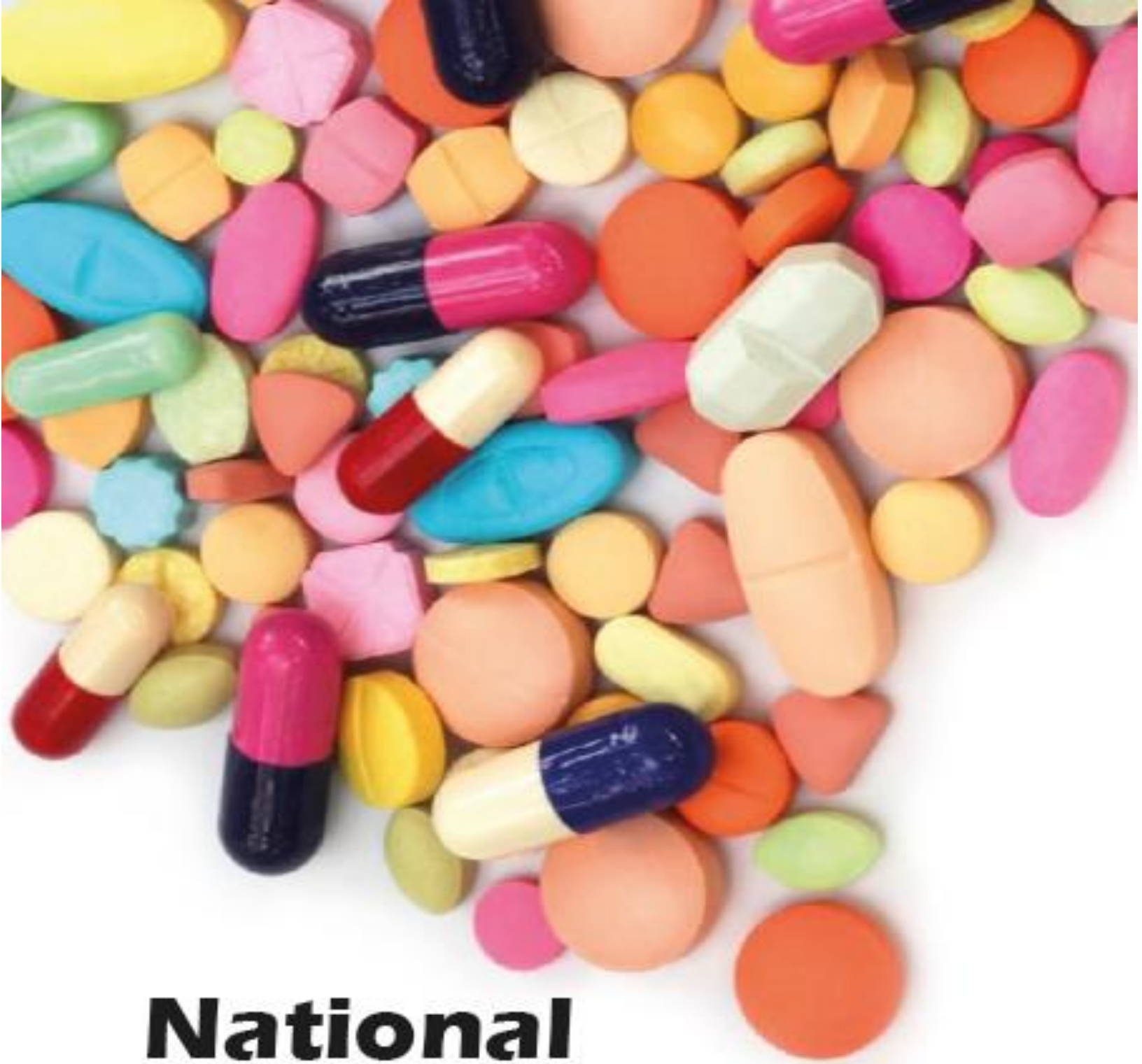

National MEDICINE Policy

2018 -2023

Maldives Food and Drug Authority
Ministry of Health
Republic of Maldives

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National Medicine Policy 2018 -2023

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Ministry of Health

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Foreword

A national medicine policy is a comprehensive framework in which each component plays an important role in achieving one or more of the general objectives of the policy (access, quality and rational use). The policy balances the various goals and objectives, creating a complete and consistent entity fitting the local context.

Following the WHO recommendation for countries to formulate and implement a comprehensive national medicines policy, Maldives has also developed this policy as a means to improve access to safe, effective medicines of good quality. This policy will enhance implementation of the existing laws and regulations and will contribute to strengthening the pharmaceutical sector.

