NEWSLETTER 2022

MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTICS GOODS DIVISION

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MALDIVES FOOD AND DRUG AUTHORITY

Food Control Division

National Health Laboratory

Medicine and Therapeutic Goods Division

Medicines are an essential part of our community and to the quality of life of its people. Medicine and Therapeutic Goods Division was established under Maldives Food and Drug Authority was established to uphold the integrity of the medicines available in Maldives.

Maldives Food and Drug Authority is divided into three main division: the National Health Laboratory, Food Control Division and Medicine and Therapeutics Goods Division.

WORD FROM ACTING HEAD OF MFDA

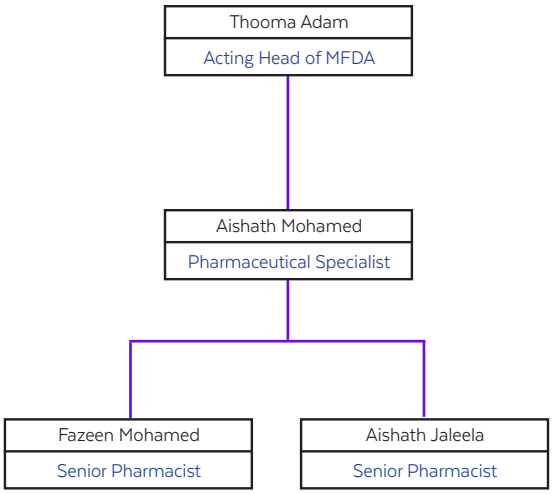
Thooma Adam, Health Laboratory Specialist

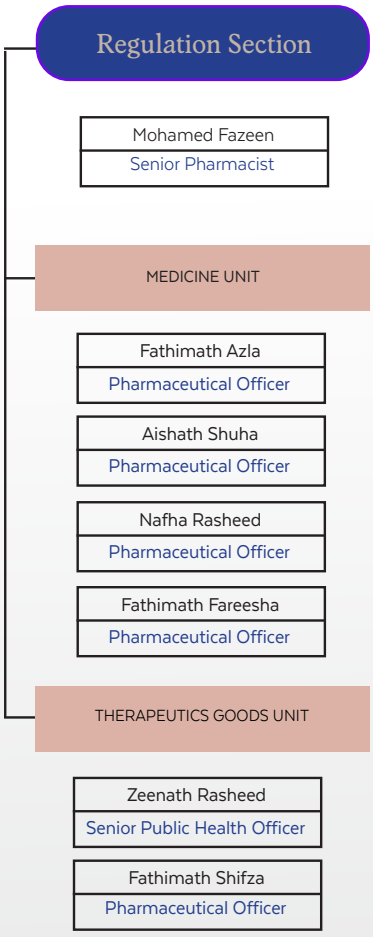
Ever since the establishment of this authority in 2006, the main aim of MTG Division, and its sections, has been to contribute to the prosperity of our country and to building a society that provides quality assured and safe medicines.

2022 was a step forward in addressing the many difficulties we face and the shortcomings our authority has. Our aim for the year was to enhance and increase the efficiency of our services. MTG achieved certification in ISO 9001:2015 QMS in 2019 and after successful maintenance of the system for three years, MTG achieved recertification for the standard in August 2022.

Furthermore to achieve our aims, in 2022 we started on the effort to achieve recognition as a WHO Listed Authority. As per WHO this initiative expects to *"foster regulatory convergence, harmonization of approaches and international cooperation*". Therefore, by achieving this goal our authority hopes to strengthen the regulation of medicines and bring immense improvement to our regulatory practices.

To continue our efforts as mentioned before, in 2023 our goal is to improve our standards and guidelines, enhance our regulatory power with amendment of the Medicine Regulation and continuously work on improving our services and eliminating issues that may hinder its effectiveness.





Regulation Section aims to ensure the safety, quality and efficacy of all medicines. In order to achieve its objectives, the section authorizes import of medicines, alternative medicines and traditional medicines (Dhivehi beys), medicine samples, medical devices and medical gases. It Also monitors the dispense and trade of medicine by ensuring that medicine are dispensed by authorized personnel and from licensed pharmacies.

All services provided through this section conforms to the rules and regulations stated in Medicine Regulation (2014/R46) ,Medicine Regulation (2016/R-49) and Health Services Act (2015/29).

Regulation Section Services in 2022

Medicine Registration

This process is carried out to ensure the medicines imported and distributed in Maldives are safe, of quality and efficacious.

