in Hong Kong.

7.2 The PCCM is of the view that a statutory Council on Traditional Chinese Medicine should be established to regulate both TCM practitioners and the supply of Chinese herbs and proprietary Chinese medicine in Hong Kong. The legislation to enable the establishment of the council should be drafted, with the primary objective of safeguarding public interest through ensuring the professional standard of TCM practitioners and the safety, quality and efficacy both of Chinese herbs and proprietary Chinese medicine. In accordance with the prevailing spirit of professional self-regulation in Hong Kong, the PCCM is also of the view that the proposed

Annex 6

Council should have its members drawn principally from the TCM profession and trade, with adequate representation from members of the lay public.

7.3 In considering the registration of TCM practitioners, the PCCM takes note of the general government policy that no one should be deprived of his/her livelihood through the introduction of legislative control. It is of the view, however, that all TCM practitioners entering into the practice of the profession for the first time should eventually sit a universal licensing examination. To accommodate the practising TCM practitioners in Hong Kong, the PCCM recommends, as an one-off measure, that:

- Practitioners who have been practising for ten or more years, as at 1 January 1995, should be registered without having to sit the licensing examination.
- Practitioners who have between five and ten years experience, as at 1 January 1995, will be required to sit a clinical test and oral examination.
- Practitioners who have less than five years experience, as at 1 January 1995, will be required to sit the full licensing examination.
- Practitioners who have a qualification and formal training recognized by the Council will have their examination requirement reduced accordingly.

7.4 TCM practitioners who fail to meet the initial requirement for registration should be allowed to continue to practise. However, they should not represent themselves as registered or enjoy the same legal status as a registered TCM practitioner until such time as they fulfil the registration requirement or pass the universal licensing examination.

7.5 The PCCM considers that the primary objectives of legislative control for Chinese herbs and medicinal materials are to ensure the safe and proper use of potent and toxic herbs and medicinal substance; to ensure that Chinese herbs are free from contamination; and to safeguard the safety, efficacy and quality of proprietary Chinese medicine. The PCCM recognizes the difficulties in establishing a comprehensive system to attain the above objectives and therefore recommends that:

- Legislative control should be implemented in a step by step manner.
- The control system should include the licensing of the TCM trade, such as importers, wholesalers, manufacturers and retailers.

- A proper labelling system should be introduced for toxic and potent herbs.

- All proprietary Chinese medicine should be registered prior to sale and the registration system could take reference from the certification of the competent authority of the country of origin.

- TCM dispensers should, in due course, be registered and consideration should be given to limiting the authority to dispense potent and toxic herbs and medicinal materials to registered TCM dispensers.

7.6 On future training needs in TCM, the PCCM recognizes that proper training and re-training of TCM practitioners and dispensers are the keys to fostering a high standard of service among the professions. It therefore recommends, amongst others, the establishment of a full-time course in traditional Chinese medicine, and proposes the cooperation of various professional associations with universities to jointly promote and strengthen training in TCM.

7.7 The PCCM recognizes that promotion and legislative control of Chinese medicine must be backed by scientific studies. It recommends that priority should be given to applied research on toxicity, toxicology and authenticity of Chinese herbs; identification of pesticides, heavy metals and active ingredients in proprietary Chinese medicine; randomized clinical trials on the efficacy of proprietary Chinese medicine; and development of new compound formularies. Universities and tertiary institutions are encouraged to adopt an active and open-minded attitude to sharing their experience in TCM research. The PCCM also sees the potential of cooperation between the academic sector and the manufacturing industry in facilitating the development of Chinese medicine.

8. Government policy and the way forward

8.1 The report of the PCCM is a timely one as the policy on future development of traditional Chinese medicine is now clearly enshrined in The Basic Law of the Hong Kong Administrative Region of the People's Republic of China. Article 138 of the Basic Law provides that the Government of the Hong Kong Special Administrative Region shall, on its own, formulate policies to develop western and traditional Chinese medicine and to improve medical and health services. Community organizations and individuals may provide various medical and health services in accordance with law.

Annex 6

8.2 The report of the PCCM, which maps out in a definitive manner the way forward for regulation, development and promotion of TCM is generally welcomed by the public and the TCM profession and trade. In his policy address delivered on 8 October 1997, the Chief Executive of the Hong Kong Special Administrative Region, the Honourable TUNG Chee Hwa said, "For the protection of public health, we aim to introduce a bill in the next legislative session to establish a statutory framework to recognize the professional status of traditional Chinese medicine practitioners; to assess their professional qualifications; to monitor their standards of practice; and, to regulate the use, manufacture and sale of Chinese medicine. The establishment of a sound regulatory system will lay a solid foundation for the future development of traditional Chinese medicine within our overall medical care system. I strongly believe that Hong Kong has the potential to develop over time into an international centre for the manufacture and trading of Chinese medicine, for research, information and training in the use of Chinese medicine, and for the promotion of this approach to medical care."

8.3 The policy address of the Chief Executive of the Hong Kong Special Administrative Region embraces the vision and plan for the recognition, development and promotion of traditional Chinese medicine in Hong Kong. Meanwhile, the PCCM is tasked to work out the details of the legislative proposal, aiming to commence registration of TCM practitioners in the year 2000 and regulation of Chinese medicine by phases also in 2000. It is firmly believed that traditional Chinese medicine, which is founded on a sound and time-tested theoretical basis, will have immense potential to further contribute to the health of the community in Hong Kong.

Annex 6

List of Potent/Toxic Chinese Herbs and Medicinal Materials

	Herbs & Medicinal Materials	中藥
1.	Root and rhizome of Podophyllum emodi	鬼臼
2	Unprocessed root of Aconitum carmichaeli	生川烏
3.	Unprocessed root of Aconitum kusnezoffii	生草烏
4.	Unprocessed lateral root of Aconitum carmichaeli	生附子
5.	Unprocessed tuber of Typhonium giganteum	生白附子
6.	Arsenolite	砒石
7.	Arsenic	砒霜
8.	Realgar	雄黃
9.	Orpiment	雌黃
10.	Mercury	水銀
11.	Mercuric oxide (mixture of mercury, nitre and alunite)	紅粉（紅升丹）
12.	Cinnabar	朱砂
13.	Calomel	輕粉
14.	Crystal of mercurous chloride and mercuric chloride	白降丹
15.	Unprocessed seed of Strychnos nux-vomica and S. pierriana	生馬錢子
16	Unprocessed tuber of Pinellia ternata	生半夏
17.	Unprocessed tuber of Arisaema erubescens, A. heterophyllum and A. amurense	生南星

Annex 6

Herbs & Medicinal Materials	中藥
18. Unprocessed fruit of Croton tiglium	生巴豆
19. Body of Mylabris phalerata and M. cichlorii	斑蝥
20. Body of Lytta caraganae	青娘蟲
21. Body of Huechys sanguinea and H. philaemata	紅娘蟲
22. Unprocessed root of Euphorbia kansui	生甘遂
23. Unprocessed root of Euphorbia fischeriana and E. ebracteolata	生狼毒
24. Unprocessed resin of Garcinia morella	生藤黃
25. Unprocessed seed of Hyoscyamus niger	生天仙子
26. Unprocessed seed of Euphorbia lathyris	生千金子
27. Flower of Rhododendron molle	閙羊花
28. Root-tuber of Aconitum brachypodum	雪上一枝蒿
29. Secretion of Bufo bufogargarizans and B. melanostictus	蟾酥
30. Flower of Datura metel	洋金花
31. Root of rhizome of Sophora tonkinensis	山豆根

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./5
3 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

JAPAN

by

Dr Motoyoshi Satake
Director
Pharmacognosy and Phytochemistry Division
National Institute of Health Sciences
Tokyo

Annex 6

HERBAL MEDICINE IN JAPAN

by: Dr Motoyoshi Satake

1. Current status of the use of herbal medicine

In Japan, Kampo therapy uses herbal medicine (Kampo medicine). This was only used during the Edo period (1600~1868) but at the end of 19th century, Western therapy was introduced in Japan by the Europeans and at that time, Kampo therapy was prohibited for the medical practice. From 1960 to 1970, the side effects of modern medicines, mainly synthetic chemical medicines, were reported in Japan, and then Kampo medicines were once again recognized for use. In 1976, Kampo medicines were introduced by the National Health Insurance System and have been used in hospitals and pharmacies. Practitioners are western doctors and pharmacists.

Manufacturers are traditional companies who produce the traditional herbal pills, Kampo extract. Modern medicine companies produce only a few herbal medicines. Herbal medicines sold in the market are estimated at about US$ 1.5 billion which is about 3.5% of the total medicine market.

2. Government policy on herbal medicine in Japan

The traditional medicines are composed of herbs and their efficacy and safety have been based solely on experience of their use over a long period of time. Traditional and modern medicines in Japan receive the same treatment from the Pharmaceutical Affairs Law. Both types of preparation are subject to the same regulations.

The traditional medicines used in Japan were used largely in primary health care, mainly as "over the counter" drugs. However, it has recently been decided that they should be of quality in order to qualify for reimbursement by the National Insurance Scheme. Since then, their use has increased substantially among physicians working in hospitals and clinics. In terms of value, prescription drugs now account for almost 75% of the total expenditures on traditional medicine.

Annex 6

The Japanese drug registration system requires that specific scientific data, determined by the degree of novelty of the candidate drug, must be submitted together with the application. A standard formula, route of administering and dosage, efficacy and indications have been established and published for 210 Kampo preparations that are available over-the-counter and that are considered to meet general efficacy and safety requirements on the basis of their use for a long period. The Kampo drugs that are prescribed come in two types: the first consists of decoctions derived from several varieties of chopped herbs, and the second are compounded extracts in accordance with Kampo formulae which are produced on an industrial scale by pharmaceutical manufacturers using dried aqueous extracts from herbs in specific proportions Even today, many physicians and others who specialize in Kampo medicine use traditionally-prepared preparations. The herbs used as raw materials for Kampo pharmacies are in accordance with physicians' prescriptions.

There are two important issues that have arisen as a result of the official recognition of Kampo drugs in Japan. There is difficulty in ensuring the quality of materials using the natural method of determining their efficacy based on the experience gained from their practice over a long period. The issue of quality is being addressed by the development of pharmacopoeia standards for crude drugs and herbs which are widely used and considered to be essential. A total of 192 herbs are already listed in the Japanese pharmacopoeia. These monographs contain detailed criteria for the identification of material, standard of purity, total ash content, acid-insoluble ash content, and essential oil content. The pharmacopoeia also lays down general methods of testing and rules for processing herbs. Another book entitled *Standards for herbs* which is not included in the Japanese pharmacopoeia provides a supplementary standard on another 83 herbs not covered by the pharmacopoeia. These standards have proven to be of value in improving the quality of marketed herbs. However, there is still room for improvement of the current standards and to extend their application to a greater number of herbs.

The possibility of objectively assessing the efficacy of traditional medicines by scientific means has evoked much discussions in recent years. Even though some progress has been achieved, no definitive proposals have yet been made and further studies need to be carried out.

In Japan, traditional medicine, including Kampo drugs, have contributed greatly to the national medical care and their use has become increasingly popular in recent years. The resurgence of interest has occurred because, in contrast to allopathic drugs, Kampo drugs are

rarely found to have serious adverse effects and are effective in providing symptomatic relief without exerting potent pharmacological actions.

3. Regulatory situation of herbal medicines in Japan

Herbal medicines are products prepared for use in accordance with Kampo formulations. They belong to the category of 'drugs' under the Pharmaceutical Affairs Law. The basic principle of regulation is as follows: thousands of Kampo formulations are classified under ancient formulations, recent formulations, and formulations by experience. Not all of them have proved effective, but the beneficial effects of the formulations on Kampo medicine described in many established and currently available books on Kampo medicine have been recognized historically. In the case of formulations mentioned in such books, it is not recommended that their contents (ingredients and composition), as well as administration and dosage, be changed without reasonable grounds, because it may produce different effects from the original ones and cause unexpected adverse reactions. Taking the specialities of Kampo medicines into consideration, the Sub-committee on Kampo medicines and Natural Drugs of the Central Pharmaceutical Affairs Council have developed basic principles of regulation. These rules apply to Kampo medicines as proprietary drugs, but they should also apply, with necessary modifications, to those considered as ethical drugs.

4. Re-evaluation of herbal drugs

Re-evaluation of herbal drugs on three Kampo preparations and 15 herbal extracts had been finished; drug re-evaluation of traditional medicines, Ethical Products in medicines 1991; Guidelines for drug re-evaluation of traditional medicines, Ethical Products in Kampo medicines. Selection of 8 formulas from Ethical Products in 210 Kampo medicines by the Pharmaceutical Affairs Law in Japan. 1992; Official meeting of drug re-evaluation of traditional medicines, Ethical Products in Kampo medicines under the Pharmaceutical Affairs Law of Japan 1996 . The following formulas had been re-evaluated by the Pharmaceutical Affairs Law of Japan:

(a) *Daioukannzou-tou* for constipation

(b) *Syouseiryuu-tou* for allergic rhinitis

(c) *Syousaiko-tou* for chronic hepatitis (A and B type)

Annex 6

The following formulas are under study but there is no available information for re-evaluation:

(a) *Keihikasyokuyokutou* for irritble colon syndrome

(b) *Ourenngedokutou* for hypertonia

(c) *Byakkoka ninjintou* for atopic dermatitis

(d) *Syakuyaku kannzoutou* for calf pain

(e) *Rikunnshitou* superior gastrointestinal trouble

The 15 herbal extracts are as follows:

(a) Extract of horse-chestnut seed;

(b) Extract of horse-chestnut leaf;

(c) Syrup of senga;

(d) Extract of *Crataegus* fruit;

(e) Water of almond;

(f) Extract of *Plantago* herb;

(g) Extract of cherry bark;

(h) Extract of *Polygara tenuifolia*

(i) Extract of *Coix* seed;

(j) Tincture of red pepper;

(k) *Cascara sagrada*;

(l) Extract of *senna*;

(m) Extract of *Vomica*

(n) Tincture of *Vomica;* and

(0) Fluid-extract of *condurango*

5. **Quality control of natural medicines in Japan**

The quality of natural medicines used in Japan are described in the Japanese Pharmacopoeia and Extrapharmacopoeia. In December 1997, a part of the Japanese Pharmacopoeia related to natural medicines will be revised and published. Outlines of Japanese Pharmacopoeia and regulation of traditional medicines will be reported during my lecture.

A. History of Japanese Pharmacopoeia

The first edition of the Japanese Pharmacopoeia had been published in July 1888 and this edition contains 468 monographs which include 97 crude drugs. Twenty-five monographs of the first edition have continued to be reported in the 13th edition (1996). Twenty-five crude drugs, stated below, are included in the first (1888) and 97 crude drugs have been added in the 1996 edition: *Acacia, Amomum seed, Bearberry leaf, Benzoin, Bitter orange peel, Calumba, Cinnamon bark, Clave, Digitalis, Fennel, Gambir, Japanese gentiana, Ginger, Glycyrrhiza, Honey, Ipeca, Japanese Valerian, Mentha herb, Nux omica, Powdered opium, Rhubarb, Saffron, Senega, Senna leaf, Tragacanth.*

The second edition (1891) includes 91 crude drugs and three monographs have been added into the 1996 edition, such as: *Coptis Rhizome, Apricot Kernel and Scopolia Rhizome.*

The third edition (1906) includes 135 crude drugs and four monographs were added in the 1996 edition, such as: *Cundurango, Gentiana, Immature Orange and Zedoary.*

The fourth edition (1920) includes 120 crude drugs and four monographs have been added in the 1996 edition, such as: *Pharbitis seed, Platycodon root, Polygala roo and Swertia herb.*

The fifth edition (1932) includes 98 crude drugs and four monographs have been added in the 1996 edition, such as: Catalpa, potato starch, rice starch and wheat starch.

Annex 6

The sixth edition (1949) include 87 crude drugs and nine monographs have been added in the 1996 edition, such as: tractylodes lancea rhizome, tractylodes Rhizome, corn starch, Geranium herb, Peony root, Phellodendron bark, and Ginseng.

The seventh edition (1961) includes 176 crude drugs and 47 monographs were added in the 1996 edition.

The general rules for crude drugs were added in the General Notices for *Achyranthes* root, *Anemarrhena rhizome*, *asiasarum* root, *Astragalus* root, *Cassia* seed, *Belladonna* root, *Bupleurum* root, *Cimicifuga* rhizome, *Cnidium rhizome*, *Cyperus rhizome*, *Evodia* fruit, *Gardenia* fruit, *Glehnia* root, *Gypsum*, *Houttuyinia* herb, *Imperata rhizome*, Japanese *angelica* root, *Jujube Lithospermum* root, *Magnolia* bark, *Montan* bark, *Morus* bark, *Nuphar rhizome*, *Ophiopogon* tuber, *Oriental bezoar*, Oyster shell, *Panax rhizome*, Peach kernel, *Plantago* herb, *Plantago* seed; *Polyporus sclerotum*, *Poria sclerotum*, *Prunella* spike, Red ginseng, *Rehmannia* root, Rose fruit, *Safflower*, *Saposhnikovia* root, *Schisandra* fruit, *Scutelaria* root, *Smilax rhizome*, *Sophora* root, Sweet *hydrangea* leaf and *Trichosanthes* root.

The eighth edition (1971) includes 176 crude drugs, the as the seventh edition.

The ninth edition (1976) includes 169 crude drugs and 10 monographs were added in the 1996 edition, such as: *Schizonepeta* spike, *Cornus* fruit, *Dioscorea rhizome*, *Perilla* leaf, *Citrus unshiu* peel, *Mentha* herb, *Angelica dahurica*, *Sapo shnikovia* root, *Longgu* and *Forsythia* fruit.

The tenth edition (1981) includes 166 crude drugs.

The eleventh edition (1986) includes 165 crude drugs and the musk has been excluded.

The twelfth edition (1991) includes 165 crude drugs.

The thirteenth edition (1996) includes 172 crude drugs with the following new monographs: *Mallotsu* bark, *Artemisia capillaris* flower, powdered *Fennel*, powdered *Dioscorea rhizome*, powdered *Polyporus sclerotum*, powdered peach kernel, and powdered ginseng.

B. General rules for Crude Drugs and Crude Drugs Test:

(1) General rule for crude drugs:

(a) Crude drugs are usually used in the forms of whole crude drug, cut form or powdered form.

(b) Unless otherwise specified, crude drugs are used in dried form. The drying is usually carried out at a temperature not exceeding 60°C.

(c) Maintain a clean and hygienic state.

(d) The description in each monograph of crude drug usually covers the crude drug derived from its typical original plant or animal and includes a statement of the characteristic properties of the crude drug to serve as a criteria.

(e) Crude drugs are preserved in well-closed containers unless otherwise specified.

(2) Crude Drugs Test

(a) Sampling: this should be done in 3 categories: 50-250g sample for small-size or powder; 250-500g for large size; and not less than five pieces for the weight of each single piece of crude drug not less than 500g.

(b) Preparation of tests sample for analysis: Samples for the preparation should be mixed well. Powdered drugs should be used as they are, and in the case of unpowdered drugs, unless otherwise specified, the sample should be ground into powder form. If the sample cannot be ground into powder, reduce it as finely as possible, spread it out in a thin layer, and obtain a typical portion for analysis. If necessary, preserve the test sample in a tight container.

(c) Loss in drying: 2-6g of the test sample for analysis. Drying at 105°C for five hours. Continue the drying at 105°C, and weigh accurately at 1-hour intervals. When the sample becomes constant, the loss of weight represents the percentage of loss of drying (%). When the period of time for drying is specified,

weigh accurately after drying for the period of time specified, and determine the loss in drying (%).

(d) Total ash: Heating to a temperature between 500-550°C more than four hours.

(e) Acid-insoluble ash: Add diluted hydrochloric acid to the total ash and boil for five minutes.

(f) Extraction: Dilute ethanol-soluble extract, water-soluble extract, ether-soluble extract.

(g) Essential oil content: The essential oil content in crude drugs is performed as directed in the essential oil determination.

(h) Microscopic examination: Apparatus, preparation for microscopic examinations, and observation of components in the description.

(3) Several monographs of each material (*Rhubarb, Ginseng, Glycyrrhiza* and so on)

Rhubarb: Rheum palmatum, Rheum tanguticum, Rheum officinale, Rheum coreanum or their interspecific hybrids. It contains not less than 0.25% of sennosides. Purity; raponticin, loss in drying; not more than 13.0%, Total ash; not more than 13.0%, Extract content (Dilute ethanol-soluble extract); not less than 30.0% component determination; HPLC

Ginseng: Panax ginseng. Identification; ginsenoside Rg1 by TLC, Total ash; not more than 4.2%, extract content (dilute ethanol-solubule extract)not less than 14.0%, Purity (1) foreign matter, (2) Heavy metals (not more than), (3) Arsenic (not more than 2ppm), (4) Total BHC's and total DDT's (not more than 0.2ppm).

Glycyrrhiza: *Glycyrrhiza uralensis, Glycyrrhiza glabra*. It contains not less than 2.5% of glycyrrhizic acid. Loss in drying; not more than 12.0%, Total ash; not more than 7.0%, Acid-insoluble ash; not more than 2.0%, extract content (Dilute ethanol-soluble extract); not less than 25.5%. Component determination; HPLC

Ephedra herb: *Ephedra sinica* or other species of the same genus. It contains not less than 0.7% of total ephedrine as ephedrine and pseudoephedrine.

Magnolia bark : *Magnolia obovata*, *Magnolia officinalis*, *Magnolia officinalis var.* biloba. It contains not less than 0.8% of magnolol. Total ash; not more than 6.0%, Extract content (Dilute ethanol-soluble extract); not less than 25.5%. Component determination; HPLC.

6. **Goverment's future plans in this area**

Japan has been harmonized on the medicines under the ICH movement. However, this movement mainly treated with modern medicines and discussed in Europe and the USA. Herbal medicine is one of the important medicines in this country and specific material and medical system used in this area. Japan wants to discuss the herbal medicines and if possible to make the same monographs in the Pharmacopoeia.

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./6
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

REPUBLIC OF KOREA

by

Dr Soo-Myung Oh
Director
and
Dr Dong-Suk Park
Deputy Director
WHO Collaborating Centre for Traditional Medicine
East-West Medical Research Insitute
Kyung Hee University
Seoul

Annex 6

SITUATION OF HERBAL MEDICINE IN THE REPUBLIC OF KOREA

by:

Dr Soo-Myung Oh and Dr Dong-Suk Park

Oriental medicine has a long history in the Republic of Korea and plays a significant role in the health of the people. Oriental medicine is a kind of traditional medicine which can cure many diseases as well as protecting health. Herbal medicines have proved very beneficial and are an important aspect of medical care in the country.

Three thousand years ago, the Chinese brought traditional Chinese medicine to the country and it was combined with Korean medicine to form a typical type of traditional medicine. Herbal medicines produced in the Republic of Korea, as well as in China, have been used for many years and for the past 500 years, the Government has been supporting the growing of herbal medicine plants.

In 1952, the national medical law was passed and an oriental medical system was established as an inclusive parallel medical system. Until the 1960s, there was only one college for oriental medicine with a four-year course. Now, there are 11 colleges providing formal education on oriental medicine which offer a six-year course, including a two-year pre-medical course. There are now more than 9000 licensed oriental medicine doctors.

Herbal medicines are produced in China, Japan, Republic of Korea, South-East Asia and other countries. The Republic of Korea imports herbal medicines which are lacking in the country.

