Revised National Medicine Policy

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Foreword

National Medicine Policy (NMP) is an integrated part of National Health Policy whose strategy is based on the Primary Health Care to protect and promote health for all Lao people and minorities.

One of important components of Primary Health Care is the availability of good quality, efficacy and safety medicines with affordable price for supplying to health care services, and to provide information on the rational use of medicines, which is the same goal as the National Medicine Policy.

The overall objective of the NMP is to improve the health of people by preventing and treating diseases through medicine procurement and management system ensuring:

- equitable availability and affordability of essential medines, especially in the remote areas, the poorer segment of the population, with a focus on priority health problems
- quality, safety and efficacy of all medicines and their rational use in health care treatment; and to promote the use of traditional medicines widely.

Having seen its importance and necessity, with the request from Ministry of Health and the financial and technical support from the government and population of Sweden through the Swedish International Development Cooperation Agency (Sida), the government of the Lao PDR endorsed the first National Medicine Policy by the Decree of Prime Minister No 49/PM, of the 13th of March 1993.

Since then the National Medicine Policy has become as a torch to effectively direct the development of the pharmaceutical sector, a guide for health staff, medical students, managers and pharmaceutical providers to be used unanimously in the whole country.

Over 10 years of the implementation of the National Medicine Policy, many of its elements have been effectively achieved. These achievements need to be continuously implemented to be able to reach the set goal. Some new more elements should be included in the NMP.

The Fifth National Workshop organised 27/2-2/3/2001 in Vientiane City, has revised and agreed on the improvement of some elements of the NMP, according to the general development of health sector especially pharmaceutical sector to be appropriate to current situation of the socio-economic in the country as well as in this region.

There are still 13 elements in the revised NMP as in the previous version. Some existing elements were combined into one element with the same contents. The new elements have been included such as operational research, organisation, management, cooperation and monitoring of the implementation of the NMP and human resource development.

The revised NMP will be used as a tool and an important reference for the management of the macro-organisation of Ministry of Health. This policy has indicated the details of the development of pharmaceutical sector.

The NMP would be successfully implemented if there have had contributions of people and minorities from all over the country, as well as the responsibilities of each local governor and participation of related stakeholders, which are important factors for the achievements.

On behalf of the leaders of the Ministry of Health, I would like to congratulate all staff members who have spent all their mental, intellectual and physical efforts contributing to the improvement of the NMP. And once again, I would like to express my sincere thank to the Swedish International Development Cooperation Agency for financial and technical support. I do hope that this revised NMP will be useful for the actual implementation of each related party. The revised NMP may have had some contents which are not accurate and enough completed, therefore it would be appreciated if you could provide us any comments. All your comments and opinion are very important for the further improvement of the NMP for more comprehensiveness.

Vientiane, 13 August 2003
Minister of MoH

Dr. Ponmek Dalaloy

Lao Peoples Democratic Republic
Peace Independence Democracy Unity Prosperity

The Revised National Medicine Policy

Based on The Decree of Prime Minister number 020/PM, dated 19/03/1999, concerning the Organisation and Performance of the MOH.
Based on Comments on the NMP by the Ministers of Justice, number 36/JD, dated 12 August 2002
Based on The proposal from the Food and Drug Department

To be used as a referenced guide and directive document for the implementation of the management and quality control in the whole country, covering production, import-export, procurement, distribution, advertisement and the use of medicines and medicinal products including human resources for pharmaceuticals, international cooperation and scientific research. After the implementation of NMP since 1993, there is a need to revise the contents of NMP, to add more relevant issues and to be more specific and clear in each component of pharmaceuticals and medical devices.

I. Objectives of National Medicine Policy

TheNational Medicine Policy is an integrated part of the National Health Policy which aims at equity and safety in access to health care to all regardless of social status and gender.