A total of 299 pharmaceutical products were registered after dossier submission, evaluation and upon the decisions made by the National Pharmaceutical Board.

Nutraceutical Registration

Nutraceuticals are products containing vitamins, and mineral (natural and synthetic which claims to have an effect on the body function or structure. MTG has established a mechanism to register such products to ensure their safety and quality. Registration of Nutraceuticals is a new service introduced in 2022.

Pre-authorization for Import

During 2022, 312 pre-authorization permits were issued. The purpose of issuing this special permit is to ensure the availability of essential medicines in the market.

Alternative/Dhivehi Beys

MTG also regulates the import and sale of alternative and herbal medicines. Permitted alternative and herbal medicines are updated in the publicly available, Alternative and Herbal Medicines List, on a monthly basis.

Veterinary Medicines Import and sale Permits

Veterinary medicine imports and sale permit is essential for the availability of appropriate medicines for the treatment of animals in Maldives.

A total of 8 import permits were issued for veterinary medicines in 2022. Currently there is only one registered seller for veterinary medicines.

Alternative/Dhivehi Beys Sale

This permit is issued to ensure the Alternative/Dhivehi Beys sold and distributed are registered products.

Within Greater Male' Region, atolls and resort 5 sale permits were issued in 2022.

Approved Drug List

Approved Drug List is published every month by MTG and it contains all the products that can be imported and distributed under the different categories. It also includes other lists such as , General Sale Items which can be sold in Pharmacies, Pharmaceutical Products that can be sold in general outlets etc.

As of 2022 the list contains 4901 products with an addition of 510 in 2022, 167 modifications and 60 products

Medicine Sample Import Permit

Medicine samples are required during the medicine registration process of new pharmaceutical products in Maldives. This permit is given for importers to import the required samples.

In 2022, 371 such permits were issued.

Pharmacy Registration

All pharmacies in Maldives can operate with a valid permit from Maldives Food and Drug Authority. This permit is issued for new pharmacies and for pharmacies renewing their existing permits.

By the end of 2022, 166 pharmacies renewed their permits and 38 new pharmacies were registered. This includes pharmacies located in Greater Male' Region, Atolls and in resorts.

Medicine Import and Warehouse Registration

Medicine import and warehouse permits are issued for ensuring medicines are imported by a registered importer and to ensure the storage conditions of medicines are regulated.

Permits are issued for new importers and warehouses and for the permit renewal of existing importers and warehouses. In 2022, 14 permits were issued for new applicants and 22 permit renewals were issued.

Health Clearance for Chemicals

Under the Regulation for Hazardous Chemical 2019/R-1057 (Ministry of Defense), chemicals imported into Maldives that could potentially be health hazardous shall be given clearance from MFDA. Requests are received through Ministry of Defense's Portal, "Makudi" and clearance is given by MFDA after necessary evaluations.

In 2022, 1376 clearances were given for such chemicals.

Alternative/Dhivehi Beys Import Permit

This permit is issued for importers and a warehouse is required for registration. The purpose of this permit is to ensure both importers and medicine storage facilities are regulated.

In 2022, 04 permits were issued.

Pharmacist Professionals ID Card

MFDA issues an ID card for Pharmacists, Pharmacy Assistants and Dispensers registered under Maldives Allied Health Council.

In 2022, 449 Pharmacist, 570 Pharmacy Assistant, 253 Dispenser ID cards were issued.

Medical Device/Consumables Import Permit

Medical Device/consumables Importers are can register as an importer and an import permit issued from MFDA prior to importing the products.

In 2022, 06 importers were registered for importing medical devices/ consumables.

Dhivehi Competency Evaluation for Foreign Pharmacists

Dhivehi Competency Evaluation is required for foreign pharmacists working without a local translator to ensure proper dispensing and pharmaceutical care is given. A local translator is required for foreign pharmacists as per the Medicine Regulation R-46/2014. Thie service aims to ease pharmacy owners from the cost of hiring a local translator.

The evaluation is conducted with a written and an oral examination conducted by MTG. By the end of 2022, 42 foreign pharmacists have completed the evaluation.

Medical Devices/consumables Registration

Medical devices are registered with submission of relevant information, device samples and based on the decisions taken through the National Pharmaceutical Board.

In 2022, a total of 35 medical devices were registered.

