NEWSLETTER 2024

MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTICS GOODS DIVISION
1st January - 31st December 2024

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MFDA AND ITS STRUCTURE

Established in 2006 under a Presidential Decree, the Maldives Food and Drug Authority (MFDA) functions as an independent authority under the Ministry of Health. MFDA is the national regulatory body responsible for safeguarding public health by ensuring the quality, safety, and efficacy of food, pharmaceuticals, medical devices, biologicals, drinking water, and related products.

MFDA's core responsibilities include setting and enforcing national standards, product registration, inspection and licensing of manufacturing and distribution facilities, issuing import and export authorizations, and overseeing compliance with regulatory requirements. It also plays a leading role in public awareness, antimicrobial resistance control, and fulfills international obligations as the national focal point for Codex Alimentarius. Through its regulatory and enforcement activities, MFDA ensures that products reaching the public meet accepted health and safety standards.

NATIONAL HEALTH LABORATORY (NHL)

The National Health Laboratory (NHL) serves as the national reference laboratory in the Maldives for the analytical testing of pharmaceuticals, food, water, and other consumer products. Utilizing internationally recognized methodologies and quality assurance systems, the laboratory helps ensure the safety, efficacy, and compliance of tested products with regulatory standards.

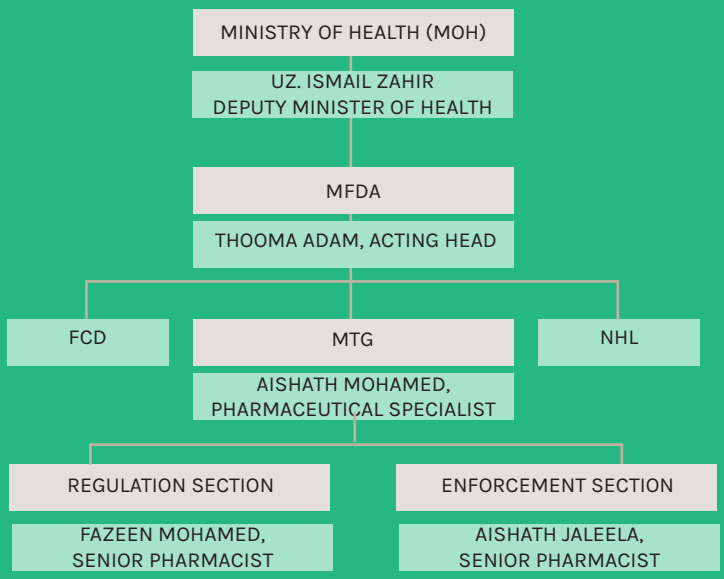
FOOD CONTROL DIVISION (FCD)

Food Control Division (FCD) is responsible for ensuring the safety and quality of food and supplements imported and distributed in Maldives. Through regulatory measures, the division aims to protect the public health and maintain the quality of food products available to the public.

MEDICINE AND THERAPEUTIC GOODS DIVISION (MTG)

The Medicines and Therapeutic Goods Division (MTG) is responsible for ensuring the safety, quality, and efficacy of all medicines and medical products imported, distributed, and sold in the Maldives. This includes pharmaceuticals, vaccines, medical gases, biologicals, diagnostic devices, and medical equipment.

MTG oversees product registration, import authorizations, licensing of facilities, and post-market surveillance to ensure compliance with national regulatory standards. It also conducts inspections, monitors adverse events, and enforces regulatory actions to protect public health. The division ensures that medical products available in the country meet established safety and performance requirements and is accredited to ISO 9001, demonstrating its commitment to quality management and continuous improvement.



