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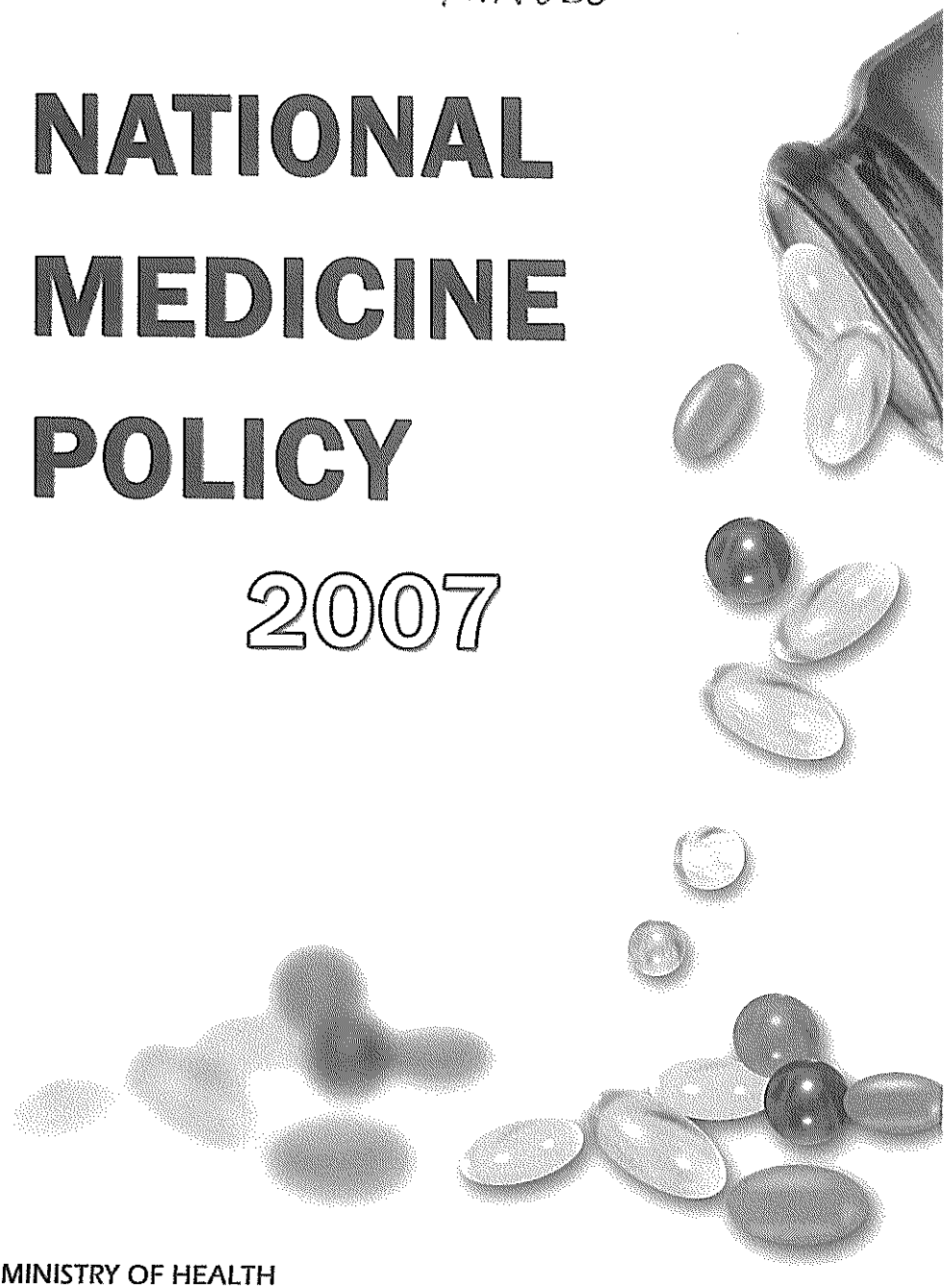
NATIONAL MEDICINE POLICY 2007



MINISTRY OF HEALTH
REPUBLIC OF MALDIVES

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Introduction

Medicines constitute an integral part of health care, in prevention and mitigation of disease.

