MALDIVES FOOD AND DRUG AUTHORITY

MEDICINE AND THERAPEUTIC GOODS DIVISION

NEWSLETTER

2019 - 2020

CONTENTS

MESSAGE FROM MINISTER OF STATE FOR HEALTH

DR. SHAH ABDULLAH MAHIR

Medicine and Therapeutics Goods Division (MTG), established in 2006 with the highest principles in ensuring the safety, quality and efficacy of medicines in Maldives. Since its establishment the authority has shown utmost compassion in fulfilling its responsiblity as the main authority regulating and providing services related to the import, distribution and sale of pharmaceutical products in Maldives.

With this the authority has taken steps to improve and strengthen the medicine regulatory system by successfully achieving certification of ISO Standard 9001:2015 Quality Management System and maintaining it since 2019. This was a vital step for the authority in overcoming its challenges, such acheiving customer confidence, transperancy and accountbiity of the medicine regulatory system.

The MTG has maintained this even through the many adversities caused due to the Covid-19 Global Pandemic. Despite the limitations faced such as during the lockdown, the division successfully provided the most crucial services by utilizing the available technology and resources.

Taking this opportunity I would like to highlight the teamwork shown by the team of Medicine and Therapeutics Goods Division, which made way for such acheivements.

MESSAGE MTG TEAM

Medicine is an essential part of our community to cope with the health prolems and improve the quality of lives. Hence, our team takes the responsiblities of our authority regarding the regulation of medicines with utmost importance and sincerity.

With the unexpected events in 2020 and the resulting setbacks our authority's main focus is to set place solutions to overcome these limitations and the continuity and improvement of our services. One of the ways we are working towards acheive this is, the launch of online services through MFDA's Dhirithi Portal.

Through these improvements clients can now recieve our services with more efficiency and safety. We aim to further improve these services and introduce more service through the online system to ensure our clients recieve the required services with the highest level of capability and assurance.

Before we conclude this newsletters, our team would like to sincerely thank all organisations who helped us to pave the way to achieve our goals in providing our services.

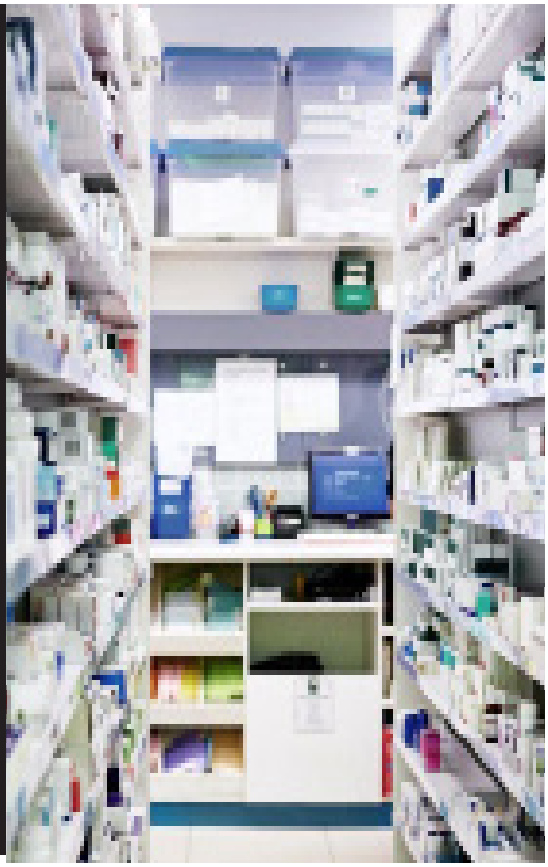
We would also like to acknowledge the efforts of atoll health facilities and hospital for giving your full coorperation in conducting our services such as inspection of pharamacies and warehouses and regulating medicines. With your dedication we were able to overcome the geographical hurdles and other restrictions in providing our services.

ABOUT MTG

The Medicine and Therapeutic Goods division (MTG), of Maldives Food and Drug Authority (MFDA), is responsible for ensuring that medicine imported, distributed and sold in Maldives, adheres to the safety, quality and efficacy standards. MTG is further divided into two main sections; Regulation Section and Enforcement Section, which undertake the tasks required to maintain the nationally accepted standards and take action on the non-compliances found against the medicine regulation standards.

NATIONAL PHARMACEUTICAL BOARD

All technical descisions taken by the Medicine and Therapeutic Goods Division are decided upon with the technical advice from National Pharmaceutical Board.