1. The overall objective of the NMP

The overall objective of the NMP is to improve the health of the people of Lao PDR by preventing and treating diseases through medicine procurement and management system ensuring:

- Equitable availability and affordability of essential medicines, with a focus on the remote areas which is the poorer segment of the population and the priority health problems.
- Quality, safety and efficacy of all medicines which will be used rationally by health professionals and consumers.
- Promotion the use of traditional medicines nationwide

2. The specific aims of the National Medicine Policy

2.1. To ensure successful implementation of the National Medicine Policy through enactments of appropriate and updated legislation, regulations relating to pharmaceutical management.

2.2. To satisfy the health needs of the population through a careful selection of medicines based on the Essential Medicines Concept.

2.3. To provide safe and effective medicines of acceptable quality at a reasonable price to the public through promotion of generic pharmaceutical products.

2.4. To ensure that medicines allowed on the market are safe, effective and of acceptable quality through evaluation and registration of medicines and inspection and licensing of pharmaceutical establishments including the promotion of local production to reach step by step the Good Manufacturing Practice Standard.

2.5. To improve rational use of medicines through the adherence to ethical criteria for medicine advertising and promotion.

2.6. To procure and distribute medicines that are safe, effective and of acceptable quality, in the necessary quantity, at lowest possible cost, and to ensure that the quality of these medicines is maintained during transportation and storage during their shelf life and to minimize wastage.

2.7. To ensure that medicines are prescribed, dispensed and used rationally in order to maximize the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices.

2.8. To ensure sufficient funding for implementing the National Medicine Policy Programme, especially procurement and distribution of adequate quantities of essential medicines of acceptable quality at lowest possible price for the public sector and for managing and monitoring the quality and use of medicines in the whole country.

2.9. To develop and promote the safe and effective use of traditional medicines and other traditional practices in disease prevention and care and to encourage the integration of traditional medicines into the general health service system, where applicable.

2.10. To identify and to promote research activities, which will provide evidence based decisions for interventions for strengthening the implementation of the National Medicine Policy.

2.11. To improve the organization and management of the National Medicine Policy, and to evaluate regularly the impact of NMP programme using selected indicators.

2.12. To ensure the provision of effective pharmaceutical services in both the public and private sectors through training of adequate number of staff at each level of the health care system.

2.13. To be well informed on international developments, to utilize resources abroad and to establish new and continue existing international collaboration in order to improve the implementation of the National Medicine Policy.

II. The contents in details of the National Medicine Policy

1. Legislation and regulations on medicines and medicinal products

Aim: To ensure successful implementation of the National Medicine Policy through enactments of appropriate and updated legislation, regulations relating to pharmaceutical management.

1.1 To ensure that authorised medicinal products of adequate quality, safety and efficacy are circulated in the market in Lao PDR, the Ministry of Health will enact and enforce the "Law on Pharmaceutical and Medical Products of April 2000".

1.2 Additional regulations will be developed for all activities related to the implementation of Law on Pharmaceutical and Medicinal Products. These regulations will be reviewed and updated when required. These activities will be done in close consultation with other related agencies, including public and private sectors as well as international agencies.

1.3 Necessary resources will be rationally provided to the Food and Drug Department (FDD) enabling the FDD to appropriately enforce the legislation.

1.4 The FDD will cooperate closely with other law enforcement agencies in enforcing the legislation.

1.5 Enforcement of drug legislation and regulations will be monitored by using suitable indicators.

2. Medicine selection

Aim: To satisfy the health needs of the population through a careful selection of medicines based on the Essential Medicines Concept.

2.1 The selection of medicines for developing the National Medicine Policy will be based on:

- The prevailing disease pattern, incidence, existing Standard Treatment Guidelines and the WHO Essential Medicines Concept, the main criteria being:
    - Quality
    - Safety
    - Efficacy
    - Therapeutic advantage
    - Cost

- The selection of medicines will be carried out by the Committee appointed by the Ministry of Health in broad consultation with relevant experts from the various levels and from relevant institutions.

2.2 The selection of medicines is compiled in the National Essential Medicine List, which will be regularly revised and updated in conjunction with the development and revision of Standard Treatment Guidelines, at least every four years.

