



**NATIONAL  
MEDICINES POLICY  
2006**

**DECREE OF MINISTER OF HEALTH - REPUBLIC OF INDONESIA**

**Number : 189/Menkes/SK/III/2006**

**March 27, 2006**



MINISTER OF HEALTH  
REPUBLIC OF INDONESIA

## **MINISTRY OF HEALTH – REPUBLIC OF INDONESIA**

### **FOREWORD**

Great thankfulness is praised to Almighty God for His Mercy and Guidance in the support of revision and re-preparation of **National Medicines Policy (KONAS)** is now completed.

Technological development has created radical changes in pharmacy mainly medicines. Globalization is indicated by entry barrier of international trade spreading pharmaceutical products throughout the regions in the mother nation and at the same time, tendency of consumption level keeps increasing.

The preparation of National Medicines Policy will serve as the underlying grounds, direction and guideline for health development particularly on medicine i.e. financing, availability, fair distribution and affordability, selection essential medicines, rational use of medicines, control and administration, research and development, human resource development, monitoring and evaluation. All represent the visions of Ministry of Health "Self-support Community toward Healthy Living" and the Mission of Ministry of Health "Creating Healthy Communities"



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The publication of National Medicines Policy is expected to disseminate information to all health providers, central government, province and districts, general communities and business enterprises and other parties concerned.

The Almighty God always bestows directions and strengths in pursuing health development by supplying quality health services for all citizens to achieve the highest standards as a manifestation of human rights.

Jakarta, September 2006

Director General



**Drs. Richard Panjaitan, Apt, SKM**

Pharmaceutical Services and Medical Devices



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**OFFICIAL ACKNOWLEDGEMENT**

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Health refers to human rights and each member of community is entitled to optimized health access in line with the public need regardless their payment capacity.

In the efforts to health services, the availability of complete, adequate, effective, safety, quality, affordable and accessible medicines is a target to be achieved.

Technological development has created radical changes in pharmaceutical and medical devices. Globalization as signified by declining *entry barrier* of international trade cause pharmaceutical products and medical devices spread rapidly to the entire nation. Meanwhile, the tendency of consumption rate on pharmaceutical products and medical devices keep increasing.

Medicine is one of irreplaceable components in healthcare services. Medicine is a single material or mixtures of materials applied to influence or investigate physiology system or pathology condition in determining diagnosis, prevention, healing, recovery, improvement of health and contraception including biological products. Access to medicines particularly essential medicines is one of the human rights. Therefore, the supply of essential medicines is the



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obligation of the government and health service institution, public or private.

Government policy on improvement of access to medicine has been established by Law No.23 on Health, Government Regulation, Healthy Indonesia 2010, National Health System and National Medicines Policy (KONAS).

In the subsystem of Medicines and Medical Supply in National Health System, emphasis is given on availability, fair distribution, affordability and the assurance of safety, efficacy and quality medicine.

National Medicines Policy will constitute the guideline and direction for health development especially on medicines which include financing, availability, fair distribution and affordability, selection of essential medicines, rational use of medicines, controlling, research and development, human resource development, monitoring and evaluation.

The establishment of National Medicines Policy is made by active role of various parties at central and regional level, non-government organization, business segment, professional organization, academicians and experts.

On this occasion, I, Minister of Health award the highest appreciation and thankfulness to all parties for attention,



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assistance, inputs and contribution in preparing National Medicines Policy.

May God the Almighty bestow His Blessedness and Charity in the realization of "Creating Healthy Communities" in creating "Self-support Community toward Healthy Living".

Jakarta, September 2006



MINISTER OF HEALTH

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



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NUMBER 189/MENKES/SK/III/2006

REGARDING

NATIONAL MEDICINES POLICY

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- Considering :
- a. whereas, in anticipating the changes and strategic challenges, both internal and external, in line with National Health System, it is considered as necessary to establish national medicines policy;
  - b. whereas, in consideration of the premises in letter a, it is considered as appropriate to re-stipulate National Medicines Policy by 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);



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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 3452 to State Gazette Number 125 of 2004);
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;



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**HAS DECIDED :**

**To stipulate :**

- First : **DECREE OF MINISTER OF HEALTH ON NATIONAL MEDICINES POLICY**
- Second : National Medicines Policy as referred to in first paragraph shall be as set forth in the Appendix hereto.
- Third : National Medicines Policy as referred to in Second Paragraph shall be applied as reference to all stakeholders in support of sustainability availability, fair distribution and affordability.
- Fourth : Upon stipulation hereof, Decree of Minister of Health Number 47/Menkes/SK/II/1983 on National Medicines Policy is hereby revoked and declared as null and void.
- Sixth : This Ministerial Decree shall come into effect as of the stipulation date.