Dr. Shah Abdullah Mahir
Minister of State for Health

Political Head of MFDA

Thooma Adam
Acting Director General

NATIONAL PHARMACEUTICAL BOARD

Aishath Mohamed
Deputy Director General,
Pharmaceuticals

REGULATION SECTION

Mohamed Fazeen
Director, Pharmaceuticals

MEDICINE UNIT

Fathimath Shareefa
Pharmaceutical Officer

Fathimath Azla
Pharmaceutical Officer

Nafha Rasheed
Pharmaceutical Officer

Aishath Shuha
Pharmaceutical Officer

THERAPEUTICS GOODS UNIT

Zeenath Rasheed
Senior Public Health Program
Officer

Fathimath Azma
Pharmaceutical Officer

TOBACCO UNIT

Fathimath Shifza
Pharmaceutical Officer

ENFORCEMENT SECTION

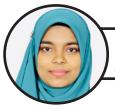
Aishath Jaleela
Director, Pharmaceuticals

MONITORING AND SURVELLANCE UNIT

Aminath Moomina
Senior Public Health Program
Officer

Aminath Haris
Pharmaceutical Officer

Aminath Jihan
Pharmaceutical Officer



Bishara Ahmed
Asst. Pharmaceutical Officer

Samia Ali
Pharmaceutical Officer

Mariyam Laisa
Asst. Pharmaceutical Officer

PORT UNIT

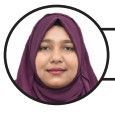
Aishath Shahidha
Pharmaceutical Officer

Rafeea Afeef
Pharmaceutical Officer

Ahmed Imyan
Pharmaceutical Officer

Mariyam Shihama
Pharmaceutical Officer

Shimla Naseem
Pharmaceutical Officer



Mariyam Leena
Pharmaceutical Officer

REGULATION SECTION

Regulation Section aims to ensure the saftey, 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 montiors 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 Medcine Regulation (2014/R46) ,Medicine Regulation (2016/R49) and Health Services Act (2015/29).

1. MEDICINE REGISTRATION

MTG ensures the safety, quality and efficacy of all pharmaceutical products imported and distributed in Maldives. The process is initiated with the submission of the product's dossier which is evaluated and submitted to the National Pharmaceutical Board for approval.

Once the product is registered and it is included in the Approved Drug List (ADL). ADL is published every month with revisions and is available on Ministry of Health website.
(www.health.gov.mv)

REGISTERED MEDICINES	
2019	2020
50	47

2. ALTERNATIVE & HERBAL MEDICINE REGISTRATION

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.

REGISTERED MEDICINES	
2019	2020
13	-

3. AUTHORISATION FOR MANUFACTURING AND SALE OF ALTERNATIVE AND DHIVEHI BEYS

MTG issues permit for manufacturing and sale of Alternative/Dhivehi Beys to ensure the products comply with Good Manufacturing Practice (GMP). Also to ensure the safety, identity, strength, quality and purity of these products.

YEAR	2019	2020
NEW PERMITS ISSUED	01	-
TOTAL PERMITS	06	06

4. IMPORT PERMIT FOR SAMPLE MEDICINES

Import permits for sample medicines are issued for the purpose of medicine registration. In addition to this MTG also regulates imported samples inor der to ensure they are not promoted or distributed in Maldives.

PERMITS ISSUED	
2019	2020
30	77

5. MEDICINE APPROVAL UNDER CLINICIAN'S REQUISITION FORM

This is the approval of exemptions for medicines that are needed by the population.

Medicines are applied for approval by doctors and health professionals through application forms provided by MTG. The final approval is given by the National Pharmaceutical Board.

APPROVALS	
2019	2020
73	68

6. PRE-AUTHORIZATION APPROVALS FOR MEDICINE IMPORTS

Pre-authorisation is a special permit given prior to the import of the product to ensure the continous availablity of essential medicines. The permit is based on criterias of medicine regulations.

PERMITS ISSUED	
2019	2020
931	586

7. REGISTRATION AND LICENSING OF PHARMACIES AND WAREHOUSES

Regulation section of MTG issues operating licenses for pharmacies and medical storage facilities according to the Medicine Regulation 2014/R-46 and 2016/R-49. The registration and licenses are issued after the pharmacies are inspected and assured they are in compliance with the standards in the medicine regulations.