National Medicine Policy 2018-2023 has been formulated and reviewed with the efforts of staff at Maldives Food and Drug Authority, and hence I would like to appreciate the diligent work and effort done by staff.

I also believe the publication of National Medicine Policy 2018 will be an avenue for overcoming the current concerns in availability and access of medicines and will contribute to regulating the rational use of quality medicine in the community.

Mr. Abdulla Nazim Ibrahim

Minister of Health

Introduction

Right to health is a fundamental human right granted by the constitution of Maldives. Attaining this right requires medicine and medicine plays an integral part in the prevention of diseases, treatment of ailments and in the overall improvement of health.

The government considers the access, quality and rational use of medicine as a top priority in its commitment to fulfill its population the right to health. Health Master Plan 2016-2025 has outcomes, critical outputs and strategic inputs exclusively dedicated to medicine. These include, "reduce inequities in access to health care services and medicines" as one it's broad three outcomes of the plan. "Improved supply and management of medical products, medicines, vaccines, technologies and other medical supplies" is mentioned as a critical output. And a specific strategic input under health service delivery focused on medicine supply which states to "ensure uninterrupted supply of good quality essential medicines, vaccines and medical products, technologies and other medical supplies". Establishment of centralized medicine supply system, introduction of generic medicine, development of Standard Treatment Guidelines, promoting the rational use of quality medicine in Aasandha and strengthening the overall system for accessibility and availability of quality medicine are also some of the activities mentioned in the Health Master Plan.

International commitments such as the Sustainable Development Goal (SDG) require the government to develop and implement relevant policies and activities to achieve these goals. Goal 3.8 of the SDGs states to "achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all."

In order to deliver to these aspirations Maldives Food and Drug Authority has developed the National Medicine Policy 2018 – 2023 specifying the goal, guiding principles, objectives and strategies. This policy will aid the process of strengthening the overall system for medicine supply, regulation and quality.

Contextual Factors

Considerable progress has been made over the years in the regulation of medicine in Maldives. The monopoly on import and distribution of pharmaceuticals was lifted by the government during the 90s. The pharmaceutical services have undergone tremendous changes and the latest development being the establishment of STO pharmacies in all inhabited islands by the government. This development led to the improved access and availability of medicine for all population which has contributed towards achieving Universal Health Coverage. However, the level of progress expected was hindered by the lack of adequate regulatory mechanisms and policy directives. Additionally, the opportunity for greater competition did not lead to affordable prices or improve medicines availability in many of the islands.

Significant changes have been brought to the health system and health service delivery in the Maldives. These include the ratification of the Health Services Act (29/2015) and Health Professionals Act (13/2015). The National Medicine Policy published in 2007 needs to be reviewed to incorporate the new obligations, mandate and responsibilities.

Contextual factors considered in the development of this medicine policy include the following

Laws and Regulations

- Health Services Act (29/2015)

The Health Services Act (29/2015) was ratified on the 7th September 2015. Chapter seven of this act mentions the roles and responsibilities of Ministry of Health, Maldives Food and Drug Authority and National Pharmaceutical Board. Under this act Ministry of Health has the responsibility to ensure the availability and affordability of essential medicines in the health system. Maldives Food and Drug Authority have the authority to develop and implement the essential medicine list and medicine related regulations. National Pharmaceutical Board is the advisory board to Maldives Food and Drug on matters relating to medicine and medicinal products. National Pharmaceutical Board is comprised of technical representatives and stakeholders. This act also stipulates about the national essential medicine list, approved medicine list, import and sale of medicine, rational prescribing and utilization of medicine, inspection powers and penalties for actions against the law.

- Health Professionals Act (15/2015)

The Health Professionals Act (15/2015) ratified on the 13th May 2015 specified provisions relating to registration and licensing of pharmacy professionals (pharmacists other dispensing personnel) and defined the scope of practice of these professionals

- Medicine Regulation (2014/R-46)

Medicine Regulation (2014/R-46) falling under the General Act (6/2008) covers all aspects of medicine relating to import, export, distribution (sale), prescription and storage. This regulation which was gazetted on 20th July 2014 accords Maldives Food and Drug Authority the sole authority to implement the regulation and regulate the use of medicine in the country. Maldives Food and Drug Authority also registers and monitors the medicines in circulation in the country·

Other Factors

- Geographic and economic factors

The geographic distribution of the islands in the Maldives has always been a challenge in the provision of adequate and quality health services to the people. There is a need to develop and implement an efficient medicine supply system that can cater to the needs of the population in a timely and affordable manner. Establishment of STO pharmacies in all inhabited islands have contributed in bridging the existing gaps on the supply and demand of medicine in smaller populations. However, the system needs further strengthening to efficiently sustain the process.

