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NATIONAL POLICY ON TRADITIONAL MEDICINES 2007



MINISTRY OF HEALTH R.I.



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**NATIONAL
POLICY ON TRADITIONAL MEDICINES
2007**

MINISTRY OF HEALTH R.I.

FOREWORD
**DIRECTOR GENERAL OF PHARMACEUTICAL
AND MEDICAL APPARATUS DEVELOPMENT**

Praise to Almighty God giving us His mercy and guidance in accomplishing National Traditional Medicines Policy (*KOTRANAS*).

Use of traditional medicines in Indonesia has been part of national culture since centuries ago. However, the efficacy and safety is not supported by comprehensive studies. Considering matter and realizing that Indonesia as the mega-center of medicinal plants in the world, it is necessary to establish national policy the stakeholders can rely on.

The establishment of National Policy on Traditional Medicines is expected to guide, direct and promote the development of quality, safe, scientifically-tested traditional medicines and to anticipate strategic changes and challenges, internal or external, in line with national health system. This represents the vision Ministry of Health committed to creating “Independent Citizens for Healthy Living” and its mission “Creating Healthy People”

The publication of this book (KOTRANAS) is aimed at disseminating information to health service providers, both at central, provincial and regency/city level, communities and industries and stakeholders.

May God the Almighty always give His direction and power to all of us in the development of health sector by providing quality health services to the communities in the pursuit of highest health standards and to protect and fulfill human rights.

Jakarta, April 2007

Director General of Pharmaceutical and Medical

Apparatus Development



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ACKNOWLEDGEMENT
MINISTER OF HEALTH OF REPUBLIC OF INDONESIA

Health services represent one of human rights all citizens are entitled to accommodate their medical requirements regardless their economic status.

The challenges and issues on health development are becoming more complicated, complex and unpredictable. Moreover, health development cannot be optimized if focused only on health sector and only by the Minister of Health. Therefore, the goals and objectives of health development can be realized if all government agencies are actively participating, including private enterprises and other national resources.

In promoting health services, the availability of medicines in all types, adequate quantity, effectiveness guaranteed, safe, effective and good quality at affordable price and accessible is the goal and objective to be achieved. In the pursuit of the objective, it is necessary to resolve issues related to sustainability of financing, realizable health and supply system and established standard quality.

Subject to Law No.23/1992 on Health, it is clearly defined that traditional medicines refer to of herbal, animal, mineral and galenics or mixtures materials or ingredients inherited from one to another generation for medication purposes.

Traditional medicines have been widely accepted in low-income to medium-income countries. In some developing countries, traditional medicines have been utilized in health services mainly first-level health services. Meanwhile, the use of traditional medicines has become more popular.

The use of traditional medicines in Indonesia is part of national culture and communities have been using same since centuries ago. In general, however, the efficacy and safety is not fully supported by adequate research. On this account, Indonesia as the mega-center of medicines, it is necessary to establish national policy the stakeholders can rely on.

National Policy on Traditional Medicines hereinafter referred to as KOTRANAS is an official document containing the statements of all parties setting national goals and objectives in traditional medicines including the priority, strategy and roles of parties in applying the fundamental components to achieve the goals of national development in health sector.

This document (KOTRANAS) is expected to serve as guideline, direction and standards in developing and promoting quality, safe, effective and scientifically-tested traditional medicines and in anticipating various strategic changes and challenges, internal and external in harmony with National Health System.

KOTRANAS is established through active role and participation of authorities at central and local level, cross-sector, non-governmental organization, industries, professional organization and experts.

On this occasion, I, the Minister of Health, highly appreciate and thank to all parties for the attention, active role, support, ideas and contribution in completing this document.

May Prosperity and Blessings of Allah Subhanahu Wa Ta'ala, the Almighty God, be with us to "Promoting Healthy Citizens" in creating "Independent Citizen for Healthy Living".

Jakarta, May 2007

The seal of the Indonesian Ministry of Health, featuring a Garuda bird in the center, surrounded by the text "MENTERI KESEHATAN" at the top and "REPUBLIK INDONESIA" at the bottom, with two stars on either side.
MINISTER OF HEALTH

Dr.dr. SITI FADILAH SUPARI, Sp JP(K)

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**DECREE OF MINISTER OF HEALTH
REPUBLIC OF INDONESIA
NUMBER 381/MENKES/SK/III/2007**

**REGARDING
POLICY FOR NATIONAL TRADITIONAL MEDICINES
MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA**

- Considering:
- a. whereas, the development and growth of quality, safe, effective, scientifically-tested traditional medicines and within the framework of anticipating various changes and strategic challenges, internal and external, in line with national health system, it is considered necessary to establish policy for national traditional medicines;
 - b. whereas, taking into full consideration letter a and b, it is considered necessary to establish policy for national traditional medicines by the issuance of Ministerial Decree;