YEAR	2019	2020
NEW PHARMACIES	37	29
NEW WAREHOUSES	14	08

YEAR	2019	2020
TOTAL PHARMACIES	384	406
TOTAL WAREHOUSES	45	53

8. APPROVAL FOR MANUFACTURING AND SALE OF MEDICAL GASES

Manufacturing plants for medical gases, such as medical oxygen, require permit from MTG for manufacturing and for the use of such gases.

Permits are issued after the inspection of plants and it is ensured that all requirements are in compliance.

REGISTERED PLANTS		
YEAR	2019	2020
NEW	01	01

9. REGULATION OF MEDICAL DEVICES

Medical devices includes all devices that provide assistance in medical purposes of pharmacological, immunological and metabolic and are intended to be used on human beings. This can include instruments such as apparatus, machines, appliances, software, material, radiation emitting devices etc.. Currently such devices are registered by importers on a voluntary basis.

REGISTERED DEVICES	
2019	2020
10	13

9. MEDICINE DISPOSAL

Medicine are disposed by the regulation section with support from Waste Management Corporation Ltd (WAMCO). Requests for disposal are received through applications by the division and the medicine are disposed by WAMCO with the presence of Regulation Section staff to check and confirm the disposal of medicines.

DISPOSED MEDICINES (VALUE IN MVR)	
2019	2020
245,680.81/-	12,859.63/-

10. HEALTH CLEARANCE FOR CHEMICALS

Any chemical which could cause potential health effects on public, requires an health assessment from MTG before it can receive the permit for use and distribution.

PERMITS ISSUED	
2019	2020
2156	1197

10. APPROVAL OF VETERINARY MEDICINES

Veterinary medicines are regulated by MTG to ensure that all veterinary medicines imported are approved and included in Approved Veterinary Medicines List. This process is conducted with consultation from Veterinarian Ministry of Fisheries and Agriculture.

APPROVALS	
2019	2020
10	28

ENFORCEMENT SECTION

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.

1. INSPECTION OF PHARMACIES AND MEDICAL STORAGE FACILITIES

MTG inspectorate consists of 2 pharmaceutical inspectors who conduct scheduled routine inspections, follow up inspections and spot inspections in pharmacies, medical storage facilities and institutions.

The inspections are carried out to check if the facilities are operating in compliance to the regulations set in Maldives. Follow up inspections and appropriate actions are taken for the non-compliances found from the pharmacies, medical storage facilities and institutions during the inspections.

MALE' INSPECTIONS		
YEAR	2019	2020
PHARMACIES	218	54
WAREHOUSES	66	**5**

ATOLL INSPECTIONS		
YEAR	2019	2020
PHARMACIES	174	132
WAREHOUSES	7	**10**

2. PHARMACOVIGILANCE

Pharmacovigilance system is vital to a pharmaceutical market. It is an important process to identify the possible adverse effects of pharmaceutical products to increase the safety and efficacy of medicines. As a middle income country the Maldives has even higher chance of facing such events compared to industrialized countries. Through a sustainable and efficient pharmacovigilance system the targets for product quality, more efficient actions against ADR (Adverse Drug Reactions) reporting can be taken and medication errors can be detected and corrected.

3. POST MARKET SURVEILLANCE

Post Market surveillance is important to further improve the medicine registration system and for the strengthening of quality assurance mechanism of medicines in National Health Laboratory.

To implement this process, MTG has established a system and finalized the guidelines and other required documents to efficiently run the system.

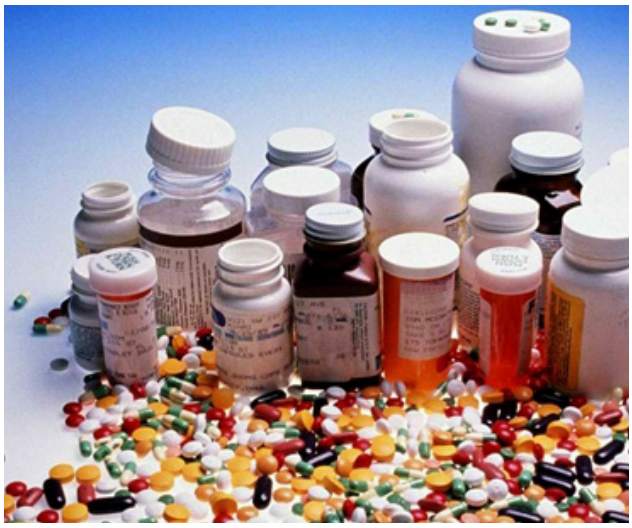
4. IMPORT OF PSYCHOTROPICS AND NARCOTICS (CONTROLLED DRUGS)

Controlled drugs are narcotics and psychotropic substances used for medical purposes. At specified intervals, MTG reports the status of controlled drugs imported and used to the International Narcotics Board (INCB).