Stipulated in Jakarta  
On March 27, 2006



MINISTER OF HEALTH

*[Signature]*  
Dr. dr. SITI FADILAH SUPARI, Sp JP(K)



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Appendix  
Decree of Minister of Health  
Number 189/MENKES/SK/III/2006  
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**NATIONAL MEDICINES POLICY**

**I. INTRODUCTION**

**A. BACKGROUND**

The essential objectives of health development toward Healthy Indonesia 2010 has directed the health development which prioritizing health paradigm. The objectives of health development toward Healthy Indonesia 2010 are to build awareness, motivation and capability to realize healthy living and to have access to quality, proportional, and fair distribution of health services.

Medicine is one of the irreplaceable components in health services. Medicine is a single material or mixture of materials applied to bear effect or investigate physiological system or pathological condition in determining diagnosis, prevention, healing, recovery and development of health and contraception including biological production. Access to medicine particularly essential medicine is one of the human rights.



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Supply of essential medicines is obligatory to the government and health institution, either public or private.

Medicine is totally different from other trade commodities, in addition to its status as a commercial commodity, it also has social functions.

Government policy on the improvement of medicine access is adopted through several policy levels i.e. Law to Decree of Minister of Health governing the provisions of medicines. SKN 2004 provides foundation, direction and guideline on health development for all health service providers, either central, provincial, districts administration, communities and business segments including all parties involved. One of the SKN 2004 subsystem includes Medicines and Medical Supply.

In the subsystem, there is strong emphasis on availability of medicines, fair distribution, affordability, safety, efficacy and quality of medicines.

In response to such policy, it is regarded necessary to make further improvement on the present national



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medicines policy stipulated by Decree of Minister of Health No.47/Menkes/SK/II/1983 on National Medicines Policy by stipulating the new National Medicines Policy.

National Medicines Policy as hereinafter referred to as National Medicines Policy (KONAS) is an official document which sets forth the commitment of all parties to set up the national objectives, targets and priorities on medicines including the strategy and role of other relevant parties in applying the essential components of policy in achieving the objectives of health development. Therefore, National Medicines Policy constitutes integral part of SKN 2004.

Developing countries have utilized traditional medicines in providing health services particularly for primary health care. The use of traditional medicines in Indonesia is part of national culture. Nonetheless, the efficacy and safety have not yet been supported by adequate research. Considering and realizing that Indonesia is the mega center of medicinal plants in the world, it is consider necessary to prepare National Traditional Medicines



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Policy (KOTRANAS) apart from this National Medicines Policy.

The implementation of local autonomy in 2000 subject to Law No 22/1999 as amended and renewed by Law 32/2004 on Local Government has caused delegation of role and authorities of Central to Local Government as primary and auxiliary tasks in health services. This has caused provision and or budget management for essential medicines for public sector to be assumed by local government. However, central government is still responsible for supply of medicines in health program and buffer stock including to control and assure the safety, efficacy and quality of medicines.

The implementation of local autonomy has created fundamental changes that necessary concerned hence the availability of essential medicines for the communities is maintained. For remote places, boundaries, islands and disaster areas, it is necessary to develop specific medicines management system.

**B. OBJECTIVES**

National Policy on Medicine is broadly aimed at assuring sustainable fair distribution and



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affordability of medicines to achieve the highest standards of public health.

Sustainable affordability and Rational Use of Medicines is regarded as one of the primary objectives to be realized. The selection of appropriate medicine by prioritizing supply of essential medicines will improve the access and rational use of medicine.

The safety, efficacy and quality of all medicines distributed for public use must be assured to provide medical benefits. Accordingly, communities must be prevented from misuse and abuse of medicines.

The objectives of National Medicines Policy are:

1. Availability, fair distribution and affordability of medicines, particularly essential medicines.
2. Safety, efficacy and quality of medicines and public protection from misuse and abuse of medicines.
3. Rational Use of Medicines.

**C. SCOPE**

The scope of National Medicines Policy covers the development of medicines to achieve the effective course of health development in generating quality human resources.





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National Medicines Policy include financing, availability and fair distribution, affordability, selection of essential medicines, Rational Use of Medicines, control and administration, research and development, human resource development, monitoring and evaluation.

**II. SITUATION ANALYSIS AND TENDENCY**

The availability of medicine as one of the essential elements in health program, i.e, health maintaining, disease prevention, diagnosis, medication and recovery must be fully assured. In contrast, medicine will bear adverse and harmful effect caused by sub-standard medicine, incorrect use or in case of misuse.

Besides, medicine is an important element for health program, medicine as pharmaceutical industry is not apart from technology and economy. The demand for technological and economic aspects have increased in line with the recent globalization, however, this demand can be minimized in such a way that communities' need of medicines can be accommodated and pharmaceutical industries may grow accordingly.



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**A. DEVELOPMENT**

The use of medicines for public health and welfare is directed to Indonesian population totaling 219 million inhabitants and projected total population in 2020 will be 252 million inhabitants with the following tendencies.

If birth rate and mortality keep decreasing in line with the decline of fertility and mortality, the population growth rate will decline from 1,2% per year in 2000-2005 to 0,79% per year in 2005-2025. Based on the number of populations, there is declining number of youths and infants, and significant increase of workforce and orphans (geriatric) in 2025, which indicated since 2005. Total workforce in 2000 was 69,9% out of total number of population and the projected number will be 76,8% in 2020.