The government is committed to a vision of safe effective, quality, essential medicines being available at affordable cost at all times to the entire population of Maldives. This commitment is emphasized in the Vision 2020, the Sixth National Development Plan 2001-2005, Health Master Plan 1996 – 2005, and the National Reproductive Health Strategy 2005-2007. Moreover access to essential medicines is in line with our commitments to reach the Millennium Development Goals.

Many factors hinder availability and affordability to medicines at various levels of health care.

Most notable among these is the lack of public sector involvement and over dependence on the private sector in making essential medicines available throughout Maldives.

In 1990 the government lifted its monopoly on import and distribution of pharmaceuticals. The benefit to the health system has been establishment of pharmacies in many islands of the country, improving availability. However this change had not been matched with adequate regulatory and policy development. Additionally there followed a gradual shift in perception and misguided reliance on the private sector to provide for universal coverage of medicines and lower prices through competition among importers and pharmacies.

However today, absence of standards and regulations has meant influx of a large variety of pharmaceuticals mainly sourced from open markets in neighboring countries. Inade-

quate provisions and mechanisms are available to improve coverage for islands with very small population where pharmacies are not economically viable.

The continued existence of a flawed price control structure (based on the imported landing price and fixed percentage mark-ups) has encouraged import of expensive medicines. Balanced pricing mechanisms that allows for affordability to all segments of the population and also encourages viability of pharmacies are required.

It is also to be noted that few regulatory or incentive based strategies have been undertaken to encourage local communities and private sector to establish pharmacies and other mechanisms to access essential medicines.

Not enough advocacies have been directed to the people and policy makers about the special place of essential medicines as a fundamental good required for healthcare.

Regulatory changes require supporting legislation. The law on *'import of medicinal substances'* Act of 75/78 is outdated. A strong legal basis is required to make regulations on medicine registration, pharmacy practice and enforcement measures

The present number of qualified pharmaceutical personnel both in the public and private sector is inadequate. This shortage must be met to develop pharmaceutical services.

There is a need to strengthen the quality assurance mechanism for all medicines. This will entail adherence to Good Distribution Practices and strengthening quality testing at the national level.

Promotion of the essential medicine concept and adherence to Standard Treatment Guidelines is required to rationalize

medicines use in the country. A Code of Good Practice is needed to promote adherence to rational dispensing practices.

A centralized procurement and supply system is essential to economize expenditure on medicines thereby ensuring availability and supply of medicines to all levels of health care in a predictable manner. Adequate financial resources are required.

However to fill the aforementioned gaps there are many policies and functions which need to be established at national level.

These functions include, among others strengthening the following areas:

a. Legislation and regulations
b. Regulatory and administrative standards
c. Medicine registration services
d. Inspection and enforcement services
e. Quality assurance services
f. Supply of essential medicines to all levels of health care.
g. Medicine and poison information services
h. Monitoring of adverse drug events
i. Monitoring rational use of medicines

To overcome these challenges a comprehensive National Medicine Policy is needed. Such a policy will provide guidance and impetus to national activities, and lead the way towards quality, safe effective and affordable medicines, available throughout Maldives.

1.The National Medicine Policy

This National Medicine Policy document contains guidance that are necessary towards developing an uninterrupted supply of safe, effective and good quality Essential Medicines at affordable prices and promoting their rational use in the country.

For the National Medicine Policy to have impact on all aspects relating to medicines in the country, it must be owned by all stake holders and implemented through legislation and regulations

The text of this National Medicine Policy is formulated with input from Ministry of Health, Board for Pharmaceuticals, international agencies and other governmental and non-governmental partners.

2. Goals for the National Medicine Policy

The three main goals of the National Medicine Policy for the Government of Maldives are:

i. **To ensure that all medicines authorized imported or locally manufactured, distributed and sold in the Maldives are effective, safe and of good quality.**
ii. **To ensure that adequate quantities of quality Essential Medicines, based on the needs of the population, are available at affordable cost at all times to the entire population.**
iii. **To promote rational use of medicines.**

For the achievement of these goals, the following **objectives** have been identified:

1. To improve the selection, procurement, storage and distribution in public and private health services for ensuring availability of Essential Medicines throughout the country
2. To strengthen the existing medicine registration system
3. To develop quality assurance mechanisms including an efficient inspection system to monitor wholesalers and distribution outlets.
4. To make medicines affordable to the community by developing appropriate price control mechanisms, promote procurement of affordable medicines from prequalified manufacturers in order to obtain maximum benefit from available limited resources
5. To promote rational prescribing, rational dispensing and rational use of medicines, targeting health care professionals and the community through educational, self-regulatory and monitoring mechanisms.
6. To ensure development of adequate technical, human resources in the field of pharmacy and medicine management by appropriate training and continuing education,
7. To ensure allocation of adequate resources for promoting the National Medicines Policy
8. To optimise the use of scarce resources through co-operation with international and regional agencies.
9. To establish a complementary partnership between the government and the private providers in the pharmaceutical sector.

3. Legislation and Regulation

3.1 The Medicines Act

A Medicines Act of the Republic of Maldives shall form a supporting legal basis for this National Medicine Policy. It shall incorporate elements of existing rules and regulations which are in line with this policy

Following enactment of the Act by the relevant bodies, detailed regulations governing the standards and procedures for carrying out the provisions of the law shall be formulated.

3.2 Scope of Regulatory Legislation

This shall include the following:

3.2.1 Medicines Regulatory Authority

a. The law shall pave the way for the establishment of a Medicines Regulatory Authority (hereinafter called MFDA), under the Ministry of Health.

b. Its duties and powers regarding the enforcement of the Act and regulations shall be clearly defined in the law.

c. It shall be the focal point for implementation of the national medicines policy.

d. It shall be advised by a multisectoral advisory body. (hereinafter called Medicines Board)

3.2.2 Marketing Authorization

a. Following approval for introduction of a particular product on the market, Marketing Authorization shall be given to the applicant. Regulations for issuing or denying marketing authorizations shall be clearly defined and shall be based on evaluation of safety, efficacy, quality and need.

b. Marketing Authorization shall be valid for a specified period of time and a review shall be required for renewal of registration, a registration fee shall be charged for pharmaceutical and other products as determined by Ministry of Health.

c. A database for registration and monitoring imports of pharmaceutical products shall be developed.

3.2.3 Licensing of Importers, Wholesalers and Pharmacies

The Ministry of Trade and Development is responsible for issuing a general trade license for medicine importers, wholesalers and pharmacies.

Legislation shall require those importers, wholesalers, pharmacies and other retail outlets:

a. Be *also* licensed by the MRA, and

b. Fulfill standard requirements of the Ministry of Health in providing and maintaining suit-

b. Regulations will define clearly the dispensing schedules of medicines. For controlled substances the scheduling will complement the stipulations under Law on Narcotics and psychotropic substances 17/77 Amended.

c. MRA will classify medicines that can be prescribed according to the type of practitioner service delivery levels and prescribing circumstances.

4.Access To Medicines And Pharmaceutical Supply Systems

A centralized procurement and supply system shall be established to ensure availability and supply of medicines to all levels of health care in a predictable manner. This system will work in coordination with the private sector to optimize access to medicines. This system shall adopt modern management practices and information communication and technology to support the supply system.

4.1 Selection of Medicines

a. Medicines shall be selected from products having marketing authorization and from prequalified sources, based on essentiality, quality, affordability safety and efficacy of the medicine.

b. Selection of medicines shall be done by the Medicines Board consisting of experts in medicine, pharmacology pharmaceutical sciences, and may include representatives from other disciplines.

4.1.1 Essential Medicines

a. A National Essential Medicine List that is reviewed regularly, shall be used as a guide for procurement and prescribing at all levels of health care.

b. Adequate stock level of Essential Medicines must be maintained at all levels of health care

c. Provisions shall be made for supply of medicines for exceptional needs, which are not registered or not on the National Essential Medicines List

4.1.2 Multisource products

a. The government encourages import and use of multisource products of assured quality and safety.

Procurement of medicines.

a. The National Medicine Policy shall promote the purchase of essential medicines of reliable quality at economical prices.

b. The government will commit resources to establish an efficient procurement system employing transparency and good practices.