Previously, the production of herbal medicines was old fashioned and unproductive, and the distribution system was outdated. This was due to the Japanese colonial policy, which tried to eradicate folk medicine, and the indiscriminate influx of western medicine into the country. There was also a lack of understanding on oriental medicine and support for its improvement. Now, it is more systematic, reasonable, there are specialized guidelines for producers, consumers and dealers, and attempts to modernize it.

Annex 6

The Government has been improving the system. A special section on oriental medicine has been established at the Ministry of Health and Welfare with national support for research. As a result of this effort, a medical insurance coverage for oriental medicine began in 1986, after two years of trials on acupuncture and herbal medicine extracts. This has played an important role in the wide use of oriental medicine and lowered medical expenditure.

In 1996, the Department of Oriental Pharmacy was opened, employing experts on herbal medicine. Previously, western medicine pharmacists could dispense some herbal medicines, but now only licensed oriental pharmacists are authorized to dispense herbal medicines.

The Government is standardizing the commonly used herbal medicines as a national project. More than 150 kinds of herbal medicine have already been standardized. However, political support for herbal medicine and products is not enough. The production and distribution system and the market have not been improved systematically and there is now a need for competent personnel who will take on this task.

National support should be increased to cope with the increasing demands of the people for herbal medicines. The role of oriental medicine should also be expanded, especially the medical aspects and there is a need for research and development in several fields.

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./7
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

LAO PEOPLE'S DEMOCRATIC REPUBLIC

by

Dr Boun Hoong Southavong
Programme Manager
Research Institute of Medicinal Plants
Vientiane

Annex 6

ACTUAL SITUATION

OF

THE USE OF TRADITIONAL LAO MEDICINE (TLM) IN LAOS

by: Dr Boun Hoong Southavong

1. INTRODUCTION

Laos is situated in tropical region and has an abundance of medicinal plants. Many plants and animals have been identified and used as ingredient in traditional Lao Medicine which the Lao people have used in their long and heroic tradition of combating natural calamities as well as illnesses. In rural areas, more than 90% of communities use traditional Lao medicine/herbal medicine to prevent and cure disease. The Government of Laos promotes the use of traditional medicine, in general, especially traditional Lao medicine, and has set up an Institution dealing with traditional Lao medicine/herbal medicine, the Research Institute of Medicinal Plants (RIMP). Recognizing the important role of traditional medicine, WHO has also paid a great deal of attention to supporting RIMP in enhancing the rational use of TRM in Laos.

2. OPPORTUNITIES AND PROBLEMS

2.1 Opportunities

Due to the efforts of RIMP's staff, support from the Government and WHO budget and the cooperation of other partner agencies (i.e. UNIDO, SIDA, Health Unlimited), the Research Institute of Medicinal Plants has progressively developed and has used available funding effectively.

In the last biennium, RIMP achieved many successes. Surveys of natural resources, medicinal plants and animals, and indigenous Lao remedies (Tarm Lar Yar Lao) were carried out in all parts of the country; 2216 medicinal plants were identified, 731 of them in the

Annex 6

Northern part of the country, 1128 in the Middle and 257 in the Southern part. Some of these plants can be considered to have a high economic value e.g., *Anoectochilus formosaus Hay.*, the herb which has a bright prospect in the treatment of cancer, diabetes, and heart disorders. There are more than 30 species of medicinal animals in Laos which have been listed in the medicinal animal inventory of RIMP.

With WHO support, a booklet entitled *The medicines in your garden* has also been published in the local language. Thirty commonly used medicinal plants are concisely introduced in this publication.

Most of the indigenous Lao remedies were found in the Pagodas and among the ethnic minorities. Since the foundation of RIMP, 2833 Tarm Lar (remedies) have been discovered, 1965 of them from the North, and 1442 from the South. Two volumes which include 570 selected remedies have been published. These booklets on indigenous Lao remedies and *The medicines in your garden* have been used as teaching materials in several seminars on the promotion of the rational use of traditional and herbal medicine in Laos. They have also been distributed to healers.

Since 1995, RIMP has been organizing national workshops to finalize the traditional medicine policy of Laos. WHO/WPRO's Medical Officer, Traditional Medicine, Dr Chen Ken, had conducted this Meeting. Many seminars on the promotion of the rational use of traditional medicine and training courses on *The medicines in your garden* and technique for medicinal plants surveys have also been organized at the central level as well as in the provinces. More than three hundred participants have taken part in these meetings.

WHO has also provided support for clinical trials of an antimalarial drug derived from plants and for building a model medicinal plant garden for the family.

In the last two years, three new Provincial Medicine Stations have been organized and have begun to implement many useful activities. These are in Champasack, Bolikhamxay and Kham Mouane.

RIMP has successfully used TLM to heal several diseases, including gastric ulcer, kidneys stone, gonorrhoea, diabetes, malaria and haemorrhoids. We are now gathering clinical data on the use of TLM to cure Basedow (toxic goitre) which healers have been practising for a long period of time.

The forms of dosage for TLM have been improved and many remedies are now available as tea, pills, tablets, fluid and dry extracts. The active ingredients of some plants have been extracted, separated and purified: *Artocarpine* from *Artocarpus lakoocha Roxb.*, *Berberine* from *Coscinium usitatum Pierre*, *l-Tetrahydropalmatine* and *Artemisinin*, from *Artemisia annua L.*, have recently been extracted and purified in our test scale production.

Over the last two years, WHO has supported many overseas fellowships for RIMP staff to increase their knowledge of processing technology and analytical methods for TRM/HBM. A considerable amount of supplies and equipment, as well as chemical reagents and solvents have also been provided. Thanks to this valuable support, the Laboratories of RIMP are able to carry out experimental work on TLM and control the quality of remedies.

2.2 Problems

In spite of considerable achievements, RIMP still encounters many difficulties. Materials and technology in the Institute are insufficient, making research on new plant derivatives very difficult. In addition, we are short of qualified staff in the fields of traditional medicine, botany and phytochemistry and a lack of English knowledge impedes access to overseas TRM/HBM research. RIMP also lacks sources of information on traditional medicine and medicinal plants.

The great majority of traditional healers are old, many of them famous, and they have a lot of experience in practising TLM. However, young people are not interested in inheriting or continuing their tradition and their work. There is therefore concern that this precious heritage will be lost. It is very important to make full use of healers' experience. As most healers do not use technology in processing the medicine, their knowledge on TRM/HBM is upgraded by organizing short-term training courses. As healers live close to the people, they will play an important part in implementing the community-based TRM project in Laos.

In spite of the support of WHO and some nongovernmental organizations in Laos, many provincial TRM Stations still lack any means of transport as well as equipment to carry out such activities as resource surveys, collection of medicinal plants, and processing.

Annex 6

3. GOVERNMENT POLICY ON HERBAL MEDICINE

The main objectives of setting up a National Policy on TLM are as follows:

- To preserve and maintain the precious national heritage of TLM.
- To realize the general policy of the Government regarding the Health care of the Lao people under the slogan "Health for all by the year 2000".
- To substitute some modern medicines which the health facilities in remote areas cannot provide to met the needs of the people's health care.
- To improve the knowledge and perception of general health workers on the rational use of TLM as well as HBM and to convince medical doctors to recognize the efficacy and safety of TLM.

TLM Policy as part of the National Drug Policy covers the following main issues:

(1) In order to realize the National Health Policy of the Government, especially the integration between the two fields of medicine, modern and traditional, the Ministry of Public Health encourages health services at all levels to cooperate with RIMP in setting up their Traditional Medicine Stations, integrating the use of TRM with modern medicine and incorporating TLM into their PHC component.

(2) Health service units should select healers according to their knowledge, prestige, aptitude and contribution, and request the Ministry of Public Health or the Government to commend and reward them.

(3) Approaches for improving TLM activities:

- RIMP has responsibility for seeking financial support to build up the material and technical basis to reinforce scientific research. RIMP also gives specialist support to TRM stations. The Government supports provincial TRM stations in surveying local latent resources, traditional remedies and medicinal plants, processing the raw material into ready-usable-forms and administering TRM products. Provincial health departments support and motivate district hospitals to practise TRM.

- There is at least one traditional practitioner or herbalist and midwife in each village throughout the whole country. Health volunteers should collaborate with them and convince them to participate in PHC activities, disseminating information on the use of TRM/HBM in the community and creating favourable circumstances for their activities related to the actual socioeconomic situation of each village.

(4) TLM should be integrated into PHC activities. Both activities, PHC and TLM should have a unified action plan, aimed at improving health care services to the community. The main approaches considered for successfully implementing this action plan are as follows:

- Continue to use the antique palm leaf manuscripts on traditional Lao medicine formulas, translate them into modern Lao language and select the good remedies to introduce to health workers and villagers.

- Compile and publish concise TLM theory, TLM remedies and medicinal plants for common diseases in the community.

- Organize short-term training courses to introduce to the community the use of medicine available in their localities.

- Take advantage of mass media to disseminate information on self-health-care or automedication using TLM/HBM to the community.

(5) Scientific research on TLM/HBM and pharmocognosia. In spite of the fact that RIMP still faces difficulties, scientific research is considered vital. Adaptive research is a priority. This focuses on traditional Lao formulas, aiming for the selection of truly effective remedies. Reference should also be made to foreign experience on the use of TRM.

(6) Protection of traditional remedies and the processing procedures of traditional products. Both the public and private sectors have always protected their own registered traditional formulas and their processing procedures. Transfer of remedies and processing procedures from one healer to another must, therefore, follow an agreement between the two parties.

Annex 6

(7) Legislation concerning the use of traditional medicine. In order to ensure the efficacy and safety as well as the quality of medicines, the Food and Drug Department (FDD) at the Ministry of Public Health promulgated legislation concerning modern and traditional drugs. This emphasized the obligation of registration for all pharmaceutical products. TRM workshops and business undertakings e.g., Traditional Medicine Stores or Import and Export Company for raw materials or TRM/HBM products, are also required to register.

4. GOVERNMENT'S FUTURE PLANS IN TLM AREA

The Government recognizes the important role of TLM and the country is endowed with an abundance of medicinal plants and herbs. " ***...8) - Study and use Traditional Lao Medicine, combine it with Modern Medicine. Traditional Lao Medicine has many advantages, if we attempt to deeply study this kind of medicine and apply it in the prevention and treatment of diseases, it might help us to solve many problems, especially in remote areas. The important issue is that we have to go to the healers who are rich in experience and old documentation and formulas. Furthermore, in order to ease the use of TLM we should thoroughly study our traditional method of healing to acquire scientific data.***" (excerpt of Mr Boun Nhang Vorachit's statement in the IVth National Congress of Health 1997).

The goal of TLM by the year 2020 was determined in the IVth National Congress of Health. The Ministry of Public Health has set up a general strategy for TRM by the year 2000 and an action plan for 1997-1998. According to the master plan of the Ministry, the Research Institute of Medicinal Plants also has strategies dealing with the development of Traditional Lao Medicine in biennium 1997-1998, by the year 2000 and 2020.

As medicinal plants are one of the country's natural resources, the Government will invest in up-to-date equipment for their production and analysis. The production and selling will be harmonized and at a higher level. Some important issues of RIMP's research and development strategy are:

- Set up necessary laboratories for the study of medicinal plants and traditional Lao medicine.

- Build up the material and technical basis of RIMP so that it can upgrade its research on the use of new molecules from medicinal plants.

- Build a national botanical medicinal plants garden.

- Attempt to transform the research so that it has economic value, in accordance with the Government's new marketing mechanism.

- Increase support at grassroots level, try to establish Traditional Medicine Stations in all provinces.

5. RECOMMENDATIONS

The Research Institute of Medicinal Plants is still facing many difficulties. In order to improve RIMP, to increase research capacity for the areas of TLM/HBM and medicinal plants, the knowledge of RIMP staff should be upgraded. The Government should continue to invest in building the material and technical basis for RIMP. RIMP itself should alter its way of working.

Short-term training courses on the promotion of the utilization of TLM should continue to be organized for medical doctors and health workers at provincial and district level.

In order to promote the rational use of TLM, it is important to set up community-based traditional medicine.

There should be cooperation with WHO and other relevant international organizations and the related institutions of neighbouring countries to enhance RIMP success.

Annex 6

Some important achievements

Activities	Achievement
1. Medicinal Plants found (Total)	2,216
- *Northern part*	731
- *Middle part*	1,128
- *Southern part*	257
2.Traditional lao remedies exploited (Total)	2,833
- *Northern part*	1,965
- *Middle part*	1,442
- *Selected and published*	570
3. Books and booklets published:	
- *Medicinal Plants in Laos Vol. 1*	200 copies
-*The Medicines In Your Garden Vol. 1*	2,000 copies (WHO support)
- *Traditional Lao Remedy (Tam lar Yar Lao) Vol. 1*	2,000 -"-
- *Tam Lar Yar Lao Vol. 2*	2,000 copies (Govt. support)
4. Workshops/Seminar/Training courses convened:	17meetings/455participants /23,934,212LAK=18,411USD
- Government support	3meetings/71participants 5,114,120LAK=3,934US$
- WHO support	11meetings/319participants 14,964,909LAK=11,511US$
- Sida support	1meeting/36participants 2,934,283LAK=2,257USD
- Health Unlimited (Canada)	2meeting/29participants 920,900LAK=708US$

Data source : Administrative office (RIMP), 1991-1997

Annex 6

LIST OF SOME MEDICINAL PLANTS WILDLY GROWN IN LAOS

Nr (a)	Local names (b)	Family & Scientific names (c)	Parts used (d)	Indications (e)	Ecology (f)
		I- ABIATACEAE:			
1	Pack horm	Pinus khasya ROYLE	Wood, resine & E.O. (Ø)	Cough, antiseptic	Wildly grown & Plantable (W&P)
		II- ANNONACEAE:			
2	Kalan nga	Canangium odorata Hook.	Flowers/wood	Hypertension	W&P
		III- ARACEAE:			
3	Hongkhao	Acorus gramineus Soland	Rhizoma	Gastrite, Arythmic, asthma	W&P
4	Bornhorm	Homalomena occulta Schoot	Rhizoma	Rheumatism	W&P
		IV- CHENOPODIACEAE:			
5	Sloanthong	Chenopodium ambrosioides L.	E.O.	Anthelmintic	W
		V- LAURACEAE:			
6	Estcoton	Cinnamomum camphora (L.) Sieb.	Wood, E.O.	Coryza, colic, Chest pain	W
7	Khae horm	C. cassia Blume	Bark, E.O.	Coryza, repletion	W&P
8	Khae moo	C. obtusifolium (Nees)	Bark, E.O.	-	-
9	Khae phet	C. iners Reinw.	Bark, E.O.	Influenza, cares	W
10	Sai juang	C. cortechinii GAMBLE.	Leaves	Influenza, cold	W
11	Seakhaiton	Litsea cubeba (Lour.) Pers.	Fruits	Stomachic...	
		VI- LABIATAE:			
12	Boulaphar	Ocimum basilicum L.	Herba, E.O.	Vegetable	P
13	Spaulomkao	O. gratissimum L.	Herba, E.O.	Vegetable, cold, cares	W&P
14	Spaulomdeng	O. sanctum L.	-	-	-
15	Maengkaeng	Perilla ocymoides Linn.	Leaves	Vegetable	P
16	Sap haeng	Hyptis suaveolens (L.) Poit.	-	Cold, insecticide	W
17	Nao mar	Elsholtzia cristata Willd.	Herba	Cold, headache...	W
		VII- MALVACEAE:			
18	Portaseua	Hibiscus abelmoschus Linn.	Seed, root, E.O.	Fixator, diuretic, purgative.	W
		VIII- MYRTACEAE:			
19	Samek	Eugenia zeylanica WIGHT.	Young leaves	Vegetable	W
20	Naunmankieo	Eucalyptus species.	Leaves, E.O.	Fluenza, cold	P
		IX- RUTACEAE:			
21	Smart	Micromelum falcatum TANAKA	Herba, leaves	Intoxicated, nsthma	W

E.O = Essential oil, W = Wildly grown, P. = Plantable.

Annex 6

List of Medicinal Plants wildly grown in Laos (contd.)

(a)	(b)	(c)	(d)	(e)	(f)
22	Mat/Khaen	Xanthoxylum sp	Fruits	Vegetable	W&P
23	Semsun	Glycosmis citrifolia Lindl.	Root, leaves	Sauna, asthma	W
		X- SCROPHULARIACEAE:			
24	Cheenaikorm	Adenosma sp.	Herba	Coryza, Cholagogue	W
		XI- ACANTHACEAE:			
25	Rasabee	Andrographis paniculata Nees	Herba	Antiseptic, tonic, dysentery	W&P
26	Hoohardong	Justicia adhatoda L.	Leaves	Fractured bone	W
		XII- ARACEAE:			
27	Karbook	Alocacia macrorrhiza Schott	Rhizoma	Malaria, asthma	W
28	Dookdeua	Amorphophallus riviera Durr.	Tuber	Malaria	W
29	Bom nam	Lasia spinosa Thwaites	Rhizoma	Angina, Oedema...	W
		XIII- ARALIACEAE:			
30	Lepuminang	Schefflera elliptica Harms	Cortex	Tonic, nervine, rheumatism	W
31	Tarng	Tetrapanax papyrifera (Hook.) Koch.	Root, lignin	Diuretic, galactogogue	W
		XIV- ASCLEPIADACEAE:			
32	Ov sarm suan	Streptocaulon extensus Wight L.	Creeper/wine	Antitussive	W
33	Khena soot	Streptocaulon juventas (Lour.)	Root	Tonic	W
		XV- BERBERIDACEAE:			
34	Baerberin	Mahonia beallil Carr.	Lignin	Conjunctivitis	W
		XVI-COMPOSITAE:			
35	Nia Kon jarm	Bidens pilosa L.	Herba	Headache, cares, hiccough	W
36	Kefinokkhum	Elephantopus scaber L.	Root	Allergy,diarrhoea, fever, diuretic	W
37	Hornkeo	Eclipta alba Hassk.	Whole plant	Hemostatic	W
38	Nat bay noy	Artemisia annua L.	Leaves	Malaria, fever	W
39	Nia kee lo	Ageratum conizoides L.	Herba	Sinus, hemostatic	W&P
40	Nat noy	Artemisia vulgaris L.	Herba	Headache	W
41	Nat luang	Blumea balsamifera (L.) DC.	Leaves	Coryza, flatulence	W&P
42	Nia falang	Eupatorium odoratum L.	Root, leaves	Hemostatic, appendicitis	W
43	Phark kaep	Gnaphalium indicum L.	Flower	Cough,	W
44	Nia nart nieo	Siegesbeckia orientalis L.	Herba	bronchitis	W
45	Park kart	Spilanthes acmella L. Murr.	Flower, leaf	Backache, numb, furuncle, boneache,	W
46	Kardum kham	Wedelia calendulacea (L.) Less.	Whole plants	Cares, vegetable Antibiotic	W
47	Nia kee on	Xanthium strumarium L.	Fruit	Allergy, goiter	W
		XVII- BORRAGINACEAE:			
48	Nguangsarng	Heliotropium indicum Linn.	Root	Backpain	W

Annex 6

List of Medicinal Plants wildly grown in Laos (contd.)

(a)	(b)	(c)	(d)	(e)	(f)
		XLIII-CAESALPINIACEAE:			
49	Keylaek ban	Cassia alata L.	Root, leaves	Yellow, eczema	W
50	Lueng knet	Cassia occidentalis L.	Seeds	Eyes disorder, purgative.	W
51	Farng daeng	Caesalpinia sappan Linn.	Lignin	Tonic, dysenteria	W
		XLV-APOCYNACEAE:			
52	Khar niom	Rauwolfia serpentina Benth.	Root bark	Hypertension	W&P
53	Khar niom	Rauwolfia verticillata (Lour.) Baill.	Root bark	Hypertension	W&P
54	Khar niom	Rauwolfia canescens L.	Root bark	Hypertension	P
55	Mook nlay	Holarrhena antidysenterica Wall.	Bark,, seeds	Dysenteria	W
56	Kao bok	Catharanthus roseus G. Don.	Leaves	Hypertension	W
57	Tin Paet	Alstonia scholaris (L.) R. Br.	Bark	Tonic	W
		XX- HYDRANGEACEAE:			
58	Horm saeng	Dichroa febrifuga Lour.	Leaves	Malaria	W
		XXI- LEEACEAE:			
59	Tarng kai	Leea sabusina WILLD.	Root	Tonic, goiter	W
		XXI- LILIACEAE:			
60	See saeng	Asparagus cochinchinensis (Lour.) Merr.	Rhizoma	Diuretic, cough, mouth coated	W
61	Jia hua	Smilax glabra ROXB.	Rhizoma	Tonic	W
		XXII-LOGANIACEAE:			
62	Seeng bena	Strychnos nux vomica L.	Seeds	Neurasthenie, tonic	W
		XXIII-MELIACEAE:			
63	Hiern	Melia azedarach L.	Root bark	Anthelmintic	W
64	Kar dau saeng	Azedarachta indica Juss.	Lignin	Antimalaria	W
		XXIV- MYRSINACEAE:			
65	Som lo	Embelia ribes Burm.	Fruits	Tapeworm killer	W
		XXV- MENISPERMACEAE:			
66	Kheua Haem	Coscinium usitatum Pierre Gagnepain.	Wine	Dysenteria, cholagogue	W&P
67	Torm ngeuan	Stephania glabra ROXB.	Bulb/tuber	Tranquilizer	W
		XXVI- MORACEAE:			
68	Hart mee	Artocarpus lakoocha ROXB.	Lignin/Wood	Tapeworm killer	W
		XXVII- POLYPODIACEAE:			
69	Karpkae heau	Drynaria fortunei J.Sm.	Rhizoma	Rheumatism, bone pain relief	W
		XXVIII- RUBIACEAE:			
70	Njo	Morinda citrifolia L.	Wood, fruits	Yellow, menses	W
71	Kaengkeenar	Cinchona ledgeriana Moens.	Steam bark	Antimalaria, tonic	W

Annex 6

List of Medicinal Plants wildly grown in Laos (contd.)