The projected Life Expectancy in 2005 was 69,0 years old and in 2025 it is projected 73,7 years old. Infant Mortality Rate in 2005 was 32,3 per 1.000 live birth and in 2025 it would reach 15,5 per 1.000 live birth. Maternal Mortality Rate in 2005 was 262 per 100.000 live birth and in 2025 it is estimated to 102 per 100.000 live birth.



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The prevalence of calorie-lack of Infant in 2005 was 23% and 2025 will be projected to 17%.

Prior to the implementation of local autonomy, there was estimated 50-80% of Indonesian population having access to essential medicines. The access to essential medicines is influenced by four primary factors i.e. Rational Use of Medicines, affordable price, sustainable financing, and health care system utilized by supply system assuring the availability, fair distribution and affordability. Interventions on compliance with Rational Use of Medicines have been initiated in several regions such as West Nusa Tenggara Province, East Kalimantan, East Java, West Kalimantan and West Sumatera, and showed remarkable results in 1991.

Evaluation on the implementation of National Medicines Policy in 1997 has shown that the Rational Use of Medicines is relatively better. However, the success of intervention in such regions has not been expanded yet, there was economic crises bearing adverse impact on the Rational Use of Medicines.



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Regulation on medicine sector includes the standards of products, production process, supply system, financing, use and et cetera. The enforcement of regulation is generally classified as fairly effective mainly before the decentralization era.

In assuring the acceptable specifications of medicine, commodity standards have been set up which include safety standards, efficacy and quality. Besides, standardized production process has been developed i.e Good Manufacturing Practice (GMP).

Before the era of decentralization, the availability of essential medicines in the public sector was assured by the government through supply system by Government Pharmaceutical Warehouse Facilities. The role and function of Government Pharmaceutical Warehouse Facilities as of decentralization has changed due to different perspectives of the local governments in relation to the role of such institutions.

Meanwhile, the medicine supply by private segments is assured by Industry, Pharmaceutical Wholesalers, Pharmacies and OTC stores.

To assure sustainable affordability of essential medicines, the government has fixed the price of



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essential medicines for health services. Meanwhile, low-income communities have been subsidized through medicine supply in primary health care.

National Essential Medicines List (NEDL) has been prepared since 1980 and periodically revised in 1983, 1987, 1990, 1994, 1998 and 2002. NEDL known as DOEN is also applied as guideline for medicine provision in public health services. The survey on availability and medicine utilization has shown that prior and during the economic crisis in Indonesia between 1997-2002, the availability of essential medicines in Community Health Center has reached above 80% and more than 90% medicines prescribed in Community Health Center are essential medicines.

High profile of essential medicines use in primary health care was not followed by other health facilities. It was shown by the prescription of essential medicines in government hospital was less below 76%, private hospital 49% and pharmacies less than 47%. The condition above demonstrated that the concept of essential medicine has not been fully understood and implemented yet.



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Availability of narcotics for health services is supplied through production, importing and distribution by pharmaceutical company appointed by the government.

**B. ISSUES**

In the context of economic affordability, medicines price in Indonesia are mostly expensive and pricing structure is not transparent.

WHO research showed that the comparison of price between one brandname and another for similar generic name is 1:2 up to 1:5.

The research is also aimed at comparing the price of medicine of brandname and generic showing that generic medicine is not the cheapest. Generic medicine, however, is generally lower at price compared to brandname medicines.

Survey on economic crisis impact on medicine price and availability of essential medicine from 1997 - 2002 showed that average prescription cost in private health services are much higher than those in public sector where pricing regulation is set up in the supply system.



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The pricing mechanism of medicine price in private health sectors is delegated to the market. Considering that medicine is not a common trade commodity and its fundamental role in the humans living, it is necessary to establish government policy on essential medicine pricing.

In recent years, some Government Pharmaceutical Warehouse Facilities has been less functional due to inadequate availability of competent personnel, organizational structure, insufficient operating fund and inadequate information system. For that reason, it is necessary to revitalize the function of medicines management in Districts and synchronize the name to Regency/City Government Pharmaceutical Installation Facilities to be more prioritize the functions.

Up to present, there has been recorded approximately 13.000 item circulated in the market. 400 types of medicines are listed in National Essential Medicine List (DOEN) and 220 types are available in the form of generic essential medicine. In public sector, mainly in primary health care, the availability of generic essential medicines ranged between 80-100%. In spite of government regulation stating that procurement of



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medicine which sourced from Local Budget or State Budget must be in generic essential medicine, however in the era of decentralization, the compliance with procurement of generic essential medicines has declined. The availability of medicine is supported by pharmaceutical industries totaling 204 and 90% located in Java islands, manufacturing 98% of national medicines demand, however, most raw materials are still imported. Dependability on importation of medicine raw materials will affect unstable supply of national medicines and cause fluctuation of medicine price.

