9 789833 433155

NATIONAL MEDICINES POLICY OF MALAYSIA

Ministry Of Health Malaysia

NATIONAL MEDICINES POLICY OF MALAYSIA

Ministry of Health Malaysia

Government of Malaysia

MALAYSIAN NATIONAL MEDICINES POLICY

Ministry of Health Malaysia

Second published 2009
First published 2007

ISBN 978-983-3433-15-5

MALAYSIAN NATIONAL MEDICINES POLICY

CONTENTS

CONTENTS

Acknowledgement

The Pharmaceutical Services Division (PSD) of the Ministry of Health would like to thank the World Health Organisation (WHO) for its assistance and all who have contributed in one way or another in making this policy a reality.

The PSD would especially like to express appreciation to the following participants and stakeholders of the two consultative workshops that were held in the preparation of this policy:

Ministry of Domestic Trade and Consumer Affairs
Statistics Department of Malaysia
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)
Association of Private Medical Practitioners
Medical Faculty, National University of Malaysia (UKM)
Pharmacy Department, National University of Malaysia (UKM)
Medical Faculty, University of Malaya (UM)
Pharmacy Department, University of Malaya (UM)
School of Pharmaceutical Sciences, University of Science Malaysia (USM)
School of Medical Sciences, University of Science Malaysia (USM)
Medical School, International Medical University (IMU)
Pharmacy and Health Sciences, International Medical University (IMU)
Kulliyah of Medicine, International Islamic University Malaysia (IIUM)
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]

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

MALAYSIAN NATIONAL MEDICINES POLICY

1 QUALITY, SAFETY AND EFFICACY OF DRUGS

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.

MALAYSIAN NATIONAL MEDICINES POLICY

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.

MALAYSIAN NATIONAL MEDICINES POLICY

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.

MALAYSIAN NATIONAL MEDICINES POLICY

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.

MALAYSIAN NATIONAL MEDICINES POLICY

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.

MALAYSIAN NATIONAL MEDICINES POLICY

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.

MALAYSIAN NATIONAL MEDICINES POLICY

7 TECHNICAL CO-OPERATION

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

MALAYSIAN NATIONAL MEDICINES POLICY

8 MANAGEMENT OF THE NATIONAL MEDICINES POLICY

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.

MALAYSIAN NATIONAL MEDICINES POLICY

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 Registratio n of Pharmacist s 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

DASAR UBAT NASIONAL (DUNAS)

Kementerian Kesihatan Malaysia

MALAYSIAN NATIONAL MEDICINES POLICY

KANDUNGAN

KANDUNGAN

DASAR UBAT NASIONAL (DUNAS)

PENDAHULUAN

Semenjak merdeka, Kementerian Kesihatan Malaysia telah memperkenalkan pelbagai dasar yang merupakan sebahagian daripada dasar ubat negara untuk kesihatan dan kesejahteraan orang ramai. Dokumen ini bertujuan untuk menyatukan komponen dan strategi dasar sedia ada dengan yang dirancang untuk masa hadapan ke dalam satu Dasar Ubat Nasional.

Dokumentasi Dasar Ubat Nasional adalah diperlukan kerana ia dapat memberi hala tuju dan garis panduan yang jelas kepada negara dalam melaksanakan program yang berkaitan dengan ubat-ubatan pada masa depan untuk menyokong keperluan perkhidmatan kesihatan Negara.

PENGENALAN

Objektif Dasar Ubat Nasional adalah untuk menggalakkan keperolehan yang sama rata dan penggunaan yang rasional ubat-ubat penting yang berkualiti, selamat, berkesan dan mampu dimiliki bagi meningkatkan tahap kesihatan orang ramai.

Sebagai komoditi yang penting dalam menentukan penjagaan kesihatan orang ramai secara keseluruhannya, ubat perlu sentiasa dikawal dan diurus untuk memastikan dasar dan program kesihatan yang dirancang oleh kerajaan disokong sepenuhnya untuk kesejahteraan orang ramai. Sektor kesihatan Malaysia memerlukan Dasar Ubat Nasional untuk memastikan semua objektif tersebut dapat dicapai.

Undang-undang sedia ada telah diperuntukkan untuk memberikan kuasa eksekutif dan rangka kerja yang sahih kepada Kementerian Kesihatan Malaysia dalam melaksanakan dasar berkaitan ubat-ubatan. Organisasi dan badan tertentu telah ditubuhkan dalam Kementerian Kesihatan Malaysia untuk mengawasi, memantau dan mentadbir perundangan ini.

Dasar Ubat Nasional hendaklah mempunyai komponen-komponen di bawah untuk memberi perhatian kepada strategi-strategi yang diperlukan ke arah kesinambungan dan pelaksanaannya yang konsisten. Komponen-komponen tersebut adalah:

(i) Kualiti, keselamatan dan keberkesanan ubat

(ii) Ketersediaan ubat

(iii) Kemampuan mendapat ubat-ubatan

(iv) Penggunaan ubat secara berkualiti

(v) Pembangunan sumber manusia

(vi) Penyelidikan dan pembangunan

(vii) Kerjasama teknikal

(viii) Pengurusan Dasar Ubat Nasional

MALAYSIAN NATIONAL MEDICINES POLICY

1 KUALITI, KESELAMATAN DAN KEBERKESANAN UBAT

1. KUALITI, KESELAMATAN DAN KEBERKESANAN UBAT

POLISI

Hanya ubat-ubatan yang selamat, berkesan, berkualiti serta memenuhi standard dan spesifikasi sahaja boleh didaftarkan dan diperolehi untuk jualan dan digunakan di Malaysia

1.1 MATLAMAT

Untuk memastikan ubat-ubatan yang dipasarkan untuk penjagaan pesakit adalah selamat, berkesan dan berkualiti tinggi serta memenuhi keperluan kesihatan sejagat.