(a)	(b)	(c)	(d)	(e)	(f)
		XXIX- ROSACEAE			
72	Mark jan	Crategus pinnatifida Bunge	Fruits	Stomachic, cardiotonic	W
		XXX- RUTACEAE:			
73	Khao mai	Evodia lepta (Spreng) Merr.	Root	Asthma	W
		XXXI- STERCULIACEAE:			
74	Mark jong	Sterculia lychnophora Hance	Fruits	Purgative	W
		XXXII- STYRACEAE:			
75	Nian khao	Styrax tonkinensis Pierre	Resine	Cough, bronchitis	W
		XXXIII- ZINGIBERACEAE:			
76	Khaar	Alpinia officinarum Hance.	Rhizoma	Cholic, stomachic	W&P
77	Mark naeng	Amomum xanthioides Wall.	Fruit	Flatulence	W&P
78	Huang bon	Costus speciosus Smith.	Rhizoma	Arthritis,	W
79	Khmean	Curcuma longa L.	-	Gastrite, yellow	W
80	Khmaemdaem	Curcuma zedoaria Rosc.	-	Cholic,	P
81	Van tupmup	Kaempfera galanga L.	-	stomachic, cough, menses	W&P
82	Khing	Zingiber officinalis Rosc.	-	Gastric ulcer, chestpain	P
83	Warn narng	Curcuma sp.	-	Influenza, cholic, hemorrhagia Prolapsus	W W&P
		XXXIV-ORCHIDACEAE:			
84	Warn lai	Anoectochilus formosanus Hay.	Herba	Cancer, diabetis, hypertension, rheumatism...	W

Some Medicinal Plants available for the Plant-based-Medicine Production in the Lao PDR

Nr.	Local name	Scientific name	Botanical family	Resource	Part used	Indication
1	Kheua huem	Coscinium sp. sp	MENISTERMACEAE	Whole country (W. C.)	Vine	Dysenteria, cholagogue
2	Torm ngeun	Stephania rotunda LOUR.	MENISPERMACEAE	-	Tuber	Tranquilizer, asthma
3	Bom horm	Homalomena occuta Schott.	ARACEAE	VTE	Rhizome	Arthritis
4	Paek (Yang)	Pinus sp.	PINACEAE	XK, BKX	Wood, resin	Terpine production
5	Mam Omling	Polygonum multiflorum Thunb.	POLYGONACEAE	HP, XK	Tuber	Tonic
6	Jeenai korm	Adenosma sp.	LABIATAE	VTE	Herba	Cholagogue, galactogogue
7	Nart soy	Leonurus heterophyllus Sweet.	LABITAE	W. C.	Herba	Emmenagogue, heart disturbance
8	Nathombavnov	Artemisia annua L.	LABIATAE	W. C.	Leaf	Antimalaria, fever
9	Nia kee on	Xanthium strumarium L.	COMPOSITAE	UDX	Fruit	Allergy, goitre
10	Baeberin	Mahonia bealii Carr.	BEBERIDACEAE	PSL	wood	Dysenteria
11	Lepum nama	Schefflera elliptica Harms.	ARALIACEAE	W. C.	Stem bark	Tonic
12	Ya hua	Smilax glabra ROXB.	LILACEAE	W. C.	Tuber	Tonic, galactogogue
13	Hart mee	Artocarpus lakooca ROXB.	MORACEAE	W. C.	Dried extract	Taenifuge
14	Kap kae hin	Drynaria fortunei J. Sm.	POLYPODIACEAE	W. C.	Rhizome	Arthritis
15	Warn Lai	Anoectochilus formosanus Hay.	ORCHIDACEAE	W. C.	Leaf	Cancer, diabetis...

Data source: Pharmacognosie Dept., Research Institute of Medicinal Plants, 1997. B.H. Southavong

Medicinal Plants in Lao PDR available for exportation

Nr.	Local name	Scientific name	Botanical family	Resource	Parts used	Indications
1	Varn Lai	Anoectochilus formosaus Hay.	ORCHIDACEAE	Whole country (W.C.)	Leaf	Cancer, Diabetis...
2	Mark Jorng	Sterculia lychnophora Hance	STERCULIACEAE	CPS	Fruit	Stomachic
3	Mark Naeng	Amomum sp..	ZINGIBERACEAE	CPS. SRV	Fruit	Stomachic
4	Koot Nok nhoong	Helminthostachys zeylanica L. (Hook.)	OPHIOGLOSSACEAE	CPS	Root	Ascite
5	(Yarng) Paek	Pinus sp.	PINACEAE	XK. BKX	Wood. resin	Arthritis. cough
6	Yar faek	Veteveria zizanoides (Linn.) Nees.	GRAMINAE	XK	Root	Cholagogue
7	Por Heuang	Aquilaria crassa Pierre/ A. agallocha ROXB.	THYMELACEAE	BKX	Wood, concrete	Parfume production
8	Iarn khao	Styrax tonkinensis Pierre	STYRACEAE	PSL. LPB	Benzoe	Cough. phlegm
9	Kar Niom	Rauwolfia serpentina Benth.	APOCYNACEAE	W.C.	Root	Blood pressure
10	Harng khao	Acorus sp.	ARACEAE	W.C.	Rhizome	Heart disturbance
11	Phack Pheo Narm	Polygonum hydropiper L.	POLYGONACEAE	W.C.	Whole plant	Hu(e)morrhagia
12	Sengkharmton	Terminalia nigrovenulosa Pierre	COMBRETACEAE	W.C.	Stem bark	Dysenteria
13	Pack Sav	Momodica charanchia L.	CUCURBITACEAE	W.C.	Whole plant	Diabetis. AIDS
14	Kheua Khao hor	Tinospora crispa (L.) Miers.	MENISPERMACEAE	W.C.	Whole plant	Fever. AIDS
15	Duk deua	Amorphophallus konjac K. Koch.	ARACEAE	W.C.	Tuber	Obesity, Hemiplegia

Data source: Pharmacognosia Dept., Research Institute of Medicinal Plants, 1997. B.H. Southavong

List of Medicinal Animals in Laos

Nr. (1)	English name (2)	Scientific name (3)	Animal family (4)	Medical usages (5)
1	Silkworm	Bombyx cum Botryte (= B. botrycatus)	BOMBYCIDAE	Glaucome, antiinflammatory, tonic.
2	Scorpion/Centipede	Buthus Martensii Karsch	BUTHIDAE	Convulsive fit, tetanus, antipyretic.
3	Toad	Bufo melanostictus	BUFONIDAE	Tonic, Asthma, convulsive.
4	Bat Natural bat's excrements	Vespertilo superans Thomas var. Kerevoula *Rhinophus ferrum equinum Schreber* Excrementum vespertilii *(= Faeces vespertiliforum)*	VESPERTILIONIDAE	Eyes dim.
5	Cricket/House--cricket	Gryllotalpa unipinalpa Sauss Gryllodes berthelus Sauss	GRYLLOTALPAE	Micturition in old man.
6	Earthworm	Pheretima asiatica Michaelsen	MELASCOLECIDAE	Fever, malaria, asthma.
7	Toger	Panthera sp. (P. tigris L.)	FELIDAE	Rheumatism, bone tonic.
8	Monkey	Macaca sp. (M. mulatta Zimmermann)	CEROPITHECIDAE	Blood tonic
9	Trionychid turtle/Turtle	Carapax amidae Trionyx sinensis Wegmann	TRIONYCHIDAE	Tonic
10	Spider's egg/spawn	Uroctea compactilis Koch.	UROCTEIDAE	Hemorrhagy, tonsilitis, enuresis (bed wetting),perspiration/sweaten.
11	Gecko	Gekko-gekko	GEKKONIDAE	Asthma, malnutrition, impotence.
12	Lizard/ House gecko	Hemydactylus frenatus Schlegel	GEKKONIDAE	Asthma, tuberculosis of glands

List of Medicinal Animals in Laos (contd.)

(1)	(2)	(3)	(4)	(5)
13	Pangolin	Manis pentadactyla L.	MANIDAE	Breast ulcer, Breast cancer
14	Boucal	Centropus bengalensis Gmelin C. sinensis intermedius Hume	CUCULIDAE	Aphrodisiac, geriatric
15	Belostomatid	Belostoma indica Vitalis (= Lethocereus indicus Lep.)	-	Impotent, digestion
16	Black carp	Myropharyndogon piceus	CYPRINOIDEI	Trachome? tonsilitis, vagina ulcer (gall bladder)
17	Grass eating fish	Ctenopharyngodon idellis		
18	Sparrow	Passer montanus malaccensis Dubois (Excrementum)	PLOCEIDAE	Tonsilitis, boil, flatulent
19	Mountain goat/ Chamois	Capri cornis sumatrensis/ Capraprisca (= C. aegagrus)	BOVIDAE	Blood tonic (blood), cough relief, general tonic, cholaguoge, conjunctivitis (Total extract)
20	Varan/Monitor lizard	Vanarus salvator	VARANIDAE	Asthma (gall bladder), malnutrition
21	Lizard	Mabuya multifasciata M. longicaudata M. chapaense	SCINCIDAE	Rheumatism, bone pain relief, dizzy
22	Python	Python molorus /P. reticulatus	BOIDAE	Bone pain relief, back pain

List of Medicinal Animals in Laos (contd.)

(1)	(2)	(3)	(4)	(5)
23	Bee	Apis spp.	APIDAE	Tonic, joint pain relief (apiserum)
24	Sambar deer	Cervus nippon Temmick	CERVIDAE	Tonic, hypotension
25	A stag /Deer	Cervis unicolor	CERVIDAE	Tonic, hypotension
26	Cantharide (F.)	Lytta vesicatoria Linn.	MELOIDAE	Antiinflamatory, gonnorrhoea, Aids
27	Copper head (Naja)/Krait/Coluber	Naia sp./ Bungarus fasciatus Schneider/ B. candidus L.	ELAPIDAE	Pain relief, rheumatism (venum, total extract), eyes dim (gall bladder)..
28	Bear	Ursus arctoslisiotus Gray/ Selenarctos thibetanus G. Cuvier	URSIDAE	Pain relief, eye pain reliaf

Data source : Department of Pharmacognosia (RIMP), 1997

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./8
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

MACAO

by

Dr Cheong Tai
Coordinator, Traditional Chinese Medicine
Pharmaceutical Department
Department of Health Services
Macao

Annex 6

REGULATION OF TRADITIONAL MEDICINES IN MACAO

by:

Dr Cheong Tai

Policy: To promote and support the further development of traditional Chinese medicines.

To ensure the safety, efficacy and good quality of traditional Chinese medicines available to Macao residents, and also attempt to improve the rational use of traditional drug products.

To set out technical guidelines on the control of importation/exportation, wholesale and distribution of traditional Chinese medicines and also the practice of traditional Chinese pharmacies.

To improve the qualification criteria for licensing traditional practitioners and set out the relevant professional guidelines.

To perfect the extent of regulations of traditional Chinese medicines in Macao continuously in the light of the development and changes of science, technology and society.

1. BACKGROUND ON PHARMACEUTICAL LEGISLATION CONCERNING TRADITIONAL CHINESE MEDICINE

Macao is a small territory with a population of 450 000, 97% of which are Chinese. The majority of the people believe in and rely mainly on indigenous traditional medicines to satisfy their primary health care needs. Macao citizens prepare soups, herbal tea or herbal tonics as food supplements.

Due to the above reasons, the health authorities became aware several years ago that, for the protection of health, it is essential to protect the safety, quality and efficacy of available traditional Chinese medicines. The channels of distribution should also be controlled.

Based on WHO objectives (1977), the Government must give adequate importance to the utilization of their traditional system of medicines, with appropriate regulations suited to their national health system.

Annex 6

Subsequently, a relevant regulation was promulgated on the control of traditional Chinese medicine (TCM) in several aspects, including import/export, wholesale and distribution, practice of traditional Chinese pharmacies and the licensing of traditional practitioners.

The first traditional Chinese pharmacy was registered in the Health Department in 1936. There are now 100 licensed traditional Chinese pharmacies in Macao.

Since there was no specific law to satisfy current technical requirements which had been developed over the past two decades up until 1994, the health authority had been cooperating closely with a group of official experts in TCM in China and also with a private association in Macao (Associacão de Medicamentos Chineses) the only one at that time, in order to prepare, promulgate and update regulations suited to local situations.

The new law, Decreto-Lei No. 53/94/M de 14 de Novembro, came into effect at the end of 1994 in both official languages in Macao (Chinese and Portuguese). It is a simple law which aims, in a pragmatic way, to control several aspects of traditional Chinese medicines as follows:

(1) ensuring the safety, efficacy and quality of traditional medicines;

(2) regulating the import/export, wholesale, distribution and the practice of traditional Chinese pharmacies, trade and dispensing chains;

(3) evaluating the qualification of technical directors in traditional Chinese pharmacies.

2. TRADITIONAL CHINESE MEDICINAL MATERIALS RESTRICTED FOR SALE IN TRADITIONAL CHINESE PHARMACIES IN MACAO

In accordance with Nº 5 Artigo 13 and Nº 2a Artigo 23 of Decreto-Lei Nº 53/94/M de 14 de Novembro, the Technical Committee of Traditional Chinese Pharmaceutical Affairs (Comisão Técnica para os Assuntos de Farmácia Tradicional Chinesa), based on the technical advice from official experts in China, has prepared the list of traditional Chinese medicinal materials (Lista de Drogas Tradicionais de Venda Exclusiva nas Farmácias Chinesas), which are restricted for sale in traditional Chinese pharmacies in Macao.

We are also working on incorporating the importation of raw and processed traditional Chinese medicinal materials into the control of our department, (SSM/AF: Servicos de Saúde de Macao/Divisão dos Assuntos Farmacêuticos).

3. ALTERNATIVE REGISTRATION FOR THE IMPORTATION OF TRADITIONAL MEDICINE PRODUCTS AND THEIR REGISTRATION IN MACAO

The importation of traditional medicine products (TMP) to Macao must have prior authorization from the Health Department to ensure their quality, safety and efficacy. The authorization also serves in the registration and is called "Alternative Registration" in the department because it is based on the conventional registration in other countries.

Alternative registration requires that all products imported into Macao must be registered and freely sold in the countries of origin or exporting countries. However, proprietary Chinese medicines are exempt from registration controls in most countries and territories, such as in Hong Kong and Singapore. In order to ensure the quality and safety of the products from these countries, the importers are required to provide an analysis certificate for each individual batch as minimum quality evidence.

For obtaining an authorization (Alternative Registration) for a particular product, the applicant is required to provide the following documents at least 15 days before importation:

(1) Original/certified copy of Registration Certificates or Analysis Certificates[1] issued by the relevant authority in the country of origin or exporting country and by a competent laboratory.

(2) Manufacturing licence issued by competent authorities;

(3) Product information, including formulas of active ingredients, labels, package inserts, etc.

(4) Others, upon request, as necessary.

---

[1] Analysis Certificate is required to be submitted for each individual batch of a particular product by a competent laboratory. The analysis results of four heavy metals (Arsenic, Mercury, Lead and Copper) must be indicated in the analysis certificate.

Annex 6

The list consists of 456 types of traditional Chinese medicinal material and is divided into two groups:

Group I Toxic traditional Chinese medicinal materials

Group II Common therapeutic traditional Chinese medicinal materials

The list comprises of 12 different categories, as follows:

I. Raízes, rizomas e bolbos

II. Frutos e sementes

III. Plantas completas

IV. Folhas

V. Flores e estigmas

VI. Cortex

VII. Caules e pedúnculos

VIII. Animais

IX. Minerais

X. Resinas e combinacão de resinas

XI. Drogas tradicionais processadas

XII. Outras

After approval by the Associacão de Medicamentos Chineses, the List was officially published in Macao Official Bulletin on Nº 4, dated 24 January 1996 (Boletim Oficial de Macao).

At present, our department is updating and perfecting this list based on the opinions and information collected from various sources, and on current developments in science, technology and society.

Annex 6

3.1 Reasons for implementing "Alternative Registration"

Due to limited resources, personnel and facilities, it is quite impossible to implement a conventional registration in such a small city with a population of only 450 000. Moreover, the Government laboratory does not have experts in quality testing of TMP nor an advisory committee for quality control of traditional medicines. It is, therefore hoped that the same target can be achieved in a better way.

Based on the above reasons, we need to depend on the Conventional Registration in countries of origin or exporting countries and the Alternative Registration System tailored to local conditions is currently practised to save cost and time.

The Alternative Registration System practised in Macao differs from the Conventional Registration in the following aspects:

(1) After Alternative Registration, no registration certificate and registration number is issued for a particular product;

(2) Any authorized company can be a legal importer if it submits proper evidence. This avoids monopolies in a such small and dependent market;

(3) No sampling analysis is regularly done for products on the market. However, when unacceptable toxicity of a particular product is suspected, the cooperation of the Hong Kong Government Laboratory and the State Administration of Traditional Chinese Medicine (SATCM) is requested.

(4) It is a trend that EC countries and Federal States have been working together to implement a common registration system in order to avoid double costs and improve the functioning and quality of the specialized Registration Centres.

Our department is currently drafting the special registration regulation for traditional medicine products produced in Macao.

There are currently five manufacturers with a licence for the manufacture of traditional medicine products issued by SSM/AF.

Annex 6

4. LABELLING REQUIREMENTS

All traditional medicine products must comply with the general labelling requirement, including the following aspects:

(1) product name
(2) name and quantity of active ingredients
(3) indication
(4) posology
(5) precautions, if any
(6) special storage conditions, if any
(7) registration number
(8) batch number
(9) expiry date
(10) name of the manufacturer
(11) others, as necessary

5. LICENSING OF IMPORTERS/EXPORTERS/WHOLESALERS AND TRADITIONAL CHINESE PHARMACIES

To apply for a licence (named Alvará) for Importers/Exporters/Wholesalers or traditional Chinese pharmacies (referred to as the site), the applicant is requested to provide the documents listed below:

(1) Application with the following information:

(a) name and address of applicant;
(b) information on the general managers, administrators or directors;
(c) name and address of the site;
(d) information on the technical director;

(2) Identification card copy of applicant (or certified copy of the notarial deed for the establishment and certified copy of the revised notarial deed, if applicant is a company or organization);

(3) Criminal record certificate of the owner of the site (or criminal record certificate of the general managers, administrators or directors, if applicant is a company or organization) and the technical director;

(4) For licence of traditional Chinese pharmacies, proof of professional qualification or working experience of the technical director should be submitted;

(5) Design and description for installation and facilities of the site;

(6) Other documents or supplementary information, as necessary.

This procedure is conducted in SSM/AF.

At present, there are 101 traditional Chinese pharmacies with a licence issued by SSM/AF in Macao. There are 80 importers/exporters/wholesalers pharmacies with a licence issued by SSM/AF which can import, export and sell by wholesale both western and traditional medicine products.

6. TECHNICAL COMMITTEE ON TRADITIONAL CHINESE PHARMACEUTICAL AFFAIRS

In accordance with Artigo 23 Decreto-Lei Nº 53/94/M de 14 de Novembro, the establishment of the Technical Committee on Traditional Chinese Pharmaceutical Affairs (Comisão Técnica para os Assuntos de Farmácia Tradicional Chinesa) was approved by the director of SSM and published officially in March 1995.

(1) The committee is composed of five members:

(a) chief of SSM/AF as Chairman of the committee;

(b) two technicians from SSM/AF knowledgeable in traditional medicines;

(c) two representatives of the Association of Chinese Medicines Macao (Associacão de Medicamentos Chineses) who are appointed by the association from the technical directors of the traditional Chinese pharmacies.

Annex 6

(2) The responsibility of the committee

(a) providing opinions concerning the following affairs:

- the issue of the licence of Importers/Exporters/Wholesalers for traditional medicines and Traditional Chinese Pharmacies;
- the list of materials traditional Chinese medicinal materials) restricted to be sold in traditional Chinese pharmacies (Lista de Drogas Tradicionais de Venda Exclusive nas Farmácias Chinesas);
- the list of toxic traditional Chinese medicinal materials restricted to be sold only with the prescription of traditional Chinese doctor or mestre (Part - I Drogas Tradicionais Tóxicas en Lista de Drogas Tradicionais de Venda Exclusiva nas Farmácias Chinesas);

(b) researching and recommending necessary measures in order to promote the perfection of the practice of traditional Chinese medicine and medicines according to the development of scientific and technological knowledge;

(c) recommending the guidelines to be adopted, in order to improve the operation of the sites which compound and trade traditional Chinese medicines;

(d) giving opinions on the affairs for examination submitted to the director of SSM concerning traditional Chinese medicine.

7. INSPECTION

In order to enforce the current law, the pharmacies or importing and wholesalers' companies are subject to regular inspection by SSM/AF. The inspections are usually carried out by the inspectorate of Division of the department. The team is composed of at least two members and the chief is usually a pharmacist. There are two ways which are usually applied to achieve the goal of Modern Methodology of Inspection:

(a) Inspection - Education

The people will cooperate with us in a better way after clarification on reasons and purposes of regulation;

To educate the owners and technicians about good practice in their daily work and also to improve the service of the companies to the public, as a result, "Auto de Noticia" and penalties will be gradually decreased, and thus saving personnel and resources.

(b) Inspection - Enforcement of the law

The routine inspection includes inspection on frontiers (including imports at the pier; imports through the airport and post office), importing companies, traditional Chinese pharmacies, and other companies.

Inspections are carried out on frontiers due to a shortage of staff and a lack of Customs Office in Macao. Only the marine police are in charge of customs duties. In seeking technical advice, marine policemen empower relevant departments to give support, such us in pharmaceutical affairs where they ask the cooperation from SSM/AF. In this way, everyday inspection is carried out for imports at the pier, through the airport and post office.

If any questionable medicines are discovered or any associated problems arise during inspection, the details will be written in a record called "Auto de Noticia" to inform superiors for further investigation and final decision. Penalty will be imposed, if necessary, based on the law.

8. TECHNICAL DIRECTOR OF TRADITIONAL CHINESE PHARMACIES

In Macao, each traditional Chinese pharmacy must have a technical director with either one of the following qualifications:

(1) traditional medicine pharmacy technician;

(2) traditional Chinese medicine doctor or "mester" licensed;

(3) with at least five years working experience in preparing or dispensing traditional Chinese medicine, proven professional experience and attested by the traditional Chinese pharmacy where they were earlier employed or by the Associacão Medicamentos Chineses (Associacão de Investigacao de Medicamentos Chineses).

Annex 6

We accept the diversity of professionals because there are more or less about 100 traditional Chinese pharmacies in Macao and so far no traditional Chinese medicine pharmacist is in charge of any.

The quality control of medicines and the training of professionals are the two basic conditions for improving the old system without causing much disturbance.

9. EDUCATION AND TRAINING ON TRADITIONAL MEDICINES

SSM/AF also attach importance to education and training on traditional medicines. Some of the achievements in recent years are as follows:

(1) Made strenuous efforts to support the training course "Curso de Aperfeicoamento Farmaceutico de Medicamentos Chineses (Mestre de Medicamentos Chineses)" organized by Associacao Medicamentos Chineses de Macao (Associacao de Investigacao de Medicamentos Chineses) in 1995;

(2) One training course for internal staff of the department held by SSM/AF in 1995, which also included a topic related to the administration of traditional medicine in Macao;

(3) One training course for outside pharmacists was held by SSM/AF in 1997, which also included a topic related to the administration of traditional medicine in Macao;

(4) One pharmacist in the Department was sent to the State Administration of Traditional Chinese Medicine (SATCM) in China in October 1997 for a one-year training on the administration of traditional Chinese medicines;

(5) One staff in the Department has also been recommended to train for one year at the SATCM on the administration of traditional Chinese medicines in 1998;

(6) In addition, SSM/AF has also actively participated in supporting other training courses and academic or promotional activities related to traditional Chinese medicines in Macao.

Annex 6

10. ACADEMIC AND TECHNOLOGICAL EXCHANGE ACTIVITIES

SSM/AF has greatly strengthened the academic and technological exchanges on traditional medicines, and some of the activities in recent years include the following:

(1) Two staff members of SSM/AF participated in the "Regional Workshop on Traditional Medicine" in Hong Kong (organized by the Department of Health, Hong Kong Government, and co-sponsored by the World Health Organization) in November 1995;

(2) Eight staff members of SSM/AF were nominated to visit Zhuhai, China on invitation of the China Pharmaceutical Association, Zhuhai Branch, in July 1995, together with other 11 pharmacists from Macao;

(3) Three staff members of SSM/AF were nominated to visit Beijing and Xian, China China, on invitation of SATCM in October 1996;

(4) Three staff members of SSM/AF participated in the "Symposium on the Development of TCM in China, Hong Kong, Macao and Taiwan in Zhuhai (organized by SATCM), on invitation of SATCM in May 1997;

(5) Over ten staff members of SSM/AF participated in the "Joint Conference on Management and Quality Control of TCM" in Macao (jointly organized by SSM/AF and SATCM in August 1997);

(6) SSM/AF received an invitation from the WHO Regional Office for the Western Pacific to send a participant to the Working Group on Herbal Medicines in Manila, Philippines in December 1997.