Watching the growth of multi-national pharmaceutical industries to merge and the implementation of Trade-Related Aspects of Intellectual Property Rights (TRIPs), there is anxiety that national pharmaceutical industry will find it difficult to compete in the domestic market. For that reason, all stakeholders must be fully aware of making earlier anticipation.

The allocation of government budget for health sector is considered as low, including those for medicines. Before decentralization era, the allocation of government budget for medicines was only 20% of all expenditures for national medicines. However, through





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effective and efficient medicine management system, the allocation of budget will cover approximately 70% of total populations.

Budget allocation for medicines for primary health care before the decentralization era is made available by central government through Fund by Presidential Instruction which amount has been gradually increased up to US\$ 0,85 per capita. At present, government budget for health is allocated to General Allocation Budget, therefore, the medicine budget for primary health care is the responsibility of the local government. Medicine budget for primary health care in one region is different from others thanks to the different vision and perception of Local Government on Health. In spite of this, the government will be responsible for supporting the regency/city to supply medicines in the event of disasters and shortage of medicines.

As per data collected to this date, the fund allocated for supply of medicine per capita in Regency/City for primary health care is less than Rp.5.000,- far below the WHO recommendation of US\$ 2 per capita.



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Since 2002, central government has supplied medicine budget for primary health care for poor communities. The budget is sourced from Energy Subsidiary Reduction Program (PKPS-BBM) at approximate value of Rp. 160 Billion per year. The budget available was distributed to the government or private health facilities appointed by the government. At present, budget allocation for medicine provision in primary health care is determined by each regency/city.

In rational medication, patients receive medicines as per the clinical requirements with correct dose for the appropriate medication period at affordable cost. Survey conducted in many health service facilities has shown high profile of Irrational Use of Medicines.

The common Irrational Use of Medicines are poly-pharmacy, use of non-essential medicines, improper antimicrobial use, excessive use of injection, incorrect medicines prescription due to therapeutical guidelines, non-compliancy and improper self-medication.

In the long run, the tendency of communicable disease prevalence such as Upper Respiratory Infection, Lung Tuberculosis and malaria are predicted increase. Diarrhea cases will slightly increase. *Schistosomiasis*



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will prevail as at present. Measles, through sustainable immunization will decline.

The prevalence of non-communicable diseases such as cardiovascular, cancer and endocrine disorder tend to increase. Meanwhile, HIV/AIDS and other new emerging infection diseases will emerge as new issue.

Pharmaceutical services is integral part of healthcare service aimed at increasing the Rational Use of Medicines, safety, efficacy and efficiency of medicine cost and improving the life quality of patients must comply with Good Pharmacy Practices recommended by WHO. The recent facts demonstrate that pharmacy practice is not properly performed almost in all second-level Individual Health Measure (C-Class and B-Non-Training Class Hospital), Third-Level (B-Training and A-Class Hospital) and Community Pharmacy (Medicinestore).

Pharmaceutical service has not yet in line with good pharmacy practice, that is not merely due to medicines management system, availability of medicine but also the availability, fair distribution and lack of professionalism of the pharmaceutical personnel.



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**C. OPPORTUNITIES**

The number of pharmaceutical industries are approximately 204 showing a great potential to improve the availability of medicines mainly essential medicines. Up to present, 67 pharmaceutical companies have manufactured generic essential medicines. The chain of distribution available from the central, provincial to local, public and private, represents the potential to ensure the availability of medicines. Indonesian population totaling 219 million people will be the enormous market share for medicines marketing.

The government assigns personnel and devices who will assist in improving the availability, fair distribution and affordability of essential medicines and rational use of medicines, administration and control of medicines.

Decentralization is an opportunity for the regions to improve service quality, budget allocation, medicines management for specific needs in each region.

The increasing number of pharmacy schools in Indonesia can be optimized to meet the demands for Pharmacists. Every year, pharmacy schools generated about 2000 Pharmacists. Likewise, the availability of D-3



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education and pharmacy senior high school will also generate Assistant to Pharmacist mostly required in primary healthcare.

The Rational Use of Medicines is not only limited to the facility of health services but also self-medication. Data from Family Health Survey in 2001 showed that 83,88% of populations performed self-medication. Most urban residents use medicines 85,04% compared to villagers of 83,02%.

**D. CHALLENGES**

For the last one and half decade, the world's pharmaceutical products increasing four times than the world's income growth rate, have been concentrated in the five industrial countries. The world's production, trade and sales of medicines have been dominated by a small number of trans-national companies. The ten largest transnational companies occupy almost half of international sales. Meanwhile, the disparity of access to medicine between developed and poor countries have widened and the medicine production volume at lower price prevail in two most densely-populated Asian countries, rapidly growing in a very competitive domestic market.



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In the long run until 2005, the availability and access to medicines will be influenced by the role of pharmaceutical companies at global scale and global distribution of communicable and non-communicable diseases which must carefully thought by Indonesia since now.