WORD FROM ACTING HEAD OF MFDA

Thooma Adam, Deputy Director General, Health Laboratory

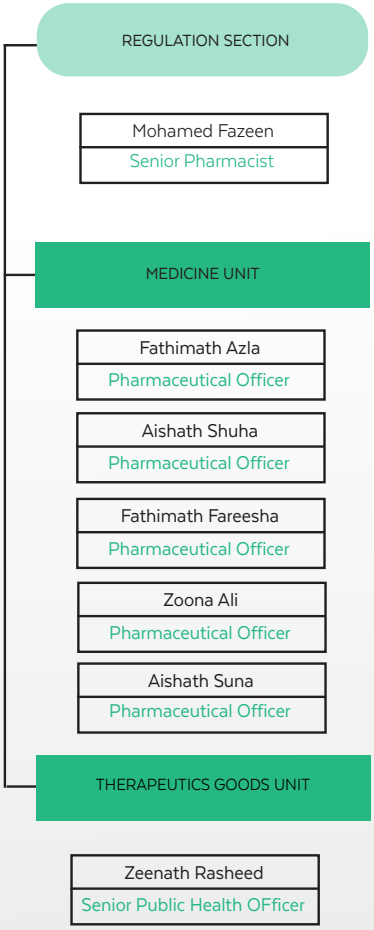
For nearly two decades, Medicine and Therapeutic Goods Division (MTG) has been dedicated in ensuring the availability of safe, efficacious and quality medicines. We strive to consistently work towards building a robust regulatory framework for the prosperity of our nation.

The year 2024 marked another milestone in this journey. Our focus was on the enhancement of regulatory effectiveness align with the global best practices. With ongoing support from WHO, our ultimate vision is to achieve to be recognized as a WHO listed drug regulatory authority. This achievement underscores our commitment to regulatory excellence and global harmonization. We believe that it will foster greater trust in our services both domestically and internationally.

Notable developments in 2024 include the implementation of reliance pathways in product registration. This change aims to expedite access to medicines, especially essential medicines, with less roadblock while enforcing thorough quality and safety standards. Additionally, the publication of the National Medicine Policy stands as a significant milestone.

Furthermore, to ensure availability of medicines MTG explores and implements mechanisms for public procurement of quality assured medicines through accredited hospitals.

As we move forward to 2025, our focus shall remain steadfast on improving our standards, guidelines, enhancing our regulatory capacity and resolving barriers to effective delivery of our services.



Regulation Section responsible for regulating medicines, alternative medicines and Dhivehi Beys, medical devices, pharmacies and warehouses, medical gas manufacturing facilities and importers to achieve its overarching aim of providing safe, quality and efficacious medicines and therapeutic goods for the health care system and the population of Maldives.

Despite the various challenges, the section continues to strive in its efforts to strengthen the regulatory system and streamline the different services provided. Notably in 2024, the Section has implemented reliance pathways for medicine registration to increase efficiency and national and international regulatory alignment.

Statistics in 2024 for Regulation Section

Medicine Registration

Our activities under medicine registration is to ensure the medicines imported based in Maldives meet the safety, quality and efficacy standards prior to entering the market.

2023	2024
474	317

Nutraceutical Registration

Nutraceuticals are products with vitamins and minerals and which claims to have an effect on the health and body. These products are registered to ensure their safety, quality and efficacy.

2023	2024
25	31

Preauthorisation for Import

Authorization allows for the temporary import and use of specific medical products that are not yet registered but are needed due its essentialness.

2023	2024
212	74

Alternative/Dhivehi Beys Registration

Alternative/Dhivehi Beys is assessed to ensure products manufactured and sold meet the statutory and regulatory requirements.

2023	2024
1	5

Approval for Clinician's Requisitions

This is the approval given for new chemicals not included in the Approved Drug List. Approval is given as per the technical advice from National Pharmaceutical Board (NPB).

2023	2024
51	03

Approval for Veterinary Medicines

Through the evaluation and approval this process aims to ensure that only approved veterinary drugs are available for use in treating animals.

2023	2024
25	28

Approval for Medicine Sample Import

For the purpose of facilitating the process of medicine registration, the section authorizes import for medicine samples for the purpose of evaluation.

2023	2024
640	730

Approved Drug List (ADL)

ADL is published by MTG on a monthly basis including the registered products under the different schedules, general sale items allowed for sale in pharmacies and pharmaceutical products allowed for sale in general stores.

	2023	2024
Total Number of Products	4835	4373
Registered Medicines	1798	1807

Issue of Pharmacy Professionals ID Card

For pharmacy professionals with a valid certificate issued from Maldives Allied Health Council, MTG issues an ID card. This is for the public to identify that a registered pharmacy professional is attending to them.

