NATIONAL MEDICINE POLICY 2024-2027

MALDIVES FOOD AND DRUG AUTHORITY
MINISTRY OF HEALTH
MALE', MALDIVES

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Ministry of Health
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FOREWORD

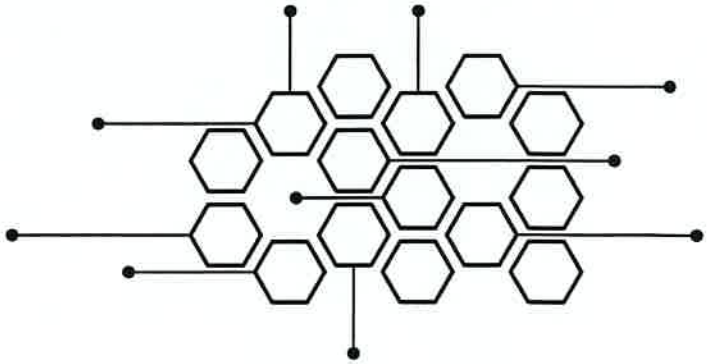
Irrational use of medicines continues to be a widespread problem with serious consequences in terms of patient outcome as well as wastage of resources which increases the government health expenditure on medicine alone. With the successful implementation of National Medicine Policy, I believe can bring significant improvement to achieve efficiency in procurement, supply and use of medicine in the Maldives.

The National Medicine Policy 2024-2027 emphasizes the government's firm commitment to achieving universal access to essential medicines of good quality and the strategies of the government to ensure medicines of good quality are available at a price the individuals and the community can afford. The policy is a comprehensive document which will aid to implement the strategic objectives in achieving this goal, and defines the role of each of the various stakeholders involved.

Following the standard guidelines from the World Health Organization, the National Medicine Policy 2024-2027 has been developed by a large group of professionals from the Ministry of Health, Maldives Food and Drug Authority, Ministry of Finance, National Social Protection Agency, Aasandha Company Limited and many other professional organizations and experts, whose contributions are gratefully acknowledged.

Taking into consideration, the multi-stakeholder collaboration required to achieve the goals set in the policy, I call upon all stakeholders to play their role in this national effort.

Abdulla Nazim Ibrahim
Minister of Health



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Abbreviations

EML: Essential Medicine List

INN: International Non-proprietary Names

MoF: Ministry of Finance

MoH: Ministry of Health

MFDA: Maldives Food and Drug Authority

NSPA: National Social Protection Agency

SDG: Sustainable Development Goal

STG: Standard Treatment Guideline

WHO: World Health organization

INTRODUCTION

The right to health is a fundamental human right granted by the constitution of the Maldives. Medicines play an integral part in the prevention of diseases, treatment of ailments and in the overall promotion of health. Universal health coverage is not possible without universal access to essential medicines. The government therefore considers universal access, and the quality and rational use of medicines as a top priority in its commitment to the progressive realization of the right to health.

The Health Master Plan of 2016-2025 includes several strategic inputs specifically directed to medicines. These include "*reduce inequities in access to health care services and medicines*" as one of three outcomes of the plan. Improved supply and management of medical products, medicines, vaccines, health technologies and other medical supplies is mentioned as one of its critical outputs.

International commitment to goal 3.8 of the Sustainable Development Goals (SDGs) also requires the government to promote universal health coverage. The period of activity for this policy has therefore chosen as 2024-2027, so that the impact of the National Medicine Policy can be evaluated as part of the evaluation of the SDGs.

Contextual factors

Equity and efficiency of the system

The concept of essential medicines stands for **equity** and **efficiency**. With regard to equity, the human rights statement in the constitution provides a very solid political and legal basis. Universal access to essential medicines has largely been achieved by the establishment of "Aasandha", the National Social Health Insurance scheme in 2012, which covers all essential medical treatment for all Maldivians and by the establishment of public pharmacies in all inhabited islands. In addition, patients who require sophisticated treatment which is not covered by the insurance, are able to apply for financial support from the National Social Protection Agency (NSPA) through their financial assistance programs. This is a very effective protection against catastrophic health expenditure. With regard to equity, the government has therefore made remarkable progress. However, this achievement has come at considerable cost through many inefficiencies in the pharmaceutical system and health financing system.