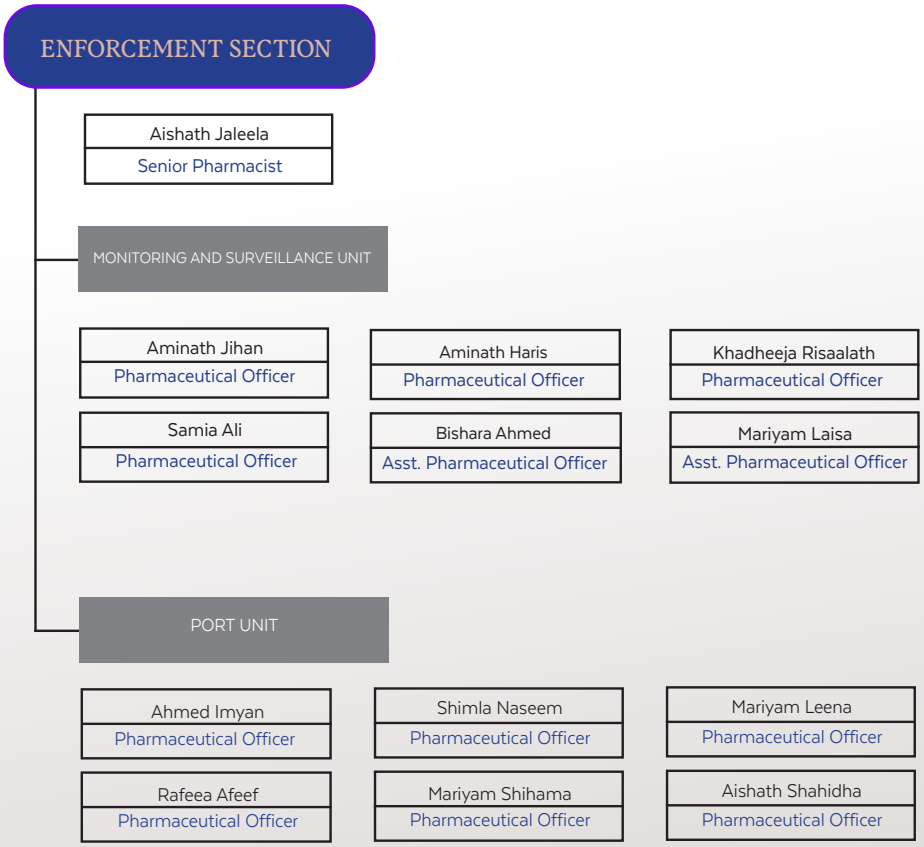
Medical Gas/Oxygen

Medical gas/oxygen are manufactured in Maldives to provide for critical care patients. MFDA inspects manufacturing plants and issues a permit to ensure the quality of the gases produced.

By the end of 2022, there are 02 registered distributors and 03 manufacturing plants.