- Taking into view:
1. Law on Ethical Medicines (State Gazette Number 419 of 1949);
 2. Law Number 23 of 1992 on Health (Supplement Number 3495 to State Gazette Number 100 of 1992);
 3. Law Number 5 of 1997 on Psychotropic (Supplement Number 3671 to State Gazette Number 10 of 1997);
 4. Law Number 22 of 1997 on Narcotics (Supplement Number 3698 to State Gazette Number 67 of 1997);
 5. Law Number 32 of 2004 on Local Government (Supplement Number 4437 to State Gazette Number 125 of 2004) as amended by Law Number 8 of 2005 on Enactment of Law in lieu of Law Number 3 of 2005 on Amendment to Law Number 32 of 2004 on Local Government (Supplement Number 4548 to State Gazette Number 108 of 2005);
 6. Government Regulation Number 72 of 1998 on Security of Pharmaceutical logistics and Medical devices (State Gazette Number 138 of 1998);
 7. Government Regulation Number 25 of 2000 on Authorities of Central and Provincial Government as Autonomous Region (Supplement Number 3952 to State Gazette Number 54 of 2000);
 8. Decree of Minister of Health Number 131/Menkes/SK/II/2004 on National Health System;

9. Decree of Minister of Health Number 1575/Menkes/Per/XI/2005 on Organization and Task Management of Ministry of Health;

HAS DECIDED

To stipulate:

- First : DECREE OF MINISTER OF HEALTH ON POLICY FOR NATIONAL TRADITIONAL MEDICINES
- Second : Policy on National Traditional Medicines as referred to in first point shall as set forth in Appendix hereto.
- Third : Policy on National Traditional Medicines as referred to in second point shall be fully considered as the primary guideline to all stakeholders in the development and growth of traditional medicines industry being integral part of national economic growth.
- Fourth : This decree shall come into full effect and force on the date of stipulation.

Place stipulated: Jakarta

Date stipulated : March 27, 2007

MINISTER OF HEALTH



Siti Fadilah Supari
SITI FADILAH SUPARI, Sp JP(K)

Appendix

Decree of Minister of Health

Number : 381/Menkes/SK/III/2007

Date : March 27, 2007

POLICY ON NATIONAL TRADITIONAL MEDICINES

CHAPTER I

INTRODUCTION

A. BACKGROUND

The primary objective of health development is to realize Healthy Indonesia 2010 by developing awareness, motivation and life skill and through the quality, fair and equal provision of medical services.

As the underlying ground, direction and reference to the health development for all medical practitioners at central, local, community and industrial level, including other relevant parties, there has been established National Health System (SKN) by the issuance of Decree of Minister of Health No.131/Menkes/SK/II/2004.

In one of SKN subsystems, it is defined that the development and improvement of traditional medicines is to produce quality, safe, effective, scientifically-tested and widely-used medicines, either for self-medication by community members or formal health services.

Subject to Law No.23 of the Year 1992 on Health, it is defined that traditional medicines mean substance or mixture of plant, animal, mineral, galenic or mixed preparations or ingredients applied empirically for medication by experience.

Traditional medicines have been widely recognized in low to medium to medium income countries. In some developing countries, traditional medicines have been widely used for health services particularly at primary health care. On the other side, the use of traditional medicines in many developed countries has been popularly growing.

The use of traditional medicines in Indonesia is part of national cultivation and has begun from centuries ago, however, the effectiveness and safety has not yet been supported by comprehensive research. Taking into account this fact and achieving that Indonesia the mega-center of herbal medicines in the world, it is regarded necessary to establish policy for national traditional medicines enable as reference for all parties involved.

Policy on National Traditional Medicines hereinafter referred to as KOTRANAS is an official document setting forth the commitment of all parties in establishing the national objectives, goals, priorities, strategies and roles of related parties in achieving the essential components of the policy for national development particularly in health sector.

B. OBJECTIVES

The objectives of KOTRANAS include:

1. Promote the sustainable use of natural resources and traditional preparations as traditional medicines in effort of improving health services.
2. Ensuring cross-sectoral management of natural potentials to achieve high competitiveness as a economic source of community and sustainable income of the nation.
3. The availability of quality, effective and safe traditional medicines, scientifically-tested and widely used for self-medication and formal health services.
4. To set traditional medicines as superior commodity providing various benefits to improve community economic growth, creating employment opportunity and poverty reduction.