Supply and reimbursement system

The key problem is very high and unnecessary expenditure on medicine, which is also rapidly increasing at an average of 18% per year over the last 5 years, threatening the financial sustainability of Aasandha scheme. This high medicine expenditure has several reasons. Firstly, the system allows for the supply and use of many non-essential medicines. In 2022, about 60% of medicine reimbursement by Aasandha scheme was spent on non-essential medicines (not listed on the national list of essential medicines (EML)), up from 37% in 2014. In many cases, these are expensive medicines, very often in irrational fixed-dose combinations.

Secondly, many medicines are procured at very high cost. In 2022 most medicines were procured and reimbursed at 3-5 times (range 2-8 times) the world market price. This difference is far too large to be explained by lack of economies of scale and is also caused by the current procurement process.

The use of non-essential medicines does not only lead to economic waste, but also to sub-optimal health outcomes. The lack of use of the Essential Medicine List (EML) by Aasandha Company Ltd and the widespread use of non-essential medicines are aggravated by the lack of evidence-based national

Standard Treatment Guidelines (STGs) for the most common therapeutic categories (e.g diabetes, hypertension, asthma, antibiotics, oncology).

Essential medicines are the most effective, safe and cost-effective treatments, representing the best value of money. A revised national EML based on national STGs can improve medical outcomes and can strongly support Aasandha Company Ltd in redefining the range of medicines for reimbursement.

Capacity of MFDA

Maldives is a small island state, and not all regulatory functions performed by large stringent authorities can realistically be expected here. The Maldives Food and Drug Authority (MFDA) is in close contact with World Health Organization (WHO) to identify the most cost-effective functions under the given circumstances. It is needed to select the most cost-effective activities for the MFDA, the technical areas where they can really add value.

Three priority functions of the MFDA are: timely and efficient review, approval and quality control of generic (multi-source) products, a fully operational website with all relevant standards and information publicly available, and enforcement through risk-based inspections of national facilities and post-marketing surveillance. For other functions the MFDA will have to rely on information from a carefully selected range of stringent medicine regulatory agencies in other countries.

Internal coordination

There are several areas where better coordination can promote government efficiency in medicine selection, procurement, use, and reimbursement:

- It is important that the National Medicine Policy is implemented in close collaboration with important stakeholders which includes MoH, MFDA and other relevant areas of MoH, NSPA, Aasandha Company Ltd, Ministry of Finance (MoF), academia and health professionals.
- STGs and the national list of essential medicines should be developed by MFDA and the MoH, in close collaboration with NSPA and Aasandha Company Ltd, who will later use these tools to define reimbursement.
- Country-wide use of electronic prescribing and the various computerized systems for procurement, distribution, inventory control and reimbursement have enormous potential for

systematic analysis of medicine supply, prescription and use, and therefore for promoting efficiency and reducing the vulnerability to corruption. Yet at present this potential cannot be used to the full, because there is no national standardized drug coding terminology.

National Medicine Policy 2024-2027

Purpose and Scope

The purpose of this policy is to define the goals and aspirations related to medicines, and to promote the coordination between the various stakeholders in ensuring the availability, affordability, quality, and cost-effective use of medicines.

Guiding Principles

The National Medicine Policy is guided by the following principles:

1. Equity and universal health coverage
2. Efficiency in medicine supply, use and reimbursement
3. Assured quality, safety and efficacy of medicines
4. Efficient collaboration between government agencies, and with the private sector

Goal

Provide universal access to effective and safe medicines of assured quality to all, at a price the individual, community, and government can afford, and used in a scientifically sound and cost-effective way.

Objectives

1. Maintain a system of **evidence-based selection** of essential medicines and health technologies for supply in the public sector and for reimbursement by the national health insurance, to ensure equitable access to quality health care and promote efficient and cost-effective use of resources.

2. Assure the **efficacy, quality and safety** of all medical products in the market by means of a well-resourced, effective and efficient system of legislation, regulation, inspection and enforcement in accordance with current international standards within the limitations of a small-island state.

3. Achieve **equitable universal access** to essential medicines and health technologies as part of universal access to health care, free of financial hardship to the consumer at the point of care.