ALERTS RELEASED IN 2022 REGARDING PHARMACEUTICAL PRODUCTS

Brand Name: Piriton 2mg/5ml; Piriton Expectorant (2mg+100mg/5ml) Generic Name: Chlorpheniramine; Chlorpheniramine + Amonium Chloride Dosage Form: Oral Syrup Manufacturer: Glaxo Wellcome Ceylone Limited, 121, Galle Road, Kaldemulla, Moratuwa, SriLanka Alert referenced from: From product recall by the product manufacturer.	This alert was issued due to batches of Piriton Syrup being recalled by the manufacturer for issues in product labeling. The batches for Pirition syrup and Piriton Expectorant were confirmed to have been imported into Maldives and recall procedure was conducted in pharmacies and warehouses. This included 32 different batches of Piriton Syrup and 8 batches of Piriton Expectorant.
Brand Name: Dysport 500U Generic Name: Clostridium botulinum type-A toxin-haemagglutinin complex Dosage Form: Powder for Injection Manufacturer: Ipsen Biopharm Limited Wrexham, LL13 9UF, UK Alert referenced from: WHO	Falsified batches of Dysport were found in 5 countries in Europe and Eastern Mediterranean according to WHO. Discrepancies in the packaging languages, type of vial, and, printing errors on the cartons. The product is listed as a pre-authorization required product in ADL. However, this product has not been imported to Maldives.
Brand Name:Desrem Generic Name: Remdesivir Dosage Form: Lypophilized Powder for Injection Manufacturer: Mylan Laboratories Ltd Alert referenced from: WHO	Antibodies Replacement Therapy, Intratect (Human Normal Immunoglobulin) was found to be falsified in Brazil, India, Bolivia and Egypt. The falsified products were identified to be manufactured without the main active ingredient alongside differences in product labeling compared to the actual product. This product is listed as a pre-authorization required product in ADL. However, as of yet the product has not been imported into Maldives.
Brand Name: Allersine Generic Name: Tetrahydrozoline Hydrochloride Dosage Form: Eye Drops Manufacturer: Duopharma (M) Sdn. Bhd Batch Number: 193033L 200827L, 200230L, 200608L, 200607L, 200825L Alert referenced from: National Pharmaceutical Regulatory Agency (Malaysia)	The batch numbers of this product was recalled and advised not to be used due to defects found.
Brand Name: Thyronorm 100mcg Generic Name: Thyroxine Sodium Dosage Form: Tablets Manufacturer: Acme Generics LLP Batch Number: AEG1233, AEG1987 Alert referenced from: Drug Control Administration (India)	Alert was issued on identified counterfeit products of Thyroxine Sodium (Thyronorm 100mcg) by India's Drug Control Administration. The batch number of the counterfeit products included AEG1233 and AEG1987. As a precautionary measure MFDA collected samples of available Thyronorm 100mcg and conducted test and increased monitoring of this product at port of entries. These batches are not available in the market however caution is advised when using other means of importing the product.
Brand Name(s) : Etumax Royal Honey for Him, Medcare Golden Royal Honey, Royal Honey, Royal Honey VIP, X Rated Honey for Men, Vital Honey, Helmi's Honey VIP, Wonderful Honey Generic Name : Contains Sildenafil and Tadalfil Alert Referenced From: Food and Drug Authority (US FDA)	Medicines used for sexual enhancement and treatment of erectile dysfunction were identified by this Authority to be included in honey products. These products are considered fraud products and as a cautionary measure the sale and use of these products are prohibited.
Brand Name: Jamu Surut Ayu Generic Name: Contains Lidocaine and Sibutramine Dosage Form: Capsules	This product was being sold on social media platforms with the claim for weight loss. It was identified to contain Lidocaine and Sibutramine. Hence, this product has been prohibited for use worldwide. Lidocaine is a local anaesthetic and the ingestion of this product can have unexpected adverse effects on the body. Likewise, Sibutramine is a prohibited product in multiple countries due to its dangerous side effects. This includes damage to the respiratory organs, heart attacks and strokes. Hence the import, sale and use of this product is prohibited in Maldives and caution is advised for using such products through Online purchases.
Brand Name(s) + Generic Name : Promethazine Oral Solution BP (Promethazine), Kofexmalin Baby Cough (Pheniramine Maleate + Ammonium Chloride+ Menthol), Makoff Baby Cough Syrup (Chlorphenamine Maleate + Phenylephrine HBR + Dextromethorphan), Magrip N Cold Syrup (Paracetamol Phenylephrine HCL + Chlorpheniramine Maleate) Dosage Form: Syrup Manufacturer: Maiden Pharmaceuticals Limited Alert referenced from: WHO	This alert was issued regarding contamination of diethlene glycol and ethylene glycol contained in cough syrups (Promethazine Oral Syrup, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup) . 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.
Brand Name: Termorex, Flurin DMP, Unibebi, Unibebi Demam (Drops), Unibebi Demam (Syrup) Paracetamol Drops, Paracetamol Syrup, Vipcol Syrup Generic Name: Paracetamol Dosage Form: Syrup Alert referenced from: WHO	Alert issued on "diethylene glycol and ethylene glycol" being found in paracetamol syrups in South East Asia in reference o WHO's alert no RPQ/REG/ISF/Alert N°7/2022. The products included in the alert are not registered for import into Maldives. However, cautioun is advised in case the product is import for prescription or imported any other way. Such products can be imported with testing results for DEG and EG.
Brand Name: Methotrex 50mg Generic Name: Methotrexate Injection IP Dosage Form: Injection Manufacturer: Celon Laboratories PVT LTD Batch Number: MTI210BAQ Alert referenced from: WHO	Substandard batches of Methotrexate used in the treatment for cancer patients, were found in two countries in Eastern Mediterranean. The product is listed as a pre-authorization required product in ADL. However, this product has not been imported to Maldives. Caution is advised for the use of the product through other means of import such as with a prescription.



Enforcement Section is responsible for ensuring the safety, quality and efficacy of medicinal products after it is in the market for consumption. It ensures public safety by monitoring products defects and adverse drug reactions, inspection of facilities and conducting public awareness programs.