2.3 Only medicines registered by the Food and Drug Department of the Ministry of Health and medicines included in the National Essential Medicine List will be procured for the public sector (with special exception such as: medicines that medical doctors need to use in hospital)

2.4 The National Essential Medicine List will be disseminated to all health workers as well as all training institutions for health workers in the whole country and to the international organizations.

2.5 The National Essential Medicine List contains all medicines selected for public sector. The List will be categorized according to the level of use and availability of trained human resources into the following classifications:

-C=Medicines for use at Central level
-P=Medicines for use at Provincial level
-D=Medicines for use at District level
-HC=Medicines for use at Health Centre Level
-V=Medicines for use at Village level.

Supplementary list for each category will be produced if and when required.

3. Medicine Nomenclature (Medicine denomination)

Aim: To provide safe and effective medicines of acceptable quality at a reasonable price to the public through promotion of generic pharmaceutical products

3.1 Selection of medicines is by generic name only.

3.2 Medicines will be registered by their Generic name. Generic labelling is a requirement for registration of medicines

3.3 The Ministry of Health will promote prescription of medicines by Generic name.

3.4 The Ministry of Health will promote medicines being dispensed and labelled using Generic name and ensure adequate packaging and labelling.

3.5 For inventory and planning all health facilities must use the generic name of medicines.

3.6 Generic name will be used in production, supply and procurement in public sector

3.7 The Ministry of Health will promote generic substitution.

4. Quality Assurance of medicines including medicine registration, licensing for sale and medicine monitoring

"Quality assurance" is a wide-ranging concept covering all matters that directly or indirectly influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality assurance therefore incorporates legislation, registration, inspection, licensing, pre- and post marketing surveillance, elements of drug procurement, distribution and storage, GMP and other factors.

Aim: To ensure that medicines allowed on the market are safe, effective and of acceptable quality through evaluation and registration of medicines and inspection and licensing of pharmaceutical establishments including the promotion of local production to reach step by step the Good Manufacturing Practice Standard.

4.1 All medicines to be placed on the market in Lao PDR (either manufactured locally or imported) will be evaluated and registered by the Food and Drug Department (FDD) of the Ministry of Health. The requirements for the evaluation will be based on the WHO recommendations on registration of generic medicines[1].

4.2 Registration of medicines included in the Essential Medicines List will be given preference.

4.3 Medicines already registered in Lao PDR, proved to be unsafe, ineffective or withdrawn from the market in some countries, will be withdrawn from the market.

4.4 The Ministry of Health will apply the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce for registration of imported products.

4.5 The Ministry of Health will make active use of existing networks between drug regulatory authorities such as "WHODRA" and "Electronic system for Drug Information Exchange in the Western Pacific Region" to obtain advice and information on drug regulatory decisions made in other countries.

[1] "Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products. A Manual for a Drug Regulatory Authority, WHO/DMP/RGS/98.5".

4.6 Food and Drug Department (FDD) of the Ministry of Health will license all pharmaceutical establishments, before they are allowed to operate. Licenses may be granted upon compliance with requirements contained in relevant regulations confirmed by inspection carried out by FDD, Provincial Food and Drug Unit, Municipality and Special Zone, which will conduct regular inspections of all establishments dealing with medicines.

4.7 In order to assure adequate product quality, the Ministry of Health will apply the current regulation and Guidelines on Good Manufacturing Practices to local manufacturers of medicines.

4.8 Quality of medicines on the market will be continuously monitored:

- by the Food and Drug Unit through inspection of the distribution chain (wholesalers, manufacturers, warehouses and pharmacies at all levels, public and private sectors).
- by the Food and Drug Quality Control Center (FDQCC) through sampling and control according to an annual plan for post-marketing quality surveillance

4.9 FDD will maintain a computerized system for medicine registration and licensing of all pharmaceutical activities.

4.10 The Ministry of Health will combat counterfeit medicines using tools developed within the country and by the WHO[2] and in cooperation with the Police, Customs, other relevant agency bodies and regulatory authorities in other countries.