- Health Workforce

Maldives employ a high number of expatriate professionals in the health system. This may be due to the lack of trained professionals or due to the lack of employment opportunities within their island of residence. Deliberate efforts are necessary to develop the capacity of the local pharmaceutical workforce in the procurement and supply of medicines.

- National Health Insurance (Aasandha)

Aasandha, the national health insurance mechanism, coordinated by the National Social Protection Agency, provides free health insurance to all Maldivians. The services include the issuance of prescription medicines as well. A strong medicine policy can positively contribute to improving the supply, quality, availability and affordability of the medicines in all parts of the country. National health insurance coupled with a national medicine policy will aid the process for achieving Universal Health Coverage.

- Medicine procurement and supply

The current practice of procuring and supplying relies both on the public and private sector. The systems requires action to improve the supply system to make it reliable efficient and to ensure appropriate medicines reach the people in a timely manner.

The National Medicine Policy

Purpose and scope

The main purpose of this policy is to define goals and aspirations relating to medicine and to identify mechanisms to implement the roles and responsibilities assigned to Ministry of Health and Maldives Food and Drug Authority in ensuring equitable access, good quality and rational use of medicine.

This policy underwent a consultative process with Ministry of Health, Maldives Food and Drug Authority, National Pharmaceutical Board, international agencies and other relevant stakeholders and includes input provided by all parties during all stages of the policy development process.

Guiding principles

The National Medicine Policy will be guided by the following principles:-

1. Universal Health Coverage –
    a. Reducing inequities in access to medicines as an important outcome under national Health Master Plan 2016-2025
    b. Reducing inequity in access to medicines across geographical areas of Maldives
2. Efficient central medicine supply mechanisms
3. Effective utilization of funds available for medicines procurement in the context of increasing chronic and non-communicable diseases
4. Introduction of generic medicines as a cost effective approach
5. Improving quality of medicines available
6. Rational use of medicines

Goal

“Provide access to safe, quality, efficacious, and affordable medicinal products to its population based on its needs”

Objectives

This medicine policy aims to achieve the following objective during the period 2018-2023.

1. Ensure a sustainable supply of Essential Medicines of quality based on the priority needs of the population.
2. Ensure affordability and cost-effectiveness to medicine to support the implementation of Universal Health Coverage.
3. Formulate and implement regulations on registration, import, quality, storage, supply, distribution, inspection, prescribing, dispensing, pricing and use of medicines under the Health Services Act 29/2015
4. Promote rational use of medicines and public awareness on medicine safety.
5. Define the roles and responsibilities of Ministry of Health, Maldives Food and Drug Authority and other relevant stakeholders

Objective 1: Ensure a sustainable supply of Essential Medicines of quality based on the priority needs of the population.

Strategies

- Compile an Essential Medicines List for selection, procurement and provision of medicines for public.
- Based on the compiled essential medicine list, make it mandatory to have uninterrupted supply of those medicines in the public health facility
- Maldives Food and Drug Authority to appoint a committee comprising of prescribers, pharmacists and nurses every two years to review and revise the essential medicine list.

Objective 2: Ensure affordability and cost-effectiveness of medicines to support the implementation of Universal Health Coverage.

Strategies

Price Regulation

- Formulate and implement policies and criteria for regulating the prices of medicines.
- Conduct consultations with National Pharmaceutical Board, National Social Protection Authority and relevant stakeholder institutions as and when necessary to review medicine pricing.
- Regulate prices of all medicines registered and imported (essential and other). Consider affordability, accessibility, quality and safety while ensuring affordability with sufficient sale margins for sustainability of the pharmaceutical importers, distributors and retail pharmacies.
- Develop and publish price regulation for medicinal products with a maximum retail price for each unit dosage form and strength.
- Specify and publish temporary (till maximum retail price is fixed) maximum permissible price at marketing authorization stage.

Procurement and distribution of medicines.

- Establish a centralized procurement, distribution and supply system within the country to ensure availability and supply of essential medicines at all public health facilities. Ensure coordination with the private sector to optimize access to medicines within the country. And adopt modern management practices and information communication and technology to support the supply system. The distribution will be through wholesalers and retailers licensed by the MFDA.
- Conduct a transparent evaluation of the procurement mechanisms and institutions for procuring medicinal products.
- Earmark fundings required for implementing this system.
- Develop and implement a logistic system and facilities to ensure reliable distribution and storage system of Essential Medicines to the various levels of health care facilities. Establish central and regional stores for necessary outreach to the peripheries.

