# NATIONAL MEDICINES POLICY OF MALAYSIA

Ministry of Health Malaysia

Government of Malaysia

# MALAYSIAN NATIONAL MEDICINES POLICY

Ministry of Health Malaysia

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# *Message by the*
# Honourable Minister of Health, Malaysia

The Malaysian National Medicines Policy (MNMP) is an official document of the Government of Malaysia, which defines and states priorities on the medium and long-term goals set by the government for the pharmaceutical sector. It provides a basic framework for organising and improving the pharmaceutical system. This policy is essential to continually ensure equitable and timely access to good quality medicines that Malaysian consumers need and at a cost individuals and community can afford. It is also essential that medicines meet appropriate quality standards; that there is rational and sustainable funding system and a viable local pharmaceutical industry.

The central tenet of the MNMP is that it encompasses the whole spectrum of medicines, including prescription, non-prescription and traditional medicines in the public and private sectors. It brings together all processes; legislation, regulation, quality control, local production, prescribing, dispensing, rational use of drugs, drug evaluation and consumer education; and all stakeholders involved, to focus on political improvement, management tools and policy guidance.

The Ministry of Health (MOH), Malaysia has taken a positive step towards developing and establishing a National Medicines Policy for the country. Reflecting the growing emphasis on shared responsibility between the government, healthcare providers, consumers and industry in meeting healthcare needs, this policy is the product of wide consultation and partnership in meeting healthcare needs. The work on the MNMP will not stop here, as the ongoing challenge is to turn this policy into action. Efforts towards the implementation of the MNMP will continually be driven by the MOH. I hope that all stakeholders and interested parties will put in their efforts to implement the strategies in the MNMP so that it will be a tangible sign that Malaysia has a cohesive, genuinely representative, fair and sustainable system to ensure continued equitable and timely access to affordable and good quality medicines.

**Y.B Datuk Seri Dr. Chua Soi Lek**
**Minister of Health Malaysia**

# *Message by the*
# Secretary-General
# Ministry of Health, Malaysia

**Bismillah hirrahmanirrahim**
**Assalamualaikum Warahmatullahhiwabarakatuh**

Alhamdulillah, thank to the Almighty Allah S.W.T for giving me a chance to share this glorious moment. I would like to extend my congratulations to the Pharmaceutical Services Division for the achievement in publishing the Malaysian National Medicines Policy (MNMP).

As we are aware, health is a fundamental human right. Access to health care, including essential medicines is central in realizing this right.

Despite many notable successes in expanding access to cheaper drugs, problems continue to persist. In both the public and private sectors, there are still problems of affordability and irrational drug use. Efforts to look at a systematic interaction between these two sectors are particularly important in an effort towards improving equity, affordability and quality of pharmaceuticals. The MNMP embodies one of many efforts towards this integration.

Within the government, structural elements crucial for the successful implementation of the MNMP are already present. There are already in existence the legislation for executive power and legal framework for the Ministry of Health (MOH) to implement the MNMP. Furthermore, there are also divisions within the MOH capable of overseeing, monitoring and administering these legislations.

With the implementation of the MNMP, limitations within the pharmaceutical sector of the health system can be identified through the monitoring of the various indicators and remedial steps can be taken to address the weaknesses. Thus, the MNMP can create an enabling environment for a better-coordinated effort among all stakeholders in the public and private sectors in achieving greater accessibility, equity and quality use of essential medicines.

I hope the public and private sectors will work together towards achieving the objectives of the Malaysia National Medicines Policy.

Thank you. Wassallam

**Dato' Dr. Hj. Mohd Nasir bin Mohd Ashraf**
**Secretary-General, Ministry of Health, Malaysia**

# *Message by the*
# Director-General of Health, Malaysia

The role of pharmaceuticals in the reduction of morbidity and mortality worldwide is well established. To ensure that pharmaceuticals continue to help save lives and improve health, issues related to quality, safety and efficacy, equity to access and rational use of drugs have to be addressed.

Governments and other providers of health have an obligation to see the right to health progressively realised. These include the responsibility for prevention, treatment and the control of diseases; and the creation of conditions to ensure access to health facilities, goods and services. Access to goods and services includes the provision of essential medicines necessary for the prevention and treatment of diseases, as access to essential medicines is fundamental to human rights.

The Malaysian National Medicines Policy (MNMP) represents a formal record of the aspirations, aims, decisions and commitments of the government and the stakeholders, towards a common goal for the pharmaceutical sector; especially in achieving accessibility, equity and quality use of essential medicines.

The Pharmaceutical Services Division of the Ministry of Health (MOH) that advises the ministry on a wide range of medicines policy issues facilitated the development of this MNMP. It has been developed through an extensive consultation processes between the government and various stakeholders with interests in health right from the outset. Although it has taken six years for the MNMP to be realised, in the end, the effort is significantly important, as the deliberations and discussions have produced a transparent framework for a coordinated implementation of strategies by stakeholders in both the public and private sectors.

The Ministry of Health, Malaysia as the custodian of the Malaysian National Medicines Policy is responsible in ensuring that the strategies in the policy are being implemented. I hope that the other stakeholders of health, in the public and private sectors will also give their utmost cooperation and commitment in making the MNMP an implementable and successful policy.

**Tan Sri Datuk Dr. Haji Mohd Ismail bin Merican**
**Director-General of Health, Malaysia**

# *Message by the*
# Director of Pharmaceutical Services

The Malaysian National Medicines Policy (MNMP) is a government policy document that unites the stakeholders in the public and private sectors towards a clear and common objective for the pharmaceutical sector in the country.