	2023	2024
Pharmacists	449	489
Pharmacy Assistants	570	625
Dispensers	253	258

Dhivehi Competency Evaluation for Expatriates

As per the Medicine Regulation R-46/2014 it is mandatory for foreign pharmacists to be assisted by a local translator during duty hours. However, to ease the cost involved in hiring a local translator, the option for foreign pharmacists to complete Dhivehi Competency Evaluation with a written and oral exam is given.

2023	2024
51	05

Medical Devices and Importer Registration

As of now the registration of medical devices is a voluntary procedure carried out to ensure the quality, safety and efficacy of medical devices imported. To import such registered medical devices, the importer must be registered and shall have a registered warehouse designated for medical devices as per the regulatory standards.

	2023	2024
Device Registrations	13	16
Importer Registrations	7	24
Warehouse Registrations	4	1

Approval for Medical Oxygen

Facilities manufacturing medical gases/ oxygen must adhere to the medicine regulations to ensure they meet the necessary safety and quality standards. Facilities must be inspected and hold a valid permit from MTG.

	2023	2024
Total authorized manufacturers	2	2
Total authorized manufacturing facilities	4	4

Health Clearance approvals for chemicals

Chemicals are permitted for import and use by Maldives National Defense Force through their online Portal "Makudi". MTG facilitates the approval of this permit by assessing the potential health hazards of such chemicals.

2023	2024
1493	1483

Medicine Disposal

Medicines that are damaged, expired or unused shall be disposed with the approval from MTG to ensure public safety and prevent harm to the environment.

	2024
Number of products (in units) verified for disposal	5,064,209

Approval for Medicine Importer

This process involves the registration and regulation of entities that import medicines and the warehouses where these medicines are stored. For import of approved medicines, it is mandatory to have a medicine warehouse as per the criteria set in medicine regulation.

	2023		2024	
	Male'	Atolls	Male'	Atolls
New Registrations	10	8	5	1
License Renewals	16	5	12	3
Total Registered	82		90	

Pharmacy Registration

This process involves the registration and regulation of entities that store and dispense medicines to the general public.

	2023		2024	
	Male'	Atolls	Male'	Atolls
New Registrations	28	10	27	11
License Renewals	74	141	96	175
Total Registered	474		497	

Approved Drug List (ADL)

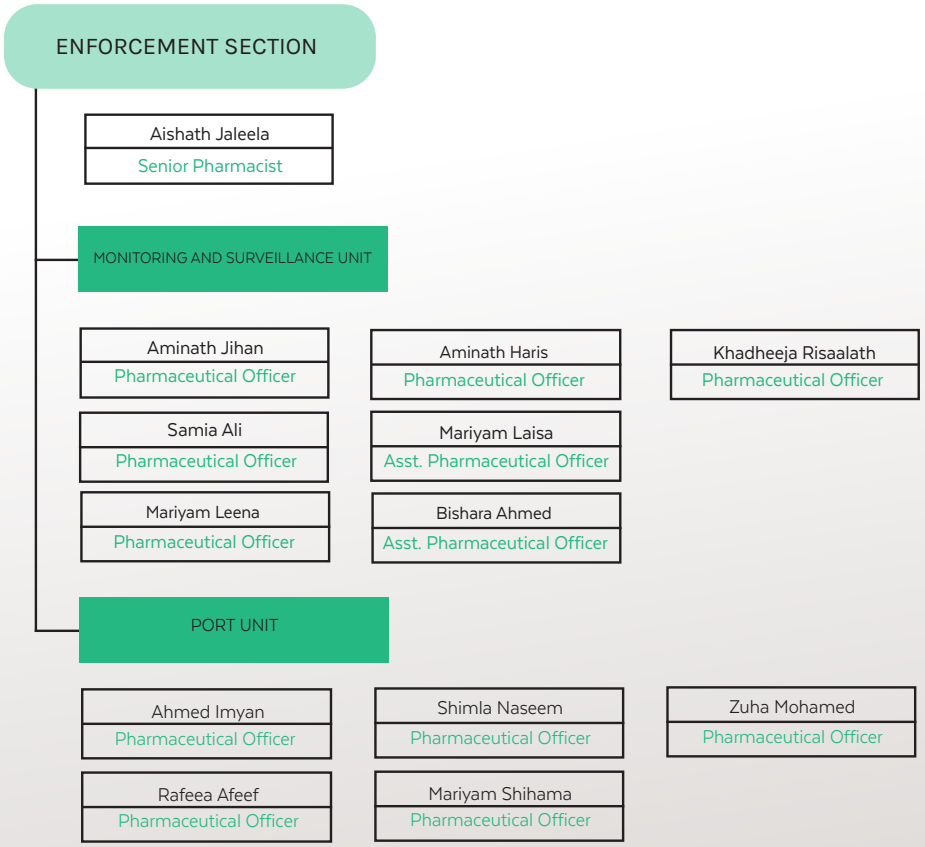
ADL is published by MTG on a monthly basis including the registered products under the different schedules. Registered medicines are divided into different categories such over-the-counter medicines (OTC), Presciption-only-medicines (POM), Hospital use only (HU), National programme (NP) and controlled drugs, which includes narcotics and psychotropics. The list also includes pre-authorisation medicines which are listed in generics