Objective 3: Formulate and implement regulations on registration, import, quality, storage, supply, distribution, inspection, prescribing, dispensing, pricing and use of medicines under the Health Services Act 29/2015

Strategies

Laws and Regulation

- Identify and formulate new regulations required to strengthen medicinal product regulatory system in the area of registration of medicines, monitoring and control of imports, medicines quality, pricing, storage, distribution, inspection and enforcement, prescribing and dispensing.
- Review the Health Services Act, Health Professionals Act and other medicine related regulations to harmonize and improve regulatory effectiveness

Licensing of Importers, Wholesalers and Pharmacies

- Review to strengthen the existing licensing standards for importers, wholesalers and pharmacies
- Develop data and record keeping mechanism to strengthen monitoring mechanism for sold medicine.
- Introduce licensing mechanisms that promotes establishment of pharmacies in underserved geographical areas
- Introduce regulatory incentives where appropriate that allows importers and wholesalers to provide affordable medicine prices and better stocking of medicines in the essential lists

Prescribing and Dispensing of Medicines

- Consider knowledge needed to make decisions on medicines and the risk/benefit of use in various situations in the scheduling of medicines.
- Encourage self-care for simple self-limiting conditions while discouraging indiscriminate self-medication.
- Specify medicines that can be prescribed by nurses and allied health professionals
- Follow the stipulations under the Drug Act 17/2011 for scheduling of controlled substances.
- Foster good medical practices for prescribing generic name for correct identification of medicine and adding the brand name if and when required.

Monitoring Adverse Medicine Events and Defective Product Reporting

- Develop mechanisms to simplify the reporting process and introduce direct reporting in cases of adverse medicine events and defective products via Maldives Food and Drug Authority Website.

- Publish annual report comprising of adverse medicine events and defective products and share with healthcare professionals and public on the findings and identified safety problems that are observed on marketed medicines
- Develop and implement procedure for product recall and a procedure for easy reporting of Adverse Drug Reaction (ADR) for all marketed medicinal products. The responsibilities for maintaining records on import, distribution and recall lies with the Marketing Authorization holder.

Quality Assurance

- Perform quality assurance of medicines through the medicine registration system, testing of marketed medicines where appropriate, inspection of medicines at ports of entry, at wholesale and retail points of distribution, and through Post Marketing Surveillance.
- Develop and implement the product registration system based on the WHO Certification Scheme for Quality of Pharmaceuticals Moving in International Commerce and utilize available information from other prequalification schemes of other institutions during the registration process.
- Publish the pharmacopoeia standards, storage conditions, requirements for a pharmacy, dispensing standards as defined by MFDA.
- Conduct regular inspections during distribution, storage facilities and outlets at both public and private institutions to assure quality shall be inspected regularly and regulations enacted to ensure that quality is maintained during transport, handling and storage.
- Upgrade the medicine testing facilities of National Health Laboratory to expand the range of quality tests.

Traditional Complementary and Alternative Medicine (TCAM)

- Develop standardization and quality control of TCAM products and its raw materials
- Promote the use of TCAM products with proven safety efficacy and quality.
- Ensure TCAM practitioners and dispensers are licensed under the Health Professionals Act 13/2015 according to prescribed licensing standards.
- Create community awareness on dangers of using unknown ingredient products and substandard and fraudulent products
- Develop strategies for Dhivehibeys (traditional medicine of Maldives) culturally and economically useful part of Maldivian heritage.
- Establish standard treatment guidelines and best practices in the area of TCAM.

Objective 4: Promote rational use of medicines and public awareness on medicine safety.

Strategies

- Formulate and make the Maldives Essential Medicines Lists as a guide for procurement, prescribing and dispensing.
- Enforce mandatory generic name prescription with the option to indicate the choice of a brand if and when required.
- Publish and update the list of marketed medicines with their maximum retail prices.
- Develop, implement and monitor adherence to national Standard Treatment Guidelines.
- Create public awareness on the rational use of medicines using mass media and other means of communication.
- Develop mechanisms to strengthen prescription-monitoring system in collaboration with health facilities and health insurance reimbursement information and provide timely feedback to health care institutions.
- Target interventions to promote rational use of medicines with a special emphasis on antibiotic use for containment of anti-microbial resistance.