1.2 STRATEGI

Matlamat ini akan dicapai dengan mengukuhkan sistem regulatori ubat-ubatan melalui satu rangka kerja perundangan ubat-ubatan yang komprehensif dan meningkatkan langkah-langkah kepastian kualiti farmaseutikal.

1.2.1 UNDANG-UNDANG DAN PERATURAN

Undang-undang yang berkesan dan komprehensif mengenai ubat hendaklah diuruskan untuk memastikan Dasar Ubat Nasional dilaksanakan secara menyeluruh dan memenuhi kewajipan negara atas perjanjian antarabangsa.

Undang-undang dan peraturan mengenai ubat hendaklah diuruskan melalui kriteria dan proses yang telus dan rasional.

Peraturan-peraturan hendaklah diperkukuhkan untuk memastikan amalan yang betul dipatuhi di dalam pembentukan, pengilangan, pengimportan, pengedaran, pemasaran, penjualan dan pengurusan (termasuk *prescribing*, pendispensan dan pelupusan) ubat.

Tahap peraturan hendaklah konsisten dengan potensi faedah dan risiko yang dihadapi oleh komuniti dan berdasarkan proses penilaian risiko yang bersesuaian.

1.2.1.1 Pihak Berkuasa Kawalan Dadah

Pihak Berkuasa Kawalan Dadah (PBKD) yang ditubuhkan di bawah Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 adalah satu badan berkuasa yang bertanggungjawab ke atas pengawalan regulatori farmaseutikal di Malaysia. Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) yang bertindak sebagai sekretariat PBKD adalah agensi yang menyediakan dan melaksanakan peraturan-peraturan yang berkaitan dengan kualiti, keselamatan dan keberkesanan ubat-ubatan. PBKD hendaklah bersama-sama menguatkuasakan undang-undang dan peraturan ini dengan Unit Penguatkuasaan Farmasi.

PBKD hendaklah berhubung dengan jabatan-jabatan dan badan-badan berkaitan yang terlibat dalam pelaksanaan dasar ini. Koordinasi inter- dan intra-agensi, kerjasama dan perkongsian maklumat antara sektor kerajaan dan swasta hendaklah dipertingkatkan untuk pembangunan dan pelaksanaan peraturan-peraturan farmaseutikal ini.

PBKD hendaklah memainkan peranan yang penting di Malaysia dalam menyelaraskan harmonisasi peraturan ubat-ubatan serantau dan antarabangsa.

1.2.1.2 Pelesenan Premis

i. Perlesenan Pengilang, Pengimport dan Pemborong

Hanya pengeluar, pengimport, dan pemborong berlesen sahaja yang boleh mengendalikan produk farmaseutikal berdaftar. Pengilangan, pengimportan dan pemborongan ubat-ubat terkawal hendaklah dilakukan oleh ahli farmasi berlesen seperti yang dinyatakan secara spesifik di dalam lesen. Aktiviti-aktiviti tersebut hendaklah di jalankan di premis berlesen dan mematuhi keperluan Amalan Pengilangan Baik (APB), Amalan Penstoran Baik (GSP), dan keperluan-keperluan lain seperti yang dinyatakan di dalam undang-undang. Pemeriksaan ke atas premis hendaklah dilakukan terlebih dahulu sebelum mana-mana lesen dikeluarkan. Semua lesen hendaklah disemak semula dan diperbaharui mengikut peruntukan undang-undang.

ii. Pelesenan runcit dan saluran pendispensan

Jualan runcit bagi ubat-ubatan terkawal hendaklah dijalankan di premis berdaftar oleh ahli farmasi berlesen. Pendispensan ubat hendaklah dijalankan oleh ahli farmasi berdaftar manakala pengamal perubatan dan pergigian berdaftar dibenarkan mendispens ubat untuk rawatan dan kegunaan pesakit-pesakit mereka sahaja.

Jualan produk berdaftar selain daripada ubat terkawal hendaklah dijalankan di premis berlesen.

Semua ubat yang didispenskan hendaklah mematuhi standard dan peraturan yang seragam untuk memenuhi keperluan bekalan ubat yang berkualiti, efektif dan selamat.

Premis-premis bagi pengamal perubatan dan pergigian berdaftar yang terlibat dalam pendispenan hendaklah memenuhi standard yang sama.

1.2.1.3 Ubat-ubat Preskripsi

Ubat-ubat preskripsi hanya boleh di preskripsikan oleh pengamal perubatan dan pergigian berdaftar.

1.2.1.4 Pemeriksaan

Perundangan dan peraturan-peraturan ubat hendaklah disokong oleh pemeriksaan profesional yang efektif dan mencukupi untuk memastikan semua aktiviti di dalam pengilangan ubat dan rangkaian bekalan mematuhi keperluan pelesenan dan undang-undang yang berkaitan.

Pegawai penguatkuasa farmasi hendaklah melakukan pemeriksaan di fasiliti-fasiliti kesihatan yang mempunyai kaitan dengan ubat-ubatan. Pemeriksaan fasiliti pengilangan dan premis borong hendaklah dijalankan oleh juruaudit GMP/GSP.

1.2.1.5 Promosi dan Iklan Ubat-ubatan

Kementerian Kesihatan hendaklah mengawal iklan dan promosi ubat-ubatan termasuk ubat tradisional. Peraturan-peraturan tersebut hendaklah selari dengan kriteria etika yang ditetapkan WHO untuk promosi ubat-ubatan.

Undang-undang berkaitan hendaklah dikaji semula dan diperkukuhkan apabila perlu.

1.2.1.6 Hak Harta Intelek

Ubat-ubatan yang masih dalam paten hendaklah dikawal mengikut undang-undang paten negara tersebut. Ubat-ubatan yang mempunyai Tanda Perniagaan hendaklah dilindungi di bawah Undang-undang Tanda Perniagaan negara tersebut. Untuk kepentingan kesihatan awam, kelonggaran dalam *Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement* boleh digunapakai.