4.11 Necessary funding will be made available to FDQCC at each level for operational costs and for the quality control and analysis of medicines.

4.12 The drug procurement system for the public sector will include mechanism for selection and monitoring of suppliers in relation to quality, performance and reliability.

4.13 Fees for licensing, registration of medicines and quality control will be charged by FDD and FDQCC. The income from fees will be deposited to national treasure accordingly to the current regulation.

4.14 FDD will regularly issue the Food and Drug Bulletin, which will contain information on newly registered medicines, results of inspections, results of quality control testing conducted by FDQCC, information on correct use of medicines and other regulatory issues.

4.15 The Ministry of Health will only allow the conduct of clinical trials after obtaining approval from National Medicine Committee assigned by the

Ministry of Health. The approval will be based on recommendations of the current WHO or Region guidelines on clinical trials[3]

5. Medicine advertising and promotion

Aim: To improve rational use of medicines through the adherence to ethical criteria for medicine advertising and promotion.

5.1 The Ministry of Health will ensure that promotion of medicines and related products is based on scientifically established evidence and that advertisements to the public are educational and restricted to over-the-counter (OTC) medicines only.

5.2 The Ministry of Health will approve advertisements and promotional material and activities based on the current legislation and regulations in the country and WHO Criteria for Medical Drug Promotion[4].

5.3 Advertisements and promotional materials will be evaluated by FDD during the process of medicine registration. Medical claims other than those documented in the approved registration of a medicine will not be allowed in advertisements and promotional materials.

5.4 The Food and Drug Units will continuously monitor and control advertising and promotional activities.

6. Medicine supply: procurement, distribution and storage

Aim: To procure and distribute medicines that are safe, effective and of acceptable quality, in the necessary quantity, at lowest possible cost, when needed and to ensure that the quality of these medicines is maintained during transportation and storage during their shelf life and to minimize wastage.

6.1 Procurement of medicines from suppliers/manufacturers to the public sector will be centralized. Estimation of medicine requirements is a decentralized function carried out on village, district and province levels. Medicine requirements will be submitted from the provinces to Medical Product Supply Centre (MPSC) for procurement. MPSC will carry out a tender based on estimates from the whole country. MPSC will inform the provinces the approved supplier and price for each product. Provinces will buy directly from the approved suppliers at the negotiated prices.

[3] Guidelines for good clinical practice (GCP) for trials on pharmaceutical products, WHO Technical Report Series, No. 850, 1995, Annex 3.
[4] WHO Criteria for Medicinal Drug Promotion, WHO Technical Report Series, No. 722, 1985

6.2 A guideline for procurement of pharmaceuticals products (international tender) will be developed.

6.3 Procurement of medicines for the public sector will be carried out by tenders. Suppliers and manufacturers that wish to participate in the tender will have to pre-qualify through fulfilment of requirements laid down by the Ministry of Health. Local manufactures will be given preference. Local procurement using funds generated through the revolving drug funds will be restricted to products and suppliers selected in the tender

6.4 The procurement and distribution will be based on the manual "A Procedure Manual for the Procurement and Distribution of Essential Medicines and Basic Medical Supplies in the Lao People's Democratic Republic" and the manual "Medicines and Medical Supplies Management".

6.5 In addition to procurement of medicines from the National Budget and donor funds, the revolving fund mechanism will be used at all levels to replenish the medicine supply system.
Recovery of the costs of medicines and other consumable medical supplies from the patients is included in the Government Policy. Procedures for cost recovery as laid down in the Ministry of Health Guidelines for Revolving Funds will be followed.

6.6 Only registered products and medicines included in the Lao Essential Medicine List will be procured for the public sector.

6.7 Medicines will be procured by Generic name and preference will be given to local manufacturers, state import/export companies, state/private joint ventures and international organizations.

6.8 The Government may apply tax exemption/reduction on import of essential medicines that cannot be manufactured locally and on imported raw materials for pharmaceutical manufacture.

6.9 The Government will endeavour to provide sufficient funding for procurement and distribution of essential medicines to the public sector.