C. SCOPE

The scope of KOTRANAS includes development of traditional medicines to promote health and economic development in gaining quality human resources.

Traditional medicines in KOTRANAS include preparations or compounds of herbal, animal, mineral and marine biota or galenical preparation which empirically utilized and has passed pre-clinic/clinical tested such as **standardized herbal and phytopharmaca**, to facilitate the development of traditional medicines for its utilization in formal health services and explore of Indonesian natural resources.

KOTRANAS means a comprehensive policy on traditional medicines from upstream to downstream, including cultivation and conservation of medicinal resource, safety and efficacy of traditional medicines, quality, accessibility, rational use, supervision, research and development, industrialization and commercialization, documentation, database, development of human resource as well as monitoring and evaluation.

CHAPTER II

TRADITIONAL MEDICINES AS CULTURAL INHERITANCE

Natural resources of chemicals substance and traditional medicines preparations are national assets to be continuously explored, examined, developed and optimized of their benefits. As a nation possessing high bio-diversity and herbal natural resources represent assets with comparative value and the superior asset in the use and development for competitive commodity.

Indonesia possesses about 400 ethnics (ethnics and sub-ethnics). Each ethnic and sub-ethnic has wide knowledge inherited from generation to generation, traditional knowledge of medicines and medications. The evidence of use of traditional medicines in Indonesia from centuries ago are represented in the relief of Prambanan and Borobudur temple, written in lontar leaf, and the inheritance and cultivation in Kingdom Palaces to this date.

For Javanese and Madurese communities, traditional medicines have been widely known as “**jamu**” (herbal medicines) either in sliced forms or servable powder. Rural communities have long time ago consumed temulawak (*Curcuma xanthornizha*) to maintain their physical fitness. Written information on herbal medicines kept in Surakarta Palace Library are “Serat Kawruh” and “Serat Centhini”. Serat Kawruh presents systematic information on herbal medicines, which contain 1.734 preparations made of natural elements and which use method is furnished by spells.

Sundanese ethnic is also rich of local courtesy. In (Dragon village) in Tasikmalaya regency, 113 types of medicinal plants have been used by the local communities and in Subang Regency, there are 75 plants used for medicines.

The results of survey performed by Medica Biota Expedition Team in 1998 in Bukit Tigapuluh National Park and Biosphere Natural Conservation Bukit Duabelas situated in Riau and Jambi Province (Sumatera), there were identified 45 preparations with 195 species of medicinal plants used by Traditional Malay ethnics, 58 ingredients with 115 species used by Talang Mamak ethnic and 72 preparations with 116 species used by Anak Dalam ethnic.

Kalimantan (Borneo) as tropical rain region possesses at least about 4.000 plants for inventing new medicines. Indigenous residents in Kalimantan have been familiar to natural extracts (*Eurycome longifolia*) used to enhance the men's vitality. Another plant is also recognized as marine bidara (*Strychnos ignatii*) which root skin water serves as tonic and against exhaustion.

The native residents in Bali have been very familiar to “*Lengis Arak Nyuh*”, versatile oil generated from refinery of various spices consisting of remaining flavors and coconut slices smoked above the kitchen stove for 4-5 months.

The communities living around Mount Rinjani National Park – NTB – use 40 medicinal plants for their medication.

In 1977, Research Team in Southeast Sulawesi discovered 449 medicinal plants and tens of herbal ingredients used as medicines by local inhabitants. Among Bugis-Makassar ethnics, it is known as medication and disease protection by the predecessors as written in *lontaraq pabbura* manuscript. Several types of plants known from generation to generation include “sanrego wood” (*Lunasia amara Blanco*), “paliasa leaf” (*Kleinhovia hospita Linn*) and “santigi” (*Phepis acidula*).

The communities in Maluku (moluccas) have been using nutmegs either in its fruit, leaves or twigs for rheumatic, headache and to strengthen men's sexual vitality.

There are 216 types of medicinal plants used by South Maluku residents. In Papua, the residents have used thousands of medicinal plants for healthcare such as Kebyar grass to improve female fertility, “akwai” (*Drymis Anthon*) for men’s sexual vitality and “watu” (*Piper methysticom*) as tranquilizer.

The use and development of traditional medicines in such areas has been traditionally inherited by experience/empirical facts later developed through scientific research made through pre-clinic and clinic test. Traditional medicines are based on “inheritance” and empirical approach known as “**jamu**” (herbal medicines), meanwhile those generated from scientific approach through pre-clinical test, defined as **standardized herbal** For those which have passed clinical test defined as **phytopharmaca**.