The initial formulation of the MNMP was started in 2000 and it was developed through a systematic and consultative process. Two workshops were held in 2001 and 2003 with the involvement all relevant stakeholders, to discuss and develop a policy that incorporates the contributions of all the stakeholders. The development of the MNMP was also assisted by the World Health Organisation by providing consultancy and funding.

The MNMP was approved by the Policy and Development Committee of the Ministry of Health on the 14th of June 2006. Subsequently, it was submitted as a Cabinet Memorandum in July 2006. The Cabinet approved the MNMP as a Government Policy Document on 11th October 2006.

The objective of the MNMP is to improve the health outcome of Malaysians through promoting equitable access to essential medicines; ensuring availability of safe, effective and affordable medicines of good quality and promoting quality use of medicines by healthcare providers and consumers. To achieve the objective of the MNMP, the policy deliberates on four core components namely; quality, safety and efficacy of drugs, drug availability, drug affordability and quality use of drugs. These four components are reinforced by four other supporting components, which are, human resource development; research and development; technical cooperation with other countries and international agencies; and management of the MNMP.

With the clear objective and elucidation of the core and supportive components in the MNMP, we hope that all stakeholders will be clear of their roles and responsibilities in the MNMP. It is also our hope that all stakeholders will give their utmost commitment towards the success of the implementation of the MNMP.

**Dato' Che Mohd. Zin bin Che Awang**
**Director of Pharmaceutical Services**
**Pharmaceutical Services Division**
**Ministry of Health Malaysia**

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# Acknowledgements

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Medical Practice Division, Ministry of Health
Medical Development Division, Ministry of Health
Family Practice Development Division, Ministry of Health
Public Health Division, Ministry of Health
Planning and Development Division, Ministry of Health
Finance Division, Ministry of Health
Oral Health Division, Ministry of Health
Institute of Medical Research, Ministry of Health
Institute of Public Health, Ministry of Health
Legal Advisor, Ministry of Health
Malaysian Organisation of Pharmaceutical Industries (MOPI)
Pharmaceutical Association of Malaysia (PhAMA)
Association of Private Hospitals Malaysia
National Poison Centre, University of Science Malaysia (USM)
Malaysian Medical Association (MMA)
Malaysian Pharmaceutical Society (MPS)
Malaysian Academy of Pharmacy
Consumer Association of Penang (CAP)
Federation of Malaysian Consumers Associations (FOMCA)
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Kulliyah of Pharmacy, International Islamic University Malaysia (IIUM)
Faculty of Pharmacy, University of Technology MARA (UITM)
Department of Pharmacy, Faculty of Health Sciences, Sepang Institute of Technology (SIT)
Faculty of Medicine, Sedaya College
Faculty of Pharmacy, Sedaya College

# MALAYSIAN NATIONAL MEDICINES POLICY (MNMP)

## MALAYSIAN NATIONAL MEDICINES POLICY [MNMP]

## [DASAR UBAT NASIONAL MALAYSIA - DUNAS]

### PREAMBLE

Over the years since independence, the Ministry of Health, Malaysia has instituted various policies that could be considered part and parcel of a national medicines policy for the health and well being of the people. This document attempts to consolidate these existing, together with future, component policies and strategies into a National Medicines Policy.

A documented National Medicines Policy is deemed necessary, as it will provide clear direction and guidance for the nation to embark on future medicines-related programmes to support the healthcare needs of the country.

### INTRODUCTION

The objective of the National Medicines Policy is to promote equitable access to, and rational use of, safe, effective and affordable essential drugs of good quality to improve health outcomes of the people.

Being a crucial commodity for overall healthcare of the people, medicines have to be duly regulated and managed to ensure that the health policies and programmes of the country are fully supported for the well being of the people. The Malaysian health sector requires a National Medicines Policy to ensure these objectives are met.

Legislation is already in place to provide the executive power and legal framework for the Ministry of Health in the implementation of policies on medicines. There are already in place structures and organizations in the Ministry of Health to oversee, monitor and administer the legislation.

The National Medicines Policy shall have the following components to address the strategies required to bring about its sustainable and consistent implementation. These components are:

(i) Quality, safety and efficacy of drugs

(ii) Drug availability

(iii) Drug affordability

(iv) Quality use of drugs

(v) Human resource development

(vi) Research and development

(vii) Technical co-operation

(viii) Management of the National Medicines Policy

# QUALITY, SAFETY AND EFFICACY OF DRUGS

# 1

## 1. QUALITY, SAFETY AND EFFICACY OF DRUGS

**POLICY**

**Only safe, efficacious and quality drugs that meet approved standards and specifications shall be registered and made available for sale and use in Malaysia**

### 1.1 AIM

To ensure that drugs marketed for patient care are safe, effective and of high quality so as to meet the health needs of the nation.

### 1.2 STRATEGY

The aim shall be achieved by strengthening the drug regulatory system through a comprehensive drug legislation framework and enhancement of pharmaceutical quality assurance measures.

### 1.2.1 LEGISLATION AND REGULATIONS

Effective and comprehensive drug legislation shall be instituted to ensure the full implementation of the National Medicines Policy and satisfy the country's obligation under international treaties.

Drug legislation and regulations shall be managed through rational and transparent criteria and processes.

Regulations shall be strengthened to ensure appropriate practices are followed in the development, production, importation, supply, marketing, sale and management (including prescribing, dispensing and disposal) of drugs.