6.10 For the public sector the Government will endeavour to provide adequate storage facilities, basic equipments and sufficient number of staff for medicine supply management at all levels of the health care system.

6.11 The Ministry of Health will develop guidelines and regulations on medicine supply management for both public and private sectors and provide training of staff at all levels and sectors to improve the services provided. Emphasis will be given to focused and intensified training on Good Pharmacy Practices (GPP).

6.12 The Ministry of Health will continuously monitor and supervise the medicine supply system through inspections conducted by the Food and Drug Units.

6.13 Medicines provided through donations need prior approval from the Ministry of Health. Donated medicines need to be included in the Lao Essential Medicine List and be registered in the country of origin. Upon arrival in the country donated medicines should have at least 18 months remaining shelf life. The Government should endorse the "*Interagency Guidelines for Drug Donations, WHO 1999"* which will be distributed to partner organizations and will develop national guidelines for medicine donations.

6.14 The poorer part of the population is exempted from paying for essential medicines prescribed for them in public sector health facilities.

6.15 Appropriate measures for disposal of unwanted medicines will carried out in accordance with WHO recommendations[5].

6.16 To counteract any negative implications of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement on availability and affordability of essential medicines, the government will, when required, request to the National Assembly to revise relevant legislation, allowing parallel imports, compulsory licensing and "early works" (early submission of application for registration of patented drugs by generic manufacturers) under the conditions specified in the TRIPS Agreement.

7. Rational Use of Medicines

Aim: To ensure that medicines are prescribed, dispensed and used rationally in order to maximize the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices.

7.1 Education and training

7.1.1 The curricula of the courses at the Faculty of Medical Sciences and curricula of other training courses for health workers at all levels involved in diagnosis, prescribing or dispensing will be revised and updated as required to include the Essential Medicine Concept, the National Medicine Policy, law on pharmaceutical and medicinal products, and rational medicine use. The Standard Treatment Guidelines will be actively used in the training.

7.1.2 In collaboration with all health programmes involved, a comprehensive programme for continuing medical training of health workers at all levels will be developed and implemented for those involved in diagnosis, prescribing and dispensing of medicines.

7.1.3 Suitable training materials on rational medicine use will be developed in consultation with health workers at all levels for use both in initial and continuing education activities.

[5] Interagency Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, WHO March 1999.

7.1.4 Information on correct use of medicines for the general public will be further developed. Emphasis will be on proper handling of medicines, compliance with medicine treatment, appropriate self-medication, safe use of traditional medicines and safe disposal of medicines. Various media including radio and TV will be used for public education of rational medicine use.

7.2 Medicine Information

7.2.1 Independent and reliable, scientifically based literature aimed at improving diagnosis, prescribing and dispensing towards rational use of medicines, will be developed and disseminated both to public and private sector.

7.2.2 Official documents of the Ministry of Health such as the Standard Treatment Guidelines, the National Essential Medicine List will be regularly updated and disseminated to health workers at all levels in public and private sector and training institutions.

7.2.3 FDD will regularly issue the Food and Drug Bulletin. The Bulletin will contain information on newly registered medicines, results of inspections, results of quality control testing conducted by FDQCC, rational medicine use and other regulatory issues and be disseminated to health workers at all levels in the country.

7.2.4 The Ministry of Health will endeavour to continuously collect accurate data on medicine utilization, which will be evaluated and disseminated to all health workers. The data will be used to better manage the medicine supply system and to detect and correct unwanted practices before such development.

7.3 Prescribing

7.3.1 Additional Standard Treatment Guidelines will be developed and the existing guideline will be regularly updated and used as models for medicine prescribing. Adherence to the Standard Treatment Guidelines will be monitored using performance indicators with interactive feedback to the prescribers as well as through evaluation of medicine utilization data.

7.3.2 The Ministry of Health will promote prescription of medicines by Generic name.

7.3.3 Patient counselling on correct use of medicines is a part of the prescribing process and will be part of education and training of prescribers.