Traditional medicines initially made by traditional healers for their patients/at particular areas, then these have developed into home industry and since the middle of 20th century has been massively produced by small-scale traditional medicines industry (IKOT) or middle-scale industry traditional medicines (IOT) in line with improvement of manufacturing technology.

The development of manufacturing technology and the proven efficacy of traditional medicines have been supported by scientific research conducted by universities/colleges and other research agencies.

CHAPTER III

ANALYSIS ON SITUATION AND TRENDS

A. DEVELOPMENT

By the last two decades, the world's attention on medicines made of natural ingredients (traditional medicines) has shown progress, both in developing and developed countries. World Health Organization (WHO) said that 65% of residents in developed countries have used traditional medicines which include the use of natural medicines. Based on data from Secretariat Convention on Biological Diversity, global market of natural medicines covered raw materials reached US\$ 43 billion in 2000.

Accurate data on market value of traditional medicines in Indonesia has not been available yet, however the estimated value is above US\$ 1 billion.

Increased use of traditional medicines must be considered wisely due to misperception that they are always safe bearing without any risk on healthy and safety of the consumers. As a matter of fact several types of traditional medicines and its bioactive may contain toxic as its natural properties or hazardous either prohibited artificial content.

WHO reported that undesired effect due to medicinal plants and added chemical *i.e. corticosteroid and non-steroid anti inflammatory medicines. Undesired effect may occur due to mistakes in selection of medicinal plants, inaccurate dose, misuse by consumer or medical professionals, interaction caused by co-treatment of other medicines, moreover the use of traditional medicines contaminated by hazardous materials/microbe such as heavy metal, pathogen microbe and agrochemical residue (pesticide).*

Most of registered traditional medicine products define as “**jamu**” (herbal medicine) group, since the evidence of efficacy and safety based on empirical use from

one generation to another. The registered products as Standardized Herbal include 18 products and 5 products define as phytofarmaca.

There is an attempt at global and regional toward harmonization in standardized and quality of traditional medicines to be tradable among the countries with equal standard and quality. WHO initiated by making the guideline as development strategy of traditional medicines, monographic of medicinal plants, guideline on quality and safety of traditional medicines, good manufacturing practice, cultivation method and collection of good medicinal plants, guideline on monitoring over the undesired effect. At regional level, ASEAN has conducted meetings to discuss standard harmonization and regulation on traditional medicines.

B. STRENGTHS

Indonesia is a mega-center of biological diversity and rank the second wealthiest in the world following Brazil. If marine biota is calculated, Indonesia will rank the wealthiest in the world. On our soil, there are approximately 40.000 species of plants where 30.000 species in Indonesian archipelago. Among them, at least there are approximately 9.600 species of plants to be effectively used as medicine and about 300 species used by the industry as raw materials of traditional medicines.

Indonesia is also rich of 400 ethnics possessing traditional knowledge on use of plants for healthcare and medication of various illnesses.

Indonesia is an agrarian country possessing agricultural area and wide plantation as well as yards to be planted by medicinal plants. Indonesia possesses many neglected areas in tropical forest keeping such abundant rich nesses as an opportunity of natural medicines.

By now, there are 1.036 licensed traditional medicine industries which comprise 129 traditional medicine industries (IOT) and 907 small-scale traditional medicines industry (IKOT).

Many research agencies conducting research on natural medicines are useful strengths to promote the development of traditional medicines.

Indonesia inherited various types of traditional medication, including traditional preparations which some of them were written in the ancient manuscripts (Pusaka Nusantara), then able to be developed through various researches.

Indonesian populations of 220 million inhabitants are very prospective market, including market for traditional medicines.

C. WEAKNESSES

For the purpose of quality assurance in traditional medicines, challenged by the limited availability of standard and method as instrument to perform quality evaluation. As described earlier, the efficacy and quality of traditional medicines was depend on many factors. Meanwhile, the researches on determinant factors are limited and hence limited availability of data, standards and methodology.

Natural resources of medicinal plants have not yet been optimized and cultivation activities have not yet professionally performed due to non-conducive business climate, no warranty of market and price. these affected to the cultivation as a side activity, then the collection of raw materials only from wild plants and yard vegetations.

Exploitations on wild plants and particular forest plants for traditional medicines continue without cultivation activities, thus several types of plants have become extinct. To prevent from such extinction, the types of extinct species should be preserved through cultivation activities.

The quality of samples is mostly sub standard due to improper post-harvest handling, limited Knowledge and Technology and low quality resource of medicine planters.

The attempts made for the development of traditional medicines have not yet properly coordinated. The stakeholders such as Government, Industry, academic and research agency, planters and health providers have not developed synergic cooperation yet.

Physicians have enjoyed increased income but not yet accommodated in the curriculum of medical Faculty.