These academic and technical exchanges enhance SSM/AF's capability in handling TCM-related matters and staff members of SSM/AF acquire experience and additional information on traditional medicines from competent authorities/associations/organizations of other countries and territories; learn many relevant circumstances on TCM in other countries and territories. In turn, SSM/AF will use these experiences and information in carrying out its task of improving the situation on traditional medicines in Macao in the future. These also enable SSM/AF and authorities, associations and organizations of other countries and territories get a deeper understanding and gain friends, and further strengthen information exchange and collaboration in related aspects in the future.

Annex 6

11. **FUTURE PLANS IN THIS AREA**

(1) To perfect the extent of law/regulations/guidelines on traditional medicines based on the current situation of the Macao society, the peculiarities of traditional medicine and the latest information on the development of scientific technology from other countries and territories as well as WHO. This includes:

(a) updating and perfecting the list of traditional Chinese medicinal materials (Lista de Drogas tradicionais de Venda Exclusiva nas Farmacias Chinesas), based on information and opinions gathered from various sources, developments and changes in science, technology and society;

(b) drafting the special registration regulation concerning traditional medicine products produced in Macao; and

(c) incorporating the importation of the raw and processed traditional Chinese medicinal materials into the control of AF/MTC;

(2) To provide assistance in the integration of the services of traditional medicines into the medical organizations of the Macao Government (medical and health care centres and hospitals) when needed;

(3) One staff member of AF/MTC will be sent for a one year training on the administration of traditional Chinese medicines to SATCM, China in 1998;

(4) To strengthen various contacts, activities and exchanges (such as scientific, technical and academic conference, symposia, visits) related to traditional medicine, such as WHO, SATCM, etc. and other countries and territories, professional and academic organizations of Macao;

(5) To plan, assist, and participate in the in-service training programme for traditional medicine practitioners and Chinese pharmacy technicians;

(6) To plan and promote the popularization of the common knowledge of traditional medicines and relevant laws/regulations/guidelines concerning traditional medicines to the public.

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./9
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

MALAYSIA

by

Mrs Napsah binti Mahmud
Head, Traditional Medicine Registration Unit
National Pharmaceutical Control Bureau
Ministry of Health
Kuala Lumpur

Annex 6

HERBAL MEDICINE IN MALAYSIA
- A COUNTRY REPORT -

by:
Mrs Napsah Mahmud

1. INTRODUCTION

The health system adopted and implemented by the Malaysian Government is the Western Allopathic model. Practice in traditional medicines including herbal medicine has been carried out for generations by different races in Malaysia i.e Malay, Chinese, Indians and other ethnic groups. The most prominent of the traditional health care systems are the Indigenous Malay traditional system, Chinese and Indian Traditional System. Others like homeopathy, acupunture, reflexology, bone setting and massage are also practised by some sectors of the population. Each group has its own philosophical framework, diagnosis, treatment, working methodology and distinctive groups of commonly used herbal materials.

The various forms of traditional healing are influenced to some extent by cultural heritage. In Malay traditional medicines, knowledge of treatment methods and materia medica was imparted orally and committed to memory. There is therefore hardly any written material on Malay Traditional Medicine. The philosophy, theory and practice of Chinese traditional medicines originated from Mainland China. When the Chinese immigrants arrived many centuries ago they brought with them their knowledge of Chinese traditional medicine practices, which were then absorbed into the Malaysian culture. Similarly, Indian immigrants brought with them the practice of Ayuverda, Siddha and Unani into the Malaysian culture. Preparations used by all of these traditional healers are mostly herbal or botanical materials.

2. CURRENT STATUS OF HERBAL MEDICINES

The Malaysian health care system is based on western medical science. Traditional medicine has not been incorporated into the health care system as yet. However, the use of herbal medicine

Annex 6

continues to be an important part of health care, especially for alleviating the symptoms of simple everyday health problems, providing first aid for dealing with minor injuries and incorporating preventive medicine for daily use to improve overall health.

2.1 Practice and Practitioners

In previous centuries, the Malay community held herbal medicine in high regard. This is obvious from the respect accorded by the community to the *bomoh* (medicine-man) and *mak bidan* (mid-wife). However, due to the progress of science and modern methods of treatment, and also due to a lack of documented material, less attention is given to these practitioners. The Chinese traditional medicine practitioners, on the other hand, are more institutionalized. The *Sinseh* (Chinese medicine practitioners) are mostly trained in various aspects of Chinese traditional medicine and they operate in *kedai sinseh* (medicine shop). In these shops are found various materia medica, either imported or produced locally. Recently, there has been a resurgence of awareness among Malaysians and a wish to revive the use and practice of herbal medicine. The Ministry of Health has formed a committee to look into the possibility of herbal medicines as alternative medicines and their possible use in hospitals. In Malaysia, herbal medicine practitioners are not registered and there is no licensing of their practice premises. Thus there is no definite data on the number of herbal medicine practitioners.

2.2 Registration of Traditional Medicine Products

The Control of Drugs and Cosmetics Regulations gazetted in June 1984, marked the beginning of regulatory control on pharmaceutical products, including traditional medicines in Malaysia. The registration exercise for traditional medicines began in January 1992 under the third phase of the implementation of the legislation. The registration exercise hopes to ensure safety and quality of traditional medicines. The implementation of the registration exercise implies that the Ministry of Health has taken up the responsibility to ensure safety and quality of imported as well as locally manufactured traditional medicines. Regulation 7(1)(a) of The Control of Drugs and Cosmetics Regulations requires all products to be registered with the Drug Control Authority (DCA) prior to being manufactured, imported, sold or supplied. Only products which meet the required standard are registered by the Drug Control Authority.

2.3 Manufacturers of Herbal Medicine

In the beginning of implementation of registration of traditional medicine it was found that most of the local manufacturers are small scale. They rarely have modern facilities and most of them lack knowledge of new technology. The registration exercise can be considered as the starting point of the government's effort to upgrade the local pharmaceutical manufacture of herbal medicine. In Malaysia, manufacturers of herbal medicine will be compelled to adhere to all basic elements of Good Manufacturing Practice. The Drug Control Authority has decided that all local manufacturers should comply with the basic GMP by end of December 1997. Some basic requirements with which herbal medicine manufacturers should comply are: suitability of location and facilities of manufacturing premises; manufacturing activity to be carried out on the premises; equipment and quality control facilities; Standard Operating Procedures (SOP) and quality control procedures; manufacturing records and recall procedures, etc. So far 20 herbal medicine manufacturers have been licensed, while another 34 manufacturers are in the process of upgrading their premises and facilities.

2.4 Marketing of Herbal Medicine

Herbal products are becoming more popular globally, and the consumption of these products in Malaysia is increasing and continues to feature prominently in the country health care. The Malaysian Government estimates the sale of traditional medicines to be valued at about RM 1 billion annually. The herbal products market is diverse encompassing herbal medicines, herbal teas, powdered herbs in capsule or tablets, liquid extracts and essential oil and dietary supplements. There is an increase in utilization of these products due to a growing fascination and desire for self care using natural products to improve health. With the rapid increase in publicity about herbal products, especially health supplements, more companies are entering the market.

3. GOVERNMENT POLICY

3.1 The government, in particular the Ministry of Health, has not interfered with the practice of traditional practitioners according to the Malay, Chinese and Indian and other traditions.

Annex 6

Nevertheless, there is legislation which is relevant to traditional medicines practice in Malaysia which includes:

3.1.1 Medical Act 1971 (Revised 1993)

An act to consolidate the law relating to the registration of and practice of medical practitioners of modern medicine

i) Traditional medicine practitioners are allowed to practise system of therapeutics according to purely Malay, Chinese, Indian or other native methods.

ii) Traditional medicine practitioners are not allowed to use the term 'doctor', 'clinic' 'hospital' or the equivalent; nor the instrument used exclusively by persons qualified to practice medicine or surgery according to modern scientific methods.

3.1.2 The Medicines Act 1971 (Advertisement and Sale) 1956 Revised 1993)

An act to prohibit certain advertisement relating to medical matters and to regulate the sale of substances recommended as medicines.

i) Advertisement of traditional medicines shall be approved by the Medicines Advertisement Board.

ii) Labels and package inserts for traditional medicine should not refer to prevention, diagnosis, or treatment of 20 serious diseases, practising contraception, improving the condition or functions of the human kidney or heart or improving sexual function or sexual performance.

iii) Advertisement of traditional medicines should indicate " This is a traditional /herbal preparations."

3.1.3 Poison Act 1952 (Revised 1980)

An act to regulate the import, possession, manufacture, compounding, storage, transport, sale, used of scheduled poisons in general, with provision for psychotropic substances.

i) Traditional medicines shall not use plants or parts of herbal plants classified as scheduled poisons.

ii) Traditional medicine manufacturers not holding Type A licence are not allowed to import, manufacture, sell or store plants or part of herbal plants classified as scheduled poisons.

iii) Traditional medicines shall not contain heavy metal, more than 0.5 ppm for Mercury, 5 ppm for Arsenic and 10 ppm for plumbum.

3.1.4 The Sale of Drug Act 1952 (Revised 1989)

An act to regulate the import, sale, supply or manufacture of any drug (including traditional medicines) through registration and licensing.

3.1.5 Wild Life Protection Act 1972

Traditional medicines manufacturers and importers shall not use animals or parts of animals that are protected under the Act.

3.2. The Government has promulgated The Control of Drug and Cosmetic Regulations 1984, under the Sale of Drug Act 1952 (Revised 1989). This Regulation was first implemented in June 1984 with the establishment of the Drug Control Authority (DCA). Beginning January 1992, the Government has implemented the registration exercise for locally manufactured as well as imported traditional medicines so as to ensure safety and quality of traditional medicines.

3.3 Malaysia has a rich tradition in the use of plants for medicinal purposes. There are over 6000 species of tropical plants all over the country, about 1200 of which are popular among traditional healers. Realizing the abundance and potential of these medicinal plants, the Government has directed a National Committee on Herbal Medicines to be formed. The National Committee, established in January 1995, are looking into various aspects, including establishing a Malaysian herbal monograph and conducting clinical trials on potential medicinal plants.

Annex 6

4. REGULATORY SITUATION - PRODUCT REGISTRATION

4.1 Commencing in January 1992, the Government has imposed regulatory requirements on traditional medicines which include premarketing evaluation, compliance with good manufacturing practices and post registration surveillance. The Government has implemented the registration of all traditional products presented in pharmaceutical dosage forms. Traditional medicines means 'any product employed in the practice of indigenous medicines, whereby the drug used only consists of one or more naturally occurring substances of plant, animal or mineral origin or part thereof, or in extracted, or non-extracted form'. Only products which meet the required standard are registered by the Drug Control Authority through its secretariat, the National Pharmaceutical Control Bureau (NPCB), Ministry of Health. Up to September 1997, over 16 000 applications have been received; of which 69.37% are for Chinese traditional medicines (local and imported), 12.38% for Malay traditional medicine, 14.98% for western, while others are for Ayuverda, Unani, Siddha and Homeopathy. The percentage of imported products is 48% while locally manufactured is 52%.

4.2 Traditional medicines should comply with the basic criteria of acceptable quality and safety to qualify for registration.

4.2.1 Quality

Quality control specifications, imposed by the Drug Control Authority on traditional medicines, could be considered as very basic but very pertinent for manufacturers to start with. Local manufacturers and importers are advised to start with basic quality control parameters even though this requirement is not mandatory. The list of requirements includes visual inspections, tests for moisture content, uniformity of weight etc. Many products of traditional medicines have already adopted modern pharmaceutical dosage forms such as tablet and capsules. Thus it is appropriate that such preparations comply with the basic physical parameters of such dosage forms. The Drug Control Authority has imposed the following parameters to be tested on all traditional preparations submitted for registration.

i) test for contamination of heavy metals;

ii) test for microbial contamination; and

iii) disintegration test.

4.2.2 Safety

Traditional medicine is considered safe when it does not cause untoward adverse reaction to the consumers and there appears to be no adverse events reported for the active ingredient used. For the purpose of registration with the DCA, a drug is safe if it has the following properties:

i) does not contain dangerous/hazardous ingredients;

ii) free from chemical drugs or scheduled poisons; and

iii) contents of heavy metals and pesticides below the accepted limit.

4.3 Labelling

4.3.1 The labels and package inserts of traditional medicines are often found to be quite misleading, vague and at times show overclaiming or exaggeration. The use of superlatives such as 'very effective', 'superior', 'unique', 'ideal', 'fantastic' are very common. Correct and adequate labelling is very important. Label of traditional medicines must give information which is adequate and clear enough for the consumers to use the product properly and safely. The following auxiliary label should be indicated on the label of traditional medicines:

- This is a traditional medicine/herbal medicine.
- If symptoms persist, consult a physician.
- All indications should use 'Traditionally used for.....
- If animal part/parts is/are included in the formulations, the label should indicate 'this product contains animal part/parts'

Annex 6

4.4 Adverse Reaction

The safe use of traditional products is also monitored under the adverse reaction monitoring programme. Any reported adverse reactions tc the active ingredients or components of the products are properly recorded and monitored.

5. FUTURE PLAN

5.1 With the objective of promoting the development of traditional medicines, the Health Ministry has recently set up committees to look into the possibility of traditional medicine playing a role as a complementary form of medical care. This is in line with the advice of the World Health Organization which advocates that Member States make full use of traditional medicines already in existence to provide basic medical and health care for the people. The main areas for focus should be the regulation of traditional medicine practice, education and training of traditional medicines practitioners and listing traditional medicines products with proven safety, quality and efficacy.

i) Regulation of traditional medicine practice

Legislation that defines and standardizes the practice of traditional medicines may have to be introduced. Practitioners of traditional medicines could be registered and a standard of practice and code of ethics defined.

ii) Education and training of traditional medicine practitioners.

At present there are no formal education or training programmes on traditional medicine other than those conducted by respective associations of traditional practitioners. The training programme to be developed should satisfy the level required for participants to practise in line with government policy on traditional medicines.

iii) Products with proven safety and efficacy

The present criteria for registration of traditional medicine products is based only on quality and safety. Efficacy of the active components is not determined or tested. Priority is to be given to research on efficacy as well as safety of herbal preparations. Perceptions that herbs or natural products cannot harm, only cure are not always correct. There are numerous examples to show that 'natural' does not necessarily mean safe. Preclinical as well as clinical studies are to be carried out on potential herbal plants.

5.2 Under the National Committee on Herbal Medicine, a sub-committee on the Malaysian Herbal Monograph has been set up. The committee is in the process of identifying commonly used herbs in the country to be monographed. The collaborative work involves the various universities and research institute in the country. It is hoped that the Malaysian Herbal Monograph will be issued in the very near future.

5.3 With the high demand for herbal medicines in the local and international market, overharvesting of medicinal plants might occur. Strategies have to be developed to conserve the medicinal plants and prevent their extinction.

6. CONCLUSION

Herbal medicine is well known for its effects to cure various ailments. Investment in training and research are needed in order to realise the potential of traditional medicines in health care. Traditional medicines of good quality not only please the consumer but also make good business to traders and manufacturers. It is hoped that with proper plan and strategies; plant-based medicines will continue to contribute towards health care and plant-based medicine industry will emerge in Malaysia.

Annex 6

REFERENCES

Anon. Guidelines for the Assessment of Herbal Medicines. Programme on Traditional Medicines. WHO, Geneva 1991.

Phillipson, J.D; Bodeker, G. - Herbal Medicines - Towards The Millennium - 16th Asian Pacific Congress of Pharmaceutical Sciences, Nov. 1996 , j

Z. Muhamad, A. M. Mustafa. Traditional Medicinal Plants, Penerbit Fajar Bakti; Kuala Lumpur, 1991

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./10
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

MONGOLIA

by

Dr Miaegombo Ambaga
Director of Medical Research Institute
Ulaanbaatar

Annex 6

CURRENT STATUS OF HERBAL MEDICINE IN MONGOLIA

by: Dr M. Ambaga

1. Historical background

Lately, medicinal plants have assumed greater importance in Mongolian medical practice. For thousands of years, the Mongolian people have used natural substances, particularly plants, to relieve pain, heal wounds and to maintain health.

Mongolia is a country, with its sharp continental climate, has an abundance of diverse plant resources and most of them are reported as being used as herbal medicine. About 600 plant species growing in the territory of Mongolia are used in Mongolian traditional medicine, and nearly 200 species in scientific medicine. One of the oldest books contains detailed information on the theoretical (philosophical) basis of various medicinal herbs (their tastes, properties, special actions, botanical characteristics) is the sutra (manuscript) called *Nad kyi dbye ba rnam shad*, written by a Mongolian physician blo bsang bstan dzin rgyan mtsan (16th century). According to the philosophical theory of Mongolian traditional medicine (MTM), poor health is a result of an imbalance among five elements (air, wind, fire, water and earth), a combination of which comprises the human body.

Based on the pharmacological theory of Mongolian traditional medicine, the herbal medicines that are used for the treatment of ill health also involve five elements. The therapeutic effect is established with the participation of these five elements, resulting in a balance which maintains normal health. For example, in cases of pathological excess of the water element, when cold diseases occur, a herbal medicine containing fire element is recommended.

Recently, more important steps have been taken towards interpreting the scientific basis of MTM theory. One of the scientific works of this trend is the confirmed new conception "Hii, shar, badkan-membrane structure" suggested by Dr M. Ambaga (1990 to 1997).

Annex 6

2. Government policy on herbal medicine

The Government of Mongolia and the Ministry of Health regard herbal medicine as an essential part of the health service and preventive care and its development has been given the highest priority. In the newly adopted programme of development, approved by the Government, it was pointed out that "... in the centre of Government's attention exist the question of rational use of herbal medicine and obtaining of new preparations from the plant origin with specific action...".

3. Current status of the use of herbal medicine in Mongolia

At present, guided by a strong policy, Mongolia has achieved significant success in strengthening research in obtaining new medicinal preparations that have been scientifically validated, evaluation of the safety and efficacy of herbal medicine, promoting the rational use of herbal medicine and forming quality control in drug production. Modern science and technology has been introduced in the production and processing of herbal medicaments. Since 1990, an industrial production system for herbal medicine has been set up. There are now ten herbal manufacturing factories of high capacity. Pharmaceutical factories in Mongolia produce more than 200 drugs of plant origin. Of these drugs, 150 are commonly used in treatment based on long time experience of traditional medicine and are not subject to special scientific analysis. The remaining 50 medicaments belong to scientifically tested new preparations and their chemical characteristics, pharmacological action, toxicity, carcinogenicity, teratogenicity are strictly established. The general principles of pharmacological, phytochemical and clinical trials of these new preparations are similar to those applied to synthetic drugs.

The Government policy on herbal medicine in Mongolia is carried out in accordance with general guidelines which are reflected in official publications of the World Health Organization such as *Guidelines for Assessment of Herbal Medicines* (1991), and *Research guidelines for evaluating the safety and efficacy of herbal medicines* (1993).

Some new medicinal plant preparations resulting from the application of modern scientific evaluating principles to tradition of herbal medicine are as follows:

- new cardioprotective preparation - "Astradin", "Asvargal"
- hepatoprotective preparation - "Barbadin", "Silodun"

- immunostimulative preparation - "Ortuuzin"", "Salorid"
- sedative preparation - "Neurovalin"

4. **Government's future plans in this area**

The plans being considered by scientists, practitioners and manufacturers of herbal medicine in Mongolia include the following:

- establishment of new indications, new dosage forms and the administration route for existing herbal medicine, i.e., verify the traditional uses of medicinal plants used in ancient times;
- obtaining and broadening the arsenal of new herbal medicinal preparations with due regard to the prevalence of some diseases in our country;
- improvement of standardization methods for pharmacologically active substances in herbal medicine;
- establishment of the medicinal value of indigenous plants;
- taking measures to ensure the appropriate balance between the quantity of plants annually collected and the natural resources, i.e., preservation and conservation of medicinal plants;
- cultivation and introduction of some valuable and rare plants in the specific geobotanical condition of Mongolia; and
- setting up a new pharmacology laboratory to study the pharmodynamic and toxicological aspects of herbal medicine, the equipment capacity level that would met the requirements of the country's scientific level.

After taking these measures, we would be able to fulfil the general principles of WHO, as indicated in *Research guidelines for evaluating the safety and efficacy of herbal medicines* (1993).

Annex 6

5. Possible direction for joint scientific work in the field of herbal medicine in coordination with the WHO Regional Office for the Western Pacific

One such kind of scientific work is research on new medicinal preparations with anti-cancer properties from Mongolian herbal medicine. For the past few years, the occurrence of all types of cancers has increased in Mongolia. The most common are liver tumours (29.6%) and stomach cancer (21%). It is for this reason that research on new medicinal preparations of plant origin to treat cancer is becoming more important.

In this regard, we are requesting the Western Pacific Regional Office of WHO to support us in carrying out a collaborative research work with foreign scientists, exchanging research experience and training specialists abroad.

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./11
3 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

NEW ZEALAND

by

Dr Paratene Ngata
Medical Officer
Rural Health Services
Tairawhiti Healthcare Ltd.
Te Pula Springs
East Coast
New Zealand

Annex 6

Herbal Medicine in New Zealand

A paper prepared for the World Health Organization Working Group on Herbal Medicines 8-12 December 1997, Manila, Philippines

(The majority of this material has been extracted from *A Framework for Purchasing Traditional Healing Services* - A report prepared for the Ministry of Health by Professor Mason Durie; Massey University; June 1996)

Annex 6

HERBAL MEDICINE IN NEW ZEALAND

1. INTRODUCTION AND BACKGROUND

2. THE CHARACTERISTICS OF TRADITIONAL HEALING

3. CONTEMPORARY INTEREST IN TRADITIONAL HEALING

4. TRADITIONAL HEALING AND MODERN HEALTH SERVICES

5. CONCLUSIONS

REFERENCES

1 INTRODUCTION and BACKGROUND

1.1 New Zealand Health Services in a Reformed Environment

Two aspects of the current health system environment in New Zealand are particularly relevant to traditional healing. First, the separation of the funder and providers allows for greater specificity as to expected services and emphasises outputs rather than professional contributions. Contracts between the funder and providers incorporate both quality and quantity measures and there is an expectation that providers of health services will be able to demonstrate benefits (to clients) according to agreed upon performance measures. Within this system traditional health services could be accommodated once agreement had been reached on the desired outputs. The second significant aspect of the health system is the ability of the Government to introduce its own priorities and to require purchasers to reflect those priorities. Four Government health gain priority areas have been identified in the Minister of Health's annual guidelines to regional health authorities - mental health, child health, Māori health and health of the environment.[1] If traditional healing contributed to one or other of those health gain areas, there would be additional justification for its introduction.