7.4 Dispensing

7.4.1 The Ministry of Health promote medicines being dispensed and labelled using Generic name and ensure adequate packaging and labelling. The minimum information which should appear on the label of dispensed drugs is:

- Name of patient
- Date of dispensing and number of days to be used
- Generic name

- Strength of the active ingredient
- Quantity dispensed
- Complete dose per time and per day in written and /or graphic form

7.4.2 Patient counselling on correct use of medicines is a part of the dispensing process and will be part of education and training of dispensers.

7.4.3 Good Pharmacy Practices will be promoted in the public and private sectors and monitored using suitable performance indicators

7.5 Medicine and Therapeutic Committees

7.5.1 The Ministry of Health continues to promote the establishment of Drug and Therapeutic Committees to encourage health workers to participate in collaborative management of medicines in their institutions to ensure rational and cost effective use of medicines.

7.5.2 Local Medicine and Therapeutic Committees at each level is responsible for estimation of medicine requirements of the health institution, selection of medicines to be used from the National Essential Medicine List and for promoting and overseeing that medicines are used rationally including training on rational medicine use.

7.6 Advertising and promotion will be controlled by the Ministry of Health to ensure correct use of medicines.

7.7 A National Poison Centre should be established which will be responsible for monitoring the adverse medicine reaction caused by the use of prescribed medicines and by self-medication and others.

7.8 The Ministry of Health continue the development of new and updating of existing Standard Treatment Guidelines in broad consultation when new medicine development and situation calls for it followed by updating the National Essential Medicine List.

7.9 The development and updating of Standard Treatment Guidelines will be based on scientifically sound principles and cost effectiveness.

7.10 The Standard Treatment Guidelines and the National Essential Medicine List will be widely disseminated in the country and form part of the curriculum for medical, pharmacy, dental, and nurse students and others.

7.11 A National Medicine Formulary will be continued to develop based on the Standards Treatment Guidelines and the National Essential Medicine List.

7.12 The current Health Insurance Scheme for the public sector will be expanded to reimburse registered essential medicines included in the National Essential Medicine List prescribed according to the Standard Treatment Guidelines.

8. Economic strategies for medicines

Aim: To ensure sustainability through sufficient funding for implementing the National Medicine Policy Programme, especially procurement and distribution of adequate quantities of essential medicines of acceptable quality at lowest possible price for the public sector and for managing and monitoring the quality and use of medicines in the country.

- **Public financing through general revenues**

8.1 To cooperate with the related Ministry to provide necessary and rational funds for procurement and distribution of essential medicines to the public sector through the National Budget based on careful estimation of actual need derived from demand and morbidity.

8.2 Provinces and Districts will allocate funds for procurement and distribution of essential medicines.

- **Cost recovery**

8.3 As the Central, Provincial and District budgets are limited, cost recover mechanisms will be used to generate additional funds for purchase of essential medicines. Income generated through fees on essential medicines will be used in a medicine revolving fund for replenishing the medicine supply system with additional medicines.

8.4 The Ministry of Health support and promote community medicine schemes such as revolving drug funds conducted at all level especially at community level or village by different resources (villagers, local and international donors).

8.5 For evaluation and registration of medicinal products Food and Drug Department/Unit will charge a fee as well as for licensing of pharmaceutical establishments (manufacturers, importers, exporters, wholesalers and pharmacies), and also fees for analysis of medicinal products during the registration process, post marketing surveillance and on request from manufacturer, other institutions etc. The fees will be retained by FDD/Unit and used for operational costs and further development.

- **Donor financing**

8.6 When appropriate financial support from donors for medicine procurement will be used to supplement government funding. Government procedures for utilization and accounting will be followed.

8.7 Development loans will be used when feasible especially for further development of infrastructure and human resources.

- **Incentives for import and local manufacture**

8.8 The Government may apply tax exemption/reduction on imported raw materials for essential medicine manufacture, and on import of essential medicines that cannot be manufactured locally

8.9 Preference will be given to locally manufactured pharmaceutical products in Government tenders and procurement.

- **Additional strategies to be used to reduce the cost of medicine use are:**

8.10 The Ministry of Health and Provincial Health Departments will implement central procurement of generic medicines from qualified suppliers as well as generic prescribing, dispensing and generic substitution.