	2023	2024
Total Number of Products	4835	4373
Registered Medicines	1798	1817
Primordial Products	806	724
Temporary Approvals	2218	1817
Radio Contrast Media	13	13

ALERTS RELEASED IN 2022 REGARDING PHARMACEUTICAL PRODUCTS

#	DATE	REFERENCE	DETAILS
1	30.01.2024	(IUL)182-reg/23/2024/1	MTG collected and tested random samples from the market under post market surveillance issues were identified in the following product. Brand Name: Panadol (Paracetamol 500 Tablets) Manufacturer: Smithkline Beecham (Pvt) Ltd From the testing tablet fragmentation was identified and this can be a result from the manufacturing process or issues in the storage and handling of the product. This can lead to decrease in the effect of the product. Hence, until further notice the product was restricted from import, sale and use. Panadol is the most commonly used product in Maldives. In addition to this there are 11 registered brands for Paracetamol 500mg and 7 registered brands for Paracetamol 650mg.
2	22.02.2024	(IUL)182-reg/23/2024/2	Following the MFDA alert (IUL)182-reg/23/2024/1 further testing was conducted on Panadol (Paracetamol 500mg Tablets) and it was concluded that the cause for the issue was from storage and handling. Furthermore, the batch with the identified issue is no longer available in the market. Hence, with this alert the import, sale and use of this product can be resumed. To prevent such issues in the future, the guidelines on transport, storage and handling published by the authority shall be followed.
3	10.06.2024	(IUL)182-reg/23/2024/6	Thailand Food and Drug Regulatory (Thai FDA) has recalled 15 products manufactured by Seven Stars Pharmaceutical Co. Ltd, Thailand. These products were recalled following the identification of a harmful chemical in the excipient, Sorbitol. These products are not registered for import to Maldives; however, caution is advised in case the product is imported through a prescription or other means.
4	22.07.2024	(IUL)182-reg/23/2024/7	Honey products sold through online social media platforms have been identified to include active ingredients such as Sildenafil and Tadalafil. The authority has previously issued an alert (182-REG/CIR/2022/4 regarding this issue. Such products have been listed as harmful in US FDA. Such products can be harmful for the health and can be life threatening in some situations. Hence, with consideration to the potential harmful effects, the import and sale of such products is restricted by the authority.