1.2 The Tohunga Suppression Act

There were at least three stated reasons for the introduction of the Tohunga (the broad definition of this word is an expert in traditional healing practice) Suppression Act in 1907: prohibition of tohunga from gathering people around them, prohibition of claims to possess supernatural powers, and prohibition of foretelling future events.[2] Particular concern had been expressed about 'bogus' tohunga who used a combination of old and new techniques in the treatment of tuberculosis. But there were also political reasons why the Act was passed.[3] Although tohunga subsequently stopped practising openly,

---

1 Shipley Hon. J (1995), *Policy Guidelines for Māori Health Ngā Aratohu Kaupapahere Hauora Māori 1996/97*, p. 14, Wellington

2 Te Aho K (1996), *Service Evaluation of Te Whare Whakapikiora o te Rangimarie a Māori traditional healing service*, Interim Report, Wellington

3 Webster P (1979), *Rua and the Māori Millenium*, Victoria University Press, Wellington

curative activities were pursued away from the gaze of the law and traditional methods of healing continued to command Mäori confidence, albeit in an abated form. The repeal of the Act in 1964 officially removed any legal prohibitions but even before then healers had emerged and were openly attracting large followings. However, because they operated outside the recognised health system, they had minimal interaction with medical or nursing practitioners. More often a climate of antagonism prevailed and dual treatment was regarded by both sides as incompatible. Clients often had to make choices between tohunga or doctor and either abandoned medication or turned away from healers.

1.3 Ngä Ringa Whakahaere o Te Iwi Mäori

A significant step forward occurred in 1992 when a number of healers gathered at Ngati Otara marae and formed a collective body, Ngä Ringa Whakahaere o Te Iwi Mäori, the National Board of Mäori Traditional Healers (Inc.). The Board advocates on behalf of healers and promotes the wise use of rongoä (traditional medicine) and other traditional healing activities. It has also taken the initiative to develop accreditation procedures for healers and to negotiate on their behalf for more formal recognition of traditional healing. Though not completely representative, the Board speaks with some authority for a substantial number of healers and is the only legally constituted body which does so. It takes the view that healing services should be part of the public health system and that they should be funded, at least in part, from Vote:Health. But it is equally adamant that traditional healing services should remain under the control of Mäori healers and that outcome measures and other indicators of effectiveness should be developed by the healers themselves.

1.4 The National Health Committee

The National Advisory Committee on Core Health and Disability Services was established as part of the health reforms to advise the Government on the types and quality of services which should be publicly funded.[4] In 1993, as part of

[4] Known originally as the Core Services Committee, and now as the National Health Committee

a major consultation exercise, the Core Services Committee was invited to attend a meeting at Ngä Marae Watea in Auckland to hear submissions on health services. The hui had been arranged by Ngä Ringa Whakahaere o Te Iwi Mäori who asked that traditional healing be regarded as a 'core service'. Even though the Core Services Committee had decided not to proceed with a simple list of publicly funded health services, there was agreement that further discussions with Ngä Ringa Whakahaere were indicated. Two further meetings were followed by a formal presentation of a document which outlined the views of Ngä Ringa Whakahaere.[5] The Core Services Committee had meanwhile commissioned a paper[6] to background traditional healing and had already debated the possible responses to Nga Ringa Whakahaere. The Core Services Committee's position was contained in the 1995 report *Core Services 1996/97*.[7] This recommendation was also written into the *Policy Guidelines for Regional Health Authorities 1996/97*.

1.5 Policy Guidelines for Regional Health Authorities (RHAs)

The National Advisory Committee on Core Health and Disability Services has recommended:

> *that RHAs may purchase aspects of traditional Mäori healing, to be provided with other primary health services, where there is reason to believe that this will improve access to effective services for Mäori and lead to better health outcomes. (Annual Report, 1995)*

Publicly funded services in Mäori traditional health must conform to contractual reporting, quality and safety requirements as agreed with the RHAs[8].

---

5 Ngä Ringa Whakahaere o Te Iwi Maori (1994),

6 Durie M H et. al. (1993), *Traditional Mäori Healing, a paper prepared for the Core Services Committee*, Department of Mäori Studies, Massey University

7 Core Services Committee (1995), *Core Services 1996/97*

8 Shipley Hon. J (1995), *Policy Guidelines for Mäori Health Ngä Aratohu Kaupapaher Hauora Mäori 1996/97*, p. 8, Wellington

Annex 6

1.6 *Safety of Herbal remedies*

Although herbal medicines generally appear to be safe, their popularity may in part be based on the misconception that because herbs are "natural" they are devoid of the toxic potential of conventional medicines. [9] While many botanicals appear to have an excellent safety record, some are potentially dangerous. There has been a substantial increase in the number of serious reactions with herbal products in the medical literature. New Zealand is not exempt from this problem.

The following table outlines the number of adverse reactions to herbal remedies reported to the National Toxicology Group over the last six years:

1992	1
1993	5
1994	9
1995	2
1996	31
1997 (up to the end of September)	11

The 1996 total is inflated with 15 reports coming in for K4 which was withdrawn from the market.

Factors contributing to potential problems with herbs include:

- inherent toxicity;
- misidentification of plant species;
- adulteration;
- contamination; and
- variability in the chemical constituents of herbs.

Both health professionals and consumers should be aware of the increasing documentation in the medical literature of serious reactions with herbal medicines. Cause-effect relationships are seldom obvious and have to be carefully sought. Although significant toxic effects with herbals are probably rare, herbals should not be perceived as harmless simply because they are "natural". As with any medicine, potential risks should be balanced against

9 Pillans PI. (1996), Potential Toxicity of Herbal Medicines. *Prescriber Update No 11* pgs 5-7, Wellington

possible benefits. Herbal remedies do not have to comply with the same strict regulatory standards of safety, efficacy and quality as allopathic medicines. Potential toxicity of herbal products underscores not only the importance of quality control but of national surveillance and, as with adverse medicine reactions, suspected cases of herbal toxicity should be reported to the New Zealand Centre for Adverse Reactions Monitoring.

1.7 *Herbal Remedies And The Medicines Legislation In New Zealand*

The Medicines Act 1981 and the Medicines Regulations 1984 control all medicines, related products, homeopathic medicines, and **herbal remedies.** Only medicines, medical devices and related products can be advertised as having a therapeutic purpose, and all medicines and related products require the consent of the Minister of Health before they can be distributed in New Zealand.

Herbal Remedies do not require the consent of the Minister of Health to be distributed as medicines provided that:

- *the product does not contain a scheduled medicine (ie a prescription medicine, a restricted medicine, or a pharmacy only medicine), and*

- *it is a simple product made from plant material that has been crushed or dried or similarly processed and mixed with water or ethyl alcohol or an inert substance, and*

- *it is labelled only with the name of the plant(s) from which it is made and the process to which the plant has been subjected. No written recommendations as to its use are permitted. (i.e. therapeutic claims or advertising.)*

1.8 *The World Health Organization*

Traditional medicine was the subject of a WHO (Western Pacific Region) Conference in Hong Kong 1995 As long ago as 1977, however, the 30th World Health Assembly urged "interested governments to give adequate importance to the utilisation of their traditional systems of medicine, with

appropriate regulations as suited their national health systems."[10] At the 1995 conference the integration of traditional medicine into the primary health care system was emphasised with a need for both regulation and legislative control of practitioners and medicines. WHO support is stronger for traditional medicines involving herbal medicine/medicinal plants and acupuncture rather than bone setting or supernatural healing, and efforts to undertake research and compare progress in several countries within the region have been made. A working party on traditional Chinese medicine for example has recommended the compilation of a list of practitioners as a step towards registration and considers that preparation of medicines should be subject to statutory control. Formal training as well as research in tertiary institutions has also been suggested. At the same time the working party has been at pains to emphasise the spirit of self regulation and has promoted the establishment of a statutory committee consisting principally of members of the traditional Chinese medicine profession to examine matters of registration, training and research, dispensing and importing and exporting potent herbs.[11]

1.9 *Draft Declaration on the Rights of Indigenous Peoples 1993*

Developed by the Working Group on Indigenous Populations since 1982, the Draft Declaration on the Rights of Indigenous is likely to be presented to the General Assembly of the United Nations for adoption[12]. Though the final wording will be the subject of considerable further debate by the nation states, the Draft Declaration has already received wide recognition and has met with general approval from a wide range of indigenous peoples, including Mäori. Article 19 endorses the concept of self determination and self regulation: "*Indigenous peoples have the right to participate fully, if they so choose, at all levels of decision-making in matters which affect their rights, lives and destinies through representatives chosen by themselves in accordance with*

---

10 Cunningham C (1995), *Report on Attendance at World Health Organisation (Western Pacific Region) Regional Workshop on Traditioal Medicine, Hong Kong November 1995*, Ministry of Health, Wellington.

11 ibid

12 Te Puni Kökiri (1994), *Mana Tangata Draft Declaration on the Rights of Indigenous Peoples 1993*, Ministry of Mäori Development, Wellington

their own procedures, as well as to maintain and develop their own indigenous decision-making institutions."

Article 24 is more specific in relationship to traditional healing. "Indigenous peoples have the right to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals and minerals. They also have the right to access, without any discrimination, to all medical institutions, health services and medical care." Clearly it is not intended that there should be no choice or that the retention of traditional practices should necessarily reduce access to other health services. Instead a dual system is supported.

2 THE CHARACTERISTICS OF TRADITIONAL HEALING

2.1 *The Context*

Before identifying the main components of traditional healing, the wider context should be considered. It is important not to equate traditional healing simply with the administration of prepared plant products any more than modern medicine should be regarded as synonymous with over-the-counter sales of pharmaceuticals. Healing is governed by established (though often unwritten) codes of practice which draw on ethical, cultural, and philosophical principles, as well as the use of particular plant materials. In this respect, the rationale for the healing activity will not be found solely in the physical remedies offered, but, just as important, in the traditions, beliefs and culture of the clients and the practitioners.

Nor is enlightenment necessarily generated by attempting to understand traditional healing in terms of biomedical concepts and scientific proof. Though certain plants may have anti-bacterial or other therapeutic activity, and can be analysed scientifically,[13] it is misleading to ascribe health changes only to those properties and to dismiss (or fail to appreciate) other components of the healing process. The point is that conventional explanations may not only be inadequate to explain traditional healing, they might impose inappropriate

---

13 Brooker S G, Cambie R C, Cooper R C, (1981), *New Zealand Medicinal Plants*, Heinmann, Auckland

frameworks which are incapable of encompassing the holistic nature of the healing context. "*Rationality must be understood to be a culture specific notion; one culture's rational thought is not necessarily the same as another's. Indeed, the rational thought that underlies scientific inquiry and biomedical practice is but one type of thought.*"[14]

Sometimes traditional healing is thought to occur only in rural areas, close to tribal villages and marae. Certainly a number of well known healers live and work in small communities supported by hapü and whänau. But traditional healing is not confined to the marae or tribal oversight. Many healers, male and female, operate within urban and metropolitan centres, both in New Zealand and overseas. In the greater Auckland region, although the numbers of healers cannot be quantified, they are thought to be "significant" 15 and it is important to note that the formation of a national association of healers took place in Auckland in 1992. A traditional healing clinic with an RHA contract to deliver services, Te Whare Whakapikiora o te Rangimarie is also urban based, serving a largely urbanised population in the Napier and Hastings area.

2.2 *Mäori Herbal Medicines*

Traditional herbal medicines (rongoä rakau) are a part of the broader traditional health and healing practices of Mäori. Traditional Mäori healing encompasses several activities at the spiritual, psychic, physical, and ecological levels.[16] Mäori Traditional Healing was an integral part of the Mäori community and the environment. The range of healing practices included:

- Ritenga and karakia (healing incantations and rituals);
- rongoä rakau (physical remedies derived from trees, leaves, berries, fruits, bark, and moss used to treat particular ailments);
- mirimiri (massage or physiotherapy)
- wai (water); and

---

14 Waldram J B., Herring D A., Young T K., (1995), *Aboriginal Health in Canada Historical, cultural, and epidemiological perspectives*, p 100, University of Toronto Press, Toronto.

15 Parsons C D F, (1985), Notes on Maori Sickness Knowledge and Healing Practices, in ed Parsons C D F, *Healing Practices in the South Pacific*, Institute for Polynesian Studies, University of Hawaii Press, Honolulu

16 Durie MH.(1994),*Whiaora-Mäori Health Development*, Oxford University Press, p 19, Wellington

- surgical interventions.

A body of medicinal knowledge is available.

2.3 *The Practice*

Of the wide range of treatments employed, most traditional healing methods use medicines derived from plants. Leaves, bark, roots, twigs, berries may be applied externally, swallowed as a potion, chewed or inhaled.17 The development of a Mäori pharmacopoeia18, despite the risks attendant on isolating one aspect of healing from the wider context, is at least an indication of the specificity and extent of traditional Mäori medicines, rongoä rakau.19 Rongoä appear to be used on both a symptomatic and syndromatic basis. Thus some medicines are used to treat a symptom such as abdominal pain, while others are used to treat an illness such as cancer. Seldom do traditional healers reveal the precise nature of their remedies to outsiders or medical practitioners, or even to patients, although they have their own consistency and set of indications.20 While the formulation of remedies is the province of the healer, kai awhina, trained assistants, do much of the actual preparation of the products and have responsibilities for storage, labeling and replenishing supplies.21

In most cultures many people have some knowledge of the medicinal properties of plants, even if it is only as domestic and occasional users. Healers, however, have a much more extensive knowledge and have recourse to a large number of medicines as well as the ability to concoct new ones. The tahu'a of Tahiti, for example, often commit to memory dozens of

---

17 Macdonald C (1973) *Medicines of the Mäori,* William Collins, Auckland

18 Rankine J (1994), *Mäori Healing Practices*, GP Weekly, 12 October, 1994

19 The term rongoa denotes a range of healing activities and is sometimes now used synonymously with traditional Mäori healing. Rongoa rakau refers to treatments derived from plants.

20 Te Aho *op cit*

21 Te Aho *op cit*

prescriptions[22] while the kahuna lā'au lapa'au of Hawaii were trained from an early age to understand the botany, pharmacology and medicinal properties of an broad range of plants.[23] Apart from plants extracts, a number of other treatments are used in traditional healing. In Asian countries acupuncture is a highly developed specialty, now often used in association with other treatments. Tohunga meanwhile have varying degrees of experience with massage (mirimiri), incantation (karakia), water therapy, suffusions, heat applications. However, as well as possessing specialised knowledge about remedies and ailments, traditional healers are also distinguished by a capacity to combine physical treatments with ritual, interpretation of symbols and signs (such as dreams), prognostication, spirituality, and an understanding of human interaction, including interaction with the environment. In this respect they operate at a level which extends well beyond a generic knowledge of plants and plant properties.

In common with healers in many developed countries, traditional healers in New Zealand also employ treatments which are based on western biomedicines. At one extreme, acupuncturists may also be qualified medical practitioners, and are able to offer an extended range of treatments. Traditional Mäori healers seldom possess a formal health qualification but are not unfamiliar with modern medical concepts and treatments and at the very least may incorporate fairly conventional health advice, including dietary counseling, into their treatment regimes.

2.4 *Water*

Mäori were conscious of the links between water and health, and avoided cross-contamination by separating clean from unclean. Importantly, the spiritual and physical values of water were deemed to be interrelated if not synonymous, and similar expectations in terms of cleanliness were held for both.

---

22 Hooper A, (1995), Tahitian Healing in ed. Parsons Claire D F, *Healing Practices in the South Pacific*, pp 168-170, The Institute of Polynesian Studies, University of Hawaii Press, Honolulu

23 Abbott I A (1992), *Lā'au Hawai'i Traditional Hawaiian Uses of Plants*, p 98, Bishop Museum Press, Honolulu

Several degrees of water purity were recognised by Mäori, and separate sources of water were used for cooking, drinking, and cleaning. Waiora, rainwater, was the most pure. Apart from its suitability for drinking, waiora was used for ritualistic purposes; indeed the symbolic properties of water were elevated to being at least as important as physical attributes. Waipuna was similarly pure, coming from hillside springs, often in Limestone country. Waimäori was "normal" water, found in most running streams and considered of sufficient purity for drinking, washing and cooking. Waikino or waimate on the other hand, was impure water, probably contaminated and unfit for human use. Waitai, salt water, was of no value for drinking but had other uses such as a source of seafood, bathing, and healing skin lesions.[24]

2.5 *The Practitioners*

Traditional healers come from diverse backgrounds. In some countries they are regarded as sacred, earning a great deal of respect not only as healers but also as the cultural and sometimes political leaders. In other countries, however, they have no special status and live very much as ordinary citizens undertaking healing activities in a low key manner and attracting little attention, except from their clientele. Australian aboriginal healers possess healing and divination powers but in other respects are "ordinary members of the community sharing in social and family life".[25] In spite of their occult powers and extraordinary intellectual arrainments, they display no signs of being unable to integrate fully into the everyday of their communities.[26]

Both profiles apply in New Zealand. Mäori healers, tohunga, were required to enter whare wananga (school of higher learning) where they underwent extensive training which was rigorous, exacting and several years long. [27] Entry requirements took into account the need for tribal accountability, the

---

24 Durie MH. *Whiaora-Mäori Health Development,* Oxford University Press, 1994; pg 13.

25 Reid J, Trompf P. (eds.) (1991), *The Health of Aboriginal Australia*, p. 313, Harcourt Brace, Marrickville

26 Elkin A P (1977), *Aboriginal Men of High Degree*, pp. 13-15, University of Queensland Press, St. Lucia

27 Rolleston, A, 1988, *He Kohikohinga: A Mäori health knowledge base,* Department of Health, Wellington

protection of tribal knowledge and the overall tribal ambitions and they were afforded respect and status. From an early age tohunga were immersed in tribal ritual and tradition and to a large extent they became the carriers of tribal culture.

Contemporary healers are not always so clearly aligned with their tribes, nor are arrangements for their selection and training always well defined. As often as not expertise and credibility has been based on a natural skill or gift which in time has been ratified by the community. Personal qualities have been valued regardless of attendance at reputable whare wananga, or reputation as a tribal leader. In short not all healers have been set apart from others since childhood, or are recognised as tribal leaders. Nor is it possible to identify specific training programmes for healers or to presume that all healers have emerged from similar wananga or training institutions.

Three classes of healers have been described: herbalists, medicine men, and shamans.[28] However shallow and simplistic that classification, it does highlight the range of practice and the varying emphases adopted by different healers. Herbalists use a variety of botanical substances, often in combination, for a variety of disorders including dressing wounds. Medicine men employ supernatural methods to restore health while shaman are able to enter into trances in order to summons the spirits to give counsel. In Africa two forms of healers practise traditional healing, the herbalist/doctor and the diviner. Herbalists serve an apprenticeship while diviners undertake a more experiential mode of learning which includes entering into state of spirit possession during which ancestors endorse the healer as a suitable practitioner of traditional healing.[29]

Most healers, however, employ more than one method. In the case of Mäori healers, plant products are usually employed within a spiritual context and often there is a parallel appeal to ancestors. And both ritual and mysticism feature in treatment, probably (but not necessarily) to a greater degree than in encounters between patients and western-trained physicians.

---

28 Waldram J B., et. al. (1995), *op cit*, p. 103-104

29 Swartz L (1995), The Politics of Culture and Mental Illness: the case of South Africa, In ed. Ihsan Al-Issa, *Handbook of Culture and Mental Illness an interrnational perspective*, pp. 74-76, International Universities Press, Madison

2.6 *Waitangi Tribunal Claim*

In 1995, partly out of concern over the possible appropriation of the pharmacopoeia of rongoä rakau, Waitangi Claim 262 was submitted to the Waitangi Tribunal for the protection of the intellectual and cultural property rights of Mäori. The claim is presently being heard by the Waitangi Tribunal. The claimants argue that they have the right to control rongoä rakau including but not limited to, the pharmacopoeia of rongoä rakau. They also argue that this right is contained within the Mäori culturally defined practice of Tino Rangatiratanga (self determination/management) and contained and legitimated (in the cultural and political sense) by the Treaty of Waitangi (Article II) and by cultural practice.[30]

3 CONTEMPORARY INTEREST IN TRADITIONAL HEALING

3.1 *Mäori Enthusiasm*

After several decades, Mäori interest in traditional approaches to healing has emerged into public arenas. The revived interest, and its openness, appears to be extensive. It was evident when the Mäori Women's Welfare League undertook a survey of Mäori women in 1984,[31] traditional healing was being raised in a positive way by many of the respondents. At all five hui attended by the Core Services Committee in 1992, questions about the place of traditional healing were asked, often with strongly worded requests that it be "recognised as part of the core". Te Waka Hauora, a Mäori Health Authority encountered the same enthusiasm when its establishment hui was held at Manuariki on 5 September 1992. Alongside many other provider groups, the healers made a strong case for their own representative on the Board of Directors. Further evidence of increasing Mäori interest was apparent in 1995,

---

30 Te Aho K (1996), *Service Evaluation of Te Whare Whakapikiora o te Rangimarie a Mäori traditional healing service*, Interim Report, Wellington

31 Murchie E, 1984, *Rapuora, Health and Mäori Women* Wellington, Mäori Womens Welfare League

when, largely because of a well demonstrated need, the Central Regional Health Authority, purchased a contract for traditional healing with Te Whare Whakapikiora o te Rangimarie.[32]

3.2 *Reasons for Revived Interest*

There are a number of reasons why Mäori interest in traditional healing has increased.[33]

3.2.1 Removal of Legal Barriers

The repeal of the Tohunga Suppression Act in 1964 removed any legal barrier to traditional healing though it is unlikely that it was still a strong deterrent. By the late 1950's for example several tohunga had established large followings and were practising quite openly on marae and in other settings. Though not well regarded by medical people, they had built up reputations within Mäori communities and centres flourished at Rotorua (Adams), Taumarunui (Phillips) and Ruatoria (Gage), well before the repeal of the Act.

3.2.2 Self Determination

In the past two decades the resurgence of interest in all aspects of Mäori culture has been associated with a call by Mäori for greater autonomy and a measure of self determination. To some extent this has coincided with greater recognition by the government and the courts of the Treaty of Waitangi, but it has also been part of a global movement in which indigenous people have claimed a right to cultural property and their own intellectual knowledge. Part and parcel of throwing off the cloak of colonialism has been revaluing traditional practices and beliefs. Mäori have been as active in that process as other peoples.

---

32 Laurenson M (1995), Mäori Traditional Healing, in *Te Kete Hauora*, 1,2, December 1995, Ministry of Health, Wellington

33 Durie Mason (1994), *Whaiora Mäori Health Development*, pp. 61-62, Oxford University Press, Auckland.

3.2.3 Limitations of Biomedical Methods

Quite apart from a reaffirmation of traditional culture there has also been some loss of confidence in western methods of treatment. Having emerged from the era of infectious diseases into a new epidemiological era - of man made and degenerative diseases - Mäori have been confronted with cardiovascular disease, mental illness,[34] hypertension, diabetes, cancer, asthma and more recently sudden infant death syndrome. Smoking, obesity, excessive alcohol use, motor vehicles, substandard housing, unemployment and stresses associated with urbanisation (and whänau destabilisation) are the new causative factors. Because of the multi-causal nature of the so called life style illnesses, medical treatment was bound to have limited effect, but many Mäori came to see the medical limitations as evidence of failure. Moreover there was something unsatisfying about clinical approaches which relied mainly on medication without the promise of a total cure and often with a host of debilitating side effects that did little to improve patient compliance.

3.2.4 Access to Primary Care

In their advice to the Core Services Committee in 1995, Ngä Ringa Whakahaere o Te Iwi Mäori identified access to primary health care and prescription part charges as two reasons why their clients had turned to traditional healing.