There is also lack of fund available for development of Indonesian traditional medicines, primarily to budget of the research. On one side, financial capacity of the Government is very limited, while pharmaceutical industries are less motivated to jointly finance the researches.

There is very small number of industries specialized in manufacturing raw materials. They specialize on individual finished products. Some extract industries in Indonesia have not run optimally and most of them emphasize on their own needs.

Among the 907 IKOT, there are 35,4% classified as home industry with minimum facilities and resources. While, out of 129 OTs, there are only 69 industries awarded with certificate of Good Traditional Medicine Manufacturing practice (CPOTB).

Traditional medicine industry pays less attention and utilizes the outcome from scientific research in product and market development. In the development of traditional medicine industry, there is more emphasis on promotion compared to scientific support on the efficacy, safety and quality.

D. OPPORTUNITY

Exportation of Indonesian traditional medicines and (simplicia dried-sliced form), even not yet in large quantity, has gradually increased. As presented by Association of Indonesian Medicinal Plant Exporter (APETOI) and Information from Herbal and Traditional Medicines Business Association (GP jamu) and Indonesia Herbal Medicine Cooperatives, exportation of medicinal plants has continuously increased. There have been large demands from countries, where several types of plants from Indonesia unable to be fulfilled.

More results of scientific research demonstrated that natural medicine affect physiology metabolism and showed effective therapy. The side effects of traditional medicines are relatively lower than the conventional medicines (chemicals).

The use of traditional medicines continuously increases in both developing and developed countries. World Health Organization (WHO) through World Health Assembly recommended the use of traditional medication including traditional medicines for healthcare, prevention and medication of disease, mainly for chronic ailment, degenerative illnesses and cancer.

Indonesian cultivation has inherited community's habit to consume herbal medicines for healthcare and disease prevention. With population of more than 220 million inhabitants, there are very prospective potentials of traditional medicines market.

The acceptance from medical practitioners rises by the establishment of Indonesian Medical Association, Eastern Traditional Health Developer and Complimentary and Alternative Medical Association.

E. THREATS AND CHALLENGES

Biopiracy by foreign parties is still in existence while no research has been conducted and developed on medicinal plants threatened to be extinct. Subject to Law No.5 of 1990 on Conservation of Natural Resource and Ecosystem and Law No.12 of 1992 on Plant Cultivation System, search and collection of (“plasma nutfah”) for courtesy by the government and it has been performed individuals and legal entity specifically licensed, while the conservation program is run by the government and with participation of local communities.

It is necessary to regulate the exchange and use of natural resources of traditional medicines and local wisdom through ideal profit shearing.

Some traditional medicines have been widely used for medication primarily degenerative illnesses. However, the price is more expensive than conventional ones. The challenges against research on traditional medicines are not merely the prove of efficacy and safety, but the way to discover traditional medicines at more competitive cost-benefit ratio.

CHAPTER IV

POLICY FOUNDATION AND STRATEGY

A. POLICY FOUNDATION

In the pursuit of the primary goals and objectives of KOTRANAS, it is necessary to establish policy foundation elaborating the basic principles of National Health System (SKN) as follows:

1. Indonesian Natural Resources shall be utilized in optimized and sustainable manner for public welfare, therefore it is necessary to improve the use of natural resources in traditional medicines in promoting health and economy.
2. Government has developed the assistance, supervision and control over traditional medicines in professional, accountable, independent and transparent manner, while entrepreneurs are responsible for the quality and safety to comply with standard in protecting the communities and to strengthen competitiveness.
3. Government must issue direction and create conducive climate to assure the availability of quality traditional medicines; safe, effective, scientifically tested and widely used, either for self-medication by communities or used in formal health services and to ensure the availability of appropriate information about traditional medicines that true, accurate and complete.

B. STRATEGY

- 1. To promote the sustainable use of Indonesian natural resources as traditional medicines to improve the health services and economy.*

Indonesian natural resources should be optimized to improve health and economic services by taking into wise consideration of the conservation through the following attempts:

- a. Plant cultivation based on superiority of biological diversity in each region and conservation of natural resource conservation for development of traditional medicines and other objectives by involving all stakeholders.
- b. Useful research for development of traditional medicines and other relevant objectives and purposes.
- c. Consistent application of standardized raw materials and commodities of traditional medicines, including foreign traditional medicines.
- d. Setting regulation on development of traditional medicines.
- e. Development and protection of intellectual property rights in connection with indigenous traditional medicine ingredients and the results of Science and Knowledge Development on Indonesian bio-diversity resource based on Natural Biological Source.