4. Make full use of all potential measures to **control and reduce the prices** of medicines and health products in the public and private sector, with the goal of ensuring universal access to health care at a cost the individual, community and government can afford.

5. Achieve an **uninterrupted, efficient and cost-effective supply** of essential medicines and health products to all public health facilities.

6. Ensure the quality and efficiency of health care through **scientifically sound and cost-effective use of medicines** by prescribers and consumers, and include measures to prevent antimicrobial resistance.

7. As a small island state, make maximum use of the potential benefits of **international collaboration and harmonization** in developing and strengthening the pharmaceutical sector, with focus on medicine regulation and national health insurance.

8. Create and maintain a system of **planning, managing, and monitoring** the implementation of the National Medicine Policy and holding stakeholders accountable.

1 Selection of essential medicines

Objective 1: Maintain a system of evidence-based selection of essential medicines and health technologies for supply in the public sector and for reimbursement by the national health insurance, to ensure equitable access to quality health care and promote efficient and cost-effective use of resources.

1.1 An evidence-based national list of essential medicines under generic name will be updated and published at regular intervals. The list will be divided according to the level of health care. One of the main purposes of the list is to define the range of products to be reimbursed by Aasandha scheme.

1.2 Both the list of essential medicines and the standard treatment guidelines will be widely disseminated to all health facilities, medical professionals and students, preferably in electronic copy.

2 Quality assurance

Objective 2: Assure the efficacy, quality and safety of all medical products in the market by means of a well-resourced, effective and efficient system of legislation, regulation, inspection and enforcement in accordance with current international standards within the limitations of a small-island state.

2.1 The development and execution of the functions of the MFDA will follow, as much as possible, the global guidance by the WHO with regard to small island states.

2.2 The MFDA will focus on the rapid and efficient assessment of generic products, using a risk-based approach and with priority for products with few alternatives on the market. The MFDA will make maximum use of information available from stringent medicine regulatory agencies in other countries.

2.3 New chemical entities will be assessed by the MFDA on the basis of their registration by a number of carefully selected stringent authorities.

2.4 The MFDA website will be upgraded and updated, and will present all relevant laws, rules, regulations and standards, lists of licensed facilities and products, products details, results of quality tests, and product recalls. MFDA will use official social media platforms to ensure this information is available to the public.

2.5 The MFDA will enforce the relevant laws and regulations by means of a risk-based approach to national facility inspections and post-marketing surveillance. The risk-based approach will be further developed and formalized.

3 Financing

Objective 3: Achieve equitable universal access to essential medicines and health technologies as part of universal access to health care, free of financial hardship to the consumer at the point of care.

3.1 The government, through Aasandha scheme, will continue to fund all essential medicines and health technologies for all its citizens. The range of essential products to be reimbursed and the maximum price of reimbursement will be defined by the MoH, the Ministry of Finance, NSPA and Aasandha Company Ltd, using the national list of essential medicines as a reference. The Aasandha reimbursement list will be updated regularly and will be publicly available through electronic means.

3.2 The NSPA will continue to support individual citizens confronted with catastrophic health expenditure on the basis of individual requests and individual assessments. The mechanisms for review and prior approval for reimbursement under this arrangement will be strengthened.

4 Affordability

Objective 4: Make full use of all potential measures to control and reduce the prices of medicines and health products in the public and private sector, with the goal of ensuring universal access to health care at a cost the individual, community and government can afford.

4.1 The Government will use the full range of available pricing policies and mechanisms to regulate and reduce the prices of all medicine and health technologies. This may include participation in international pooled procurement (bulk procurement) mechanisms or direct procurement from a small number of approved wholesalers in other countries.

4.2 The use of International Non-proprietary Names (INN) or generic names will be promoted in medicine procurement, inventory control, prescribing, dispensing, reimbursement, and medicine use studies.

4.3 For single-source products MoH will set the maximum reimbursement price which would be approved by NSPA and implemented by Aasandha Company Ltd. The reimbursement price will be based on the price of the same product in a number of reference countries ("external reference pricing") except for those procured through bulk procurement mechanisms The list of reference countries will be published.