In the present globalization era, regulations have been developed through harmonization of technical specifications in medicines control and administration as initiated by industrial countries. Technical advancement (strict technical specifications) must be carefully anticipated to prevent from adverse impact on access to essential medicines.

In 1994, Indonesia ratified WTO treaty, to which there were five agreements relevant to health sector, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP); Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); Agreement on Technical Barriers to Trade (TBT); General Agreement on Tariffs and Trade (GATT); and General Agreement on Trade in Services (GATS).



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WTO Agreements brought implications of patent right protection, abolition of *tariff* and *non-tariff barrier*, simplification of registration process and harmonization of technical requirements. On one side, these conditions have burdened the control and administration of medicines and on the other side, it demanded domestic pharmaceutical companies to increase its competitiveness. Agreement on TRIP extended the valid term of patent right protection which also means to extend monopoly rights of transnational innovator companies bearing adverse impact on public medicine affordability. For that reason, the government must make good use of the existing opportunities in TRIP as Statutory License and Patent by the Government in order to assure the availability and affordability of medicine in Indonesia.

Synchronization of technical requirements will bear implication on the latest technical requirements and causing additional burden to domestic company for the consumers. Therefore, Indonesia must face such difficulties by studying scientific technical research. Free trade will also bear implication on the control and administration of medicines in threats of passing medicines not meeting the required standards.



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Anticipating such threats, the control and administration of medicines must be strengthened by the relevant capacity in harmony with science and technology development. Government must adopt strategy to minimize any possible impacts of such threats.

Affordability of medicines can be perceived from geographical, economic, socio-politic aspects. Some number of Indonesian populations live in remote places, boundaries and disaster-prone areas. Through the aforesaid distribution scheme, it is necessary to make adjustment to medicines management as per characteristics of each region.

**III. FUNDAMENTAL FOR POLICY AND STRATEGY**

**A. FUNDAMENTAL FOR POLICY**

In realizing the objectives of National Medicines Policy, it is regarded necessary to set up the fundamental for policy representing the elaboration of the National Health System principles as follows;

1. Medicines must be treated as irreplaceable components in healthcare services. In this respect, technological and economic aspects must be harmonized with socio-economy aspect.





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2. Government is responsible for the availability, affordability and fair distribution of essential medicines in order to fulfill the need of public.
3. Government and Health Service Providers are responsible for assuring rational medication or treatment for the patients.
4. Government must present guidance, control and administration of medicines, meanwhile, pharmaceutical companies are held responsible for the quality of medicines as per the functions. The tasks related to the control and administration being the responsibilities of government must be assumed in professional, accountable, independent and transparent manner.
5. Communities are entitled to receive correct, full and non-misleading information on medicines. Government must empower the communities in decision-taking process on medicines.

**B. STRATEGY**

1. Availability, Fair Distribution and Affordability of Essential Medicines.

Access to essential medicines for communities is generally influenced by four primary factors; Rational Use of Medicines, affordable price,



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sustainable financing, healthcare system and reliable medicine supply.

Taking into account the foregoing, the availability, fair distribution and affordability of essential medicines can be realized through the following strategies.

- a. Sustainable financing of medicine supply, public or private, under the Law No 40/2004 on National Social Security System elaborated in various forms of Community Healthcare Security.
- b. Rationalization of medicine price and use of generic medicines.
- c. Application of bulk purchasing system or pool procurement in public sector including effective, efficient and accountable distribution of medicines in public and private sectors.
- d. Continuous development and evaluation particularly on models and schemes of public medicine management in remote areas, under-developed areas, boundary areas and natural disaster-prone areas.



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- e. Strict application of standardized process and medicines commodities to facilitate the restriction on types and quantity of medicines.
  - f. Utilizing the scheme under TRIP e.g. Statutory License and Patent Rights by the Government.
2. Safety Assurance, efficacy and quality of distributed medicines including the community protection from medicines misuse and abuse.

Medicines control and administration from imports, production to the patient is inseparable cycle. In realizing such objectives, the following strategies must be adopted:

- a. Evaluation on safety, efficacy and quality through registration, guidance, control and administration on import, export, production, distribution and medicine services is integral part through reliable competence, accountable, transparent and independent efforts.
- b. Legal ground and consistent law enforcement with deterrence effect for each violation or infringement.



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- c. Deregulation on production facilities, distribution facilities and medicine service facilities.
- d. Community empowerment through supply and dissemination of reliable information to prevent from use of non-standard medicines.
- e. Revision and development of various standards and guidelines.

3. Rational use of medicines

Development and implementation of therapy guideline and compliance with National Essential Medicine List is the underlying ground of rational medicine use development.

One of the fundamental issues on irrational use of medicines is the incorrect, incomplete and misleading information. Therefore, assurance on safety for users, either healthcare service providers or communities will receive correct, full and not misleading information. Based on the foregoing, efforts shall be made to assure rational use of medicine through the following strategies:

- a. Application of National Essential Medicine List in each health service, personal or



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public, through the use of therapy guideline and best-scientifically proven based formularies.