2. ***Assuring safe, quality and efficacy of traditional medicines and protecting communities from using inappropriate traditional medicines.***

Supervision and control over traditional medicines should be initiated from the preparation of raw materials, production until delivery to end consumers as inseparable part of the activities.

In accomplishing these objectives, the following measures must be adopted:

- a. Assessment on safety, quality and efficacy through registration, assistance, supervision and control over import, export, production, distribution and services of traditional medicines as integral part, high competency, accountability, transparency and independency.

- b. Consistently grounds and law enforcement resulting in punishment against each violation.
- c. Amendment to production materials and commodities of traditional medicines.
- d. Community empowerment through provision and distribution of reliable information as to prevent the risk from sub-standard and misuse.
- e. Revision and development of standards and guideline relevant to the quality of traditional medicines.

3. *Availability of traditional medicines possessing proven efficacy as scientifically tested and widely used for self-medication and formal health services.*

One of the issues related to the limited use of traditional medicines for self-medications and formal services is the absence of scientific test showing the efficacy. Hence, research must be initiated through the measures below:

- a. Reliable research or study on the efficacy and unwanted effect of traditional medicines with cost-effectiveness ratio.
- b. Setting regulation to promote the acceptance of well proven traditional medicines in formal health care.
- c. Promotion and advocacy of traditional medicine use.
- d. Proper training aimed at up scaling the knowledge of collector and production personnel of traditional medicine.
- e. Improved international cooperation on technical aspects and exchange of knowledge of traditional medicines.

- f. Coordination among competent authorities in handling medicinal plants, mainly in exchange of information related to species of medicinal plants discovered in the survey.

4. *Promoting the development of accountable and transparent industry in traditional medicines to serve as host in the country and to gain recognition from other countries.*

The growth of traditional medicine industry is the responsibilities of all stakeholders : government, communities and industrial sectors.

- a. Improved cooperation and coordination among the stakeholders in adherence to the principles of Good Governance.
- b. Allowing incentive and facilities for development of traditional medicines taking into account the affordability of community.
- c. Creation of conducive climate for the development of traditional medicines taking into account the development of global, regional and local markets.
- d. Improved promotion of traditional medicines in international market by utilizing various development of communication technology.
- e. Active role in harmonizing regulations and standards in traditional medicines at regional and international level.

CHAPTER V

PRINCIPLES AND MEASURES OF POLICY

The development of traditional medicines represents extended series of activities, wide scope and complex issues which involve many parties. Meanwhile, the resources are still very limited. In achieving these goals, development must be designed integrally and comprehensively, starting from upstream to downstream involving all related sectors and programs, researchers, entrepreneurs, professionals and communities in compliance with the duties and authorities, skills and competency in each discipline by rational and mutually agreed priorities.

Medicinal plant based agribusiness policy is integral part under the policy of agribusiness system development from upstream to downstream by taking into account the interests of various sectors, including health and global tendencies. In addition, uniform perception is necessary to cope with rising issues and therefore, it is necessary to establish well-defined vision toward the challenges and opportunity in the future.

Reminding the long series of activities and complexity of issues in the development of traditional medicines, thus, it is necessary to establish clear principles and policies being the commitment of all stakeholders:

A. CULTIVICATION AND CONSERVATION OF TRADITIONAL MEDICINE

RESOURCE Goal:

The sustainable availability of raw materials for traditional medicine comply with the quality standards for health service and public welfare.

Policy Measures

In achieving this goal, it is necessary to set up the following policy measures:

1. Improved cross-program development for mapping of commodity and development area for primary medicinal plants.

2. Improved competency of human resource through education and training to supply competent human resourced in supply of natural ingredients for traditional medicines and other relevant purposes.
3. Up-scaled production, quality and competitiveness of superior plants through Good Agricultivication Practices, Good Agricultivication Collecting Practices (GAPC) and Standard Operational Procedures (SOP) of each commodity.
4. Comprehensive survey and evaluation on usable medicinal plants.
5. Mapping of land suitability showing potential areas for development of medicinal plants.
6. Conservation to prevent from extinction due to excessive exploitation or biopiracy through regulation, research and development.
7. Community empowerment for cultivication and conservation of natural resources.
8. Establishment of germ plasma/genetic source for medicinal plants.

B. SAFETY AND EFFICACY OF TRADITIONAL MEDICINES

Goal:

Traditional medicines distributed in the market must comply with the requirements of safety and efficacy.

Policy measures

In achieving these goals, it is necessary to establish policy measures below:

1. Developed data inventory of pre-clinical tests.
2. screening based on pre-clinical and economic data.
3. Advanced of clinical test on medicinal plants/ingredients based on interpretation.
4. Establishment of communication forum and cross-sector and program among central, provincial, Regency/City and related institutions.