Uneven access to primary medical services was a further factor. Costs for visits to the doctor and then for prescriptions, as well as cultural barriers and difficulty arranging schedules, resulted in an under utilisation of primary health care services by Mäori. A survey of 200 Mäori adults by Ngati Raukawa[35] revealed that cost was the major inhibiting factor but that motivation was another. Scarcely any of those surveyed would have taken a mental health problem to a medical practitioner or nurse, regardless of whether the professional was Mäori or not.

---

34 Before 1970, proportionately fewer Mäori than non-Mäori were admitted to mental hospitals. Since then the situation has reversed.

35 Health Committee, 1991, *Barriers to Health Care, Report to the Runanga*, Te Runanga o Raukawa, Otaki (unpublished)

Annex 6

3.2.5 Taha Wairua

The major deficiency in modern health services has been identified by many Mäori as *taha wairua i.e. a spiritual dimension.* It has been argued on marae and at regional and national health hui[36] that an over-emphasis on physical aspects of illness and quantitative measurements has been associated with corresponding inattention to emotional, cultural and spiritual factors. Traditional healers, however, incorporate a spiritual dimension in both diagnostic and therapeutic activities and do so in a culturally relevant manner which makes an otherwise spiritually neutral healing session into a rewarding and satisfying experience. For many patients recovery cannot be measured in physical terms only; and in any event there is now ample evidence to suggest that spiritual enrichment is associated with physical change.

4 TRADITIONAL HEALING AND MODERN HEALTH SERVICES

4.1 Philosophical Issues

While there are similarities between traditional healing and biomedical medicine in so far as both are based on distinct methodologies and are carried out by practitioners who are recognised by their respective communities as having acquired skill and knowledge, there are also substantial and quite fundamental differences. Aboriginal medicine is based on tradition, which is to say that as a medical system it accepts that the medicines, techniques, and knowledge of the past were effective because they had been time tested and, in many instances, shared with humans by the Creator. In a sense, while new approaches to treatment are incorporated, this medicine is primarily informed and guided by the traditions of the past. Because the acquisition of knowledge relies heavily on the oral tradition and healers tend to gain understanding over a life time, they are relatively old by the time they are able to use their skills wisely and exhibit considerable variation in their mode of practice. They are less concerned with proving the efficacy of their methods because they have faith in traditional medicines and do not need to question them.

---

36 Komiti Whakahaere (ed), 1984, *Hui Whakaoranga Mäori Health planning Workshop*, Department of Health, Wellington

In contrast, biomedicine is empirical and positivist, based on a philosophy of scepticism. While its origins could also be described as traditional, it is constantly seeking new medical knowledge which in turn is scrutinised and verified. This means that medical knowledge is always changing and that older practitioners have difficulty keeping abreast of modern trends. But between physicians there is a fairly standard level of knowledge which is the same no matter where the doctor was trained.

Essentially the difference is between science and faith.[37] And scientists have difficulty accepting faith - or indeed any knowledge base which has not been subjected to scientific investigation. This does not necessarily mean that faith has no validity or that it can be dismissed because it lacks scientific credibility. But it does present barriers in terms of using one set of criteria to understand the other. However, in practice the distinction between traditional healing and biomedicine is not always as sharp or as clear as might be supposed. Many traditional healers do employ aspects of the scientific tradition and build new elements into their range of healing techniques. In addition there are many biomedical healers who depend on faith as much as science when healing patients, and who prescribe medication according to time honoured practices rather than up to date developments in medical science.

4.2 *Accreditation Issues*

At the WHO Workshop on Traditional Medicine in Hong Kong in 1995, it was recommended that a mechanism for the recognition of traditional healers should be introduced by Governments either in the form of statutory registration or enrollment with recognised professional bodies.[38] The intention appears to have been to encourage a minimum standard of practice as well as opportunities for systematic training and to afford a measure of protection to both healers and their clients.

Healers themselves are divided on issues of accreditation, validation and formalisation. On the one hand they recognise the need to distinguish their

---

37 Waldram et al *op. cit.* p.p. 214-215

38 Cunningham *op. cit.*

own practices from charlatans who have some traditional knowledge but prey on the credulity of their clients by using any novel approach which is fashionable. In the process traditional healing itself is undermined. On the other hand, however, healers fear that any accreditation process which is imposed, especially if it means using measures designed for biomedicine, will either lead to the professionalisation of healing or to the reconstruction of traditional medicine according to the same principles which underlie biomedical practice.

Accreditation also brings problems of disclosure. Most healers are humble and reluctant to make claims about themselves or their capabilities; instead, their reputation is promulgated by others, usually clients. Accreditation would not only require their "official" recognition, but would make public a status which some would prefer not to announce. At the same time, with increasing interest in traditional healing, clients will inevitably want to be assured not only of their safety but also that they are seeing a healer appropriate to their circumstances. While informal networks will furnish some of that information, many Mäori will feel disadvantaged (in terms of access) if there is no accessible listing to inform them about healers and the services they offer.

4.3 Issues of Collaboration

The relationship of healers to western practitioners can be complementary, oppositional, tolerant, or competitive. Over time all relationships have been observed and in addition dismissal has been a further option. However, far from dismissing traditional healing out of hand, or requiring patients to opt either for modern or traditional healing, as if the two approaches were incompatible, there is generally a greater willingness by modern health professionals to explore opportunities for working with indigenous healers. By the same token, whereas some traditional healers still insist that their clients take no other concurrent treatments, most now encourage continued medical treatment or a visit to a doctor if it seems necessary. It is this new tolerance, based on mutual recognition of the complexities of health and of healing which have contributed to collaborative efforts.

Traditional healing within New Zealand hospitals is by no means recent nor unusual. Psychiatric Hospitals have been inviting healers to participate in

treatment for more than a decade[39] and Kai Awhina, healers, have had ready access to hospitalised Mäori patients for just as long.[40]

Models for collaborative effort have caused some concern, equally to traditional healers and modern health professionals. A round table discussion on collaboration organised by the Aboriginal Nurses Association of Canada in 1990, was unable to reach consensus on the type of collaborative model which was most appropriate or even if collaboration was desirable.[41] Nonetheless, the WHO Workshop in 1995 recommended the integration of traditional healing into the health care system[42] and stressed primary health care as the most suitable level.

New Zealand has some limited experience with this approach. The 1995 Report of the National Advisory Committee on Core Health and Disability Support Services, suggested a complementary role for Mäori traditional healing vis a vis the health system. "*In some contexts the provision of traditional healing services can assist in establishing effective therapeutic relationships ... the complementary provision of traditional services alongside other primary care providers (e.g. GPs independent nurse providers, Mäori community health initiatives) will assist in more Mäori with ill health being seen by an appropriate primary care practitioner.*" [43]

Te Whare Whakapikiora o te Rangimarie, a Mäori traditional healing clinic which has a contract with the Central Health a division of the Transitional Health Authority, has so far been able to demonstrate a collaborative approach, all clients being referred to a medical practitioner. In contrast, however, medical referrals to the clinic are few, most clients being self or whanau referred.[44]

---

39 Rankin J F A (1986), Whaiora: a Mäori cultural therapy unit, *Community Mental Health of New Zealand*, 3:38-47

40 Salmond G (1987), *Traditional Services and Kai Awhina in Health Services*, Department of Health Circular memorandum N0 1987/9, Department of Health, Wellington

41 Waldram et al *op. cit.* p. 220

42 Cunningham, *op. cit.*

43 Core Services Report 1995, *op. cit.* p. 24

44 Te Aho *op. cit.*

Annex 6

5 CONCLUSIONS

5.1 The purchase of traditional healing will inevitably require some formalisation of healing activities in order to develop acceptable standards, satisfactory arrangements for monitoring and appropriate indicators.

5.2 Formalisation is often seen as a risk to autonomy and to the retention of the essential characteristics of healing, especially if measures of effectiveness and efficiency are based on biomedical philosophies, criteria and measurements.

5.3 It is important therefore that any process of formalisation involve healers themselves or their representative bodies. This will reduce the likelihood of the terms of formalisation undermining the essential nature of the activity or reinterpreting it in biomedical terms.

5.5 The inclusion of traditional healing in the health system is consistent with developments in other parts of the world, as well as WHO recommendations. Having already identified traditional healing as a component of primary health care, New Zealand is already well placed to take further steps to formulate more comprehensive policies for a range of traditional health services.

Annex 6

REFERENCES

Abbott I A (1992), *Lā'au Hawai'i Traditional Hawaiian Uses of Plants*, Bishop Museum Press, Honolulu

Blaisdell K, Mokuau N (1994), Kānaka Maoli, Indigenous Hawaiians, in ed. Hassager U., Friedman J., *Hawai'i Return to nationhood*, International Work Group for Indigenous Affairs, Copenhagen

Brooker S G, Cambie R C, Cooper R C, (1981), *New Zealand Medicinal Plants*, Heinmann, Auckland

Core Services Committee (1995), *Core Services 1996/97*, National Advisory Committee on Core Health and Disability Support Services, Wellington

Cunningham C (1995), *Report on Attendance at World Health Organisation (Western Pacific Region) Regional Workshop on Traditional Medicine, Hong Kong November 1995*, Ministry of Health, Wellington

Durie M H et. al. (1993), *Traditional Māori Healing, a paper prepared for the Core Services Committee*, Department of Māori Studies, Massey University

Durie Mason (1994), *Whaiora Māori health development*, Oxford University Press, Auckland

Elkin A P (1977), *Aboriginal Men of High Degree*, University of Queensland Press, St. Lucia

Frideres J S (1993), *Native Peoples in Canada*, Prentice Hall Canada, Scarborough

Hooper A, (1995), Tahitian Healing in ed. Parsons Claire D F, *Healing Practices in the South Pacific*, The Institute of Polynesian Studies, University of Hawaii Press, Honolulu

Komiti Whakahaere (ed), 1984, *Hui Whakaoranga Māori Health planning Workshop*, Department of Health, Wellington

Kunitz Stephen J (1994), *Disease and Social Diversity the European Impact on the health of non-Europeans*, Oxford University Press, New York

Laurenson M (1995), Māori Traditional Healing, in *Te Kete Hauora*, 1,2, December 1995, Ministry of Health, Wellington

Macdonald C (1973) *Medicines of the Maori*, William Collins, Auckland

Murchie E, 1984, *Rapuora, Health and Māori Women* Wellington, Māori Womens Welfare League

Annex 6

Parsons C D F, (1985), Notes on Maori Sickness Knowledge and Healing Practices, in ed Parsons C D F, *Healing Practices in the South Pacific*, Institute for Polynesian Studies, University of Hawaii Press, Honolulu

Rankin J F A (1986), Whaiora: a Mäori cultural therapy unit, *Community Mental Health of New Zealand*, 3:38-47

Rankine J (1994), *Maori Healing Practices*, GP Weekly, 12 October, 1994

Reid J, Trompf P. (eds.) (1991), *The Health of Aboriginal Australia*, Harcourt Brace, Marrickville

Rolleston, A, 1988, *He Kohikohinga: A Maori health knowledge base*, Department of Health, Wellington

Salmond G (1987), *Traditional Services and Kai Awhina in Health Services*, Department of Health Circular memorandum N0 1987/9, Department of Health, Wellington

Shipley Hon. J (1995), *Policy Guidelines for Mäori Health Ngä Aratohu Kaupapahere Hauora Mäori 1996/97*, Wellington

Sijuwola O A, (1995), Culture, Religion, and Mental Illness in Nigeria, in ed. Ihsan Al-Issa, *Handbook of Culture and Mental Illness an interrnational perspective*, International Universities Press, Madison

Swartz L (1995), The Politics of Culture and Mental Illness: the case of South Africa, in ed. Ihsan Al-Issa, *Handbook of Culture and Mental Illness an interrnational perspective*, International Universities Press, Madison

Swinomish Tribal Mental Health Project (1991), *A Gathering of Wisdoms Tribal mental health a cultural perspective*, Swinomish Tribal Community, Washington

Te Aho K (1996), *Service Evaluation of Te Whare Whakapiktora o te Rangimarie a Mäori traditional healing service*, Interim Report, Wellington

Te Puni Kokiri (1994), *Mana Tangata Draft Declaration on the Rights of Indigenous Peoples 1993*, Ministry of Mäori Development, Wellington

Waldram J B., Herring D A., Young T K., (1995), *Aboriginal Health in Canada Historical, cultural, and epidemiological perspectives*, University of Toronto Press, Toronto

Webster P (1979), *Rua and the Mäori Millenium*, Victoria University Press, Wellington

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./12
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

PHILIPPINES

by

Dr Alfonso T. Lagaya
National Program Manager
Traditional Medicine Unit
Department of Health
Manila

Annex 6

World Health Organization (WHO) Working Group on Herbal Medicines
8-12 December 1997, Manila, Philippines

Current Status of the Use of Herbal Medicine in the Philippines

(A Country Report presented by *DR. ALFONSO T. LAGAYA*, National Program Manager
Traditional Medicine Unit, Department of Health, Manila, Philippines)

CONTENTS

Annex 6

World Health Organization (WHO) Working Group on Herbal Medicines
December 8-12, 1997, Manila, Philippines

Current Status of the Use of Herbal Medicine in the Philippines

(A Country Report presented by *DR. ALFONSO T. LAGAYA*, National Program Manager
Traditional Medicine Unit, Department of Health, Manila, Philippines)

I. CURRENT STATUS OF THE USE OF HERBAL MEDICINE IN THE PHILIPPINES

A. PRACTICE

1. USE OF HERBAL MEDICINES WITH SCIENTIFIC PROOF OF SAFETY & EFFICACY

Based on western-oriented pharmacological research conducted by the Department of Science & Technology - Philippine Council for Health Research & Development -National Integrated Research Program on Medicinal Plants (DOST-PCHRD-NIRPrOMP), eighty (80) Philippine medicinal plants have passed safety and efficacy testing.

Ten (10) medicinal plants from these 80 are actively being promoted by the Department of Health as a component of Primary Health Care. These 10 plants are: Vitex negundo (anti-asthma & anti-cough); Mentha cordifolia (analgesic); Blumea balsamifera (diuretic & anti-urolithiasis); Carmona retusa (Gastro-intestinal hypomotility); Quisqualis indica (anti-parasitic); Psidium guajava (wound antiseptic); Cassia alata (skin anti-fungal & anti-scabies); Peperomia pellucida (Lowers blood uric acid); Allium sativum (lowers blood cholesterol; and Momordica charanti (hypoglycemic agent).

Three (3) medicinal plants out of these 10 medicinal plants, namely Vitex negundo , Blumea balsamifera and Carmona retusa are now included in the National Drug Formulary and manufactured for national distribution and marketing.

2. POPULAR / FOLKLORIC / COMMUNITY-BASED USAGE OF HERBAL MEDICINES

Based on traditional, folkloric and popular usage of indigenous healing traditions in the Philippines as well as the number of published materials on medicinal plants in the Philippines **(Madulid, D.A. and F.J.M. Gaerlan. 1994. A Bibliography on Philippine Ethnobotany, Ethnopharmacology, and Related Subjects. National Museum, Manila.),** ***medicinal plants continue to be the predominating practice in the community nationwide.***

Annex 6

Medicinal plants are almost always available, accessible and culturally-acceptable to the community.

Most knowledge on herbal medicines is passed from one generation to another, although some traditional healers claim that their knowledge originated through magico-religious experiences.

B. PRACTITIONERS

1. WESTERN-ORIENTED HEALTH WORKERS:

A handful of Filipino physicians, pharmacists, nurses, midwives and other professional health workers are prescribing or recommending medicinal plants approved through western-oriented pharmacological research conducted by the DOST-PCHRD-NIRPrOMP. Occasionally, some rural practitioners may even recommend medicinal plants not included in the DOST listing.

2. TRADITIONAL MEDICAL PRACTITIONERS:

There are approximately 250,000 traditional medical practitioners in the Philippines who recommend the medicinal plants available in their community. They instruct their patients to prepare decoctions, poultices and other folkloric preparations needed for health care. The prescriptions may occasionally involve prayers, incantations, changes in lifestyles and things like "it should be taken during the holy days of the week to attain better results.

Although such practices are often considered superstitious and are often laughed at by the urban settlers, they carry the potential for substantial anthropological and pharmacological research in the future.

C. MANUFACTURERS

1. INDUSTRIAL-SCALE

The intention of Philippine manufacturers of plant products is to market them for medicinal and food usage.

The Government, through the DOST-PCHRD-NIRPrOMP, has collaborated with the Department of Health (DOH) to pioneer in the manufacturing of medicinal plant products. At present, there are four (4) government herbal processing plants, namely:

a) Cagayan Valley Herbal Processing Plant, Tuguegarao City. Cagayan Valley, Region II.

b) Tacloban Herbal Processing Plant, Tacloban City, Leyte, Region VIII.

c) Davao Herbal Research & Processing Plant, Davao City, Region XI

d) Cotabato Herbal Processing Plant, Cotabato City, Region XII

Among the new private Herbal Processing Plants & Marketing Units also approved by the DOST-PCHRD-NIRPrOMP, as of 1997, are the following:

e) Pascual Laboratories Incorporated

f) Natrapharm Company

g) Grupo Medica Company

The greater number of manufacturers of plant and natural health products are registered and licensed to produce food supplements.

2. COMMUNITY-BASED HERBAL MEDICINE PRODUCTION:

The community processes plant products both for medicinal and food usage but only on a limited scale to be distributed within their own area. Such products are simply in the form of tea bags, decoctions, ointment and syrups.

II. GOVERNMENT POLICY ON HERBAL MEDICINE

A. RESEARCH & DEVELOPMENT:

Research & development on herbal medicine is being encouraged by the government through two major government agencies. The DOST-PCHRD-NIRPrOMP focuses on biomedical research while the DOH-Essential National Health Research (DOH-ENHR) focuses on social and policy researches. There may occasionally be some overlapping.

The academic sector plays a major role in contributing valuable research on medicinal plants.

Annex 6

B. **DOST TRANSFER OF TECHNOLOGY**:

The result of research conducted by the DOST-PCHRD-NIRPrOMP are published for national dissemination. DOST also compiles a list of research studies conducted by other agencies.

To hasten the public dissemination of scientifically-proven medicinal plant products, collaboration has been established with the DOH to manufacture into tablet and ointment forms.

Likewise, the private sectors were awarded the rights to use their clinical and pre-clinical data for registration.

C. **DEPARTMENT OF HEALTH - TRADITIONAL MEDICINE UNIT**

The DOH, through the Traditional Medicine Unit, is active in the promotion of scientifically-proven herbal medicines.

They also encourage collaboration with the academic sector, national government agencies, local government units, nongovernmental organizations and the private sector for promotion, research, production and distribution.

III. REGULATORY SITUATION OF HERBAL MEDICINE

A. **PRACTICE:**

1. *The Professional Regulatory Commission (PRC) provides qualifying examinations for the licensure of Filipino physicians to practice medicine, and to prescribe drugs, including herbal medicines.*

2. *The Department of Health (DOH) is training community health care workers and traditional health practitioners in the community-based use of medicinal plants to augment its manpower on the implementation of the world-wide thrust of primary health care.*

B. **PRODUCT**:

1. **THE DEPARTMENT OF HEALTH - BUREAU OF FOOD & DRUGS**

a) *Based on Republic Act No. 3720, the government agency responsible for the regulation of the production, sale and traffic of herbal medicines to ensure the safety and good quality of such products to protect the health of the people is the Department of Health - Bureau of Food & Drugs (DOH-BFAD).*

b) The DOH Administrative Order No. 99-A s. 1984. Regulation Part C-11: Listing of Local Herbal and/or Traditional Drugs. This Order provides for the definition of local herbal and/or traditional drugs. After the definition, this Order prescribes the

requirements before herbal and/or traditional drugs may be distributed and sold in the market.

c) *The DOH Administrative Order No. 67 s. 1989. Revised Rules and Regulations on Registration of Pharmaceutical Products.*

This A.O. gives comprehensive guidelines on the registration of pharmaceutical products to be consistent with R.A. 6675 known as the "Generics Act of 1988."

d) *The DOH Administrative Order No. 56 s. 1989. Revised Regulations for the Licensing of Drug Establishments and Outlets.*

This order prescribes the activities involving drug products that need to be covered by a license from BFAD. Identifying these activities, the regulations provide for the general requirements applicable to all categories or activities and the specific requirements applicable for each category. The order further provides for the conditions for renewal and sanctions for deficiencies or failure to comply with the requirements.

e) *The DOH Administrative Order No. 60 s. 1968. General Regulations for the Enforcement of the Food, Drug and Cosmetic Act (A-7 Operation for Drug Establishments and A-8 Requirements for Cosmetic Laboratory)*

This order prescribes the activities involving products that need to be covered by a license from BFAD. It also describes the specific requirements and fees applicable for each category.

2. *DOH Administrative Order No. 2 s.1993. "Botika sa Barangay"*

The Botika ng Barangay (BnB) Program essentially aims to rationalize the distribution of common drugs and medicines among intended beneficiaries, i.e., indigents. Moreover, this programme shall serve as mechanism for the DOH to establish a partnership with Local Government Units (LGUs) and Community Organizations. It shall also optimize involvement of the Barangay Health Workers in addressing the health needs of the community. Recognizing too, the various successful efforts and approaches in establishing the Botika ng Barangay initiated by various community sectors in the spirit of partnership among groups and organizations, the DOH shall also encourage all sectors to support the BnB Program particularly towards its sustainability and in support of community health development.

Annex 6

3. ***OTHER LEGAL DOCUMENTS FOR THE PROTECTION OF HERBAL & NATURAL HEALTH PRODUCTS***

Executive Order No. 247. Regulating access to biological and genetic resources in the Philippines.

"It shall be the policy of the State to regulate the prospecting of biological and genetic resources to the end that these resources are protected and conserved, are developed and put to the sustainable use and benefit of the national interest. Further, it shall promote the development of local capability in science and technology to achieve technological self-reliance in selected areas."

The E.O. establishes a framework to regulate biodiversity prospecting with four (4) basic elements:

a) ***A system of mandatory research agreements between collectors and the government containing minimum terms concerning the provision of information and samples, technology cooperation and benefit sharing;***

b) ***An Inter-Agency Committee (IAC) to consider, grant, monitor and enforce compliance with research agreements as well as to coordinate further institutional, policy and technology development;***

c) ***A requirement and minimum process standard for obtaining prior informed consent from local and indigenous communities where collection of materials is carried out; and***

d) ***Minimum requirements to conform with environmental protection laws and regulations.***

IV. GOVERNMENT FUTURE PLANS IN THIS AREA

A. ***The country's political will on herbal medicine is exemplified by the inclusion in President Fidel V. Ramos' priority to pole-vault the Philippines towards the year 2000 through the "Establishment of the Alternative Medicine Research & Development Center". The existing functions of the DOH Traditional Medicine Unit will be maximized through this Center.***

B. ***There are two (2) related legislative bills concerning Traditional Medicine. Senate Bill No. 1471, entitled, "An Act Creating the Philippine Institute of Traditional & Alternative Health Care" is authored by Honorable Flavier, Webb, Mercado, Romulo, Honasan, Magsaysay Jr., Revilla, Shahani, Angara, Roco, Sotto III, Gonzales and Coseteng.***

The House of Representative Version is HB No. 10070, entitled, "An Act Creating the Philippine Institute of Traditional & Complementary Health Care" is authored by Honorable Ty, Bondoc, Avila, Recto, Colambo, Teves, Calalay, Abad, Ramirez, Aumentado, Andaya R., and Belmonte and the Members of the Committee on Health.

These Bills, once approved into law, will focus on the research & development, human & institutional resource development, and legislative and policy formulations on traditional & alternative / complementary health care, as well as the production of herbal medicines and other natural health products.