Enforcement Section monitors regulatory compliance and compliance to the standards (both national and international adopted standards). Inspectors empowered by the Health Services Act (2015/29) medicine regulation (2014/R-46) and medicine Regulation (2016/R-49) inspects premises where any medicinal products are being manufactured, dispensed, distributed, stocked or offered for sale.

Enforcement Section Services in 2022

Post Market Surveillance

Post Market surveillance is important to monitor the quality of the medicines available in the market. Based on annual plan samples are taken for selected products in the market and laboratory testings are carried through the National Health Laboratory and in collabration with international laboratory.

In 2022, samples of 46 different products were taken for quality testing.

Controlled Drugs

Controlled Drugs including psychotropics and narcotics are regulated under Narcotics Law 17/2011 Schedule 2. MFDA regulates the import and sale of controlled drugs. This information is shared with International Narcotics Control Board (INCB). INCB also controls the quote of controlled drugs for each country.

In 2022, 49 import permits, and 769 purchase authorizations were issued for narcotics and psychotropics combined.

Border Control (Airport/Seaport)

MFDA's pharmaceutical units in Maldives Airports Company Ltd (MACL) and Maldives Ports Limited (MPL) inspects shipments to verify if they are registered products imported by an registered importer.

During the year 2022, a total quantity of 151,398,501 medicines were imported from seaport and a total quantity of 120,412,737 were imported from airport. The top 20 imported products based on quantity is included in this newsletter.