Controlled drugs can be imported with the import license issued by the MTG. Importers for controlled medicines are designated by MFDA. MTG also issues purchase authorizations to registered pharmacies and health facilities that meet the required conditions.

PURCHASE AUTHORIZATION		
TYPE	2019	2020
PSYCHOTROPICS	630	399
NARCOTICS	203	194

IMPORT LICENSE		
TYPE	2019	2020
PSYCHOTROPICS	62	58
NARCOTICS	35	16



5. PORT CONTROL (AIRPORT AND SEAPORT UNITS)

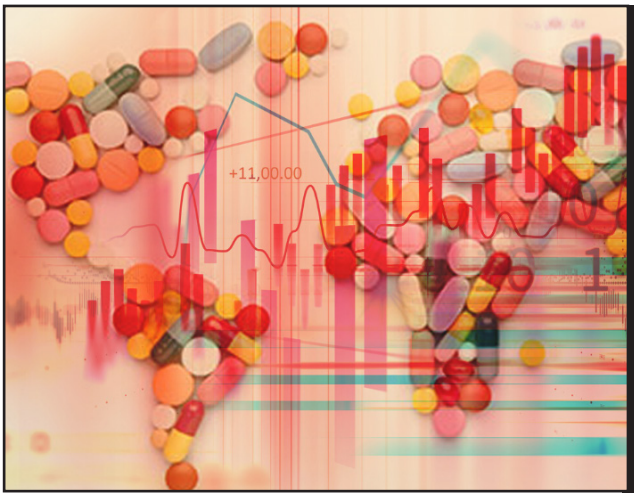
MTG's pharmaceutical port units collaborates with other government agencies such as Maldives Airports Company Ltd (MACL), Maldives Ports Ltd (MPL) and Maldives Customs Service.

- MACL provides the facilities for the inspection of shipments at Velana International Airport.
- MPL provides the inspection facilities at Male' Commercial Harbour.
- Maldives Customs service provides the required support on the clearance of goods.

All medicines imported into the Maldives should be listed on the Approved Drug List and Approved Alternative Medicines/ Dhivehi Beys and should be imported by an authorized importer include on the Authorized Importers lists. MTG inspectors stationed at the ports are responsible of inspecting the shipments and evaluating whether the imported product can be released for use in Maldives.

MTG takes the decision as to whether give clearance, in the case where no issues are found, permanently hold goods that violate the regulatory standards or temporarily withhold goods that may need further investigation.

IMPORTED MEDICINES (IN UNITS)		
PORT	2019	2020
SEAPORT	58,222,294	281,510,826
AIRPORT	**125,233,387**	**17,261,594**



6. MEDICINE IMPORT STATISTICS

With a registered medical storage facility according to the medicine regulation standards, registered importers are able to import pharmaceutical products into the country.

TOP MEDICINE IMPORTS 2019

#	Product Name	Dosage Form	Strength	Quantity (Units)
1	Panadol	Tablet	500mg	10,432,180
2	Uphamol	Tablet	650 mg	4,748,580
3	Milical Tablets	Tablet	1000 mg(USP) + 200 IU(USP)	3,216,352
4	Ecosprin 75	Extended Release Tablet	75mg	2,411,538
5	Dompan OD	Tablet	30 mg(in SR form) (BP) + 40 mg (USP)	2,373,800
6	Panadeine	Tablet	8mg + 500mg	2,213,690
7	Voltaren SR 75	Tablet	75 mg	2,088,705
8	CARTIPLUS 750	Capsule	750 mg(USP)	2,060,130
9	Dolo 650	Tablet	650 mg BP	1,848,380
10	Diabetmin	Tablet	500 mg BP	1,800,000
11	Thyronorm 50mcg	Tablet	50 mcg	1,787,444
12	Dexona	Tablet	0.5 mg	1,594,130
13	Neurobion Forte	Tablet	10mg + 3mg + 15mcg + 100mg + 50mg	1,571,556
14	Lioresal	Tablet	10mg	1,518,800
15	Becosules	Capsule	50MG+25 MG + 10 MG +15 MCG +100 MG +25 MG +1 MG +150 MG + 5 MG	1,494,536
16	Thyronorm 25mcg	Tablet	25 mcg	1,462,894
17	Meftal	Tablet	500 mg BP	1,332,400
18	Stamlo 5	Tablet	5mg	1,255,696
19	Atorin - 10	Tablet	10mg	1,216,488
20	R.B. Tone	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)	1,199,400
21	Thyronorm 100mcg	Tablet	100 mcg	1,185,240