C. ***DOH Administrative Order (A.O.) on the regulation & product certification of herbal medicines at a limited-scale manufacturing capability. This A.O. intends to reclassify the manufacturers of herbal and natural health products into the industrial-scale from the limited-scale, to encourage the small and medium scale entrepreneurs in its production, marketing and distribution.***

Annex 6

DEFINITIONS:

Based on Republic Act No. 3720, Section 10. (e) "Food" means (1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article; and in

Section 10 (f) "Drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or animals; and (4) articles intended for use as component of any articles specified in clauses (1), (2), or (3), but does not include devices or their components, parts, or accessories.

Section 10 (h) "Cosmetics" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (2) articles intended for use as a component of any such articles.

DOH Administrative Order No. 42 s. 1982 and A.O. 99-A s. 1984

defines the rules and regulations governing the registration and sale of herbal and/or traditional drugs to ensure their quality and safety. The sections applicable to local herbal and/or traditional drugs are superseded by A.O. 99-A s. 1984 dated August 14, 1984 Re: Listing of Local Herbal and/or Traditional Drugs. The sections on imported herbal and/or traditional drugs remain valid.

Imported herbal and/or traditional drugs shall be distributed and sold only after having been duly registered with the BFAD by an establishment with a current license to engage in importation, sale or distribution of such herbal and/or traditional drugs.

Annex 6

DOH Administrative Order No. 42 s. 1982 and A.). 99-A s. 1984

C-11.0 ***Republic Act No. 3720, otherwise known as Food, Drug and Cosmetic Act, states among other things that the policy of the state is to ensure safe and good quality supply of drugs and to regulate the production, sale and traffic of the same to protect the health of the people. For the proper implementation of the above policy, the following rules and regulation governing the listing of local herbal and/or traditional drugs is adopted to ensure the quality and safety of the drug supply in the country.***

C-11.1 ***Local herbal and/or Traditional Drugs means -***

Processed dosage forms produced in the Philippines from indigenous plant, or animal or mineral material other than foodstuffs, which are intended for use in man to cure or mitigate manifestations of disease, injury or bodily defect or to modify some physiological functions.

C-11.2 ***Requirements for Listing of Herbal and/or Traditional Drug for Local Productions:***

11.2.1 ***Application Letter***

This should state that the applicant wishes the drug to be regarded as a local herbal and/or traditional drug, the indications claimed for it. It should also specify the name and address of the applicant who must be the manufacturer.

11.2.2 ***License to Operate:***

No herbal and/or traditional drug shall be accepted for listing from any applicant unless such applicant is a holder of a current permit issued by the Bureau of Food and Drugs to engage in the manufacture and sale of distribution of such herbal and/or traditional drugs

11.2.3 ***Pharmaceutical data:***

11.2.3.1 Technical specifications, such as pharmacognosy of the herbal ingredients, provenance, propagation, and culture management processing, storage and preservation of the natural constituents / plant material and quality control of other constituents.

11.2.3.2 Manufacturing methods and in-process control.

11.2.3.3 Technical and quality specification of the finished product as may be available such as physical characterization, bioassay of potency, impurities likely to occur and level of acceptable impurities.

11.2.3.4 Packaging materials specifications, stability studies and recommended storage condition.

11.2.3.5 Labels, package insert and sufficient sample for analysis.

11.2.4 Pharmacological Documentation:

11.2.4.1 Acute toxicity testing and any other toxicology data available.

11.2.4.2 Pre-clinical pharmacodynamic studies including "in-vitro" test of tissue isolates where available.

11.2.4.3 Clinical data on safety and efficacy.

11.2.5 Local Herbal and/or Traditional Drugs shall be distributed and sold only after having been duly listed with the Bureau of Food and Drugs.

11.2.6 Where a drug is to be distributed and sold in several dosage forms separate listing in respect to each form shall be made.

11.2.7 In addition to the requirements of Sec. 18 and 19 of R.A. 3720, the Listing number shall be printed on the label of the herbal and/or traditional drug after it is officially listed with the Bureau of Food and Drugs.

11.2.8 Initial Listing Fee:

11.2.8.1 Each preparation of herbal drugs shall be charged of fee of twenty five pesos (PhP 25.00) as listing fee.

11.2.9 The listing of a local herbal and/or traditional drug product shall be valid only for one (1) year from the date of issuance to be renewed yearly.

11.2.10 The listing of a local herbal and/or traditional drug product shall be considered not effective or canceled:

11.2.10.1 If the holder of the listing of the product so requests; or

11.2.10.2 If the holder of the listing of the product fails to renew the registration of such local herbal and/or traditional drug pursuant to Sec. 11.2.11 of the regulation, or

11.2.10.3 If the holder of the listing of the product advertised or promoted the local herbal and/or traditional drug is not in accordance with the particulars submitted, pursuant to Section C-11 of this Order; or

11.2.10.4 If new development; findings or considerations of public interest and protection so warrants such cancellation; or

11.2.10.5 If the composition of labeling of the local herbal and/or traditional drug had been modified without authorization from the Bureau of Food and Drugs; or

Annex 6

11.2.10.6 If the local herbal and/or traditional drug product is manufactured by a firm who is not a holder of a current listing of the drug product.

11.2.11 Any local herbal and/or traditional drug product whose listing is not renewed shall be subsequently be subject to a new listing requirements specifies in Section C-11.2 of this regulation.

11.2.12 Quality Control Requirements (BFAD Analysis)

11.2.12.1 Tests for the presence of synthetic drugs;
- *11.2.12.1.1 Aspirin*
- *11.2.12.1.2 Acetaminophen*
- *11.2.12.1.3 Dipyrone*
- *11.2.12.1.4 Phenylbutazone*
- *11.2.12.1.5 Pyrazolone*
- *11.2.12.1.6 Corticosteroid*
- *11.2.12.1.7 Anabolic steroids*
- *11.2.12.1.8 Gonadal hormones*

11.2.12.2 Tests for the presence of heavy metals:
- *11.2.12.2.1 Lead*
- *11.2.12.2.2 Mercury*
- *11.2.12.2.3 Arsenic*
- *11.2.12.2.4 Cadmium*

11.2.12.3 Alcohol content should not be more than 10% w/v

11.2.12.4 Analysis for impurities - U.S.P. for gross contaminants.

11.2.12.5 Tablets
- *11.2.12.5.1 Weight variation*
- *11.2.12.5.2 Disintegration rate*
- *11.2.12.5.3 Physical uniformity*
- *11.2.12.5.4 Hardness*

11.2.12.6 Liquids, suspensions or syrups
- *11.2.12.6.1 Suspendibility*
- *11.2.12.6.2 Homogeneity*
- *11.2.12.6.3 Viscosity*
- *11.2.12.6.4 Standard Plate Count*
- *11.2.12.6.5 Coliform count*
- *11.2.12.6.6 Yeast count and mold count*

11.2.13 Manufacturers of listed local or traditional herbal drugs shall have to file a report or the progress of the drug is as far as clinical data, toxicology data, adverse effects as well as progress on the identification of active ingredients to the Bureau of Food and Drugs. This report shall be due every 12 months.

C-11.3 This order shall take effect thirty (30) days after publication in the Official Gazette.

(SGD) J.D. Azurin

Minister of Health

Annex 6

REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS:

Based on Department of Health Administrative Order No. 67 s. 1989, Section 1. "Registration" means the process of approval for the manufacture, importation, exportation, sale, offer for sale, distribution or transfer of pharmaceutical products containing active ingredient (s) of known chemical structure and properties determined to be safe, efficacious, and of good quality according to standards of BFAD.

"Pharmaceutical Product" means any pharmaceutical or biological product containing active ingredients responsible for its desired effect intended foe use in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body of man or animal.

1. ***The General Requirements for Registration of a Pharmaceutical Product:***

   a) ***License to operate of the drug manufacturer, trader, distributor / importer, distributor / exporter.***

   b) ***Certificate of clearance from the Bureau of Patents and information on patent status.***

   c) ***Technical data which shall include:***

      (1) ***Physical description of the product.***

      (2) ***Complete formulation and technical specifications for the raw materials and finished product.***

      (3) ***Process of manufacturing including facilities and control used in the manufacturing and packaging of the product.***

      (4) ***Description of all quality control tests performed including Dissolution Test, if applicable, and results obtained.***

      (5) ***Samples and corresponding reference standards.***

      (6) ***Two copies of labels or specimens of the proposed label and labeling materials such as inserts, brochures, etc.***

      (7) ***Relevant literature and/or scientific evidence based on foreign or local studies to show safety, efficacy and therapeutic value of the drug.***

2. ***The Specific Requirements for Registration of a Pharmaceutical Product:***

   a) ***"Investigational Drug" refers to a new chemical or structural modification of a Tried and Tested or Established Drug proposed to be used for a specific therapeutic indication. An investigational drug needs further clinical pharmacology studies (Phase I, II or III) to determine its safety and efficacy and meets the requirements of a new drug.***

(1) Medical Director registered with BFAD per A.O. 34 s 1979
(2) Animal Studies
(a) Acute toxicity
(b) Sub-Chronic toxicity
(c) Teratogenicity
(d) Other studies
(3) Clinical Pharmacological Studies
(a) Phase I and II tolerance and efficacy studies
(b) Phases III clinical trial
(i) Foreign
(ii) Local

b) "New Drug" refers to a new chemical or structural modification of a Tried and Tested or Established Drug proposed to be used for a specific therapeutic indication, which has undergone adequate clinical pharmacology Phase I, II and III studies but which needs further Phase IV Clinical Pharmacology studies before it can be given regular registration.
(1) Medical Director registered with BFAD per A.O. 34 s 1979
(2) Results of animal and clinical studies.
(3) Phase IV Clinical Trial
(a) Provisional monitored release study
(b) Post-Marketing surveillance.

c) "Tried and Tested Drug" is a drug which has been used for at least five (5) years involving at least 5000 patients.
(1) Dissolution test for solid oral dosage forms, if applicable.
(2) Bioavailability / Bioequivalence study for certain drugs as determined by BFAD.
(3) Clinical trial to determine effective therapeutic dose range in Filipinos, when applicable.

d) "Established Drug" is a drug, the safety and efficacy of which has been demonstrated through long years of general use and can be found in current official USP-NF and other internationally-recognized pharmacopoeias.

(1) Dissolution test for solid oral dosage forms, if applicable.
(2) Bioavailability / Bioequivalence study for certain drugs as determined by BFAD.

e) "Pharmaceutical Innovation and Therapeutic Innovation of Tried and Tested or Established Drug" includes any or all of the following: an innovation involving use for new indication (s); new mode of administration; new dosage form; and/or new fixed dose combination of two or more active ingredients.
(1) Dissolution test for solid oral dosage forms, if applicable.
(2) Bioavailability / Bioequivalence study for certain drugs as determined by BFAD.

f) "Therapeutic Innovation of Tried and Tested or Established Drug" includes any or all of the following: an innovation involving use for new indication (s); new mode of administration; new dosage form; and/or new fixed dose combination of two or more active ingredients.
(1) Local clinical trial to test efficacy of the therapeutic innovation.

Annex 6

CURRENT HEALTH CARE DELIVERY SYSTEM IN THE PHILIPPINES

- **Legal & Formal Health Care:**
  - » Western (Modern, Allopathic, Mainstream) Medicine

- **Popular Health Care:**
  - » Folkloric Health Care (Philippine Indigenous Healing Traditions)
  - » Traditional Chinese Medicine
  - » Indian Ayurvedic Medicine
  - » Alternative Health Care:
    - – Homeopathy, Reflexology, Chiropathic, Iridology, others.
  - » Others

Philippines DOH-TMU

Components of Traditional Medicine Program in the Philippines

- **Indigenous Philippine Medicine**
  - » **Herbal Medicine**
    - – Community-Based
    - – Industrial-Scale
  - » **Indigenous Healing Traditions**
    - – Massage Therapy
    - – Pranic Healing
    - – Psychic (Spiritual) Healing

- **Asian Oriental Medicine**
  - » Traditional Chinese Medicine
  - » Indian Ayurvedic Medicine
  - » Korean Oriental Medicine (New)
  - » Others
- **Alternative or Complementary Medicine**

Philippines DOH-TMU

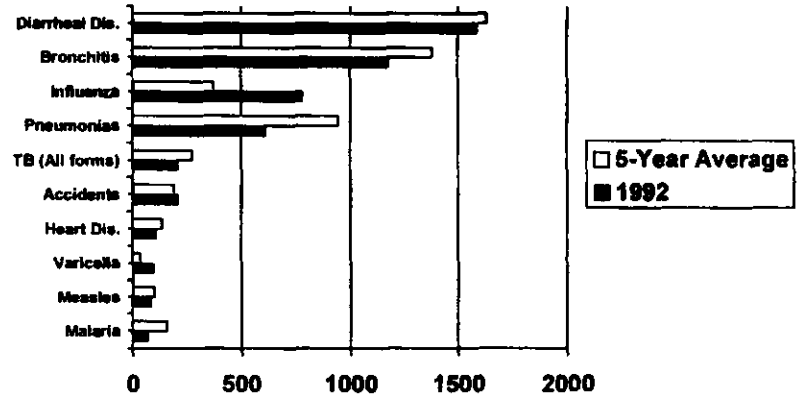
Annex 6

APPENDIX

PHILIPPINE HEALTH STATISTICS (SELECTED CASES)

Philippines DOH-TMU

Ten (10) Leading Causes of Morbidity
Philippines, 1992



Philippines DOH-TMU

Annex 6

Functions of Traditional Medicine Program in the Philippines

- Research & Development
- Policy Formulations & Implementation
- Human Resource Development
- Institutional Development

- Clinical Service Delivery
- Herbal & Natural Products Production

Philippines DOH-TMU

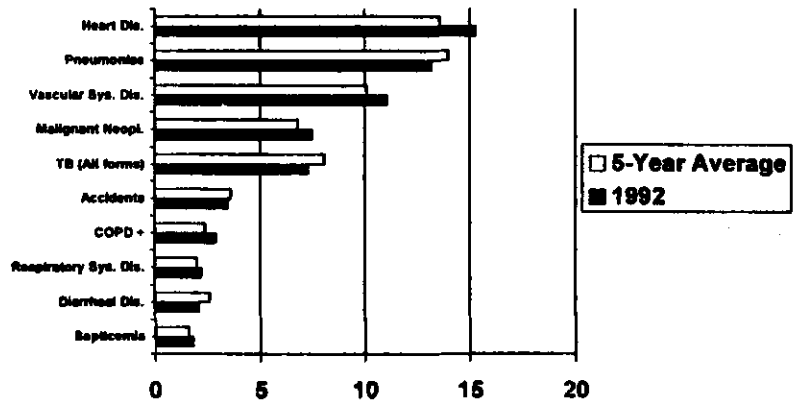
Development of Traditional Medicine Program in the Philippines

- **Establishment**
  - » Department of Health - Traditional Medicine Unit (1993)
  - » A Legislative Bill in the Establishment of the "Philippine Institute of Traditional & Alternative / Complementary Health Care" (1995 to the present)
- **Detailed Functions** (1993 to the present)
  - » R & D, Policy Formulation & Implementation, Human & Institutional Development, Clinical Services, Production
- **Integration of Traditional Medicine in the Current Health Care Delivery System**

Philippines DOH-TMU

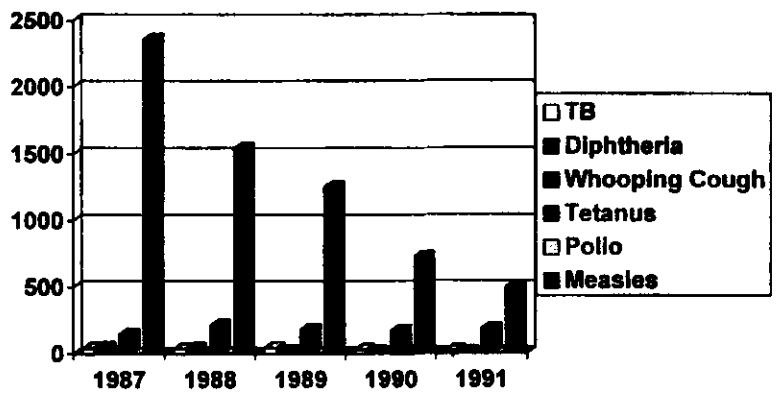
Annex 6

Ten (10) Leading Causes of Mortality
Philippines, 1992



Philippines DOH-TMU

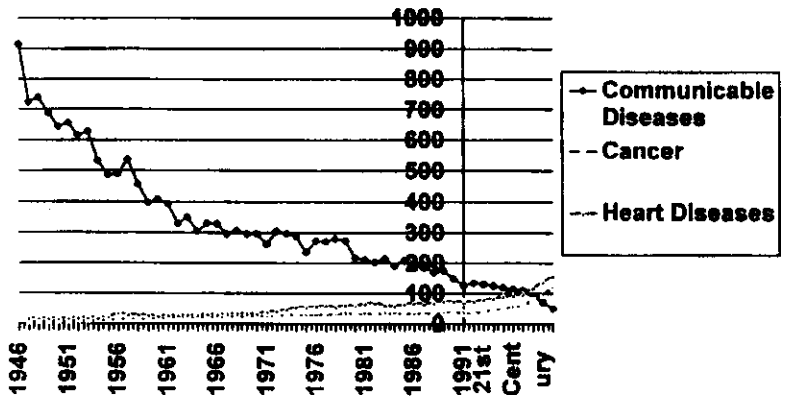
Immunization-Preventable Diseases
(Infants <1 Yr)



Philippines DOH-TMU

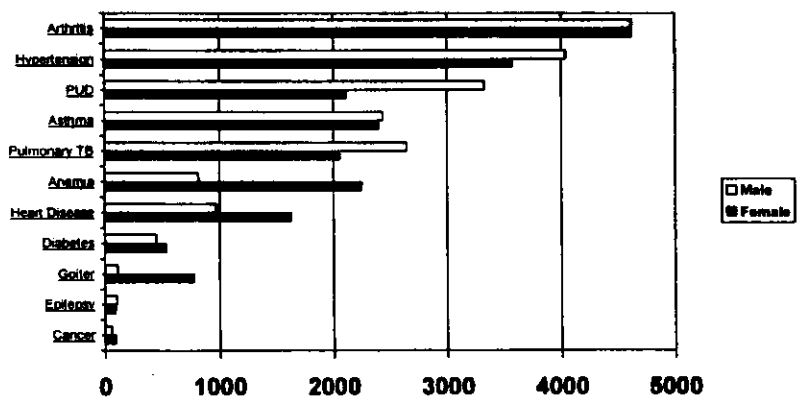
Annex 6

Mortality Trends, Selected Causes
(Rate/100,000 Population)
Philippines 1946 - 1992



Philippines DOH-TMU

Prevalence of Selected Diagnosed Chronic Diseases (Rate per 100,000)
Philippines 1992



Philippines DOH-TMU

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTÉ

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./13
2 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

SINGAPORE

by

Dr Wong Kum Leng
Deputy Director
Medical Services
Ministry of Health
Singapore

Annex 6

REPORT ON THE PRACTICE AND USE OF CHINESE HERBAL MEDICINE IN SINGAPORE

by: Dr Wong Kum Leng

BACKGROUND

It is generally recognized and accepted that western medicine is the main form of health care in Singapore. However, herbal medicine continues to enjoy considerable popularity in Singapore. In particular, traditional Chinese medicine (TCM) appeals to the public in some areas, such us in the building up the body's resistance to disease, restoring health after serious illness and during convalescence, raising energy levels and relieving symptoms of sores and pain. The use of Chinese medicine in Singapore is considered an integral part of the Asian culture and TCM has played a unique role as alternative form of medical treatment and maintenance of health in Singapore.

A survey carried out by the Ministry of Health in 1994 showed that 45% of Singaporeans had at some time consulted TCM practitioners and that 19% of the population had consulted a TCM practitioner in the past year. Unexpectedly, the percentage that had never sought care from TCM practitioners was highest among the Chinese (54%). Sixteen per cent of the Indians surveyed had consulted a TCM practitioner, while only 8% of the Malays surveyed had done so. TCM is favoured more by older persons. The treatment given by TCM practitioners is mainly for sprains, aches and pain and most commonly for colds.

The different forms of TCM practitioner in Singapore are:

(a) Chinese herbal medicine practitioners (majority);

(b) Acupuncturists;

(c) Bone-setters; and

(d) Others (practitioners of Qigong, acupressure and reflexology).

Annex 6

Of these, (a) and (b) are the two most common in Singapore.

PART A: TRADITIONAL CHINESE MEDICINE PRACTICE (HERBAL MEDICINE)

PROFILE OF TCM (HERBAL MEDICINE) PRACTITIONERS IN SINGAPORE

Based on a survey conducted in 1996 by the Singapore Traditional Chinese Medicine Organizations Coordinating Committee (STCMOCC), an umbrella body representing eight local TCM organizations, the number of TCM (herbal medicine) practitioners in Singapore totals to 1807. Of this number, 708 (39.18%) are above 50 years old, 689 (38.12%) are between 40 to 49 years old, and 410 (22.7%) are below 40 years old. Of these practitioners, 68% are males.

The survey showed that 907 (50.2%) of TCM practitioners are working full-time, 568 (31.4%) part-time, and 332 (18.4%) are currently not practising.

The majority of TCM practitioners either work in TCM clinics (including free clinics) or Chinese medical halls. There are about 350 TCM clinics and 900 Chinese medical halls/herbal shops in Singapore. The two most common areas of practice by TCM practitioners in Singapore are herbal medicine and acupuncture.

TCM practice in Singapore is restricted to outpatients. There is no inpatient component unlike in some other countries. It is estimated that about 10 000 persons visit TCM clinics each day, compared to an estimated daily outpatient attendance of 74 000 in western medical clinics, i.e., 12% of outpatients are seen by TCM practitioners. TCM's role in medical care in Singapore is thus insignificant.

TCM practitioners in Singapore acquire their TCM knowledge and skills either through apprenticeship, learning from masters, by attending training courses conducted by local TCM schools or from overseas training.

The two major local TCM schools that conduct TCM courses are the Singapore Chinese Physicians Training College, run by the Singapore Chinese Physicians Association, and the

Chinese Medical Studies, run by the Association for Promoting Chinese Medicine. Both schools now conduct part-time training courses of 6-year duration. Survey results showed that the majority of TCM practitioners in Singapore received their training from local TCM schools, 34 (1.9%) from TCM institutions in China, 375 (20.7%) received less formal training such as through apprenticeship, short courses, etc.

GOVERNMENT POLICY ON TCM PRACTICE

In July 1994, the Ministry of Health appointed a Committee headed by the Senior Minister of State for Health and Education to review the practice of TCM and recommend measures to safeguard patients' interests and safety and to enhance the standard of training of TCM practitioners.

The committee on TCM advocated the need to regulate TCM practice in Singapore and also recommended steps to upgrade the standard of training in TCM. In line with the committee's recommendations, the Ministry of Health set up the TCM Unit in November 1995 to oversee and coordinate the implementation of their recommendations.

REGULATORY STATUS OF TCM PRACTICE

Singapore has adopted a phased approach to regulation, i.e., self-regulation by the TCM community initially, followed by statutory regulation at a later stage. We are currently in the self-regulatory phase.