The level of regulation shall be consistent with potential benefits and risks for the community and based on appropriate risk-assessment processes.

#### 1.2.1.1 Drug Control Authority

The Drug Control Authority (DCA) established under the Control of Drugs and Cosmetics Regulations 1984 is the authority responsible for pharmaceutical regulatory control in Malaysia. The National Pharmaceutical Control Bureau (NPCB) as its secretariat is the agency that develops and implements the regulations concerning the quality, safety and efficacy of drugs. The DCA shall concurrently enforce these legislations and regulations with the pharmacy enforcement units.

The DCA shall liaise with relevant departments and organizations involved in the implementation of this policy. Inter and intra-agency coordination, cooperation and information sharing between the public and private sectors shall be enhanced for the development and implementation of pharmaceutical regulations.

The DCA shall play a prominent role in facilitating regional and international harmonisation of drug regulations in Malaysia.

#### 1.2.1.2 Licensing of Premises

**i. Licensing of Manufacturers, Importers and Wholesalers**

Only licensed manufacturers, importers and wholesalers shall handle registered pharmaceutical products. The manufacturing, import and wholesale trading of controlled medicines shall be undertaken by a licensed pharmacist at the specified address on his/her license. These activities must also be conducted in licensed premises in accordance with the requirements of Good Manufacturing Practice (GMP), Good Storage Practice (GSP) and other additional requirements as stipulated by the law. Inspections of the premises shall be done prior to issuance of any licence. All licences shall be reviewed and renewed in accordance with the law.

**ii. Licensing of retail and dispensing outlets**

The retail sale of controlled medicines shall be carried out in licensed premises by licensed pharmacists. Dispensing of medicines shall be carried out by a registered pharmacist while registered medical and dental practitioners may dispense drugs for the treatment and use of their patients only.

The sale of registered products other than controlled medicines should only be made through licensed premises.

All dispensing of medicines shall comply with uniform standards and regulations to meet the requirements of quality, effective and safe drug supply.

Premises of registered medical and dental practitioners involved in dispensing shall also conform to the same standards.

#### 1.2.1.3 Prescription of drugs

Prescription drugs shall only be prescribed by registered medical and dental practitioners.

#### 1.2.1.4 Inspection

Drug legislation and regulations shall be supported by adequate and effective professional inspections to ensure that all activities in the drug manufacturing and supply chain comply with the requirements of the relevant licences and regulations.

The pharmacy enforcement officers shall perform inspections of healthcare facilities in relation to medicines. Inspection of manufacturing facilities and wholesale premises shall be conducted by GMP/GSP auditors.

#### 1.2.1.5 Medicines advertisement and promotion

The Ministry of Health shall regulate all advertisement and promotion of drugs including traditional medicines. The regulations shall be in line with the WHO ethical criteria for medicinal promotion.

Prevailing relevant legislation shall be reviewed and strengthened when necessary.

#### 1.2.1.6 Intellectual Property Rights

Drugs under patent shall have the protection conferred under the patent law of the country. Drugs bearing the Trade Marks shall have the protection conferred under the Trade Mark Law of the country. For public health interests, the flexibility of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement may be applied.

#### 1.2.1.7 Counterfeit Drugs

An appropriate legal and technical framework for concurrent enforcement of laws and regulations by the Ministry of Health for market surveillance shall be established to combat the problem of counterfeit drugs.

### 1.2.2 PHARMACEUTICAL QUALITY ASSURANCE

An effective pharmaceutical quality assurance system shall be implemented to ensure all medicines received by consumers are safe, effective, of good quality and meet all specifications and standards at every stage of supply throughout their shelf life. Pharmaceutical quality assurance activities shall involve all parties in the drug supply chain.

Legislation shall be provided to control both the quality of drugs and all professional activities and services, which have a bearing on drug quality.

#### 1.2.2.1 Drug Registration

Only medicines registered by the DCA shall be allowed to be marketed and used in Malaysia.

Assessment of safety, quality and efficacy based on adequate and scientific data is the prerequisite for registration. Registration of traditional medicines will be based on safety and quality until such time research in traditional medicines can be developed to enable efficacy be also a prerequisite for registration. Registration criteria shall be reviewed when necessary in accordance with the policies of the DCA, national legal requirements or international standards. The registration shall only be valid for a specified period as deemed appropriate by the DCA after which every drug is required to be re-evaluated for re-registration.

There shall be appropriate procedures for the timely registration of life-saving products and essential drugs without jeopardizing the elements of safety, quality and efficacy.

#### 1.2.2.2 Inspection

Inspections shall be conducted to ascertain that all activities within the drug manufacturing and supply chain comply with the regulations. Current GMP and GSP principles and any other requirements deemed necessary by the regulatory authority shall form the basis of these inspections.

Inspection shall be extended to drug quality control laboratories to ensure compliance with current Good Laboratory Practice (GLP). The clinical trial centres shall be inspected to ensure conformity with Good Clinical Practice (GCP).

Legal provision shall be made for the drug regulatory auditors to immediately enforce the regulations whenever necessary.

Training programmes for auditors in collaboration with relevant training institutions shall be developed and inspection guidelines shall be established to facilitate effective inspection services.