- b. Medicines procurement in health services and National Health Security (JKN) scheme by reference to National National Essential Medicine List (DOEN).
- c. The application of pharmacy-economy approach through cost-effective analysis and cost-benefit on selection of medicines applied at all levels of health services.
- d. Good Pharmacy Practices
- e. Community Empowerment through communication, information and education.

**IV. POLICY FUNDAMENTALS AND STEPS**

**A. MEDICINE FINANCING**

**Goal**

**Community, mostly poor communities will have access to essential medicines at any time necessary.**

The primary factor assuring the availability of essential medicines for communities is the assured sufficient and sustainable financing. Sufficient financing by the government will highly determine the



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availability and affordability of essential medicines to the public.

Healthcare and medicine services will be far from affordable to public if public health services facilities become the source of local revenue.

One of the efforts to secure the medicine financing for communities is to enroll all community members in National Social Security System.

**Policy Steps:**

1. Establishing public medicine financing target at national scale (WHO recommended minimum allocation of US\$ 2 per capita).
2. Development of public medicine finance monitoring scheme in each region.
3. Supply of medicine budget for national health programs.
4. Supply of Government Budget in national buffer stock for disaster control and to fulfill deficiency of medicine in regencies/cities.
5. Adequate supply of medicine budget allocated from General Allocation Fund and other sources.
6. Application of JKN scheme and other Healthcare Security System must implement full healthcare services.



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7. Levies imposed on patients in Community Health Center must be fully repaid for health services including provision of medicines.
8. Receipt of medicine aid from donors in the event of emergency case, in complementary nature.

The mechanism of medicine aid must comply with international and national practices.

**B. AVAILABILITY AND FAIR DISTRIBUTION OF MEDICINES**

**Goals :**

**Sustainable availability of medicines for healthcare services, particularly essential medicines.**

The availability and fair circulation of medicines, particularly essential medicines at national level must be ensured by the Government. Independence is impossible in the globalizing market.

Government must facilitate local companies with technical viability and supporting national economy through various efforts and utilizing opportunities.

Efficiency and effectiveness of distribution system must be continuously developed in support of availability, affordability and fair distribution of medicines. Facilities and infrastructures such as



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Regency/City Pharmacy Warehouse should be revitalized to support the availability, affordability and fair distribution of medicines.

**Policy Steps :**

1. Grant of incentives to domestic manufacturing company of finished medicines and raw materials and use of existing opportunities under WTO Agreements.
2. Increasing medicine exports to economic production scale to promote the growth of national economy.
3. Expansion of regional cooperation, public and private, in support of international medicine trade for domestic product development.
4. Development and production of phytopharmacy from Indonesian natural resources as per criteria against efficacy and safety of medicines.
5. Improvement of effective and efficient distribution of medicine through proper regulations on availability, affordability and fair distribution of medicine.
6. Improvement of pharmacy services through professionalism of pharmaceutical personnel as per applicable service standards.





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7. Grant of incentives for medicine service in remote areas.
8. Development of monitoring scheme of essential medicine availability and corrective measures.
9. Availability of public medicines:
  - a. Development of Pharmaceutical installation at the Provincial and Regency/City level and empowerment of Regency/City Pharmacy Warehouse as medicines management unit by utilizing information system on medicines management in effective and efficient manner.
  - b. Application of efficient principles in medicines procurement by reference to National National Essential Medicine List (DOEN) and pool procurement and bulk procurement at regency/city level.
  - c. Good Medicines Management in Pharmaceutical Installation at Regency/City level.
  - d. Implementation of transparency principles in public medicines procurement.
  - e. Use of opportunity in Statutory License and Patent Rights by the Government to fulfill the need of medicines in public sector (parallel imports?).



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10. Medicine supply in emergency case
  - a. Organization of medicine supply in emergency case subject to the applicable rules and regulations.
  - b. Preparation of guideline on medicine supply in emergency case must be periodically reviewed.
  - c. Supply of medicine in emergency case must comply with the applicable guideline and the government must adopt measures to assure proper quantity, type, quality and punctuality of medicine delivery.
11. Supply of medicine in remote areas, boundary areas and disaster-prone areas and orphan medicines must be specifically governed by the government.

**C. AFFORDABILITY**

**Goal :**

**Price affordability of essential medicines to the communities.**

The efforts aimed at realizing affordability or accessibility to medicines shall be made from two directions, market demand and supply. In respect of market demand, Essential Medicine Concept will be implemented and use of generic medicines through



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various efforts i.e. promotion of generic medicines at each level of healthcare services, regulation, medicines management in public sector.

Meanwhile, the implementation of National Health Security scheme will increase the affordability of medicine, mainly essential medicines. For that purpose, the implementation of JKN must be continuously maximized.

In realizing affordable price in public sector, bulk procurement or pool procurement will be made.

In terms of supply made through various efforts, i.e. formulation on policy for medicine pricing, mainly essential medicines and development of price information system and prevention from monopoly.