#	DATE	REFERENCE	DETAILS
5	04.08.2024	(IUL)-182-REG/23/2024/18	Quality issues identified in 3 batches of the following product: Brand Name: Allegra (Fexofenadine Suspension 30mg/5ml) Manufacturer: Sanofi India Limited, India Batch No.: AL1223019, AL1223029 and AL1223060 Hence, the import, sale and use of these 3 batches are restricted.
6	29.09.2024	(IUL) 182-Enf/182/2024/20	In the previously issued alert for Cofsy Syrup by the authority the import, sale and use of Cofsy Syrup 5mg/100ml (MMC Health Care Ltd) was temporarily prohibited due to quality concerns identified in the initial testing. However, with further testing it was concluded the product has no quality issues. Hence, with this alert the import, sale and use of this product can be resumed.
7	01.10.2024	(IUL)182-REG/182/2024/30	Alert in reference to CDSCO's alert on the recall of 48 products manufactured in India due to quality issues. From this list the 44th product, Telmisartan 40mg (M/s. Swiss Garnier Life, India) was a previously registered product in the Approved Drug List. This product was removed from the list in 2018. After evaluation it was noted that any of the 48 products were not imported to Maldives. These products are not registered for import to Maldives; however, caution is advised in case the product is imported through a prescription or other means.
8	02.10.2024	(IUL)182-REG/182/2024/31	Alert in reference to CDSCO's alert on the recall of 16 products manufactured in India due to quality issues. After evaluation it was noted that any of the 16 products were not included in the Approved Drugs List and these products were not imported to Maldives. These products are not registered for import to Maldives; however, caution is advised in case the product is imported through a prescription or other means.
9	23.10.2024	(IUL)182-REG/182/2024/9	Alert in reference to Sri Lanka's National Medicine Regulatory Authority regarding quality issues found in the following product: Brand Name: Immuglo (Normal Immunoglobulin IV BP 5%) Manufacturer: Ichor Biologicals Ltd, India This product and manufacturer are not registered for import to Maldives; however, caution is advised in case the product is imported through a prescription or other means.
10	26.11.2024	(IUL)182-reg/23/2024/10	Through the ongoing efforts of MFDA to ensure the quality and safety of medicines, screening of medicines was conducted with samples collected from the market. From this two mefenamic acid pediatric oral liquids were identified to be positive for DEG/EG. Product 1: Mefnac Suspension 50mg/5ml by Efroze Chemical Industries (Pvt) Ltd., Pakistan Product 2: Axcel Mefenamic Acid Suspension 125 mg/ml by Kotra Pharma (M) Sdn.Bhd, Malaysia These products were sent to international laboratory for further confirmatory testing. Hence, the import, sale and use of all batches of the 2 products were prohibited temporarily.



Enforcement Section is responsible of conducting functions related to monitoring and surveillance which is critical for ensuring compliance with regulatory standards. Working alongside Regulation Section, this section ensures registered products and entities continue to adhere to requirements after registration. By conducting pharmaceutical and warehouse inspections, market surveillance, clearance of imported pharmaceutical products at entry ports, Enforcement Section aims to safeguard the safety, quality and efficacy of medicines and pharmaceutical products available in Maldives.

Statistics in 2024 for Enforcement Section

Pharmaceutical Inspection

Pharmaceutical Inspections is an integral part of our regulatory system to ensure the stringent regulations are enforced following the registrations and licensing issued from the Regulation Section. This includes inspections in pharmacies, warehouses and other facilities that may hold medicines for the purpose of import, distribution, storage etc.

	Pharmacies				Warehouses			
	2023		2024		2023		2024	
	Male'	Atolls	Male'	Atolls	Male'	Atolls	Male'	Atolls
Routine Inspections	28	25	5	1	-	-	1	-
License Renewal Inspections	67	140	12	3	20	5	12	3
Inspection for New Registrations	28	14	35	9	12	6	7	1
Total pharmaceutical inspections	123	179	52	13	32	11	20	4

Post Market Surveillance

To ensure the quality, safety and efficacy of medicines imported, sold and used in Maldives. MTG conducts continuous sample collection, quality testing and appropriate actions based on the results.

Notably, from the 301 products tested in 2024, 116 products were screened for DEG/EG. From these, 2 products were found to be positive for DEG/EG. In addition, confirmatory testing was conducted for 22 batches through international laboratory.

	2024
Total samples collected	301
Total product tested and received results	279

Controlled Drugs

Controlled drugs are psychotropic and narcotics regulated under the Drug Act 17/2011 Schedule 2. These include nationally and internationally controlled drugs. MTG issues import license and purchase authorizations based on the quota given by International Narcotics Control Board (INCB).