1.2.1.7 Ubat Palsu

Undang-undang dan rangka kerja teknikal yang sejajar dengan penguatkuasaan undang-undang dan peraturan oleh Kementerian Kesihatan untuk pengawasan pasaran hendaklah ditubuhkan untuk membanteras masalah ubat palsu.

1.2.2 KEPASTIAN KUALITI FARMASEUTIKAL

Sistem kepastian kualiti farmaseutikal yang efektif hendaklah dilaksanakan untuk memastikan semua ubat yang diterima oleh pengguna adalah selamat, efektif, berkualiti dan memenuhi semua tentuan dan standard dalam setiap peringkat bekalan sepanjang jangka hayat ubat tersebut. Aktiviti kepastian kualiti farmaseutikal hendaklah melibatkan semua pihak dalam rangkaian pembekalan ubat.

Undang-undang hendaklah diperuntukkan untuk mengawal kualiti ubat, perkhidmatan dan aktiviti profesional yang mempunyai kesan terhadap kualiti ubat.

1.2.2.1 Pendaftaran Ubat

Hanya ubat yang berdaftar dengan PBKD sahaja yang dibenarkan untuk dipasarkan dan digunakan di Malaysia.

Penilaian keselamatan, kualiti, dan keberkesanan yang berdasarkan data saintifik yang mencukupi adalah prasyarat untuk pendaftaran. Pendaftaran ubat tradisional adalah berdasarkan keselamatan dan kualiti sehingga satu masa penyelidikan ubat tradisional boleh dihasilkan di mana keberkesanan juga merupakan prasyarat untuk pendaftaran. Kriteria pendaftaran juga hendaklah dikaji semula apabila perlu dan mematuhi dasar PBKD, keperluan undang-undang negara atau standard antarabangsa. Pendaftaran hendaklah hanya sah untuk satu tempoh masa tertentu yang dianggap berpatutan oleh PBKD, selepas itu setiap ubat perlu dinilai semula untuk pendaftaran semula.

Prosedur yang sesuai adalah dikehendaki untuk pendaftaran yang tepat pada waktunya bagi produk-produk penyelamat nyawa dan ubat-ubat penting tanpa membelakangkan elemen keselamatan, kualiti dan keberkesanan.

1.2.2.2 Pemeriksaan

Pemeriksaan hendaklah dijalankan untuk memastikan semua aktiviti dalam pengilangan dan rangkaian pembekalan produk adalah mematuhi peraturan. Prinsip GMP dan GSP terkini dan keperluan-keperluan lain yang dianggap perlu oleh pihak regulatori hendaklah menjadi panduan untuk pemeriksaan.

Pemeriksaan hendaklah dilanjutkan ke makmal kawalan kualiti ubat untuk memastikan kepatuhan kepada *Good Laboratory Practice (GLP)* semasa. Pusat percubaan klinikal perlu diperiksa untuk memastikan kepatuhan kepada *Good Clinical Practice (GCP)*.

Peruntukan undang-undang hendaklah diadakan untuk juruaudit regulatori ubat supaya boleh menguatkuasakan peraturan dengan serta-merta apabila perlu.

Program latihan untuk juruaudit dengan kerjasama institusi latihan yang berkaitan hendaklah dibangunkan dan garispanduan pemeriksaan hendaklah diwujudkan untuk memudahkan perkhidmatan pemeriksaan secara efektif.

1.2.2.3. Kawalan Kualiti

Satu makmal kawalan kualiti ubat kebangsaan *(Quality Control)* yang rasmi hendaklah diwujudkan di bawah Kementerian Kesihatan. Keputusan ujian dari makmal ini dan apa sahaja operasi di bawah kawalannya hendaklah mempunyai keutuhan undang-undang.

Makmal tempatan di Malaysia hendaklah ditubuhkan bagi memenuhi keperluan tempatan untuk menjalankan pemantauan ke atas produk-produk yang telah dipasarkan.

1.2.2.4 Pemantauan Pasca Pemasaran

Sistem pemantauan pasca pemasaran yang efektif termasuk pemantauan kesan advers ubat akan dijalankan secara berterusan untuk memastikan kualiti, keselamatan dan keberkesanan ubat.

PBKD dengan kerjasama pegawai penguatkuasa farmasi hendaklah memastikan produk yang terdapat di pasaran telah berdaftar dan mematuhi keperluan pendaftaran. Penggunaan yang terhad dan penarikan produk dari pasaran perlu dilakukan apabila keadaan mewajarkannya.

MALAYSIAN NATIONAL MEDICINES POLICY

KETERSEDIAAN UBAT 2

2. KETERSEDIAAN UBAT

POLISI

Pengurusan ubat yang efisien dan berintegrasi serta rangkaian pembekalan ubat hendaklah dikekalkan.

2.1 MATLAMAT

Untuk memastikan ketersediaan ubat-ubat penting yang selamat, berkesan dan berkualiti secara berterusan kepada seluruh penduduk.

2.2 STRATEGI

Tujuan ini hendaklah dicapai melalui pemilihan ubat secara teliti, penambahbaikan pengurusan perolehan dan rangkaian pembekalan ubat, dan melalui penggunaan sumber-sumber kewangan secara optimum.

2.2.1 Pemilihan Ubat

Pemilihan ubat hendaklah berdasarkan konsep ubat-ubat penting yang melibatkan kriteria pemilihan seperti corak penyakit, keberkesanan kos dan faedah terapeutik.

Ini hendaklah dicapai melalui pembangunan Program Ubat-ubat Penting termasuk promosi 'Senarai Ubat-Ubat Penting Kebangsaaan' *(National Essential Drugs List (NEDL)* dan pembangunan Garispanduan Rawatan Standard berdasarkan bukti *(evidence-based)* yang selaras dengan 'Garispanduan Amalan Klinikal' *(Clinical Practice Guidelines)* sedia ada.