4.3 Distribution of medicines

a. The government will organize sufficient and appropriate logistic facilities to ensure a systematic and reliable distribution system so that adequate supplies of Essential Medicines are always available to the various levels of health care even in remote islands. In this regard supply depots shall be established at central and regional levels.

b. Hospital and health center pharmacies shall be introduced and developed to promote the concept of Essential Medicines and rational prescribing.

c. Community participation to set-up and operate pharmacies on self sustainable basis shall be encouraged and supported.

d. Regulations shall be developed to provide incentives to encourage setting up of pharmacies in islands with low population

e. Regulations shall be revised to allow for clinicians and nurse practitioners to dispense in islands with low population.

d. All parties involved in procurement import, and distribution of medicines of medicines shall be encouraged to follow WHO guidelines on good storage practices and good distribution.

4.4 Active Players in the Pharmaceutical Sector

a. Activities of all sectors should complement each other and aim towards effective medicines distribution, availability and rational medicine use throughout the country.

b. Every effort shall be made to minimize wastage of medicines at national level.

c. The role of the active players in the pharmaceutical sector in the emergency response and preparedness to national disasters shall be stipulated.

d. All agencies donating medicines must ensure compliance to WHO Medicine Donation Guidelines

5. Quality Assurance

Quality assurance of medicines shall be achieved through a comprehensive medicine registration system, testing of marketed medicines, inspection at ports of entry and at points of distribution and retail

a. As part of the product registration system, the *WHO Certification Scheme and Prequalification Scheme* shall continue to be adopted as a means of ensuring quality of medicines imported in to the country

b. Medicines storage facilities and outlets at both public and private institutions shall be inspected regularly.

c. Regulations and practices shall be put in place to ensure that quality is maintained during transport and handling

d. The medicine testing facilities of Public Health Laboratory shall be upgraded to expand the range of quality tests possible.

e. The government will take action against medicines of unacceptable quality

6. Rational Use of Medicines

The National Medicine Policy aims at promoting rational use of medicines in areas of prescribing, dispensing, self-medication.

To promote the rational use of medicines at all levels, the government shall:

a. Provide and up-date the National Essential Medicine List to be used as a guide for procurement, prescribing and dispensing.

b. Encourage prescribing medicines in their generic (non-proprietary) names.

c. Update and regularly make available to the prescribers, pharmacists, public, and the pharmaceutical sector the list of marketed medicines.

d. Provide continuing education programs and refresher courses for health care professionals on rational use of medicines.

e. Develop, implement and monitor adherence to national Standard Treatment Guidelines and Medicine Formularies.

f. Encourage use of telemedicine in rational medicine use.

g. Create public awareness on the rational use of medicinal medicines using mass media and other means of communication in local language.

h. Strengthen prescription monitoring system to improve prescribing habits.

i. Ensure correct dispensing, labeling and patient counseling procedures.

j. Ensure disposal of expired and banned medicines environment friendly in accordance with regulations.

7. Medicine Information

a. Mechanisms shall be developed to provide current and objective information on medicines for health care professionals and prescribers to promote rational use of medicines.

b. A medicine and poison information unit shall be established at central level for health professionals and consumers

c. The MRA shall disseminate information in Dhivehi language to raise public awareness on the Essential Medicine Concept and Rational Use of Medicines.

8. Human Resources Development

For effective implementation of various elements of the National Medicine Policy:

a. Training of technical, administrative and health care personnel who are required for organizing and operating at different levels of implementing the National Medicine Policy shall be facilitated.

b. Pharmacists and other professionals needed for inspection, enforcement, and regulatory activities shall be trained.

c. Local pharmacy education shall be up-graded to a diploma level.

d. More funds and loans shall be allocated for pharmacy education

e. Regulatory incentives shall be provided to encourage more locals to enter into the pharmacy profession.

f. More students shall be sent for training abroad in the field of pharmacy, to meet the country's need for pharmacists in the areas of hospital pharmacy, regulatory activities, as well as medicine supply and management.

g. Pharmaceutical and health care professionals shall be provided regular education and training on Essential Medicines concept, Rational Medicine Use and Management of Supplies.