	2023	2024
Import Licenses	41	60
Purchase Authorizations	517	769

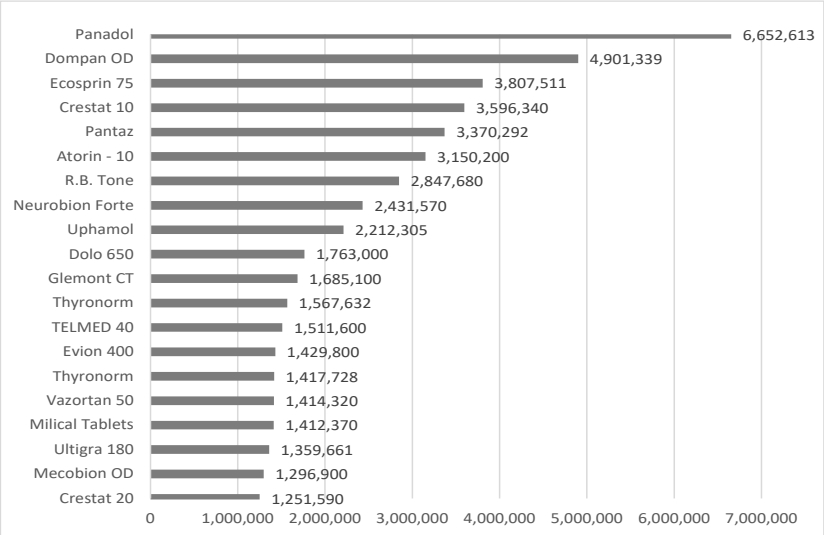
Border Control

MTG has border control units to conduct health clearance for shipments imported to Maldives through air and sea. Currently, the units are in Velana International Airport and Male' Commercial Harbour. This is the first physical verification of imported products which is followed by the activities under post market surveillance. This verification aims to ensure registered products are imported by registered importers.

	2023	2024
Released products (in units) from Airport	129,315,150	115,461,525
Released products (in units) from Seaport	156,089,566	159,840,971

	2023	2024
Permanently held products (in units) in Airport	247,594	184,111
Permanently held products (in units) in Seaport	750,404	763,162

Top 20 Imports 2024



1. Panadol

Paracetamol
6,652,613 units
Tablet | 500 mg
Analgesic ; Antipyretic
Treatment for fever and pain

2.Dompan OD

Domperidone + Pantaprazole
4,901,339 units
Tablet | 30 mg + 40 mg
Drugs for acid related disorders
Treatment of gastric and stomach issues

3. Ecospirin 75

Acetyl Salicylic Acid
3,807,511 units
Tablet | 75 mg
Antiplatelet ; Anticoagulant
Prevent platelet clumping and blood clots

4. Crestat 10

Rosuvastatin
3,596,340 units
Tablet | 10 mg
Antilipid
Treatment of hyperlipidemia

5. Pantaz

Pantaprazole
3,370,292 units
Tablet | 40 mg
Drugs for acid related disorders
Treatment of gastric and stomach issues

6. Atorin-10

Atorvastatin
3,150,200 units
Tablet | 10 mg
Antilipid
Treatment of hyperlipidemia

7. R.B Tone

Ferrous gluconate, calcium, vitamin B12 and Folic acid
2,847,680 units
Capsule | 200 mg (BP) + 38 mg(BP)+ 12 4 mcg(BP)+ 3 mg(BP)+2.5 mg (BP) +1 mg(BP)+ 2.5 mg(BP) + 23 mg(BP) + 150 mg(BP)
Nutritional Supplement
Iron Deficiency anaemia ; General Weakness

8. Neurobion Forte

Thiamine Mononitrate IP + Riboflavine IP + Pyridoxine Hydrochloride IP + Cyanocobalamin Triturate in Gelatine EQV. Cyanocobalamin IP + Nicotinamide IP + Calcium Pantothenate IP
2,431,570 units
Tablet | 10 mg + 10 mg + 3 mg + 15 mcg + 45 mg + 50 mg
Vitamin Complex
For relief of nerve damage symptoms

9. Uphamol

Paracetamol
14,091,376 units
Tablet | 500 mg
Analgesic ; Antipyretic
Treatment for fever and pain

10. DOLO 650

Paracetamol
1,763,000 units
Tablet | 650 mg BP
Analgesic ; Antipyretic
Treatment for fever and pain

11. Glemont CT

Montelukast
1,685,100 units
Chewable Tablet | 5 mg
Respiratory stimulants
Treatment of obstructive airway diseases

12. Thyronorm

Thyroxine Sodium
1,567,632 units
Tablet | 50 mcg
Hormonal preparation
Treatment of thyroid dysfunction

13. Telmed 40

Telmisartan
1,511,600 units
Tablet | 40 mg
Diuretic
Treatment of high blood pressure

14. Evion 400

Vitamin E
1,429,800 units
Capsule | 400 mg
Vitamin
Treatment of vitamin deficiency