C. QUALITY OF TRADITIONAL MEDICINES

Goal:

Traditional medicines and it's raw materials for traditional medicines distributed in the market must comply with the quality requirements.

The quality of traditional medicine is highly depend on many factors from planting, collecting, raw material processing, production process to circulation.

Policy Measures

In achieving the goal, it is necessary to establish the following measures:

1. Setting-up specifications on medicinal plants
2. Setting-up specifications and reference standards of raw materials/revision of Materia Medika Indonesia.
3. Setting-up Specifications and standards of galenic preparation.
4. Setting-up developing and implementation of quality system for post-harvest handling and product processing.
5. Establishing pharmacopoeia of Indonesian Traditional medicines.

D. ACCESSIBILITY

Goal:

Health service facility and community able to access traditional medicines which comply with the requirements for safety and quality and proven efficacy at affordable price.

Policy Measures:

In achieving this goal, it is necessary to establish the following policy measures:

1. Development of national traditional medicine industry.

2. Special access for foreign traditional medicines where on patented and/or fully imported for disease treatment due to absence of proven efficacy of conventional medicines.
3. Development, protection and conservation of traditional ingredients with proven efficacy by taking into full consideration the benefits of the indigenous/ local communities as the owner of such ingredients.
4. *Use of Family Medicinal Plants in healthcare, disease prevention and simple medication.*

E. RATIONAL USE

Goal:

The use of traditional medicines in proper quantity, formulation form, dose, indication and content of ingredients enriched with accurate and proportional information.

The tendency of increased use of traditional medicines for healthcare and medication must be supported by rational use pattern. This measure must be adopted to optimize the use of traditional medicines.

Policy Measures:

In achieving this goal, it is necessary to establish the following policy measures:

1. Supply of accurate and proportional information on traditional medicines.
2. Education and community empowerment on rational and proper use of traditional medicines.
3. Setting-up regulations in support of policy implementation of rational traditional medicines use.
4. Communication, information and education in support of proper use of traditional medicines.

F. CONTROLLING

Goal:

Protection of community from sub-standard traditional medicines.

Controlling of traditional medicines must involve all stakeholders i.e. government, industry and community.

Policy Measures:

In achieving this goal, it is necessary to establish the following policy measures:

1. Assessment and registration of traditional medicines.
2. Licensing and certification of production facilities.
3. Quality assessment in accredited laboratory.
4. Controlling over labeling and promotion of traditional medicines.
5. Improving the surveillance and vigilance of traditional medicines marketing integrated to medicine.
6. Re-assessment on distributed traditional medicines.
7. Improvement of facility and infrastructures of traditional medicines and controlling, strengthen the personnel in quantity and quality related to competency standards.
8. Improvement of regional and international cooperation in controlling.
9. Proper controlling to prevent from traditional medicines containing chemicals and smuggled materials.
10. Development of community participation to protect themselves from sub-standard traditional medicines through communication and education.

G. RESEARCH AND DEVELOPMENT

Goal:

Improved research on traditional medicines in support of KOTRANAS implementation.

Research and development of traditional medicines in promoting the development of high-quality, safe, effective and scientifically-tested traditional medicines for wide use either for self-medication or formal health services.

Policy Measures:

In achieving the goal, it is necessary to establish the following policy measures:

1. Identification of relevant research and priority setting in close work mechanism, between the stakeholders in traditional medicines and formal health service providers and those in research and development.
2. Improved coordination and synchronization of research and setting of research priority among research agencies.
3. Improved international cooperation in research and development of traditional medicines.
4. Assistance to relevant research and development for traditional medicines from the application of conventional to the latest technology.
5. Improved benefit sharing by intellectual property rights acquisition for local courtesy.
6. Drafting regulations on exchange of natural resource for traditional medicines and use of research results and development of traditional medicines at national and international level.

H. INDUSTRIALIZATION OF TRADITIONAL MEDICINES

Goal:

Development traditional medicines industry as integral part of national economic growth.

Policy Measures:

In achieving the goal, it is regarded necessary to establish the following policy measures:

1. Establishment of strategic alliance in development of traditional medicines.
2. Creation of conducive investment climate for traditional medicines industry through incentive in tax and banking policy including the assurance of licensing.
3. Drafting regulations to assure the development and growth of traditional medicines industry.
4. Improving promotion of traditional medicines through exhibitions and expo at national and international level.

I. DOCUMENTATION AND DATABASE

Goal:

The availability of the up-dated and comprehensive database in support of traditional medicines development.

Documentation and database possesses strategic position in promoting all measures and activities related to traditional medicines development.