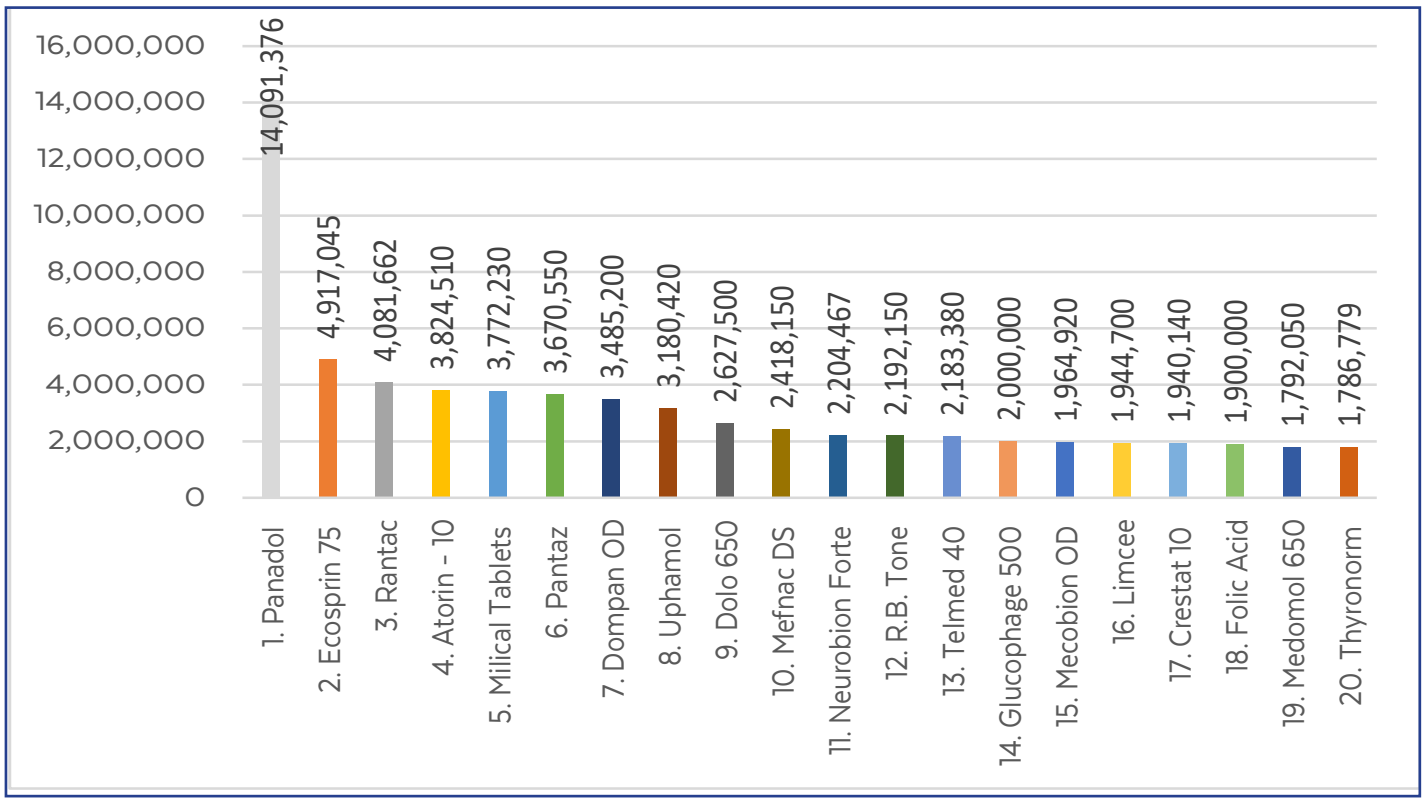
Pharmaceutical Inspections

Pharmaceutical Inspections are carried out to monitor and ensure if pharmacies, warehouses and institutions adhere to the Medicine Regulations. Inspections include, routine inspection (conducted annually), new permits and permit renewals, follow up inspections (to confirm corrective actions), controlled drug inspections (to monitor the handling of controlled drugs), spot inspections (investigative inspections under circumstances) and health facility

For the year 2022, 81 routine inspections , 283 inspections prior to permit renewals, 73 new pharmacy registrations, 92 follow up inspections, 8 spot inspections and 7 health facility assessments were conducted.

Based on the findings from these inspections appropriate actions were taken against violations of the Medicine Regulation.

Top 20 Imports in 2022



1. Panadol

Paracetamol
14,091,376 units
Tablet | 500 mg
Analgesic
Pain relief; Fever reduction

2. Ecosprin 75

Acetylsalicylic Acid (Aspirin)
4,917,045 units
Extended Release Tablet | 75 mg
Antiplatelet; Antilipid
Prevent platelet clumping; reduction in bad cholestrol

3. Rantac

Ranitidine
4,081,662 units
Tablet | 150 mg
Antacid
Prevent gastric and stomach issues

4. Atorin-10

Atorvastatin
3,824,510 units
Tablet | 10 mg
Antilipid
Reduce bad cholestrol (LDL)

5. Milical Tablets

Calcium + Vitamin D3
3,772,230 units
Tablet | 1000 mg(USP) + 200 IU(USP)
Calcium
Treatment of low blood calcium levels: Vitamin D deficiency

6. Pantaz

Pantaprazole
3,670,550 units
Tablet | 40 mg
Antacid
Prevent gastric and stomach issues

7. Dompan OD

Domperidone Bp + Pantoprazole Usp
3,485,200 units
Tablet | 30 mg(in SR form) (BP) + 40 mg (USP)
Antiemetic
Relief from nausea and vomiting

8. Uphamol

Paracetamol
3,180,420 units
Tablet | 650 mg
Antipyretic; Analgesic
Pain relief; Fever reduction

9. Dolo 650

Paracetamol
2,627,500 units
Disperible Tablet | 10 mg
Immunosuppressive
Relieve swelling, redness, itching, and allergic reactions

10. Mefnac DS

Mefenamic Acid
2,418,150 units
Tablet | 500 mg
NSAID
Relieve swelling, pain or fever

11. Neurobion Forte

THIAMINE MONONITRATE IP + RIBOFLAVINE IP + PYRIDOXINE HYDROCHLORIDE IP + CYANOCOBALAMIN TRITURATE IN GELATINE EQV. CYANOCOBALAMIN IP + NICOTINAMIDE IP + CALCIUM PANTOTHENATE IP
2,204,467 units
Tablet | 10mg + 10mg + 3mg + 15mcg + 45mg + 50mg
Improve nerve function

12. R.B. Tone

ferrous gluconate, calcium, vitamin B12 and folic acid
2,192,150 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

13. Telmed 40

Telmisartan
2,183,380 units
Tablet | 40 mg
Anti-hypertensive
Reduce blood pressure

14. Glucophage 500

Metformin
2,000,000 units
Tablet | 500 mg
Anti-diabetic
Treatment of Type 2 Diabetes

15. Mecobion OD

Mecobalamin , Alpha lipoic acid and Vitamin
1,964,920 units
Tablet | 1500mcg + 100mg + 200mcg + 3mg + 45mg + 1.5mg + 50mg
Nutritional Supplement
Treatment of Vitamin B12 Deficiency

16. Limcee

Ascorbic Acid
1,944,700 units
Tablet | 500mg
Nutritional Supplement
Treat Vitamin C deficiency