15. Thyronorm

Thyroxine Sodium
1,417,728 units
Tablet | 25 mcg
Hormonal preparation
Treatment of thyroid dysfunction

16. Vazortan 50

Losartan Potassium
1,414,320 units
Tablet | 50 mg
Diuretic
Treatment of high blood pressure

17. Milical

Calcium + Vitamin D3
1,412,370 units
Tablet | 1000 mg (USP) + 200 IU (USP)
Nutritional Supplement
Treatment of low blood calcium levels: Vitamin D deficiency

18. Ultigra 180

Fexofenadine
1,359,661 units
Tablet | 180 mg
Antiallergant
Treatment of allergy symptoms

19. Mecobion OD

Mecobalamin IP + Alpha Lipoic Acid USP + Chromium Picolinate USP + Pyridoxine Hydrochloride IP + Nicotinamide IP + Folic Acid IP + Calcium Pantothenate IP
1,296,900 units
Tablet | 1500 mcg + 100 mg + 200 mcg + 3 mg + 45 mg + 1.5 mg + 50 mg
Nutritional Supplement
For nerve health; Treatment of vitamin deficiencies

20. Crestat 20

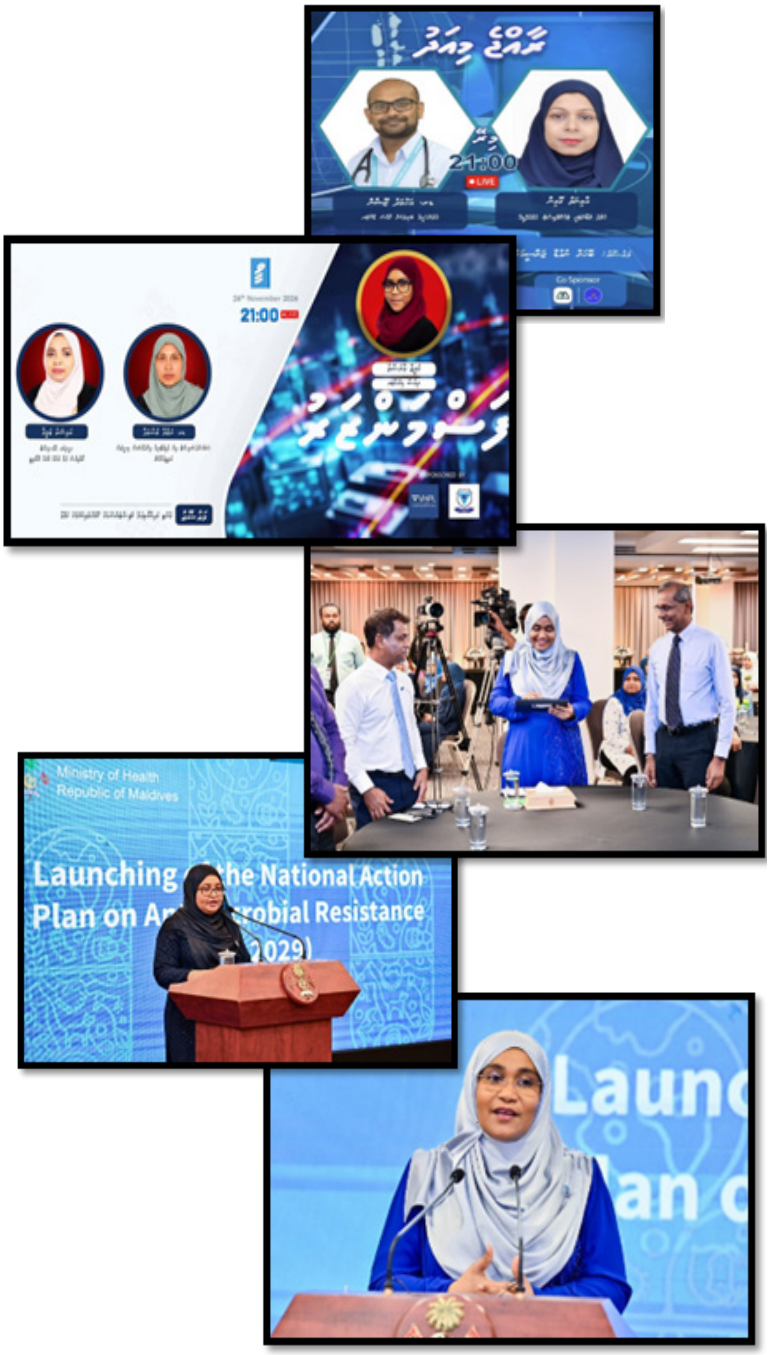
Rosuvastatin
1,251,590 units
Tablet | 20 mg
Antilipid
Treatment of hyperlipidemia