8.11 Medicine selection of generic medicines and essential medicines based on therapeutic value and cost of therapy.

8.12 The Government will control the price of medicines through controlling the producer prices and the margins throughout the supply chain. Price information to the public and prescribers/dispensers will be developed.

9. Traditional medicines

Aim: To develop and promote the safe and effective use of traditional medicines and other traditional practices in disease prevention and care.
To encourage the integration of traditional medicines into the general health service system.

9.1 The Ministry of Health develop and promote traditional medicines as a part of the national heritage and as an integral part of the health care system.

9.2 The Ministry of Health requires the related organisation to revise the traditional medicine policy, appropriate legislation and registration of traditional medicinal products in order to ensure safe and effective use of traditional medicines of acceptable quality based on WHO recommendations.[6]

[6] Guidelines for the assessment of herbal medicines, programme on traditional medicine, Geneva, World Health Organization, document, 1991 (WHO/TRM/91.4)
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)
Guidelines for the appropriate use of herbal medicines, World Health Organization, Regional Office for the Western Pacific, Manila, 1998 (ISBN92 9061 124 3)

9.3 To develop and promote the rational use of traditional medicines, medicinal plants, the Ministry of Health will be carried out some important activities through various ways:

- Information on the practice of traditional medicines and traditional medicine formula will be systematically and continuously collected to document and conserve the heritage, and choose the best formula to serve society.
- Establishment of standards related to quality and safety of pharmaceutical bio diversity and traditional medicines.
- Education in proper use of traditional medicine and the integration of the use between modern and traditional medicines, for general practitioners, other health workers and the general public.
- Develop the list of essential medicinal plants to introduce the safe use among population to decrease the disease symptoms or common diseases in communities.
- To control, inspect and promote the business activities related to medicinal plants, animals and traditional medicines following national and international law and regulations

9.4 Conservation of medicinal plants, animal and traditional medicines by issuing a decree governing control and prevention of national natural, as well as promoting the establishment of a Medicinal Plant Garden.

9.5 The Ministry of health will actively collaborate with Traditional Healers organizations, Buddhist, forestry and agricultural organizations in the country and abroad to further develop and promote the practice of traditional medicines and to preserve medicinal plants from extinction.

9.6 Initiate the development of traditional medicine association or the association of national traditional medicines.

9.7 To promote scientific research on medicinal plants and traditional medicines aiming at development of new medicines to serve society and become a national revenue, in cooperation with different agencies in country and internationally.

9.8 Cooperate with neighbouring countries and international organisations to obtain technical knowledge and resources for personnel development and necessary fundamental technique for traditional medicine development at all levels.

10. Operational Research

Aim: To identify and to promote research activities which will provide evidence based decisions for interventions and strengthening the implementation of the National Medicine Policy.

10.1 Operational research will continue to be used in order to identify practical and cost effective interventions to solve problems faced during implementation of the National Medicine Policy, to support evidence based decision making and to effectively implement the National Medicine Policy.

10.2 To ensure that research results are turned into practice, to continue to develop the research in close collaboration with decision makers in the Ministry of Health, the Food and Drug Department, the National Drug Policy Programme and managers from other disease control programmes.

10.3 Operational research will be used for developing suitable performance indicators as well as testing and validation of such before they are being used. Performance indicators will be developed for all elements of the National Medicine Policy.

10.4 The operational research will cover the impact of the National Medicine Policy on health services and care, problems related to medicine use by patients and the role and use of traditional medicines.

10.5 Health systems research will be used to identify better and effective means and methods for all elements of the National Medicine Policy.

11. Organization, Management and Overall Co-ordination and Monitoring of the National Medicine Policy and its implementation process.

Aim: To improve the organization and management of the National Medicine Policy and to initiate corrective measures through regular evaluation of the implementation and the impact of NMP programme using selected indicators.