17. Crestat 10

Rosuvastatin
1,940,140 units
Tablet | 10 mg
Antilipid
Lower cholestrol

18. Folic Acid

Folic Acid
1,900,000 units
Tablet | 5 mg BP
Vitamin
Treatment of folic acid deficiency

19. Medomol 650

Paracetamol BP
1,792,050 units
Tablet | 650 mg
Analgaesic ; antipyretic
Pain relief; Fever reduction

20. Thyronorm

Thyroxin Sodium I.P
1,786,779 units
Tablet | 50 mcg
Synthetic Thyroid Hormone
Treatment of underactive thyroid (Hypothyroidism)

World Antimicrobial Resistance Awareness Week

"World Antimicrobial Resistance Awareness Week" is celebrated annually worldwide form 18th to 24th of November 2022. Antimicrobial Resistance is a major global threat to the effective and efficient treatment of diseases caused by microbial agents.

In response to this crisis, the Global Action Plan (GAP) was adopted through the 68th World Health Assembly (2015). The WAAW was initiated based on this plan as an effort to increase awareness and understanding of antimicrobial resistance and help optimize the use of antimicrobial medicines in human and animal health purposes.

Similar to previous years, in 2022 this week was observed in Maldives. Maldives conducted different activities with the aim of increasing public awareness through sessions and mass media. The theme for WAAW 2022 was "Prevention of Antimicrobial Resistance Together" with emphasis on enhancing the involvement of different sectors in the effort to reduce the misuse of antibiotics. These activities were conducted with the target audience of the general population and relevant stakeholders and the aim was to increase awareness on the abuse of antibiotics and the consequences of such actions. All activities were conducted with the support from WHO Maldives.

Special Inspection Operation for WAAW

The dispense of antimicrobial agents without a valid prescription is recognized as one of the most significant contributing factors to the spread of AMR in Maldives. Although the dispense of antimicrobials without prescription is prohibited in the Maldives by the Medicines Regulation R46/2014, it is observed to be a common occurrence.

Dispense of antibiotics without a valid doctor;s prescription is prohibited under Medicine Regulation R-46/2014 and such acts have been identified as a major reason for AMR in Maldives.

This special Inspection Operation was conducted to determine the severity and occurrence of this issue in Maldives. For conducting the inspections staff form all division of MFDA including, Medicine and therapeutic Goods Division (MTG), Food Control Division (FCD) and National Health Laboratory (NHL). Teams were formed from these staff and different areas were assigned to each team. Inspection was conducted in a total of 128 pharmacies in Greater Male' Area.

Staff were instructed to request for antibiotics as a customer without a prescription from the pharmacies. In cases where the pharmacies dispensed antibiotics appropriate action were taken including issue of notice and fine for violation of Medicine Regulation R-46/2014. The respective owners and pharmacists of the pharmacies were warned on the consequences of dispensing antibiotics without a prescription.

Compared to the 2021 inspection operation for WAAW, there was an increase in the number of dispenses. This issue was further discussed at policy level for possible actions to prevent misuse of antimicrobials.

Information Sessions on AMR

I. Awareness Sessions through TV programs

Information sessions on TV were conducted over the timespan of a week, touching up on crucial subjects such as ration use of medicine, common methods of AMR spread, and ways of prevention. This information was conveyed on Hedhunu Hendhunaa program where a significant population of the public tune in. The sessions were contributed to by a senior official of the MFDA MTG unit, Ms. Aishath Jaleela.

Throughout the week of WAAW 2022 information sessions were conduction through TV on subjects such as rational use of medicines, common channels of AMR and prevention methods. Sessions were broad casted through Hendhunu Hendhunaa program which has the probability of reaching a significant number of the general public. These sessions were led by MTG's Senior Pharmacist, Ms. Aishath Jaleela.

II. Sessions at Primary and Secondary schools

The youth of Maldives play an important role for the future of AMR related activities. By educating our children on the severity of AMR and its consequences, we are perhaps able to produce a passionate group of people that can contribute towards our efforts to stop the spread of AMR in the future.

It is of utmost importance to educate our youth on the topic of AMR. The aim of these sessions was to build a passionate group to contribute to the efforts of AMR now and in the future. Topics such as the severity of AMR and the consequences were discussed.

These sessions were conducted in various schools lead by school teaches, healthcare professionals and MFDA officials. Schools included Immadudhin school, I'zzudhdheen school, Iskandhar school, Muhyidheen school, Aminiya school and Hiriyaa School.