To facilitate self-regulation, eight local TCM organizations have formed an umbrella body, the Singapore Traditional Chinese Medicine Organizations Coordinating Committee (STCMOCC), to enlist TCM practitioners to set up ethical codes and disciplinary process, and to upgrade courses for TCM practitioners and acupuncturists. It also acts as a channel of communication between the TCM community and the Ministry of Health.

Annex 6

Lists of TCM practitioners and acupuncturists have been drawn up by STCMOCC under the guidance of the Ministry of Health to serve as a reference point, as well as to serve as a public reference to enable informed choices by the public seeking TCM care. A data collection survey was carried out in 1996 to form the basis for listing of TCM practitioners and acupuncturists. These lists are expected to be published by STCMOCC by the end of 1997.

For effective self-regulation, the STCMOCC has drawn up an Ethical Code for TCM practitioners with the guidance of the Ministry of Health. It was distributed to TCM practitioners for compliance since January 1997. The Code covers the following:

(a) ethical behaviour;

(b) guidelines on advertising;

(c) guidelines on the use of title, qualifications and clinic names; and

(d) guidelines for fees for consultation and housecalls.

STCMOCC is currently in the process of drafting the Disciplinary Process.

GOVERNMENT'S FUTURE PLANS IN TCM PRACTICE

Statutory registration for acupuncturists will be implemented by the year 2000 while that for TCM (herbal medicine) practitioners will be in place several years later.

Regulation of TCM-related practices, such as Chinese therapeutic massage, tuina, etc., may also be systematically looked into at a later stage.

Working towards upgrading of the training of local TCMPs, the Singapore Government has so far enlisted the local TCM schools' support in adopting a new standardized 6-year TCM diploma course, and has invited TCM experts from China to evaluate both the new course and the local TCM schools. The admission of better quality students has also been ensured by

encouraging holders of full GCE A-level certificate or higher to enrol into the 6-year TCM diploma course.

Upgrading courses for existing acupuncturists will be in place by 1998 while that for TCAM practitioners will be done later. Standardized syllabi and the structure for upgrading courses will be set with the input of STCMOCC and overseas TCM experts.

PART B: HERBAL MEDICINES

THE USE OF HERBAL MEDICINES IN SINGAPORE: CURRENT STATUS, GOVERNMENT POLICY AND REGULATION

Herbal medicines have been widely used in Singapore for many years. They consist mainly of Chinese herbal medicines, Jamu from Indonesia and Malaysia and ayurvedic from India.

It is estimated that about 6000 herbal medicinal preparations are currently on the market. At present, herbal medicines are exempted from product registration unless they contain controlled ingredients. This essentially means that no licence is required from the Ministry of Health for their manufacture, import and sale.

However, various aspects of traditional/herbal medicines are controlled under the following legislation:

(a) Medicines Act 1975 and its Regulations

(b) Medicines (Advertisement & Sales) Act

(c) Sales of Drugs Act and its Regulations

Annex 6

Details of controls are as follows:

Raw Herbs

Dealers must ensure that the raw herbs do not contain the following:

(a) any substances controlled under the Poisons Act;

(b) any substance listed under the Sale of Drugs (Prohibited Drugs) Regulation; or

(c) heavy toxic metals viz arsenic, copper, lead or mercury in quantities that exceed limits stipulated under the Medicines (Prohibition of Sale & Supply) Order 1995 (5 ppm, 150 ppm, 20 ppm and 0.5 ppm, respectively).

Preparations of traditional/herbal medicines

Dealers of traditional/herbal preparations must ensure that:

(a) the products do not contain any substances controlled under the Poisons Act;

(b) the products do not contain any substance listed under the Sale of Drugs (Prohibited Drugs) Regulations;

(c) the products are not adulterated with synthetic drugs or substances not stated on the labels;

(d) the products do not contain heavy toxic metals viz arsenic, copper, lead or mercury in quantities that exceed limits stipulated under the Medicines (Prohibition of Sale & Supply) Order 1995;

(e) the composition and quantities of all the ingredients of the products are printed in English on the product labels;

(f) the labels and packaging materials do not stipulate any of the 19 serious diseases/conditions (e.g., cancer, sexual dysfunction, etc.) set out n the Schedule to the Medicines (Advertisement and Sales) Act; and

(g) the advertising and sales promotion of the products require permits from the Ministry of Health.

The Ministry of Health constantly monitors reports of adverse reactions to traditional medicines. Under the Ministry's quality surveillance programme, random samples are regularly taken from the local market for testing on a regular basis.

FUTURE PLANS ON THE CONTROL OF HERBAL MEDICINES

The Ministry of Health has a plan to control herbal medicines in various phases. The first to be controlled will be the Chinese Proprietary Medicines (CPM) as this is the major group of traditional medicines available in the local market.

Definition of Chinese Proprietary Medicines

Chinese Proprietary Medicine (CPM) products are defined as any medicinal product used in the system of therapeutics according to the Chinese method which consist wholly of one or more substances derived from natural sources, that is to say, plants, animals or minerals or a combination of any or more of them under Medicines Act but shall not include (a) any medicinal products to be injected into the human body; and (b) any item listed in the poisons list in the schedule to the Poisons Act (Cap 234).

Annex 6

Control of CPM

New legislation to control CPM will be made under the present Medicines Act with the following objectives:

- to ensure that CPM products sold locally are safe and of good quality; and
- to ensure that CPM products are labelled properly.

These objectives will be achieved by licensing all local importers, wholesalers, manufacturers and assemblers of CPM products.

Scope of control

There will be no product registration for CPM products. However, the following CPM dealers will be licensed:

- CPM importers;
- CPM wholesalers;
- CPM manufacturers; and
- CPM assemblers.

Local CPM manufacturers and assemblers will need to upgrade their facilities and manufacturing processes in stages to eventually achieve the WHO GMP standard within five years of issuance of their licences.

Submission of product details and certificates

Local importers and manufacturers will need to submit the following details of the products they intend to import/manufacture for sale when they apply for the relevant licences.

Annex 6

Product labelling requirements

CPM product labels will need to contain the required information in both English and Chinese.

Prohibition of stipulation of certain diseases/conditions

The labels, packaging, package inserts and advertisements of CPM products should not make reference to any of the 19 diseases stated below:

(1) Blindness
(2) Cancer
(3) Cataract
(4) Drug addiction
(5) Deafness
(6) Diabetes
(7) Epilepsy or fits
(8) Hypertension
(9) Insanity
(10) Kidney diseases
(11) Leprosy
(12) Menstrual disorders
(13) Leprosy
(14) Tuberculosis
(15) Sexual function
(16) Infertility
(17) Impotency
(18) Frigidity
(19) Conception and pregnancy

Report of adverse drug reaction

Licence holders will be required to report to the Ministry of Health as soon as possible or within seven days upon receipt of any information on adverse drug reactions to the CPM products with which they are dealing.

Annex 6

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU REGIONAL DU PACIFIQUE OCCIDENTAL

WORKING GROUP ON HERBAL MEDICINES

WPR/TRM/TRM(1)97/INF./14
1 December 1997

Manila, Philippines
8-12 December 1997

COUNTRY REPORT

SOCIALIST REPUBLIC OF VIET NAM

by

Professor Lê Van Truyen
Vice-Minister of Health
Ministry of Health
Hanoi

Annex 6

TOWARDS THE ESTABLISHMENT OF THE VIET NAM NATIONAL POLICY ON TRADITIONAL MEDICINE

by:

Professor Lê Van Truyen

1. BACKGROUND

1.1 Viet Nam Traditional Medicine heritage

- Originated from ancient times and created during the Hung Dynasties.
- From the awareness of simple ways in disease treatment and prevention, experimentalized into theory.
- Having access to exchanges with China and regional countries in traditional medicine.
- Strongly developed during the country's independent periods.

1.2 Decision of President Ho Chi Minh after the August 1945 revolution

On 27 February 1955, President Ho Chi Minh's letter to the Health Personnel Conference states the following: "to inherit valuable experiences from traditional medicine and at the same time to study the possibility to combine traditional medicine with modern medicine and to establish our own medicine".

2. THE PARTY'S AND THE VIET NAM GOVERNMENT'S STRATEGIES ON TRADITIONAL MEDICINE

2.1 Party resolutions

- Resolutions adopted by the National Congresses of Party: III (1960), IV (1976), V (1982), VI (1986), VII (1991), VIII (1997)

Annex 6

- Resolution No. IV adopted by the Central Committee VII

2.2 State documents

- Constitution 1980 (Article 44; Section III)
- Adjusted Constitution 1992 (Article 39; Section III)
- Law on People's Health Care and Protection 1989 (Articles 34, 35, 36, 37; Section V)

2.3 Government documents

- Instruction 101/TTG, dated 13 March 1961, on Promotion of Traditional Medicine
- Instruction 210/TTG, dated 6 December 1966, on Exploration and Development of Medicinal Plants and Animals Used for Traditional Medicine
- Instruction 21/CP, dated 19 February 1967, on Promotion of Traditional Medicine Studies and Combination of Traditional Medicine and Modern Medicine
- Resolution 15/CP, dated 14 January 1975, on Improvement of Local Health Facilities
- Resolution 200/CP, dated 21 August 1978, on the Development of Domestic Pharmaceutical Materials
- Resolution 266/CP, dated 19 October 1978, on the Development of Traditional Medicine in Close Combination with Modern Medicine to Build Up the Viet Nam Health Sector

3. ACHIEVEMENTS

3.1 Re-establishment of traditional medicine as a component of public health care

A regulatory system on traditional medicine activities has been established.

Annex 6

3.2 Establishment of the public traditional medicine network from central to local level

- Department of Traditional Medicine, Ministry of Health, and 5 traditional medicine institutes under the Ministry of Health
- 42 traditional medicine hospitals, 265 departments of traditional medicine in general hospitals
- 1000 to 12 000 grassroots traditional medicine facilities in 10 000 commune health centres, nearly 8000 public and private facilities provide traditional medicine services and medicines

3.3 Traditional medicine personnel training

- Initial establishment of the Traditional Medicine Personnel Training System, including 7 departments of Traditional Medicine in Medical Schools (Hanoi, Thai Binh, Hai Phong, Hue, Ho Chi Minh City, Thai Nguyen, Can Tho and Buon Ma Thuot)
- 2 secondary traditional medicine schools (Hanoi, Ho Chi Minh City)
- 1 private traditional medicine school in Hanoi
- Traditional medicine personnel, including 9 professors, 13 associate professors, 20 candidates for Doctor of Science degree, 25 candidates for Master of Science degree, 48 specialized doctors at level II, 331 specialized doctors at level 1, 1384 doctors and 1678 assistant medical doctors, have been trained.
- Many books and documents on traditional medicine have been compiled and translated.

3.4 Inheritance and Scientific Research

- Inheritance: There is a collection of nearly 40 000 traditional medicine prescriptions experimented by 12 531 traditional practitioners; 497 traditional medicine books written in Chinese, Vietnamese hieroglyph, and 202 traditional medicine books written in Vietnamese. Inherited recipes from 241/289 (83.5%) old, skilled, veteran traditional practitioners are also available.

Annex 6

- Scientific Research: More than 1000 traditional medicine experiments, with applications for different specialized areas of traditional medicine, have been conducted. Investigation and data collection have been carried out on nearly 2000 medicinal plants which originated from 238 different species and more than 70 animals used for traditional medicine. Many medicinal plants which originated from abroad have been transplanted and acclimatized successfully. The Regulation on Evaluation of Traditional Medicine Safety and Effectiveness has been adopted. The Traditional Pharmacopoeia has been compiled and the Traditional Medicine Sector has been standardized.

3.5 Curative health care

Thirty per cent of all outpatients are treated by traditional medicine. This contributes substantially to people's health care and protection, especially those living in poor and remote areas where public health services are not available.

3.6 Development of pharmaceutical materials - production of traditional medicines

The country has a Research Institute of Materia Medica and a number of facilities in the research and cultivation of medicinal plants. It has two traditional medicine institutes and a number of pharmaceutical enterprises which have produced 1500 different kinds of traditional medicine. There are also three traditional pharmaceutical companies and nearly 1000 private facilities producing and selling traditional medicine.

3.7 Socialization of traditional medicine in primary health care

The Ministry of Health has adopted Instructions No. 11 and 03 on the restoration of medicinal gardens and the promotion of the use of traditional methods in community health care, such as massage and acupuncture. The Ministry of Health has renewed its instructions and guidelines on the establishment of "green medicine for families".

3.8 International cooperation

International cooperation in the field of traditional medicine is being expanded and it has helped strengthen and develop traditional medicine in Viet Nam.

Annex 6

4. PROBLEMS THAT NEED ATTENTION

4.1 Ideological awareness

Many leaders at the central and local levels do not pay due attention to traditional medicine and they often make light of traditional medicine activities. Some leaders are not aware of the importance of the role of traditional medicine in community health care and they lack determination in their leadership and in implementation. Health workers whose areas are in modern medicine may be at the threshold of awareness but lack concrete actions. Health workers whose areas of expertise are in traditional medicine focus too much on traditional medicine and only see its advantages. The majority of the people like utilizing traditional medicine for medical care but their demand is not met because of a lack of traditional medicine facilities. Moreover, the influx of western medicine everywhere in the market has significantly affected the public attitude towards the utilization of traditional medicine.

4.2 Organization of the traditional medicine system and personnel

The organization of traditional medicine from central level to localities is being gradually stabilized but not in a synchronized manner. There are still 19 provinces without traditional medicine hospitals and 60% of the health institutions and hospitals do not have traditional medicine departments.

Health facilities at grassroots level still lack traditional medicine personnel, especially those who are leading and specializing in traditional medicine.

4.3 Training

There is no college or university in Viet Nam specializing in training personnel on traditional medicine. Traditional medicine curricula at various medical schools are inferior and outdated. There is no coherent and close coordination between the institutes and schools.

4.4 Inheritance

As a whole, the knowledge of traditional medicine has been handed down from generation to generation by traditional healers and manuscripts on traditional medicine have been collected.

Annex 6

However, the inheritance of theoretical arguments, ethnic and popular experiences is still limited and specific policies and plans for their compilation are still lacking.

4.5 Scientific research

Scientific research has been carried out to a limited degree. There is a lack of scientific personnel and specific policies to encourage scientific studies on traditional medicine. There is inadequate investment in scientific studies (lack of facilities, equipment and budget). The integration of traditional medicine with modern medicine has been discussed but there is no common consensus on the matter. There have been no scientific studies on the production and utilization of traditional medicine.

4.6 Traditional pharmacy

There is not enough support for the cultivation and development of medicinal plant resources. There is no master plan to promote and develop the Vietnamese medicinal plant resources to respond to public demands for health care and protection, and the demand for exportation. There are a few studies in creating new forms of traditional medicines to adapt to the traditional medicine theory. There is no strong management of traditional medicines in the market.

4.7 State management

Efforts have been made towards state management of traditional medicine but are still insufficient. There is a lack of a complete legislation system for traditional medicine activities. There is also no master plan or integrated system of policies for long-term development of traditional medicine.

5. PRINCIPAL CONSTRAINTS

5.1 The State has put forward directions and plans for traditional medicine. However, guidance is mainly provided by the Ministry of Health who do not have the authority to promote full awareness of traditional medicine among other sectors.

5.2 There are few changes towards full awareness of traditional medicine among health managers and specialized health workers, therefore combined strength has not been promoted.

5.3 The traditional medicine network has been established but still not up to standard. With this constraint, it cannot promote and steer the traditional medicine sector satisfactorily.

5.4 There is a lack of adequate traditional medicine personnel and the knowledge and skills of current traditional medicine personnel are not up to standard.

5.5 The traditional medicine training system has not been completed and training capability is still limited.

5.6 The state health budget allocated for traditional medicine is too little compared with that for modern medicine. The situation is not favourable towards developing traditional medicine in all areas, such as enhancement of screening and treatment quality, training of health personnel, modernization, scientific studies, inheritance, and integration of traditional and modern medicine.

6. TOWARDS THE ESTABLISHMENT OF A NATIONAL POLICY ON TRADITIONAL MEDICINE IN VIET NAM

6.1 Consolidation, completion and development of traditional medicine system from central level to localities

The Personnel Organization Committee of the Government coordinates with the Ministry of Health and other relevant ministries and sectors and the City and Provincial People's Committee to consolidate and develop traditional medicine system as follows:

- The Ministry of Heath is planning the establishment of a "Traditional Medicine Administration", which is under the leadership of the Vice Minister of Health, rather than the current Department of Traditional Medicine, to make it capable of acting as an adviser to the Ministry's leaders and the Government so that proper leadership and guidance can be delivered during the industrialization and modernization of the country.

Annex 6

- Establishment of a group of experts responsible for supervising all activities concerning traditional medicine at each city or provincial health service.

- Consolidation and completion of the current traditional medicine hospitals and at the same time building new traditional medicine hospitals with 100 to 200-bed capacity in cities or provinces which have traditional medicine hospitals. The hospitals should be equipped with modern medicine equipment to verify the effectiveness of traditional medicine methods which are applied in the treatment and screening of diseases.

- Establishment of a department of traditional medicine in each health institution and hospital at central and local levels to coordinate with other departments in conducting studies on adjustment, enhancement and development of traditional medicine, and a combination of traditional and modern medicine.

- Restoration and promotion of the use of Vietnamese traditional medicine and the prevention and treatment of disease by traditional methods without using medicine at grassroots level and at the same time developing traditional medicine health care services in order to mobilize community participation.

- The Ministry of Health and the Ministry of Education and Training, in coordination with the Traditional Medicine Association, should conduct the re-compilation of traditional medicine curriculum to make it unified throughout the country. They should accelerate the activities at the Department of Traditional Medicine at the University of Medicine and Pharmacy, Ho Chi Minh City. They should also promote the establishment of a Traditional Medicine Academy by integrating the Department of Traditional Medicine of Hanoi Medical School, the Secondary Traditional Medicine School Tue Tinh 1, the Viet Nam Institute of Traditional Medicine, the Acupuncture Institute and the Institute of Medicinal Plant Research in order to select and train personnel who have good knowledge and skills in both traditional and modern medicine practice and prepare them for applied studies which can respond to the needs of the people for traditional medicine. The Health Sector should coordinate closely with the Traditional Medicine Association to further train personnel at grassroots level (communes and villages); each commune and village health station has health workers who provide traditional medicine services to the population. There should be frequent checks if all activities concerning traditional medicine are in compliance with the laws

and current regulations adopted by the Government and the Ministry of Health in order to enhance the quality of traditional medicine services provided to the population as well as to ensure the safety of traditional medicine methods applied to patients.

- The Ministry of Health should coordinate closely with the General Tax Office and General Customs Office in order to ensure that the importation and exportation of pharmaceutical materials and traditional medicines have suitable tax policies to protect local pharmaceutical products.

- The city and provincial people committees are responsible for the Traditional Medicine Association and Acupuncture Association's activities. Based on the actual circumstances at localities and cities, the provincial people's committees can directly arrange for financing and staffing of these associations. The Ministry of Health, in coordination with the Hanoi People's Committee and the Ministry of Culture and Information, are planning to renovate the Thang Long Temple of Traditional Medicine to preserve its historical value and the long history of the Vietnamese traditional medicine.

- The Ministry of Health, together with the Ministry of Labour, Invalid and Social Affairs and the Ministry of Finance, should compile policies to be submitted to the Government in order to encourage traditional medicine practitioners to divulge good formulas or valuable experience, especially experiences from ethnic minorities living in mountainous areas and to encourage and attract health workers to participate in studying the application of traditional medicine in curative health care and the combination of traditional medicine and modern medicine.

6.2 Intensify investment in the promotion and development of traditional medicine and pharmacy

Based on specific studies on the application of traditional medicine and the combination of traditional and modern medicine in health institutions, the Ministry of Health will identify the types of diseases and disorders that can be treated by either traditional medicine or modern medicine methods, identify the principal advantages of traditional medicine which can be expanded into projects and recommend the study of feasibility and investment priorities in each stage of a specific project to the Government. At the same time, it will adopt regulations on the

Annex 6

application of traditional medicine in curative health care of the people so that all health workers can thoroughly carry out their work.

The Ministry of Science, Technology and Environment should coordinate closely with the Ministry of Health in conducting scientific research on traditional medicine. Such research, which includes study of theories, practical applications, medicine conversions, new medicine, medicinal plants, etc. should be carried out at the same time. Results obtained from studies must be applied to curative health care of the people and production of traditional medicine.

The Ministry of Planning and Investment and the Ministry of Finance will design plans to finance these projects and programmes to modernize traditional medicine, based on the proposals made by the Ministry of Health. At present until 2005, investment is concentrated in the procurement of equipment, prsonnel training, studies on practical applications and on industrialization of traditional medicine production.

6.3 Carry out socialization of traditional medicine and pharmacy in community health care

The people's committees at different levels, together with other sectors for which the Health Sector play a key role, are responsible for health education, encouraging people to grow and utilize popular medicinal plants and to apply simple disease prevention methods without using medicine in the community. The cultivation of medicinal plants must be closely coordinated with the Society of Gardening (Vacvina), and the Society of Bonsai and carried out together with the movement on poverty elimination, family economy development, and restoration and improvement of the nature and environment. Health insurance should be promoted among the population and bring social equity in health care to the poor farmers.

The Ministry of Education and Training coordinates closely with the Ministry of Health to provide guidance on designing botanical gardens in secondary schools in which some common medicinal plants are introduced to the students to promote awareness about medicinal plants and to foster good attitudes towards their utilization and protection.

6.4 Develop the cultivation and growing of medicinal plants and animals used as medicine

The Government has two goals for traditional medicine: exporting and responding to the internal demands.

Annex 6

The Ministry of Agriculture and Rural Development, together with the Ministry of Health, designs specific plans to restore and grow medicinal plants and animals used as medicine, emphasizing adaptation and development of acclimatized medicinal plants and animals used as medicine, and at the same time plans to centralize the growing and processing of medicinal plants and animals of high economic values. On the basis of these plans, the Agricultural and Forestry Sectors should coordinate to guide the implementation of Programme 327 and effectively integrate the restoration of forests and the development of medicinal plants and animals used as medicine.

The plans to develop medicinal plants and animals used as medicine must satisfy the following criteria:

- For wild medicinal plants and animals used as medicine, the exploitation areas must be mapped for restoration and protection of natural resources.

- For medicinal plants and animals used as medicine which are rich and abundant, the protection and rational exploitation are considered to be principal measures.

- Design gardens for medicinal plant saplings and pedigree animals which are rare or of high economic value to minimize the risk of extinction. This kind of garden can be expanded in different areas.

- For medicinal plants and animals used as medicine which are grown in agricultural lands, plans to centralize cultivation must be designed to adapt to the location. As an initial step, it is necessary to support localities where people currently not only grow medicinal plants or animals used as medicine but have also mastered techniques and have gained experience that can be popularized in other areas.

  Medicinal plants grown in family gardens should be linked with the movement on poverty eradication and family economic development. Households should be encouraged to grow plants which can be:

  - both ornamental and medicinal
  - used both as vegetables and medicine
  - both fruit-bearing and medicinal

to provide them a cheap, effective and readily available medicine resource. This garden is called "green medicine for families". It provides family members with medicine when they are sick and it is also an important source of family income.

- The pharmaceutical sector of the Ministry of Health is responsible for planning the development of medicinal plants and animals used as medicine, standardization, production and processing, and providing professional guidance on the utilization of medicinal plants and animals used as medicine. The Agriculture-Forestry sector and other relevant sectors are responsible for such issues as investigation of climate, soil, mapping activities, cultivation techniques, etc.