#### 1.2.2.3 Quality Control

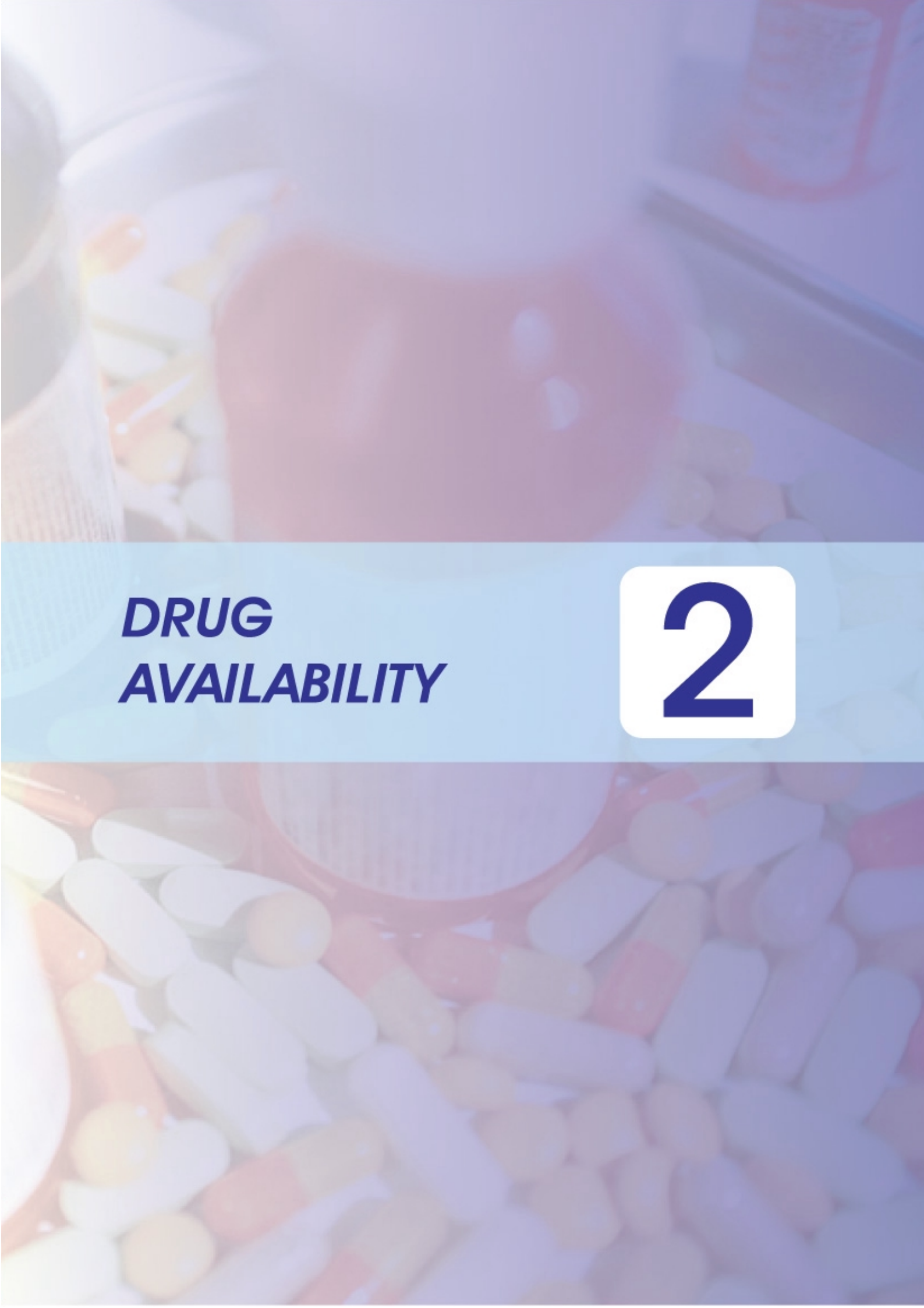
There shall be an official national drug quality control (QC) laboratory under the Ministry of Health. The test results of this laboratory and those operating under its control shall have legal standing.

Regional laboratories within Malaysia shall be established to fulfil local needs for surveillance of marketed products.

#### 1.2.2.4 Post- Marketing Surveillance

An effective post-marketing surveillance system including monitoring of adverse drug reactions will be ongoing to ensure drug quality, safety and efficacy.

The DCA in collaboration with the pharmacy enforcement officers shall ensure that products in the market are duly registered and comply with the conditions of registration. Restrictions on usage and removal from the market should be instituted where circumstances warrant.



# DRUG AVAILABILITY

# 2

## 2. DRUG AVAILABILITY

**POLICY**

**An efficient and integrated drug management and supply network shall be maintained.**

### 2.1 AIM

To ensure an equitable, adequate and continuous availability of safe, effective and quality essential drugs to the entire population.

### 2.2 STRATEGY

The aim shall be achieved through the careful selection of medicines, improvement in the management of drug procurement and the supply chain, and through optimal utilization of available financial resources.

### 2.2.1 SELECTION OF MEDICINES

Selection of medicines should be based on the essential drugs concept that includes selection criteria such as disease pattern, cost-effectiveness and therapeutic advantage.

This shall be achieved through the development of an Essential Drugs Programme, which includes promotion of a National Essential Drugs List (NEDL) and the development of evidence-based Standard Treatment Guidelines reconciled with existing Clinical Practice Guidelines.

An NEDL technical committee comprising experts in medicine, pharmacy, dentistry, pharmacology, public health, consumer affairs, health economics and others appointed by the Ministry of Health shall be responsible for the selection of medicines.

The process of drug selection by the technical committee shall be carried out independently after transparent and wide consultation with interested parties such as representatives of health professionals, pharmaceutical manufacturers and consumer organizations.