III. Distribution of AMR pins

AMR awareness pins were distributed to signify WAAW 2022 to all staff of Ministry of Health, relevant stakeholders such as Ministry of Fisheries, Marine Resources and Agriculture and Ministry of Environment, to all hospitals and some health care centers in regional islands. The pins were distributed alongside a booklet with a small message regarding AMR.

IV. Awareness through Social Media

Maldives being a geographically challenging area, it is difficult to relay the message through physical materials, hence social media was used to reach a wider audience. Digital materials were shared on different platforms such as Twitter, Facebook and Instagram. These materials, including posters, were shared in both Dhivehi and English.

Achievements in 2022

- Completed Global Benchmarking Tool (GBT) Pre-benchmarking Assessment in September 2022
- Achieved Recertification for ISO 9001:2015 Quality Management System

Frequently Asked Questions

1. What are regulated under MTG/MFDA?

- Import and Distribution of Pharmaceutical Products
- Registration of Pharmaceutical Products
- Import, Manufacture and Sale of Alternative/Herbal medicines
- Registration, import and distribution of Nutraceuticals
- Registration, import and Distribution of Medical Devices and Consumables
- Medicine advertisements
- Pharmacies and medical storage facilities
- Import and sale of Controlled Drugs (Narcotics and Psychotropics)
- Medicine Disposals
- Import and Sale of veterinary medicines
- Issue of ID card for pharmacy professionals (Pharmacists, Pharmacy assistants and dispensers)
- Manufacture and distribution of medical oxygen

2. What is not covered under MTG's activities?

- Regulation of cosmetic products
- Licensing of clinics and health facilities
- Import of medicines (MTG does not import or distribute medicines)

3. How are our services provided?

As of now, the main channel for providing our services is through Dhirithi Portal. Our aim is to incorporate all of our service into Dhirithi Portal, however the following services are being provided through the portal:

- Product and importer Registration (Pharmaceutics, alternative/herbal medicines, nutraceuticals)
- Pharmacy and warehouse registrations
- Medical device and medical device importer registrations
- Pre-authorization for pharmaceutical products
- Issue of ID card for pharmacy professionals (Pharmacists, Pharmacy assistants and dispensers)
- Authorization for import of medicine samples
- Medical Oxygen

Services not mentioned here can be sought through our email and phone.

4. How to get started on Dhirithi Portal?

The first step in using Dhirithi Portal is registering as portal user. "Dhirithi Portal User Registration form" has to be shared with MTG through email and once this form is processed the user will be associated with the relevant company. A registration guide for Dhirithi Portal is also available through the official website of Ministry of Health.

5. Where can guidance documents be accessed from?

MTG provides guidance documents including, guidelines and standards on the different services provided through Dhirithi Portal and the official website of Ministry of Health.

6. Who can import and distribute pharmaceutical products?

Medicines can be imported by registering as an importer. The importer must also have a registered warehouse to store the medicines. The details of the criteria required for the importer and the warehouse are included in the "MTG Guideline for Authorization of Medicine Importer". For importers of other categories of products such as alternative/herbal products, nutraceuticals and veterinary medicines are included in their relevant guidelines.

For the distribution of medicines, the pharmacy must meet the criteria as per the Medicine Regulation R-46/2014 and there should be an assigned pharmacist to dispense the medicines.

7. How to submit complaints and other issues to MTG?

Anyone can submit complaints regarding issues with MTG, dispensing error, faulty or low quality medicines, unauthorized medicines or person, issues with pharmacies (non-compliances to the medicine regulation) through our "Complaint and Incidents Reporting Form".

Quality defects can also be reported through "Quality Defect Reporting Form" and adverse drug reactions are also encouraged to be reported with the form "Suspected Adverse Drug Reaction Form". For further feedback, clients can also use the "Customer Service Feedback form". Such information can help us to improved our services and helps us in ensuring the provision of safe and quality medicines.

Maldives Food and Drug Authority
Medicine and Therapeutics Goods Division

MTG Hotline : 7200321
Pharmacy Registration : 3014308
Pharmaceutical Product Registration : 3014379
Chemical Health Clearance : 3014316
Medical Device Registration : 3014316
Medical Oxygen : 3014316
Alternative/Herbal Medicine : 3014316
Controlled Drugs : 3014379
Pharmacy Inspection : 3014308
E-Mail : mtg@Health.gov.mv
Complaints : mtg@Health.gov.mv
Website : www.health.gov.mv/en/departments/maldives-food-and-drug-authority