Jawatankuasa Teknikal NEDL yang terdiri daripada pakar-pakar dalam bidang perubatan, farmasi, pergigian, farmakologi, kesihatan awam, hal-ehwal pengguna, ekonomi kesihatan dan lain-lain yang telah dilantik oleh Menteri Kesihatan hendaklah bertanggungjawab dalam pemilihan ubat-ubatan.

Proses pemilihan ubat oleh jawatankuasa teknikal hendaklah dijalankan secara bebas selepas rundingan yang telus dan menyeluruh dilakukan dengan pihak yang berkepentingan seperti wakil-wakil dari profesional kesihatan, pengilang-pengilang farmaseutikal dan persatuan pengguna.

NEDL ini hendaklah sentiasa dikemaskini agar seiring dengan kemajuan terapi ubat dan untuk memastikan ia memenuhi keperluan untuk menambahbaik hasil klinikal. Perhatian hendaklah diberikan kepada ubat-ubatan yang digunakan dalam penjagaan kesihatan tahap primer. Nama generik *(International Non-proprietary Name (INN))* hendaklah digunakan dalam NEDL.

NEDL yang berdasarkan kepada 'Garispanduan Terapi Standard' *(Standard Treatment Guidelines)* hendaklah digunakan sebagai panduan untuk :-

- perolehan, pengagihan dan penggunaan ubat-ubatan di sektor awam.
- mahasiswa(i), pasca ijazah, latihan dalam perkhidmatan untuk profesional kesihatan dan pendidikan pengguna tentang penggunaan ubat yang berkualiti.
- maklumat ubat kepada pengamal kesihatan
- sokongan kepada industri farmaseutikal tempatan
- pembiayaan ubat /skim bayaran balik
- pendermaan ubat

2.2.1.1 Ubat Tradisional

Satu Jawatankuasa Teknikal yang terdiri daripada pengamal kesihatan dan perubatan tradisional, pakar-pakar dalam bidang fitoterapi, farmakognosi, toksikologi dan lain-lain bidang berkaitan hendaklah dibentuk dan dilantik oleh Kementerian Kesihatan. Jawatankuasa ini hendaklah menentukan syarat pemilihan ubat tradisional untuk sistem penjagaan kesihatan dengan berpandukan garispanduan penilaian produk tradisional yang telah ditetapkan oleh WHO.

2.2.2 BEKALAN

Pembekalan ubat yang selamat, berkesan dan berkualiti hendaklah sama rata, mencukupi dan berpatutan kepada kesemua pengguna.

Ini hendaklah dicapai melalui pelaksanaan :

- Perolehan ubat yang kos-efektif
- Sistem pengurusan ubat secara efektif yang berdasarkan konsep pengurusan kualiti menyeluruh.
- Sistem pembekalan ubat yang efisien dan selaras
- Sistem teknologi maklumat dan komunikasi yang efektif untuk menyokong jaringan pembekalan ubat.

2.2.2.1 Perolehan

Sistem perolehan ubat-ubatan perlu diperkukuhkan untuk memastikan ubat yang kos-efektif mudah didapati dan dibekalkan dalam kuantiti yang mencukupi ke seluruh negara. Matlamat jangka panjang adalah untuk mengubah tahap kebergantungan negara kepada ubat-ubatan yang diimport dari luar negara kepada ubat-ubatan keluaran tempatan.

Mekanisme yang sesuai hendaklah dikekalkan untuk memastikan sumber kewangan yang diperuntukkan adalah mencukupi berdasarkan kepada anggaran kuantiti sewajarnya untuk populasi yang menerima perkhidmatan, mobiditi, harga ubat sebenar dan data-data yang berkaitan penggunaan ubat.

Mekanisme perolehan hendaklah dirancang dan status pencapaian pembekal perlu dipantau dan diaudit secara berkala.

Kuantiti ubat yang ditempah hendaklah berdasarkan anggaran wajar keperluan yang sebenar. Proses perolehan hendaklah berpandukan Senarai Ubat Penting Kebangsaan. Nama ubat dalam dokumen-dokumen perolehan hendaklah disenaraikan mengikut nama generik (INN).

Dalam pemilihan pembekal, keutamaan hendaklah diberikan kepada pengilang ubat-ubatan domestik. Matlamat utama adalah untuk memperolehi harga yang paling rendah untuk produk ubat berdasarkan spesifikasi yang ditetapkan.

2.2.2.2 Pengeluaran Ubat Tempatan

Pengeluaran ubat secara tempatan dalam kuantiti yang mencukupi terutama untuk ubat yang terkandung dalam senarai NEDL hendaklah digalakkan.

Matlamat utama adalah untuk menyokong pembangunan industri farmaseutikal domestik yang berdaya maju dan kemampuan pengilangan dalam pengeluaran ubat-ubatan yang membawa kepada peningkatan pembekalan mampu diri nasional dalam bekalan farmaseutikal dan mengurangkan kebergantungan kepada yang diimport.

Pengilang-pengilang tempatan adalah layak untuk menerima insentif sekiranya memenuhi syarat yang ditetapkan oleh pihak kerajaan. Pengeksportan ubat-ubatan keluaran tempatan hendaklah digalakkan untuk merangsang perkembangan industri farmaseutikal tempatan.

2.2.2.3 Pengagihan, Penyimpanan Dan Pelupusan

Rangkaian pengagihan ubat-ubatan yang efektif dan ekonomik hendaklah diperkukuhkan untuk memastikan ubat-ubat penting berkualiti yang mencukupi dibekalkan kepada fasiliti-fasiliti penjagaan kesihatan mengikut masa yang ditetapkan.

Tempoh pengagihan ubat-ubatan perlu diminimumkan untuk memastikan ubat yang diterima tepat pada masanya. Konsep *"just-in-time"* dan pembekalan secara terus ke fasiliti-fasiliti kesihatan hendaklah dilaksanakan sekiranya praktikal.