Objective 5: Define the roles and responsibilities of Ministry of Health, Maldives Food and Drug Authority and other relevant stakeholders

Strategies

Roles of Maldives Food and Drug Authority

- Act as the focal point for implementation of National Medicines Policy.
- Identify barriers to affordability and accessibility to medicine and support Ministry of Health to remove these barriers
- Introduce various incentives including accelerated processing of the applications for registering generic medicine to encourage cost effectiveness.
- Publish information such as database of registered medicinal products with the marketing authorization holder, manufacturer and other information to improve transparency and accountability.

Human Resources Development

- Develop and implement a human resources development plan for training and capacity building for the pharmaceutical sector and regulation of the sector. These should include pharmacists and other professionals needed for inspection, enforcement, procurement and regulatory activities and other professionals in specialized branches of pharmacy including hospital and clinical pharmacy
- Upgrade the minimum education requirement of a local pharmacy education to undergraduate degree level.

Financial Strategies

- Purchase essential medicine (by generic tender) based on per capita expenditure. A percentage allocation of the above for purchase in exceptional situations of medicines that are not in the Maldives Essential Medicines Lists.
- Plan and implement capital investment in the medicines supply system (warehouses, storage depots).
- Secure funding for human resource development and regulatory activities

Research

- Conduct and promote research on
    - ‘Effectiveness of strategies / interventions to achieve the objectives of National Medicines Policy’,
    - ‘Economic evaluation of medicines procurement, supply and utilisation with particular focus on implementation of a generic policy’,

- ‘Evaluation of health insurance and other incentives in medicines in achieving National Medicines Policy goals’,
- ‘Usage of medicines, trends, evaluating underlying influences (rational prescribing and rational use of medicine with a special focus on antibiotics’,
- ‘Social and cultural aspects of medicines use, self-medication, and attitudes of consumers to their medicines’, and
- Intellectual property rights and access to medicines

National, Regional and International Collaboration

- Identify and develop collaborations with regional and international partners to provide training, technical expertise including partnerships in procurement and mutual recognition agreements. Focus areas for collaboration include
  - public private partnerships in medicines procurement and supply
  - strengthening enforcement of regulations
  - technical and regulatory links with Medicine Regulatory Authorities of other countries to benefit in mutual regulatory recognition mechanisms and medicines procurement and to explore the experience of other small Island states to strengthen medicines regulation and related areas.
  - International trainings for pharmacist and upgrading the current pharmacy curricula at the Maldives National University
  - Implementation of international conventions on narcotics and psychotropic substances, which the country is signatory to.
- Coordinate with Ministry of Trade and Economic Development and other government and non-government sectors, to ensure that public health interests are taken into account in negotiations and implementation of international, regional and bilateral trade agreements by Maldives.

Policy Enforcement

The endorsement of the policy will proceed to the implementation of the policy. Maldives Food and Drug Authority is the lead implementation agency and it is the responsibility of MFDA to develop an operational plan within 6 months of endorsement.

Monitoring and evaluation

Monitoring and evaluation is a core component to understand progress made in the implementation.

- The Ministry of Health in close collaboration with Maldives Food and Drug Authority and relevant national bodies will form a committee and set indicators using existing tools for monitoring and evaluating the implementation of the National Medicines Policy and achievement of its objectives.
- Policy Planning and International Health Division of Ministry of Health in collaboration with Maldives Food and Drug Authority will annually monitor the implementation of National Medicine Policy
- The implementation status of the National Medicines Policy shall be reviewed by National Committee in collaboration with MFDA every two years. Data from the research activities will be used for this review.
- Address challenges and issues in a timely manner for a smooth and successful implementation of the policy.

Definition

Generic medicines: Generic medicines (essential and others) of adequate quality are a well-established concept of providing affordable medicines; the National Medicines Policy would therefore emphasise generic medicines in all aspects in the health care system. The term "generic medicine" is used here to mean the technical term "*multisource pharmaceutical product**";*** however, the term "generic medicines" is kept because of common usage and familiarity. The term generic medicine is meant to include all medicines other than the innovator product and includes what is commonly referred to as "Branded Generics" and those with generic name only.

Essential Medicine: According to World Health Organization "Essential medicines are those that satisfy the priority health care needs of the population" and are "selected with due regard to disease prevalence, public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness".

References

1. Health Professionals Act 13/2015
2. Health Services Act 29/2015
3. Medicine regulations 2014/R-46
4. National Medicine Policy 2007
5. Drug Act 17/2011