Since accessibility to essential medicines is one of the human rights, essential medicines must be exempted from taxes and import duty.

Policy Steps:

1. Maximized implementation of Essential Medicine Concept and Generic Medicine Program:
  - a. Dissemination of Essential Medicine Concept in healthcare services, public or private.



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- b. Implementation of National National Essential Medicine List (DOEN) at all levels of healthcare services.
  - c. Integration of DEON in educational curriculum and training for health professionals.
  - d. Consistent and continuous dissemination of generic medicines.
  - e. Controlling over generic medicine price by utilizing information on international medicine price.
  - f. Grant of incentives for facilities and health professionals serving essential medicines.
2. Periodic price evaluation in adopting policy steps on essential medicine price by:
    - a. Price comparison to other countries.
    - b. Price comparison of urban and village and health service facilities, public and private.
    - c. Assessment on impact of policy on medicine price.
  3. Use of pharmacy-economic approaches in healthcare service units to maximize efficiency.
  4. Implementation of statutory license of medicines in accordance with the prevailing laws and regulations.



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5. Development of information system on medicine price.
6. Development of effective and efficient medicines procurement system, public and private.
7. Exemption from tax and import duty for essential medicines.
8. Regulation on price of essential medicines to assure affordability of medicine price.

**D. SELECTION OF ESSENTIAL MEDICINES**

**Goal :**

**Availability of National Essential Medicine List in line with the scientific development for wide application in healthcare services.**

Essential medicine is selected medicines necessary for healthcare services including diagnosis, prophylaxes, therapy and rehabilitation to be made available in any healthcare service units as per the functions and levels. In assuring effective function of healthcare service system, essential medicine must be continuously available in adequate type and quantity, proper stocks, assured quality, adequate information and at affordable price.



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The selection process of essential medicines is very crucial. Essential Medicine Register as unilaterally designated will not reflect the actual need and unacceptable to the health professionals. Thus, the selection process must include consultancy, transparency, clear selection guideline, proper selection by best scientifically guideline, different clinical register and guideline at each service level to be periodically renewed and updated.

**Policy Steps :**

1. Selection of essential medicines must be in harmony with the therapy guideline or standard medication based on best scientific proof.
2. Selection of essential medicines shall be made through in-depth scientific review and transparent decision-taking process which involve Pharmacist, pharmacologists, clinicians and public health experts from various levels of healthcare services and health professional education institutions.
3. Revision of National Essential Medicine List (DOEN) shall be made periodically at minimum of 3-4 years through similar decision-taking process.
4. Dissemination of DOEN to public health service facilities to remote areas, health professional



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education institution, either in printed or electronic media.

**E. RATIONAL USE OF MEDICINES**

**Goal:**

**Use of medicine in proper type, dosage form, dose and quantity furnished with correct, complete and not-misleading information.**

Rational use of medicine is one of the measures to realize good health services. In general, the use of medicine in health services is irrational.

In dealing with irrational use of medicines, the monitoring over medicine use must consider the type of irrationality, degree of issue, causing factor of irrational use of medicines in order to select proper, effective and viable strategy.

The efforts aimed at rational use of medicines must be systematically made at all levels of health services by adopting successfully proven strategies.

**Policy Steps:**

1. The preparation of best-scientific proven standardized therapy to be periodically revised.
2. Selection of medicine by main reference to DOEN.



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3. Formation and/or Empowerment of Pharmacy and Therapy Committee at the Hospital.
4. Clinic-based pharmacotherapy learning in University degree curriculum for health professionals.
5. Sustainable education as one of the mandatory requirements for granting license and authorization in professional practices.
6. Supervision, audit and feedback in medicine use.
7. Supply of accurate, full and non-misleading information on medicines through information centers at public and private healthcare facilities.
8. Community education and empowerment for accurate and appropriate use of medicines and building compliance with medicine use.
9. Regulation and implementation to prevent from incentives for medicine use and prescription.
10. Regulation in support of various measures related to policy on rational medicine use.
11. Promotion of rational medicine use through effective and continuous communication, information to health professionals and community through various media.





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**F. MEDICINES CONTROL**

**Goal:**

1. Distributed medicines must fulfill the requirements for safety, efficacy and quality.
2. Communities are prevented from misuse and ab-use of medicines.

Medicines control is a very complex task which involves the stakeholders i.e. government, entrepreneurs and communities. There are requirements to be satisfactorily met by government agency to perform such control e.q. legal grounds, human resources and adequate financial resources, accessibility to experts, international relationship, accredited, independent and transparent quality examination laboratory.

The objective of medicines control and administration include the aspects of safety, efficacy, quality and validity of medicines in protecting the communities from misuse and inaccurate use of medicines due to lack of knowledge, information and education which must be coped with through cross-sector and program.