The NEDL shall be updated regularly to keep up with the advances in drug therapy and to ensure it meets the need to improve clinical outcomes. Particular attention shall be given to medicines used at the primary healthcare level. Only generic (international non-proprietary names (INN)) names shall be used in the NEDL.

**The NEDL based on Standard Treatment Guidelines shall serve as a guide for:**

- public sector drug procurement, distribution and utilization.
- undergraduate, postgraduate and in-service training of health professionals and public education on quality drug use
- drug information to healthcare providers
- support to the domestic pharmaceutical industry
- drug financing/ reimbursement schemes
- drug donations

#### 2.2.1.1 Traditional Medicines

A technical committee comprising health and traditional practitioners, experts in phytotherapy, pharmacognosy, toxicology and other related fields appointed by the Ministry of Health shall be set up. This committee shall establish the criteria for selection of traditional medicines for the healthcare delivery system with the help of WHO guidelines for the assessment of traditional medicines.

### 2.2.2 SUPPLY

There should be an equitable, adequate, affordable and regular supply of safe, effective and quality essential drugs to the population.

This shall be achieved by implementing:

- cost-effective drug procurement
- effective management of the drug supply system based on total quality management concept
- efficient and coordinated drug delivery system
- effective Information and Communication Technology (ICT) to support the supply network

#### 2.2.2.1 Procurement

The drug procurement system shall be strengthened to ensure adequate and timely availability of the most cost-effective medicines nationwide. The long-term goal is to achieve self-reliance through a shift from importation to increased local production.

A reliable mechanism shall be maintained to ensure adequate financing for procurement of medicines in the public sector based on proper quantification of estimates on population served, morbidity, actual drug prices and related to consumption data.

Procurement shall be planned and performance of suppliers monitored and audited regularly.

Order quantities shall be based on reliable estimates of actual needs. Drug procurement shall be guided by the National Essential Drugs List and all procurement documents shall list drugs by their generic name (INN).

In the selection of suppliers, priority shall be given to domestically manufactured medicines. Procurement shall aim at securing the lowest available prices for products of defined specifications.

#### 2.2.2.2 Domestic Medicines Production

Domestic production of medicines in sufficient quantities shall be encouraged especially those in the NEDL.

The aim is to support the development of a viable domestic pharmaceutical industry and manufacturing capacities in the production of medicines leading to increased national self-sufficiency in pharmaceutical supplies and reduced excessive dependence on imports.

Domestic manufacturers may be eligible for incentives subject to fulfilment of criteria established by the government. Export of locally produced medicines shall be encouraged to stimulate the expansion of the domestic pharmaceutical industry.

#### 2.2.2.3 Distribution, Storage and Disposal

An effective and economical distribution network shall be strengthened to ensure prompt distribution of adequate quantities of quality essential medicines to all healthcare facilities.

Transit time in the supply chain should be minimal to ensure timely delivery. The concept of just-in-time and direct supply to health facilities shall be implemented wherever practical.

The Information and Communication Technology (ICT) network for logistics, inventory and financial transactions shall be established in all health facilities.

Storage, inventory control and quality assurance in facilities shall comply with GSP requirements to ensure maintenance of quality and security of drugs throughout the storage period. Disposal of expired or obsolete drugs shall be in accordance with prevailing environmental laws and regulations.

#### 2.2.2.4 Drug supply in emergency situations and drug donations

Receipt of drugs in emergency situations or as donations shall be based on expressed needs as recommended by the WHO Guidelines for drug donations for donors and recipients.

# DRUG AFFORDABILITY

# 3

## 3. DRUG AFFORDABILITY

### POLICY

**The pharmaceutical industry shall be organized and regulated to create incentives and foster competition in drug prices. Appropriate financing mechanisms shall be developed to ensure essential drugs needed for quality healthcare are affordable**

### 3.1 AIM

To ensure continuous access and financial sustainability of essential drugs at prices affordable to all.

### 3.2 STRATEGY

The aim can be achieved by implementing cost-containment measures and developing appropriate and reliable financing mechanisms to ensure equitable access to essential drugs for the population.

#### 3.2.1 Prices of Drugs

Maintaining the prices of essential drugs at a reasonable level affordable by all shall be achieved by monitoring drug prices, ensuring a rational pricing system and promoting the use of generic drugs.

The prices of essential drugs shall be monitored to obtain information on price trends with early detection of price increases and other influences in the market so that prompt action can be taken to contain any undue price increases.

Drugs shall continue to be exempted from taxes and import duties to help maintain prices at the lowest possible level.

##### 3.2.1.1 Pricing Policy

A rational pricing structure shall be developed to ensure fair, reasonable, affordable and stable prices of drugs especially essential drugs.

A database shall be developed to monitor the cost of drugs especially essential drugs in Malaysia in comparison with prices in other countries.

#### 3.2.1.2 Price Information

Independent and objective information on price of medicines shall be disseminated to health professionals and consumers.

Price labelling on ready-to-dispense packages shall be implemented to ensure price transparency and healthy competition in the market.

Itemized billing indicating the price of each item bought or supplied shall be required.

### 3.2.2 Generic Medicines Policy

Procurement of multi-source products by generic names shall be promoted to foster healthy competition in drug pricing.

Appropriate incentives to promote the use of generic drugs and their production in the country shall be introduced.

A formulary of interchangeable generic drugs and the list of products that cannot be substituted shall be made available.