4.4 For multi-source (generic or branded generic) products MoH will set the maximum reimbursement price which would be approved by NSPA and implemented by Aasandha Company Ltd. The reimbursement price will be based on the average price of the three lowest-priced generic products of assured quality registered and marketed in the Maldives, except for those procured through bulk procurement mechanisms. This maximum reimbursement price will be updated at regular intervals and will be published by MoH and Aasandha Company Ltd.

5 Supply and distribution

Objective 5: Achieve an uninterrupted, efficient, and cost-effective supply of essential medicines and health products to all public health facilities.

5.1 MoH including MFDA, will establish one standardized medicine coding system, to facilitate exchange of data on procurement, price, supply, prescription and reimbursement.

5.2 The supply and distribution of medicines by MoH and will be restricted to Aasandha Company Ltd's list of reimbursed medicines, in a phased manner, based on the national list of essential medicines. A separate mechanism will be created for ordering, stocking and prescribing some additional non-EML items.

5.3 Any interested parties who have a permit to import medicines shall have the opportunity to import medicines by registering in accordance with the rules and guidelines of medicine registration without any discrimination.

6 Quality use of medicines

Objective 6: Ensure the quality and efficiency of health care through scientifically sound and cost-effective use of medicines by prescribers and consumers, and include measures to prevent antimicrobial resistance.

6.1 Evidence-based standard treatment guidelines will be developed for the most common and/or most costly therapeutic categories, including non-communicable diseases, infectious diseases, and oncology. These guidelines will be widely promoted, preferably in electronic form, using generic names.

6.2 Standard treatment guidelines will be used to define the national list of essential medicines and will also serve as the basis for undergraduate training, introductory training of expatriate doctors, continuing medical education, and progammes to promote scientifically sound and cost-effective prescribing. For diseases and conditions for which no national STGs are available, reference will be made to STGs from WHO.

6.3 A Prescription analysis will be regularly conducted by MoH and MFDA in collaboration with NSPA, Aasandha Company Ltd, to regularly perform studies of routinely collected prescription data, and national surveys on the availability, price, and quality use of medicines. These data will be used to improve scientifically sound and cost-effective prescribing. The reports will be made publicly available.

7 International collaboration

Objective 7: As a small island state, make maximum use of the potential benefits of international collaboration and harmonization in developing and strengthening the pharmaceutical sector, with focus on medicine regulation and national health insurance.

7.1 MFDA will further expand its close collaboration with external partners, such as WHO and regulatory authorities in the region, to maximize the use of available technical guidance, common standards, and joint assessments.

7.2 MOH, NSPA and Aasandha Company Ltd will actively seek technical advice and support from international agencies and other health insurance schemes to promote efficiency and cost-effectiveness in medicine expenditure.

8 Implementation, monitoring and evaluation

Objective 8: Create and maintain a system of planning, managing, and monitoring the implementation of the National Medicine Policy and holding stakeholders accountable.

8.1 In implementing the National Medicine Policy (NMP), MFDA will involve all important stakeholders, including other relevant areas of MoH, the Ministry of Finance (MOF), NSPA, Aasandha Company Ltd, Customs, STO, academia and medical professionals.

8.2 MFDA with guidance from MoH policy level will establish a committee for NMP, with operational-level representatives from MFDA, MoH, MOF, NSPA, Tertiary Hospitals and Aasandha Company Ltd.

8.3 The NMP Implementation Committee will develop two-yearly implementation plans, as well as a monitoring plan based on simple indicators, milestones, and targets.

8.4 An external evaluation of the National Medicine Policy 2024-2027 will be done in 2027.

Acknowledgements

The National Medicine Policy 2024-2027 has been developed in consultation and collaboration with many national and international experts. There are many individuals and stakeholders who have helped in formulating this policy and without their help it would not have been possible. Hence, we highly appreciate and are grateful for the support and assistance provided by them.

These organizations and the stakeholders include World Health Organization, Ministry of Health, Health Protection Agency, Maldives Allied Health Council, ADK Hospital, IGMH, Hulhumale Hospital, Treetop Hospital, Senahiya, Aasandha Company Ltd, National Social Protection Agency), Ministry of Finance, medicine importers and retail pharmacies.

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