TOP MEDICINE IMPORTS 2020

#	Product Name	Dosage Form	Strength	Quantity (Units)
1	Diabetmin	Tablet	500mg BP	101,794,900
2	Compound Sodium Lactate Intravenous Infusion	Injection	500ml	82,182,708
3	Normal Saline Injection	Injection	0.9%w/v in 500 ml	20,695,693
4	Panadol	Tablet	500mg	8,372,868
5	Thyronorm	Tablet	100mcg	7,964,920
6	Montef	Tablet	10mg	6,222,688
7	Valparin	Tablet	200mg BP	4,727,040
8	Neurovit Fofrte	Tablet	242.5 mg+250 mg+ 1 mg	4,500,000
9	Thyronorm 50 mcg	Tablet	50mcg	3,829,490
10	Thiamine Mononitrate IP + Riboflavine IP + Pyridoxine Hydrochloride IP + Cyanocobalamin Triturate in Gelatine EQV. Cyanocobalamin IP + Nicotinamide IP + Calcium Pantothenate IP	Tablet	10mg + 10mg + 3mg + 15mcg + 45mg + 50mg	3,827,763
11	Thyronorm 25 mcg	Tablet	25 mcg	3,418,770
12	Ultigra 180	Tablet	180mg	3,288,116
13	Ecosprin 75	Extended Release Tablet	75mg	3,138,562
14	Dompan OD	Tablet	30 mg(in SR form) (BP) + 40 mg (USP)	2,746,330
15	Wysolone	Tablet (Disperible)	20 mg	2,453,655
16	Evion 400	Capsule	400mg	2,415,430
17	Levipil	Tablet	500mg	2,363,620
18	Pantaz	Tablet	40mg	2,289,304
19	Uphamol	Tablet	650 mg	2,160,540
20	Fludac	Capsule	20mg	1,943,700
21	Epilex	Tablet	200mg IP	1,909,200

ANTI-MICROBIAL RESISTANCE

"Anti-microbial Resistance" is one of the most significant health challenges being faced around the world. As a member country of WHO, Maldives has developed the "National Action Plan for Containment of Antimicrobial Resistance 2017-2022". MFDA is the allocated authority for the implementation of this plan. Five committees have been created to achieve the aims of the plan.

IMPORTANT EVENTS IN 2019 - 2020

As every recurring year, "World Antibiotics Awareness Week" was also celebrated colourfully in 2019 and in 2020 despite the many limitations faced due to the Covid19 Pandemic.

WORLD ANTIBIOTICS AWARENESS WEEK 2019

1. **Distribution of awareness materials (18th – 24th November 2019)**

To increase awareness, glass water bottles were printed with awareness messages which were then distributed to

- Doctors of IGMH
- Doctors of ADK
- Nurses in IGMH and ADK
- AMR Committee members
- National Pharmaceutical Board
- MOH Staffs
- MFDA staffs

The aim was to help carry the message to health professionals and public. This event was successfully completed with the help of WHO.

2. **Distribution of Awareness Posters (18th – 24th November 2019)**

Throughout the week awareness posters developed by WHO were distributed among government hospitals and private hospitals. The recipients were instructed to display the posters in waiting areas and places where the messages can be easily conveyed to the public.

3. **Conducted awareness session for MNU Students (10th October 2019)**

Prior to the awareness week, AMR awareness session for MNU students was conducted. This awareness session was in collaborated effort between MNU, WHO and MFDA. Dr Arvind Mathur, WHO Representative for the Republic of Maldives and Dr Shah Abdulla Mahir, Minister for state for health. Speakers explained how the resistance is spreading and how it can be controlled. After the session speakers answered some of the questions from students.