All dispensed drugs shall be labeled with the generic (INN) name of the medicine with or without the brand name.

Generic prescribing and labeling should be encouraged, and generic substitution permitted and eventually legislated, in order to improve affordability of medicines.

### 3.2.3 Drug Financing

Reliable drug financing mechanisms shall be established to achieve universal access to essential drugs.

There shall be planning, budgeting and securing of sufficient funding for the supply of medicines with emphasis on cost-containment measures.

The financing mechanism shall ensure that the poor are not denied access to essential medicines.

# QUALITY USE OF DRUGS

# 4

## 4. QUALITY USE OF DRUGS

### POLICY

**Quality use of drugs by healthcare providers and consumers shall be promoted. Activities of the government, industry and media in support of informed and appropriate use of drugs by consumers shall be encouraged**

### 4.1 AIM

To contribute towards quality of care and cost-effective therapy.

### 4.2 STRATEGY

The aim shall be achieved by promoting rational prescribing and appropriate use of medicines by consumers through:-

- training and education
- provision of independent, evidence-based drug information
- establishment of therapeutic committees, development of standard treatment guidelines and standards of professional practice
- ethical promotion of drugs
- provision of relevant legislations

### 4.2.1 Education and Training

#### 4.2.1.1 Healthcare Providers

All healthcare providers involved in prescribing and dispensing of drugs shall possess at least the relevant minimum qualifications and shall receive adequate theoretical and practical training in drug use.

The core curricula of training programmes for all healthcare providers shall be revised to include the concepts of essential drugs, quality use of drugs, generic drug policies, patient-counselling and communication. These concepts shall also be emphasized during in-service training programmes.

Systematic and comprehensive programmes of continuing education shall be developed and implemented.

#### 4.2.1.2 General Public

The Ministry of Health shall collaborate with relevant ministries and agencies including the mass media to educate the general public regarding the benefits and risks of drugs.

Public education to promote compliance and ensure good treatment outcomes shall be enhanced. The emphasis shall be on:

- objective and practical information on drugs and their proper use
- developing a more discerning attitude to advertising and commercial information
- encouraging informed decision-making on use of drugs based on adequate scientific information
- responsible self-medication
- confidence to interact with healthcare providers

This shall be done through partnerships among government and nongovernmental organizations (NGOs), academia, professional associations, pharmaceutical industry, consumer and community groups.

### 4.2.2 Drug Information

Accurate, unbiased and relevant information on drugs shall be widely disseminated to all healthcare providers as well as to patients and the general public.

Drug information centres shall have adequate ICT facilities, human and financial resources. Pharmacists shall have access to sources of reference. The central drug information system shall provide any additional information if required.

Networking between all drug information centres shall be established to enable the sharing and optimising of resources. This shall also facilitate the effective dissemination of drug information and the monitoring of adverse drug reactions.

Product information leaflets and drug labelling shall be regulated to ensure the availability of accurate, adequate and unbiased information understandable by patients.

### 4.2.3 Drugs and Therapeutic Committees

The national and hospital drugs and therapeutic committees shall play important roles in improving the quality use of drugs.

At the national level, the committee shall coordinate the development of a National Essential Drugs List and matching Standard Treatment Guidelines.

Hospital drugs and therapeutic committees should be responsible for the development and coordination of in-house policies related to pharmaceuticals and adopting the National Essential Drugs List to their local needs. Standard Treatment Guidelines if developed at the national level should be adapted for local use.

### 4.2.4 Standard Treatment Guidelines

Evidence-based Standard Treatment Guidelines harmonized with existing clinical practice guidelines shall be developed by experts in related disciplines including representatives of general practitioners and community pharmacists and coordinated by the national drugs and therapeutic committee.

The Standard Treatment Guidelines shall indicate the most cost-effective therapeutic approach on the basis of clinical evidence and define the desired prescribing and drug use behaviour. They shall constitute the foundation of all educational, regulatory and managerial interventions to promote quality drug use by health professionals.

The guidelines shall cover the common diseases and conditions. They shall be the basis for differential availability of drugs at various levels of healthcare. The guidelines shall be made available to all healthcare providers.

### 4.2.5 Prescribing and Dispensing Practices

Prescriptions should be written using generic names.

Currently medical and dental practitioners are allowed to dispense medicines for the treatment of their patients. Nevertheless, ultimately, to improve the quality use of medicines, prescribing and dispensing functions must be separated.

### 4.2.6 Role of Pharmacists

Pharmacists have a central role in dispensing medicines and counselling patients on their use.

Pharmacists shall be involved in the multi-disciplinary approach to the quality utilization of drugs.

### 4.2.7 Medicines Advertisements and Promotions

All medicinal promotion and marketing activities should be done ethically and in accordance to the related law. Information given shall be reliable, accurate, informative and up-to-date.

# HUMAN RESOURCES DEVELOPMENT

# 5

## 5. HUMAN RESOURCES DEVELOPMENT

### POLICY

**The human resource needs of the pharmaceutical sector shall be planned and developed**

### 5.1 AIM

To ensure sufficient experts, professionals and trained personnel in the pharmaceutical sector.

### 5.2 STRATEGY

The aim shall be achieved through manpower planning and training.

#### 5.2.1 Planning

The planning and effective development of human resources, both short and long term, shall be implemented.

#### 5.2.2 Education and Training

Quality assurance mechanisms shall be strengthened to ensure that training institutions meet the required standards.

Accreditation of relevant programmes offered by institutions of higher learning and other training centres shall be established to maintain the quality of professionals produced.