Rangkaian Teknologi Maklumat dan Komunikasi (ICT) untuk logistik, inventori dan transaksi kewangan hendaklah ditubuhkan di semua fasiliti kesihatan.

Penstoran, kawalan inventori dan jaminan kualiti di fasiliti-fasiliti hendaklah mematuhi keperluan GSP untuk memastikan pengekalan kualiti dan keselamatan ubat-ubatan sepanjang tempoh penyimpanan. Pelupusan ubat yang telah tamat tarikh luput hendaklah mematuhi undang-undang dan peraturan-peraturan alam sekitar.

2.2.2.4 Pembekalan Ubat Untuk Kes Kecemasan Dan Pendermaan Ubat

Penerimaan ubat-ubatan untuk kes-kes kecemasan atau pendermaaan hendaklah berpandukan keperluan yang disarankan oleh garis panduan WHO yang berkaitan dengan pendermaan ubat, penderma dan penerima.

MALAYSIAN NATIONAL MEDICINES POLICY

KEMAMPUAN MENDAPAT UBAT-UBATAN

3

3. KEMAMPUAN MENDAPAT UBAT-UBATAN

POLISI

Industri farmaseutikal hendaklah diurus dan dikawal selia untuk menghasilkan insentif dan menggalakkan persaingan bagi harga ubat-ubatan. Mekanisme-mekanisme pembiayaan yang bersesuaian hendaklah dibangunkan untuk memastikan ubat-ubat penting yang diperlukan untuk penjagaan kesihatan yang berkualiti adalah mampu dimiliki.

3.1 MATLAMAT

Untuk memastikan akses yang berterusan dan pembiayaan kewangan yang lestari bagi ubat-ubat penting pada harga yang mampu dimiliki oleh semua.

3.2 STRATEGI

Matlamat di atas dapat dicapai dengan pelaksanaan langkah-langkah batasan kos dan membangunkan mekanisme pembiayaan yang bersesuaian dan boleh dipercayai bagi memastikan akses ubat-ubat penting yang sama rata bagi semua penduduk.

3.2.1 Harga Ubat-ubatan

Pengekalan harga ubat-ubat penting pada tahap yang berpatutan dan mampu dimiliki oleh semua hendaklah dicapai dengan memantau harga ubat-ubatan, memastikan sistem harga yang rasional dan mempromosikan penggunaan ubat-ubat generik.

Harga ubat-ubat penting hendaklah dipantau untuk mendapatkan maklumat mengenai corak harga melalui pengesanan awal kenaikan harga dan pengaruh-pengaruh lain dalam pasaran agar tindakan segera dapat diambil bagi mengatasi kenaikan harga yang tidak sepatutnya.

Pengecualian cukai dan duti import untuk ubat-ubatan hendaklah diteruskan untuk membantu mengekalkan harga pada kadar yang paling rendah.

3.2.1.1 Dasar Harga

Satu struktur harga yang rasional hendaklah dibangunkan untuk memastikan harga ubat-ubatan yang adil, berpatutan, mampu perolehi dan stabil terutamanya bagi ubat-ubat penting.

Satu pangkalan data perlu dibangunkan untuk memantau kos ubat-ubatan terutamanya ubat-ubat penting di Malaysia berbanding harga di negara-negara lain.

3.2.1.2 Maklumat Harga

Maklumat harga ubat yang objektif dan bebas hendaklah disebarkan kepada profesional kesihatan dan pengguna.

Pelabelan harga pada pek pendispensan hendaklah dilaksanakan untuk memastikan ketelusan harga dan persaingan sihat di dalam pasaran.

Bil terperinci yang menunjukkan harga bagi setiap item yang dibeli atau dibekalkan adalah dikehendaki.

3.2.2 Dasar Ubat-Ubat Generik

Perolehan produk daripada pelbagai sumber melalui nama generik hendaklah digalakkan bagi merangsang persaingan sihat dalam harga ubat.

Insentif yang bersesuaian untuk menggalakkan penghasilan dan penggunaan ubat generik hendaklah diperkenalkan.

Formulari untuk ubat-ubat generik yang boleh saling bertukarganti dan senarai produk yang tidak boleh digantikan hendaklah disediakan.

Semua ubat-ubatan yang didispen hendaklah dilabelkan dengan nama generik (INN) bersama dengan atau tanpa nama jenama ubat .

Prescribing dan pelabelan dengan menggunakan nama generik hendaklah digalakkan, dan penggantian ubat generik adalah dibenarkan dan sah dari segi perundangan bagi tujuan meningkatkan kemampuan kepada ubat-ubatan.

3.2.3 Pembiayaan Ubat-ubatan

Mekanisme pembiayaan ubat-ubatan yang wajar hendaklah dibentuk bagi membolehkan akses sejagat kepada ubat-ubatan.

Perancangan, belanjawan dan jaminan dana yang mencukupi bagi bekalan ubat-ubatan hendaklah diadakan dengan memberi penekanan kepada batasan kos *(cost-containment)*.

Mekanisme pembiayaan tersebut hendaklah memastikan golongan miskin tidak dinafikan untuk mendapatkan akses kepada ubat-ubat penting.

MALAYSIAN NATIONAL MEDICINES POLICY

PENGGUNAAN UBAT-UBATAN SECARA BERKUALITI 4

4. PENGGUNAAN UBAT-UBATAN SECARA BERKUALITI

POLISI

Penggunaan ubat-ubatan secara berkualiti oleh pengamal perubatan dan pengguna hendaklah digalakkan. Aktiviti-aktiviti pihak kerajaan, industri dan pihak media dalam menyokong penggunaan ubat berdasarkan bukti dan bersesuaian untuk pengguna hendaklah digalakkan

4.1 MATLAMAT

Untuk menyumbang kepada penjagaan yang berkualiti dan terapi berkeberkesanan kos.