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**Policy Steps:**

1. Assessment and Registration of Medicines.
2. Preparation and implementation of product standards and quality system.
3. License and certification of production and distribution facilities.
4. Inspection on production and distribution facilities.
5. Quality test by accredited laboratory.
6. Monitoring over Medicine promotion
7. Post-marketing surveillance and vigilance.
8. Re-assessment on distributed medicines.
9. Improvement of facilities and infrastructures of medicines control and administration and development of health professionals in quantity and quality as per competency standards.
10. Formation of Medicine Information Center at central and local levels for intensified dissemination of information on medicines.
11. Improved regional and international cooperation.
12. Controlling over counterfeit and smuggled medicines (illegal medicines).
13. Development of community role in self protection from substandard, counterfeit and illegal



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medicines through communication, information and education.

**G. RESEARCH AND DEVELOPMENT**

**Goal :**

**Strengthened research and development on medicines in support of implementation of National Medicines Policy.**

Research and development of medicines is aimed at supporting the development on medicines which include study on financing, availability and fair distribution, affordability, selection of essential medicines, rational use of medicines, control, research and development, human resource development, monitoring and evaluation.

**Policy Steps:**

1. Identification of relevant study and setting priority by close work mechanism between the development agents in medicines and research and development agency.
2. Improvement of cross-sector and foreign cooperation on research and development of medicines and improvement of coordination and synchronization of research among various agencies and individuals related to medicines.



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3. Developing and assisting the research as relevant and necessary for development in medicine sector.

**H. HUMAN RESOURCE DEVELOPMENT**

**Goal:**

**Availability of reliable and qualified human resources in promoting the goals of National Medicines Policy.**

Human Resources required in various institutions must be adequate in terms of quantity, competency or distribution. In this respect, it is necessary to improve and develop Human Resources on Health in systematic and sustainable manner in line with the development of science and technology.

Pharmaceutical Warehouse (GFK) as previously existing in each Regency/City has been developed into Pharmacy Installation of Regency/City (IFK) furnished with reliable information system. For such purpose, it is necessary to supply adequate and competent human resources.

The availability of pharmaceutical professionals in community health center, public and private hospital, pharmaceutical companies, pharmaceutical wholesalers, Pharmacist and OTC store will be highly required. Besides, it is also necessary to appoint Pharmacist



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as the administrator at regency/city, province and central level.

**Policy Steps:**

1. Setting up plan for pharmaceutical professionals.
2. Fair supply and distribution of pharmaceutical personnel in each region and healthcare service level.
3. Integration of National Medicines Policy into educational curriculum and training for health professionals.
4. Integration of National Medicines Policy into continuous education by health professional organizations.
5. Strengthening national, regional and international cooperation for human resource development.

**I. MONITORING AND EVALUATION**

**Goals:**

**Supporting the implementation of National Medicines Policy by establishing mechanism for monitoring and evaluation on performance and policy impact to identify barriers and establish effective strategies.**

The implementation of National Medicines Policy will require periodic monitoring and evaluation.



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This is important to make prompt anticipation or correction of environmental changes and complex and rapid development in the communities.

Monitoring and evaluation is inseparable and integral part of activities related to policy development. Necessary corrections will be based on policy monitoring.

Evaluation on policy is aimed at gaining information on implementation, output reporting, outcome measuring, impact evaluation on target group, giving recommendation and revision to policy.

Policy Steps

1. Monitoring and evaluation is periodically performed at maximum interval of 5 years.
2. Implementation and monitoring indicators must comply with WHO recommendation and in collaboration with WHO or other parties concerned to compare the results to other countries.
3. Use of monitoring and evaluation results for:
  - a. Synchronization of policy, policy selection or setting up priority.
  - b. Negotiations with related agencies.



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c. Discussion materials with international agencies and overseas donor.

**V. CLOSING**

The successful implementation of National Medicines Policy is highly dependent on moral, ethics, dedication, competence, integrity, persistence, hard work and sincerity of the stakeholders on medicine sector.

The implementation of National Medicines Policy will require organization, mobilization, monitoring, supervision, control and evaluation. National Medicines Policy must be applied by the as guideline and direction to take further actions by the stakeholders in medicine sector in Indonesia.

National Medicines Policy is a transparent, interactive, interrelation and inter-dependent system by strategic environment at dynamic local, national, regional and global level.



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In the preparation process which also involves various parties during the workshop/seminar as follows:

**Workshop**

**Workshop** on discussion topics 1). National Essential Medicine Lists: Concept and Updating Process; 2) Rational Use of Medicines; 3) Financing: Medical Finance in Public Service Institution After Decentralization and Revitalization of



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Regency Pharmaceutical Warehouse; 4) Distribution of Illegal Medicines & Circulation of Counterfeit Medicines.

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All parties supporting the preparation of KONAS not mentioned herein.

We are sorry for mistakes and errors in the writing of names, title, position or name of agency

I, **Eko Tjahyadi Sworn & Certified Translator**, hereby declare that this document is an English translation of a document prepared in Indonesian language. In translating this document an attempt has been made to translate as literally as possible without jeopardizing the overall continuity of the text. However differences may occur in translation and if they do the original text has precedence in law.

Jakarta, October 08, 2007