The training for various categories of healthcare providers shall include principles of the National Medicines Policy, standard treatment guidelines, essential medicines and the quality use of medicines.

On-the-job training, continuing education programmes, distance learning and innovative training approaches such as virtual campuses within the health institutions shall be utilised.

# RESEARCH AND DEVELOPMENT

6

## 6. RESEARCH AND DEVELOPMENT

### POLICY

**Research in utilization, management and development of medicines shall be enhanced.**

### 6.1 AIM

To improve medicines utilisation and management and to encourage drug research and development.

### 6.2 STRATEGY

The aim shall be achieved through partnerships among the policy makers, healthcare providers, industry, academia, research institutions, professional bodies, NGOs and consumer associations in the following areas:-

- development of capability and capacity for research
- development of trained and competent researchers
- promotion of a research culture among healthcare providers
- creation of a conducive environment for research
- integration and enhancement of drug research facilities and capabilities.

### 6.2.1 Drug utilization and management

Research to identify the best approach for managing the drug delivery system and pharmaceutical care shall be emphasized.

**The priority areas are:-**

- Impact of the National Medicines Policy
- Pharmacoeconomics
- Issues related to prescribing and dispensing
- Behavioural and socio-cultural aspects of drug use

### 6.2.2 Drug research and development

Research for safe, effective and efficacious drugs aimed at alleviating common diseases and conditions as well as newly emerging and re-emerging health problems shall be encouraged. This shall include both basic and industrial research.

Transfer and acquisition of technology by domestic companies are strongly recommended.

Drug-related clinical trials shall be organized and conducted in accordance with Good Clinical Practice Guidelines including the need for institutional ethics review. Relevant regulation will be introduced to safeguard the integrity of clinical trials and the welfare of trial subjects.

Research in traditional medicines shall also be encouraged.

# TECHNICAL CO-OPERATION

7

## 7. TECHNICAL CO-OPERATION

### POLICY

**Technical collaboration and co-operation in the implementation and strengthening of relevant areas in the pharmaceutical sector shall be established with various stakeholders at the national, regional and international levels**

### 7.1 AIM

To ensure that relevant technical co-operations are explored, best practices and agreed standards promoted to optimise the effective use of resources and strengthen national and regional policies.

### 7.2 STRATEGY

The aim shall be achieved by training, sharing of information, expertise, skills and facilities and through harmonisation of legislation, regulations and guidelines pertaining to medicines at national, regional and international levels.

Partnerships involving various stakeholders and key players in the healthcare sector shall be enhanced to achieve the desired goals, setting strategies and priorities, and implementing policies.

#### 7.2.1 National Perspective

The Ministry of Health shall play a leading role in facilitating inter and intraagency coordination, cooperation and information sharing between public and private sectors for pharmaceutical services planning and implementation.

Effective partnerships with consumers, industry, research institutions, academia, professionals, practitioners, government agencies and NGOs shall be further developed to provide support for continued progress towards a globalised environment in the pharmaceutical sector.

Strategic alliance through mutual and shared understanding of roles, open communication, consultative arrangements and consensus agreement between stakeholders, regulators and implementers shall be fostered to achieve the appropriate standard of regulations and enforcement.

### 7.2.2 International Perspective

International cooperation and liaison in related areas shall be established by participating actively in relevant international organisations such as Association of South East Asian Nations (ASEAN), World Health Organization (WHO), International Conference on Harmonisation (ICH) and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Common efforts towards improvement and harmonization of technical standards and procedures shall be continued to establish mutual recognition agreements in harmonization standards and policies amongst ASEAN and other economies.

Benchmarking against current international requirements shall be established to improve local standards and foster confidence in relevant aspects.

A global information network for effective communication shall be established to provide a framework for exchange and sharing of information.

Continuous training and technical support in related areas shall be provided to promote training and human resource development.

### 7.3 Areas For Technical Co-operation

Technical co-operation shall be enhanced to include the following areas:

- Regulatory practices - Drug quality, efficacy and safety
- Drug accessibility - Equity, availability and affordability
- Quality use of drugs
- Training and human resources development
- Drug research and development

# MANAGEMENT OF THE NATIONAL MEDICINES POLICY

# 8

## 8. MANAGEMENT OF THE NATIONAL MEDICINES POLICY

### POLICY

**All stakeholders shall be committed to the successful implementation of the National Medicines Policy**

### 8.1 AIM

To ensure successful implementation of the National Medicines Policy.

### 8.2 STRATEGY

The aim shall be achieved by developing a master action plan. Monitoring and evaluation of performance and impact shall be established.

#### 8.2.1 Master Action Plan

The government in collaboration with relevant bodies shall develop a six-year master action plan. The plan shall facilitate the implementation of the National Medicines Policy.

#### 8.2.2 Monitoring and Evaluation

The government shall develop the functional capabilities to monitor and evaluate the progress of the National Medicines Policy.

Data for indicators recommended by WHO for monitoring drug policies shall be compiled and form part of the National Health Information System for the pharmaceutical sector. Progress in the National Medicines Policy implementation shall be monitored every three (3) years and a full evaluation of the policy will be done every six (6) years. The results of the monitoring and full evaluation of the National Medicines Policy should be made public.

# GLOSSARY

## GLOSSARY

***Clinical Practice Guideline*** ~ Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. (Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine. Clinical practice guidelines: directions for a new program. Washington: National Academy Press; 1990. p.38.)