4.2 STRATEGI

Matlamat ini hendaklah dicapai dengan menggalakkan *prescribing* secara rasional dan penggunaan ubat-ubatan yang bersesuaian oleh pengguna melalui:

- latihan dan pendidikan
- pemberian maklumat ubat yang bebas dan berdasarkan bukti *(evidence-based)*
- penubuhan jawatankuasa terapeutik, pembangunan garispanduan rawatan standard dan standard praktis profesional.
- promosi ubat-ubatan secara beretika
- peruntukan undang-undang yang berkaitan

4.2.1 Pendidikan dan Latihan

4.2.1.1 Pengamal Penjagaan Kesihatan

Semua pengamal penjagaan kesihatan yang terlibat dengan *prescribing* dan pendispensan ubat-ubatan perlu memiliki sekurang-kurangnya kelayakan minimum yang relevan dan hendaklah mendapat latihan yang mencukupi dari segi teori dan praktikal dalam penggunaan ubat.

Kurikulum utama bagi program latihan untuk semua pengamal penjagaan kesihatan hendaklah dikaji semula dengan memasukkan konsep ubat-ubat penting, penggunaan ubat-ubatan secara berkualiti, dasar untuk ubat generik, kaunseling pesakit dan komunikasi. Konsep-konsep tersebut juga hendaklah diberi penekanan semasa program latihan dalam perkhidmatan.

Program-program pendidikan secara berterusan yang komprehensif dan sistematik harus dibangunkan dan dilaksanakan.

4.2.1.2 Orang awam

Kementerian Kesihatan hendaklah bekerjasama dengan kementerian-kementerian dan agensi-agensi yang relevan termasuk media massa untuk mendidik orang awam mengenai faedah dan risiko ubat-ubatan.

Pendidikan kepada orang awam untuk menggalakkan kepatuhan kepada ubat-ubatan dan memastikan hasil rawatan yang baik hendaklah dipertingkatkan. Penekanan hendaklah dilakukan ke atas:

- Maklumat yang objektif dan praktikal mengenai ubat-ubatan dan penggunaannya yang betul.
- Membangunkan sikap yang lebih menilai *(discerning attitude)* kepada pengiklanan perdagangan.
- Menggalakkan pengambilan keputusan yang berasaskan pengetahuan ke atas penggunaan ubat-ubatan berdasarkan maklumat saintifik yang mencukupi.
- Pengubatan kendiri yang bertanggungjawab.
- Keyakinan untuk berinteraksi dengan pengamal penjagaan kesihatan.

Perkara ini hendaklah dilaksanakan melalui kerjasama antara badan kerajaan dan badan bukan kerajaan (NGOs), akademia, persatuan-persatuan profesional, industri farmaseutikal, pengguna dan kumpulan-kumpulan masyarakat.

4.2.2 Maklumat Ubat-ubatan

Maklumat ubat-ubatan yang tepat, tidak berat sebelah dan relevan perlu disebarkan kepada semua pengamal penjagaan kesihatan, pesakit dan orang awam.

Pusat maklumat ubat hendaklah mempunyai kemudahan teknologi maklumat dan komunikasi, sumber manusia dan kewangan. Ahli Farmasi hendaklah mendapat akses kepada sumber-sumber rujukan. Pusat sistem maklumat ubat hendaklah membekalkan maklumat tambahan jika perlu.

Rangkaian antara semua pusat maklumat ubat perlu diwujudkan supaya sumber rujukan dapat dikongsi dan digunakan secara optimum. Ia dapat memudahkan penyebaran maklumat ubat-ubatan dan pemantauan terhadap kesan advers ubat-ubatan secara berkesan.

Maklumat pada sisip pembungkusan produk dan label ubat hendaklah dikawal untuk memastikan maklumat yang diperolehi adalah tepat, mencukupi dan tidak berat sebelah serta boleh difahami oleh pesakit.

4.2.3 Jawatankuasa Ubat-ubatan dan Terapeutik

Jawatankuasa ubat-ubatan dan terapeutik di peringkat hospital dan kebangsaan hendaklah memainkan peranan penting dalam meningkatkan penggunaan ubat-ubatan secara berkualiti.

Di peringkat kebangsaan, jawatankuasa-jawatankuasa hendaklah menyelaras pembangunan Senarai Ubat-ubat Penting Kebangsaan *(National Essential Drugs List)* dan selari dengan Garispanduan Rawatan Standard *(Standard Treatment Guidelines)*.

Jawatankuasa ubat-ubatan dan terapeutik peringkat hospital perlu bertanggungjawab terhadap pembangunan dan penyelarasan ke atas dasar-dasar setempat yang berkaitan dengan farmaseutikal dan menggunapakai Senarai Ubat-ubat Penting Kebangsaan untuk keperluan tempatan. Garispanduan Rawatan Standard yang dibangunkan di peringkat kebangsaan perlu digunapakai untuk kegunaan tempatan.

4.2.4 Garispanduan Rawatan Standard

Garispanduan Rawatan Standard *(Standard Treatment Guidelines)* yang berdasarkan bukti yang diharmonikan dengan garispanduan amalan klinikal sedia ada hendaklah dibangunkan oleh pakar-pakar dalam disiplin berkaitan termasuk wakil-wakil dari pengamal perubatan dan ahli farmasi komuniti dan diselaraskan oleh jawatankuasa ubat-ubatan dan terapeutik kebangsaan.

Garispanduan Rawatan Standard hendaklah menggunakan pendekatan terapeutik yang berkeberkesanan kos, berdasarkan pendekatan bukti klinikal dan mentakrifkan corak tingkahlaku *prescribing* dan penggunaan yang dihasratkan. Ianya hendaklah menjadi asas bagi semua intervensi pendidikan, pengawalan dan pengurusan bagi menggalakkan penggunaan ubat secara berkualiti oleh professional kesihatan.

