NATIONAL MEDICINE POLICY 2024-2030

MEDICINE AND THERAPEUTIC GOODS DIVISION
MALDIVES FOOD AND DRUG AUTHORITY
MINISTRY OF HEALTH
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CONTENTS

FOREWORD

A national medicine policy is a comprehensive framework in which the government expresses its commitment to the goal of achieving universal access to essential medicines of good quality, at a price the individual and the community can afford. The policy is also a practical tool to describe the chosen strategies to achieve this goal, and the role each of the various stakeholders are expected to play. The policy balances the various goals and objectives within the local context.

Following recommendations from the World Health Organization, the Maldives National Medicine Policy 2024-2030 has been developed by a large group of professionals from the Maldives Food and Drug Authority, the Ministry of Health, the Ministry of Finance, the national health insurance Aasandha, and many other professional organizations and experts, whose contributions are gratefully acknowledged.

The overall goal of the government is to achieve equity and efficiency in access to essential medicines for the whole population. I believe the national medicine policy can be a very effective tool to strengthen the national pharmaceutical sector and I call upon all stakeholders to play their part in this national effort.

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Minister of Health

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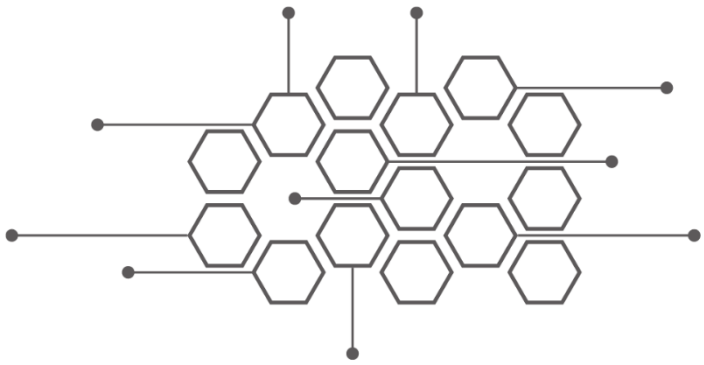

INTRODUCTION

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 (SDG) also requires the government to promote universal health coverage. The period of activity for this policy has therefore chosen as 2024-2030, so that the impact of the national medicine policy can be evaluated as part of the evaluation of the SDGs.

Equity has been achieved, but at a cost

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 the public health insurance scheme Aasandha in 2015, which covers all essential medical treatment; and by the establishment of public pharmacies on nearly all inhabited islands. In addition, patients in need of very sophisticated treatment not covered by the insurance can apply for financial support from the National Social Protection Agency. This is a very effective protection against catastrophic health expenditure. With regards to equity, the government has therefore made remarkable progress. However, this achievement has come at considerable cost through many inefficiencies in the pharmaceutical system.

Widespread inefficiency in the supply and reimbursement system

The key problem is very high and unnecessary medicine expenditure, which is also rapidly increasing at an average of 18% per year over the last 5 years, threatening the financial sustainability of Aasandha. This high medicine expenditure has several reasons. Firstly, the system allows for the supply and use of many non-essential medicines. In 2022, about sixty percent of medicine reimbursement by Aasandha 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 3-5x (range 2-8x) the world market price. This difference is far too large to be explained by lack of economies of scale and is caused by wide-spread inefficient procurement. Many important decisions to select the product, formulate the specifications and agree to the procurement price are often taken by the same institution or even by the same individuals. However, all costs are fully reimbursed by Aasandha who is no party to the decisions and has no power to select the most cost-effective products. Vulnerability to inefficiencies and even corruption

is further aggravated by a lack of transparency about the selection of products and the prices paid. So far Aasandha has not used its power to restrict reimbursement.

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 EML by Aasandha 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 in redefining the range of medicines for reimbursement. The lack of STGs is also felt by the many young expatriate doctors in rural areas who do not receive any introductory training on what is expected from them, and are therefore free to prescribe on the basis of their own professional education and/or practice guidelines from other countries. This is yet another reason why there are so many different (and often non-essential) medicines prescribed and reimbursed.

Limited capacity of MFDA (small island state)

The 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 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.

Lack of internal coordination

There are several areas where better coordination can promote government efficiency in medicine selection, procurement, use, and reimbursement. Firstly, it is very important that this national medicine policy is developed and implemented in close collaboration with the most important stakeholders: the MFDA, the Ministry of Health (departments of health systems, health promotion, and quality assurance), Aasandha, the Ministry of Finance, academia, and health professionals.

Secondly, the standard treatment guidelines and the national list of essential medicines should be developed by MFDA and the Ministry of Health, in close collaboration with Aasandha, who will later use these tools to define reimbursement.

Thirdly, **t**he 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 the different computer systems do not use the same medicine coding systems. Up till now some agencies, including the Customs Service and the State Trading Organisation, have been unable to exchange their data with Aasandha and with the Ministries of Health and Finance.

The Maldives National Medicine Policy

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 within the limited resources of a small-island country
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 contain the development of 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. The main purpose of the list is to define the range of products to be reimbursed by the national health insurance system Aasandha.

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 Maldives Food and Drug Administration will follow, as much as possible, the global guidance by the World Health Organization (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.

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 the national health insurance scheme Aasandha, 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 Ministry of Health, the Ministry of Finance and Aasandha, 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 government will introduce mechanisms for partial patient co-payment for medicines which are considered as non-essential and are not listed for reimbursement by Aasandha; and for the difference between the price charged by the pharmacy and the maximum reimbursement price set by Aasandha.

3.3 The National Social Protection Agency (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) (generic names) will be promoted in medicine procurement, inventory control, prescribing, dispensing, reimbursement, and medicine use studies.

4.3 For single-source products Aasandha will set the maximum reimbursement price which is based on the price of the same product in a number of reference countries ("external reference pricing"). The list of refence countries will be published.

4.4 For multi-source (generic or branded generic) products, Aasandha will set a maximum reimbursement price based on the average price of the three lowest-priced generic products of assured quality registered and marketed in the Maldives. This maximum reimbursement price will be adapted at regular intervals and will be published along with the list of products reimbursed by Aasandha.

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 The MFDA, the Customs Authority, the State Trading Organization, Aasandha, ADK and the national pharmacy association will agree on one standardized medicine coding system, to facilitate exchange of data on procurement, price, supply, prescription and reimbursement data.

5.2 The supply and distribution of medicines by the MOH and the STO will be restricted to Aasandha's list of reimbursed medicines based on the national list of essential medicines. A separate mechanism will be created for ordering, stocking and prescribing some additional non-EML items by specific specialist departments, and for individual patients.

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 contain the development of 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, antimicrobials, and oncology. They will be widely promoted, preferably in electronic form, using INN (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 national pharmaceutical analysis unit will be established by Aasandha and the MOH, 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 as part of the rights-based approach demanded by the Constitution.

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 The Maldives FDA 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 Aasandha 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 developing and implementing the NMP the Ministry of Health will involve all important stakeholders, such as the MFDA, the MOH quality assurance department, the Ministry of Finance (MOF), Aasandha, NSPA, Customs, the MOH procurement unit, the State Trading Organisation, academia and medical professionals.

8.2 The Ministry of Health will establish a small NMP implementation committee, with operational-level representatives from MFDA, Aasandha, MOH and MOF.

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 2024-2030 will be done in 2030, as part of the national evaluation of the Sustainable Development Goals.

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