9. Allocation of Financial Resources

a. Adequate financial resources shall be allocated to ensure availability of essential medicines throughout the country by the public health services

b. Adequate financial resources shall be available to procure medicines in times of disaster.

c. Seeding funds, developmental loans and other incentives shall be made available for the community to establish community pharmacies.

d. Both private and public health insurance schemes shall be encouraged to make medicines affordable.

e. Special funding provisions shall be made for the low-income group of the population who are unable to pay for their treatment.

f. Special funding provisions must also be made for providing treatment priority diseases and conditions. These diseases and conditions shall be decided at national level based on prevalence, mortality and chronic nature.

10. Domestic production of medicines

For domestic production of medicines, the standards, technology and personnel required for pharmaceutical production shall confirm to the international standards of Good Manufacturing Practice (GMP). For non-pharmaceutical "traditional medicines" local standards and best practices shall be developed.

11. Research

Research shall be carried out to try and solve operational problems such as medicine selection, procurement and distribution so as to achieve the goals of the National Medicines Policy. It will focus particularly on the following areas:

a. Health systems research to measure the impact of the National Medicines Policy.
b. Behavioural research on prescribing and dispensing problems at different levels of the health systems.
c. The economics of medicine supply, utilisation and pharmacoeconomics.
d. Social and cultural aspects of medicines use, self-medication, acceptability and utilisation of medicine supply systems, and attitudes of medicine consumers.
e. Medicine research and development will focus particularly on the following areas:
f. Explorative research into local raw material as sources for new medicines
g. Alternative medicines for treatment of common illnesses and complaints.
h. Monitoring of adverse medicine reactions
i. Clinical trials in medicine

12. Traditional Complementary and Alternative Medicine (TCAM)

For all TCAMs the Government shall:

a. Develop standardization and quality control of TCAM products and raw materials.

b. TCAM with proven efficacy, safety and quality shall be promoted and used in the community.

c. Develop a system to register and license traditional medicine prescribers and monitor their practices.

d. Protect the community from danger and consequences of using unknown ingredient products or which are fraudulent or do not meet required quality and standards.

e. Additionally for Dhivehi beys (the traditional medicine of Maldives) the government shall:

f. Find ways to modernize Dhivehi beys and make it culturally and economically useful part of our heritage.

g. Work with relevant stake holders for protection of Dhivehi beys including national commitments under Convention on Biodiversity and WTO Trade related intellectual property agreement (TRIPS)

h. Document Dhivehi beys and traditional knowledge

i. Develop standard treatment guidelines that incorporate best practices.

13. Monitoring and Evaluation

a. The Ministry of Health in close collaboration with relevant national bodies will form a committee and set indicators for monitoring and evaluating the implementation of the National Medicine Policy

tions:

- marketing authorisation of new products and variation of existing products;
- quality control laboratory testing;
- adverse medicine events monitoring;
- provision of medicine information and promotion of rational medicine use;
- good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels;
- enforcement operations;
- Monitoring of medicine utilisation.

Essential Medicines

"*Essential Medicines*" are those medicines which are most needed or indispensable for health care of the majority of the population, and should be made available, accessible at all times, in adequate amounts, and in proper dosage forms.

Generic Product and Multisource pharmaceutical product

The term *generic product* has somewhat different meanings in different jurisdictions. Use of this term is therefore avoided as much as possible, and the term ***multisource pharmaceutical product*** should be used instead. Generic products may be marketed either under the approved nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different from those of the innovator products. Where the term *generic product* is used, it means 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 expiry of the patent or other exclusivity rights. The term should not be confused with generic names for active pharmaceutical ingredients.

Approved Medicines

These are Pharmaceutical products that have been granted marketing authorization. A list of approved products is published by the Ministry of Health.

Marketing Authorization

An official document issued by the national medicine regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, *inter alia*, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Non-proprietary Names or national generic names where they exist), the shelf -life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based. It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.
Once a product has been given marketing authorization, it is included on a list of authorized products - the *register* - and is often said to be *registered* or to *have registration*. Marketing authorization may occasionally also be referred to as product license.

CBD Convention on Biodiversity

TRIPS Trade Related Intellectual Property Rights Agreement: a binding agreement of World Trade Organization of which Maldives is a member.

Intersectoral advisory board on medicines and regulation.

This document is a broad revision of the original 'The National Drug Policy' document prepared in July 1999 after consultation with stake-holders. This current document has also been circulated to stakeholders