Garispanduan ini hendaklah merangkumi penyakit-penyakit dan keadaan-keadaan yang lazim berlaku. Ianya hendaklah berdasarkan kepada ketersediaan ubat-ubatan yang berbeza-beza pada pelbagai peringkat penjagaan kesihatan. Selain itu, garispanduan ini hendaklah sentiasa ada untuk semua pengamal penjagaan kesihatan.

4.2.5 Amalan *Prescribing* dan Pendispensan

Preskripsi hendaklah ditulis dengan menggunakan nama generik.

Pada masa ini, pengamal perubatan dan pergigian dibenarkan untuk mendispen ubat untuk merawat pesakit mereka. Bagaimana pun, pada akhirnya fungsi *prescribing* dan pendispensan mestilah diasingkan supaya penggunaan ubat-ubatan secara berkualiti dapat dipertingkatkan.

4.2.6 Peranan Ahli Farmasi

Ahli Farmasi mempunyai peranan utama dalam pendispensan dan kaunseling mengenai penggunaan ubat-ubatan kepada pesakit.

Ahli Farmasi hendaklah terlibat dalam pendekatan pelbagai disiplin ke arah penggunaan ubat-ubatan secara berkualiti.

4.2.7 Iklan dan Promosi Ubat-ubatan

Semua aktiviti promosi dan pemasaran ubat-ubatan hendaklah dilakukan secara beretika dan mematuhi undang-undang yang berkaitan. Maklumat yang diberikan hendaklah boleh dipercayai, tepat, berinformasi dan terkini.

MALAYSIAN NATIONAL MEDICINES POLICY

PEMBANGUNAN SUMBER MANUSIA

5

5. PEMBANGUNAN SUMBER MANUSIA

POLISI

Keperluan sumber manusia dalam sektor farmaseutikal hendaklah dirancang dan dibangunkan

5.1 MATLAMAT

Memastikan pekerja yang mahir, profesional dan terlatih adalah mencukupi di dalam sektor farmaseutikal.

5.2 STRATEGI

Matlamat ini hendaklah dicapai melalui perancangan dan latihan sumber manusia.

5.2.1 PERANCANGAN

Perancangan dan pembangunan sumber manusia yang berkesan untuk jangkamasa pendek dan panjang hendaklah dilaksanakan.

5.2.2 PENDIDIKAN DAN LATIHAN

Mekanisme kepastian kualiti hendaklah diperkukuhkan untuk memastikan institut-institut latihan memenuhi standard yang ditetapkan.

Akreditasi bagi program-program yang relevan yang ditawarkan oleh institusi pengajian tinggi dan pusat latihan lain hendaklah diwujudkan untuk mengekalkan kualiti ahli profesional yang dihasilkan.

Latihan untuk pelbagai kategori pengamal penjagaan kesihatan hendaklah mengandungi prinsip-prinsip Dasar Ubat Nasional, garis panduan rawatan standard, ubat-ubat penting dan penggunaan ubat secara berkualiti.

Latihan di dalam perkhidmatan, program pembelajaran berterusan, pembelajaran jarak jauh dan pendekatan latihan inovasi seperti kampus maya dalam institusi-institusi kesihatan hendaklah dilaksanakan.

MALAYSIAN NATIONAL MEDICINES POLICY

PENYELIDIKAN DAN PEMBANGUNAN 6

6. PENYELIDIKAN DAN PEMBANGUNAN

POLISI

Penyelidikan dalam penggunaan, pengurusan dan pembangunan ubat-ubatan hendaklah dipertingkatkan

6.1 MATLAMAT

Untuk menambahbaik penggunaan dan pengurusan ubat-ubatan dan seterusnya menggalakkan penyelidikan dan pembangunan ubat-ubatan.

6.2 STRATEGI

Matlamat ini hendaklah dicapai melalui kerjasama antara penggubal dasar, pemberi penjagaan kesihatan, industri, akademia, institusi-institusi penyelidikan, badan profesional, badan bukan kerajaan (NGOs) dan persatuan pengguna dalam bidang seperti berikut:

- perkembangan kemampuan dan keupayaan untuk penyelidikan
- pembangunan penyelidik yang kompeten dan terlatih
- menggalakkan budaya penyelidikan di kalangan pemberi penjagaan kesihatan
- mewujudkan persekitaran yang sesuai untuk tujuan penyelidikan.
- penyepaduan dan peningkatan fasiliti dan keupayaan untuk penyelidikan untuk ubat-ubatan.

6.2.1 Penggunaan dan Pengurusan Ubat

Penyelidikan untuk mengenalpasti pendekatan terbaik dalam menguruskan sistem penyampaian ubat dan penjagaan farmaseutikal hendaklah diberi penekanan. Keutamaan hendaklah diberikan untuk bidang-bidang seperti :

- Impak Dasar Ubat Nasional
- Farmakoekonomik
- Isu yang berkaitan dengan *prescribing* dan pendispensan
- Aspek tingkah laku dan budaya sosial penggunaan ubat

6.2.2 Pembangunan dan Penyelidikan Ubat

Penyelidikan untuk keselamatan dan keberkesanan ubat-ubatan yang bertujuan untuk meringankan keadaan dan penyakit biasa serta masalah-masalah kesihatan yang baru berlaku dan berulang semula hendaklah digalakkan. Ini hendaklah melibatkan penyelidikan asas dan industri.

Pemindahan dan perolehan teknologi oleh syarikat tempatan adalah amat disarankan.

Kajian klinikal yang berkaitan ubat hendaklah dirancang dan dijalankan berpandukan *Good Clinical Practice Guidelines* termasuk keperluan kajian semula etika institusi. Peraturan yang relevan akan diperkenalkan untuk melindungi integriti kajian-kajian klinikal dan kebajikan subjek-subjek yang terlibat dalam kajian tersebut.

Penyelidikan ubat-ubatan tradisional juga hendaklah digalakkan.