***Counterfeit Drug*** ~ One which is deliberately and fraudulently labelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging (Dept. Essential Drugs and Other Medicines, WHO 1999).

***Dispensed Medicine*** ~ A medicine supplied by a registered medical practitioner, registered dentist or veterinary surgeon under and in accordance with section 19 or supplied, for the purpose of the medical, dental or animal treatment, of a particular individual by a licensed pharmacist on the premises specified in his license. (Poisons Act, 1952)

***Drug*** ~ Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. (The Use of Essential Drugs. Ninth report of the WHO Expert Committee (2000)

The words "drugs", "medicines" and "pharmaceuticals" are used interchangeably in this document.

***Drug Enforcement Officer*** ~ Any registered pharmacist in the public service duly authorized in writing by the Licensing Officer under section 31 (1) Poisons Act, 1952. (Poisons Act, 1952)

***Efficacious*** ~ Scientifically shown to be effective in the prevention, alteration, management and/or cure of an illness. The evidence for efficacy will ideally be established from controlled clinical trials. In some cases, traditional or complementary medicine where only low level claims for efficacy are to be made [e.g. relief of minor symptoms] requirement for evidence of efficacy may be less stringent although quality and safety must be established.

***Essential Drugs*** ~ Drugs that are required to treat the majority of conditions that are prevalent in a country in a cost-effective and efficient manner. The concept does not imply that no other drugs are useful, but these are most basic, indispensable and necessary for the health care of the majority of the population. They should be available at all times, in adequate amount and in the proper dosage forms, to all segments of the society. (WHO 1975)

***Generic Drugs*** ~ A generic medicine is a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after the expiry of patented or other exclusivity rights (WHO 1997, Comparative Analysis of National Drug Policies, Geneva, WHO/DAP/97.6)

***Good Clinical Practice*** ~ A standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented. (Guidelines for good clinical practice (GCP) for trials on pharmaceutical products, WHO Technical Report Series, No. 850, 1995, Annex 3)

***Good Manufacturing Practice*** ~ Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. (Good Manufacturing Practices for Pharmaceutical Products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report, Geneva, WHO 1992. WHO Technical Report Series, No. 823. Annex 1)

***International Nonproprietary Names*** ~ Identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name. (Guidelines on the Use of International Non-Proprietary Names (INN) For Pharmaceutical Substance, WHO/PHARM S/NOM 1570)

***Licensed Pharmacist*** ~ A registered pharmacist who is the holder of a Type A License issued to him under section 26 Poisons Act, 1952. (Poisons Act, 1952)

***Pharmaceutical product*** ~ Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form that is subject to control by pharmaceutical legislation in both the exporting state and the importing state. (Good Practices for National Pharmaceutical Control Laboratories. Annex 3. WHO Technical Report Series. No.902.2002)

***Controlled Medicine*** ~ Any substance specified by name in the first column of the Poisons List and includes any preparation, solution, compound, mixture or natural substance containing such substance, or other than an exempted preparation or an article or preparation included for the time being in the second Schedule (Poisons Act, 1952)

***Prescription-only drugs*** ~ These are drugs supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these drugs must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription drugs are further subdivided into controlled drugs (narcotic drugs and psychotropic substances) and non-controlled drugs. (Guidelines for inspection of drug distribution channels. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fifth report. Geneva, WHO 1999, Annex 6 (WHO Technical Report Series, No. 885).

***Primary Health Care*** ~ Primary health care is essential health care made accessible at a cost a country and community can afford, with methods that are practical, scientifically sound and socially acceptable. (Alma Ata Declaration, WHO, Geneva, 1978)

***Quality Assurance*** ~ A wide-ranging concept covering all matters that individually or collectively influences the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use (Quality Assurance of Pharmaceuticals. A Compendium of guidelines and related materials Vol.2: Good manufacturing practices and inspection. Geneva, WHO 1999)

***Quality Control*** ~ Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics. (Quality Assurance of Pharmaceuticals. A Compendium of guidelines and related materials Vol.2: Good manufacturing practices and inspection. Geneva, WHO 1999)

***Registered Dentist*** ~ A dental practitioner registered in Division I or Division II of the Register kept under section 11 (1) of the Dental Act 1971; and "registered dentist Division I" and "registered dentist Division II" means a dental practitioner whose name has been registered in the first or second division respectively of the said Register (Poisons Act, 1952)

***Registered Medical Practitioner*** ~ A medical practitioner registered under the Medical Act 1971. (Dangerous Drug Act, 1952) Registered Pharmacist ~ A person whose name appears for the time being in the Register kept under Registration of Pharmacists Act, 1951. (Registration of Pharmacists Act, 1951)

***Traditional medicine*** ~ Any product used in the practice of indigenous medicine, in which the drug consist of solely one or more naturally occurring substance of a plant, animal or mineral, or parts thereof, in the unextracted or crude extract form, and a homeopathic medicine (Control of Drugs and Cosmetics Regulations 1984)

## ABBREVIATIONS

| | |
|---|---|
| **CPG** | – Clinical Practice Guidelines |
| **DCA** | – Drug Control Authority |
| **GCP** | – Good Clinical Practice |
| **GLP** | – Good Laboratory Practice |
| **GMP** | – Good Manufacturing Practice |
| **GSP** | – Good Storage Practice |
| **ICT** | – Information and Communication Technology |
| **INN** | – International Non-proprietary Names |
| **NEDL** | – National Essential Drug List |
| **STG** | – Standard Treatment Guidelines |
| **TRIPS** | – Trade Related Intellectual Property Rights |