World Antimicrobial Resistance Awareness Week 2024

"World Antimicrobial Resistance Awareness Week" is celebrated annually worldwide form 18th to 24th of November. The theme for WAAW 2024 was "Educate. Advocate. Act now ". Antimicrobial Resistance is a major global threat to the effective and efficient treatment of diseases caused by microbial agents.

The following activities were conducted by MFDA to participate in WAAW and promote the message on antimicrobial resistance.

- AMR Surveillance data from Tertiary care hospitals submitted to GLASS - 24th August 2024
- Assessment of the AMR surveillance capacity of Maldives by WHO consultant - 20th and 28th October 2024
- Introductory Workshop on AMR Surveillance for healthcare professionals (conduct in Kulhudhuffushi Regional Hospital in hybrid mode) - 24th October 2024
- AMR Awareness through mainstream media including Villa TV's Fasmanzaru and PSM's Raajje Miyadhu - 24th November 2024
- MFDA shared awareness through social media platforms such as X and Facebook.
- Launching of the 2nd National Action Plan on AMR 2024-2029 - 1st December 2024



Notable Developments in 2024

- In June 2024, reliance pathways were introduced and the "Guideline on Product Registration and Emergency Use Approvals" was reviewed. Through these changes, MTG aims to enhance efficiency in product registration while reinforcing the quality, efficacy, and safety of medicines.
- Successful completion of Surveillance Audit of ISO 9001:2015 Quality Management System by the Accreditation body, Sri Lankan Standards Institute (SLSI) in August 2024.
- A follow-up meeting for the WHO Global Benchmarking Tool (GBT) pre-benchmarking was conducted in November 2024, as part of ongoing efforts to achieve Maturity Level 4 and become a WHO-listed authority.
- Following the expansion of Velana International Airport, the MFDA's Pharmaceutical Unit has relocated to new premises, resulting in an improved working environment.

Outlook for 2025

- MTG has taken the initiative to ease and facilitate the process of importing essential medicines through the introduction of approving import of medicines through accredited international hospitals. Throughout 2025 our aim is to further develop this process and ensure the quality, efficacy and safety of these products.
- The recertification process is to be conducted for ISO 9001:2015 QMS during the second half of 2025. This will be the second recertification for the division since achieving certification in March 2018.
- The review of the Essential Medicines List (EML) is scheduled for completion in 2025 and is being carried out in consultation with specialists from relevant fields.
- With the establishment of the Implementation Committee for the National Medicine Policy, implementation activities are set to begin in the first half of 2025

MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTIC GOODS DIVISION
mfda.gov.mv | dhirithi.egov.mv

Medicine Registration	medicine.registration@health.gov.mv	3014379
Medicine Disposal	medicine.disposal@health.gov.mv	3014316
Medicine Import and Pharmacy Licensing	mtg.licensing@health.gov.mv	3014316
Approved Drug List	mtg@health.gov.mv	3034236
Medical Devices, Nutraceutical Registration	mtg@health.gov.mv	3014316
Approval for Veterinary Medicines	mtg@health.gov.mv	3034236
Pre-authorization Approvals	mtg@health.gov.mv	3014308
Health Clearance for Chemicals	mtg@health.gov.mv	3034236
Pharmaceutical Inspections	mtg.inspection@health.gov.mv	3034235
Controlled Drugs	mtg.controldrug@mfda.gov.mv	3034237
Pharmacovigilance	mtg@health.gov.mv	
Aiport Pharmaceutical Unit	mfda.airport.pharmaceutical@health.gov.mv	
Seaport Pharmaceutical Unit	mfda.seaport.pharmaceutical@health.gov.mv	7962815
General Inquiries and Complaints	mtg@health.gov.mv	7200321