MALAYSIAN NATIONAL MEDICINES POLICY

KERJASAMA TEKNIKAL 7

7. KERJASAMA TEKNIKAL

POLISI

Usahasama dan kerjasama teknikal dalam pelaksanaan dan pengukuhan bidang-bidang yang relevan di dalam sektor farmaseutikal hendaklah ditubuhkan dengan pelbagai pemegang amanah di peringkat kebangsaan, serantau dan antarabangsa

7.1 MATLAMAT

Untuk memastikan kerjasama teknikal yang relevan diterokai, amalan terbaik dan standard yang dipersetujui digalakkan untuk mengoptimumkan penggunaan sumber-sumber secara efektif dan memperkukuhkan dasar-dasar negara dan serantau.

7.2 STRATEGI

Matlamat ini hendaklah dicapai melalui latihan, perkongsian maklumat, kepakaran, keterampilan dan kemudahan-kemudahan melalui harmonisasi perundangan, peraturan-peraturan dan garis panduan berkaitan ubat-ubatan di peringkat kebangsaan, serantau dan antarabangsa.

Perkongsian yang melibatkan pelbagai pemegang amanah dan barisan utama dalam sektor penjagaan kesihatan hendaklah dipertingkatkan untuk mencapai matlamat yang dikehendaki, menetapkan strategi dan keutamaan, dan melaksanakan dasar-dasar .

7.2.1 Perspektif Nasional

Kementerian Kesihatan hendaklah memainkan peranan sebagai peneraju dalam mempermudahkan koordinasi inter- dan intraagensi, kerjasama dan perkongsian maklumat di antara sektor awam dan swasta untuk perancangan dan pelaksanaan perkhidmatan farmasi.

Perkongsian efektif dengan pengguna, industri, institusi-institusi penyelidikan, akademia, profesional, pengamal, agensi-agensi kerajaan dan badan-badan bukan kerajaan (NGOs) hendaklah terus dibangunkan untuk memberi sokongan kepada perkembangan berterusan sektor farmaseutikal ke arah persekitaran global.

Pakatan strategik melalui perkongsian dan saling kesefahaman tentang peranan, penentuan perundingan terbuka, khidmat perunding dan persetujuan perjanjian di antara pemegang amanah, pengawal selia *(regulator)* dan pelaksana hendaklah digalakkan untuk mencapai peraturan-peraturan dan penguatkuasaan standard yang bersesuaian.

7.2.2 Perspektif Antarabangsa

Kerjasama antarabangsa dan hubungan dalam bidang yang berkaitan hendaklah diwujudkan melalui penyertaan secara aktif dalam organisasi antarabangsa yang relevan seperti *Association of South East Asian Nations (ASEAN), World Health Organization (WHO), International Conference on Harmonisation (ICH)* dan *Pharmaceutical Inspection Co-operation Scheme (PIC/S)*.

Usaha-usaha lazim ke arah penambahbaikan dan harmonisasi standard teknikal dan prosedur hendaklah diteruskan untuk mewujudkan pengiktirafan perjanjian bersama dalam harmonisasi standard dan polisi di kalangan ASEAN dan negara-negara ekonomi yang lain.

Penanda aras yang menurut keperluan antarabangsa semasa hendaklah dibangunkan untuk meningkatkan standard tempatan dan memupuk keyakinan dalam aspek yang relevan.

Jaringan informasi global untuk komunikasi yang efektif hendaklah dibangunkan untuk menyediakan rangka kerja bagi pertukaran dan perkongsian maklumat.

Latihan berterusan dan sokongan teknikal di dalam bidang berkaitan hendaklah disediakan untuk menggalakkan latihan dan pembangunan sumber manusia.

7.3 BIDANG-BIDANG KERJASAMA TEKNIKAL

Kerjasama teknikal hendaklah dipertingkatkan untuk merangkumi bidang-bidang seperti berikut:

- Amalan regulatori - kualiti, keberkesanan dan keselamatan ubat
- Akses ubat - sama rata, ketersediaan dan kemampuan
- Penggunaan ubat yang berkualiti
- Latihan dan pembangunan sumber manusia
- Penyelidikan dan pembangunan ubat

MALAYSIAN NATIONAL MEDICINES POLICY

PENGURUSAN DASAR UBAT NASIONAL

8

8. PENGURUSAN DASAR UBAT NASIONAL

POLISI

Semua pemegang amanah hendaklah memberi komitmen kepada kejayaan pelaksanaan Dasar Ubat Nasional

8.1 MATLAMAT

Untuk memastikan kejayaan pelaksanaan Dasar Ubat Nasional.

8.2 STRATEGI

Matlamat tersebut hendaklah dicapai dengan membangunkan satu pelan tindakan induk. Pemantauan dan penilaian pencapaian dan impak hendaklah diwujudkan.

8.2.1 Pelan Tindakan Induk

Pihak kerajaan, dengan kerjasama badan-badan berkaitan yang relevan hendaklah membangunkan Pelan Tindakan Induk untuk enam tahun. Pelan tersebut hendaklah memudahkan pelaksanaan Dasar Ubat Nasional.

8.2.2 Pemantauan dan Penilaian

Pihak Kerajaan hendaklah membangunkan fungsi dan keupayaan untuk memantau dan menilai perkembangan Dasar Ubat Nasional.

Data untuk indikator yang disarankan oleh WHO untuk memantau dasar ubat-ubatan hendaklah dikumpulkan dan dijadikan sebahagian daripada Sistem Maklumat Kesihatan Nasional untuk sektor farmaseutikal. Perkembangan dalam pelaksanaan Dasar Ubat Nasional hendaklah dipantau setiap tiga (3) tahun dan penilaian penuh dijalankan setiap enam (6) tahun. Keputusan pemantauan dan penilaian penuh Dasar Ubat Nasional hendaklah diumumkan kepada orang awam.