11.1 The Organization and Management of the National Medicine Policy will be strengthened through reviewing the current organization, make changes if required, defining responsibilities for programme areas and activities, review and improve the reporting system.

11.2 A masterplan for the implementation of the National Medicine Policy will be developed in collaboration with the relevant stakeholders.

11.3 Management tools for planning, implementation, follow-up and evaluation of all activities of the National Medicine Policy will be developed and staff will be trained in their use.

11.4 A system for financial management including planning, budgeting, accounting and cash management will be developed and staff will be trained in its use.

11.5 Technical and financial support from external organizations will be planned and executed in a coordinated manner ensuring best use of resources avoiding duplication.

11.6 Evaluation of the impact of the implementation of the National Medicine Policy will be carried out regularly by the use of suitable indicators. Not only the policy's progress towards the achievement of the objectives but also the implementation process will be evaluated.

11.7 Availability, quality and rational use of medicines are among the main factors to be monitored.

11.8 Based on evaluation and monitoring of the implementation of the National Medicine Policy as well as results of operational research studies, corrective measures will be put in place when required.

11.9 The Ministry of Health will conduct regular meetings with all concerned stakeholders and donors/partners to review the implementation and impact of the National Medicine Policy and to plan for the future.

12. Human resources development

Aim: To ensure the provision of effective pharmaceutical services in both the public and private sectors through training of adequate number of staff at each level of the health care system.

12.1 The roles, functions and job descriptions for each position should be clearly defined for improving the organization, and staffing review within department, and divisions. A plan for development of adequate human resources will be designed, including gender equality, enabling successful implementation of the NMP.

12.2 The Ministry of Health will endeavour to implement the plan for development of adequate human resources for food and drug staff by education of staff locally and abroad.

12.3 In cooperation with relevant organizations, curriculum for medical, pharmacy, dental and nursing students will be revised and updated with emphasis on elements of the NMP, especially rational use of medicines and the essential medicine concept. The Standard Treatment Guidelines and the National Essential Medicine List will be actively used in training of health workers when appropriate.

12.4 In addition to education and training in the pharmaceutical areas, emphasis will be on management, including administrative and financial aspects.

12.5 A programme for continuing education for all categories of health workers will be developed ensuring sufficient number of qualified staff for implementation of the National Medicine Policy

12.6 Training of drug sellers in good pharmacy practice, dispensing practice, and informing customers on the rational use of medicines will be conducted.

12.7 Career structure, bonding, remuneration will be reviewed to ensure that trained staff remains in the public sector, where they are most needed.

13. International Technical Cooperation

Aim: To be well informed on international development, to utilize resources abroad and to establish new and continue existing international collaboration in order to improve the implementation of the National Medicine Policy.

13.1 The Ministry of Health will actively increase the international technical cooperation whenever feasible to be informed about new development and to take advantages of such into the development.

13.2 As a member of the Association of South-East Asian Nations (ASEAN), Lao PDR will participate in the ASEAN Working Group on Technical Cooperation in Pharmaceuticals and in the Product Working Group for Pharmaceuticals of the ASEAN Consultative Committee for Standards and Quality.

13.3 The Ministry of Health will make active use of existing networks between drug regulatory authorities such as "WHODRA" and "Electronic system for Drug Information Exchange in the Western Pacific Region".

13.4 Technical support from WHO Collaborating Centers in the Region will be sought when relevant.

13.5 The Ministry of Health will continue to use and apply WHO guidelines on national medicine policies, effective medicine regulation, quality assurance, rational medicine use, and financing mechanisms where appropriate.

13.6 The Ministry of Health will continue its collaboration with international organizations, non-governmental organizations and governments. Technical and financial support from external organizations based on the masterplan for the NMP implementation, will be planned and executed in a coordinated manner ensuring best use of resources and avoiding duplication. External organizations will take part in annual reviews of the implementation of the National Medicine Policy.

13.7 The Ministry of Health will conduct regular meetings with partners to review the implementation and impact of the National Medicine Policy as well as plan and coordinate further external support.