Policy Measures:

In achieving the goal, it is necessary to establish the following policy measures:

1. Collection and processing of accurate data relevant to the development of traditional medicines.

2. Study and analysis on scientific and empirical data on efficacy and safety of traditional medicines.
3. Development of Data Bank which include all aspects related to Indonesian Traditional Medicines.
4. Exchange of information either by electronic means or printed forms.
5. Information services and business consultancy.

J. DEVELOPMENT OF HUMAN RESOURCES

Goal:

Availability of Human resources in support of achieving the objectives of Kotranas.

The availability of Human Resource necessary for various related institutions in traditional medicines should be fully adequate in terms of quantity and competency. For such purpose, it is necessary to improve and develop Human Resource in systematic and sustainable manner in line with the development of Science and Technology.

Policy Measures:

In achieving the goal, it is necessary to establish the following policy measures:

1. Integration of KOTRANAS and other related aspects to traditional medicines into education and training curriculum primarily in medical education.
2. Integration of KOTRANAS into sustainable education curriculum by related professional organizations.
3. Improved national and international cooperation scheme for Human Resource Development.

K. MONITORING AND EVALUATION

Goal:

Supporting the implementation of KOTRANAS through establish mechanism of monitoring and evaluation on performance and policy impact to identify difficulties and to set up effective strategy.

The implementation of KOTRANAS would require period monitoring and evaluation. This is essential to anticipate and perform corrective measures on environmental change and complex and rapid development in the communities. Monitoring and evaluation serves as integral part of policy development. Necessary correction will be made by reference to the monitoring policy.

Policy evaluation is aimed at collecting and generating information on the implementation, output reporting, outcome measuring, impact evaluation on target groups, giving recommendation and policy amendment.

Policy Measures

In achieving this goal, it is necessary to establish the following policy measures:

1. Periodic monitoring and evaluation at maximum of 5 (five) years.
2. Implementation and indicators of monitoring in compliance with the guideline and establish cooperation with other parties.
3. Use of monitoring output and evaluation on follow-up in policy adjustment.

CHAPTER VI

CLOSING

KOTRANAS is established as guideline and direction for action of all stakeholders in national traditional medicines.

The implementation KOTRANAS would require organizing, mobilization, monitoring, supervision, control and evaluation.

The success of KOTRANAS will highly depend on moral, ethics, dedication, competence, integrity, consistency, hard work and earnestness of all stakeholders in the sector of traditional medicines.

MINISTRY OF HEALTH



[Handwritten signature]
Dr.dr. SITI FADILAH SUPARI, Sp JP (K)

GLOSSARY

1. **Benefit Sharing of Local Courtesy** means share of benefits for place of origin.
2. **Biopiracy** means biodiversity resource piracy
3. **CPOTB** means Good Pharmaceutical Manufacturing Practices
4. **Fitomarka** means medicine stocks which safety and efficacy is proven, standard materials comprised of galenic supplies meeting the applicable standards.
5. **IKOT** means Traditional Medicine Small-Scale Industry
6. **IOT** Traditional Medicine Industry
7. **Standardized Herbal Medicines** mean herbal medicines manufactured of standardized raw materials and which efficacy is pre-clinically proven.
8. **Surveillance** means measures adopted to assure that distributed products comply with the applicable standards and requirements.
9. **Medicine Material Biodiversity Resources** means sources of raw materials of plants/animals applied as medicines.
10. **Vigilance** means acceptance of report and evaluation on unexpected events.
11. **Germ plasm** means substances being the sources of hereditary properties contained in each class of organisms to be utilized, developed or manufactured in creating superior type or new cultivar.

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Chairman: Ministerial Expert Staff of Health Technology and Globalization Sector.

Deputy Chairman: Deputy II of Traditional Medicine, Cosmetic, and Complimentary Product Administration POM.

Secretary I: Secretary of Directorate General of Pharmaceutical and Medical Apparatus Development.

Secretary II: 1) Director of Indonesian Aboriginal Medicines (POM).

Members: 1) Director of Rational Medicine Administration, 2) Director of Community and Clinic Pharmacy, 3) Director of Public Medicines and Health Supplies, 4) Director of Health Apparatus Production and Distribution, 5) Head of Biomedical and Pharmaceutical Research and Development, 6) Head of Legal Bureau and Organization, Ministry of Health, 7) +++ 21) Head of Research Center-IPB (Bogor Institute of Agriculture), 27) Head of Sub-Directorate of Standardization and +++28) Head of Sub-Directorate of Non-Electromedical Health Apparatus, 29) Head of Laws and Regulation Department, Rohukor, Ministry of Health.

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