4. **Awareness messages through Social Media (18th – 24th November 2019)**

Awareness messages, WHO posters and other awareness materials were shared through Facebook, Twitter, Viber, Instagram and other social media platforms by MOH, MFDA, WHO.

5. **Awareness messages through TV and Radio (18th – 24th November 2019)**

Aim of this session was to convey the awareness messages to reach a wider audience through TV and radio. Information was provided by Doctors from ADK, IGMH and MFDA Staffs in various sessions. Sessions included information about antibiotic resistance such as what AMR is and how and why it's been spreading throughout the world. They also highlighted the importance of completing the dose and when and how antibiotics should be used.

6. Conducted awareness session at AA. Thoddo (21st November 2019)

AA. Thoddo is an island specialized in farming and agriculture. For this reason these sessions were targeted towards farmers, council members, students, teachers and parents. In this session they gave information about the side effects of using antibiotics when growing crops and farming. Also the environmental issues faced due to the misuse of antibiotics were discussed. The importance of AMR was also highlighted in this session. This event was funded by WHO.

7. Events Organized by ADK (throughout the week /18th – 24th November 2019)

ADK the main private hospital conducted awareness sessions for patients and public throughout the week.

8. Awareness session for Pharmacist working in STO pharmacies (24th November 2019)

This session was targeted twowards STO as it is the largest medicine distributing, importing and issuing state owned company in the country. the company also has state owned pharmacies located in every island of Maldives. Information was provided by MFDA staff and doctors from IGMH. More than 15 pharmacist participated in this event. Pharmacists were given information on how antibiotics should not be sold over the counter and how full dose of antibiotics should not be issued without a prescription.This event was organized by STO.

9. Awareness for public (throughout the week /18th – 24th November 2019)

MFDA staff visited different government and public owned offices and provided AMR awareness messages on proper use of antibiotic and how to prevent its misuse. They also answered some question regarding AMR.

WORLD ANTIBIOTICS AWARENESS WEEK 2020

The activities for the year were mainly conducted through media. The following activities were held throughout the week from 18th to 24th November 2020.

1. Awareness through social media

Awareness materials including:

Social media posts

Animated photos

Videos

Produced by WHO for WAAW 2020, were translated and shared on Facebook, Instagram and Twitter. The materials were also shared with health facilities to be displayed in waiting areas.

The general slogan included in the materials were "Antimicrobials: handle with care" and specific slogan for the human health sector as "United to preserve antimicrobials".

2. Information about AMR by technical expertise

Due to the restrictive measures, public awareness activities were conducted through local broadcasting channels.

Slots were received from both TV and radio channels and information regarding AMR were presented by technical experts including doctors, officials from Maldives Food and Drug Authority and Ministry of Fisheries and Agriculture.

Each program focused on sending key messages to the public on the responsible use of antimicrobials, compliance and to prevent misuse.

3. Youth Art Competition

As part of WAAW activities, the first AMR youth art competition was held in 2020. The purpose of this art competition was to create an interest on AMR among youth. The artworks will be used in future for AMR awareness programs targeting the youth population.

This competition was open to all Maldivians in the age group 16 to 25 years on the theme. Antimicrobial Resistance. The competition was opened on the 24th of November 2020, for a week and was organized by the consultancy firm, ‘Think Associates Private Limited’ with WHO funding.

The competition received a huge support from the youth with 41 entries. Prizes were awarded for the 1st, 2nd and 3rd; an iPad Air, voucher of MVR. 5,000 and MVR 3,000 respectively. Winners were awarded prizes by the Minister for State Dr. Shaah Abdulla Mahir .

NEW INITIATIVES

Following are the new intiatives our division has taken in 2020 to further enhance our services.

GENERIC MEDICINE

The price of generics is substantially lower as compared to their original branded products. Prescribing generic medicines would improve access to the needed medicines as the same amount of funds could be used to cover the needed medicines for more people in need.
The policy on generics would also stimulate competition among generic products in the market which would further reduce the price. Thus generic medicines can provide substantial saving to health care cost.

MAXIMUM RETAIL PRICE (MRP) POLICY

The policy sets a maxium retail price for sale of essential medicines distributed and sold in Maldvies.

With the implementation of this policy our authority aims to acheive the following:

1. Reduce the medicine related expenses by the government
2. To provide national insurance (Aasandha) in a sustainable manner
3. To reduce the medicine related expenses for the public
4. To provide quality medicines at affordable prices

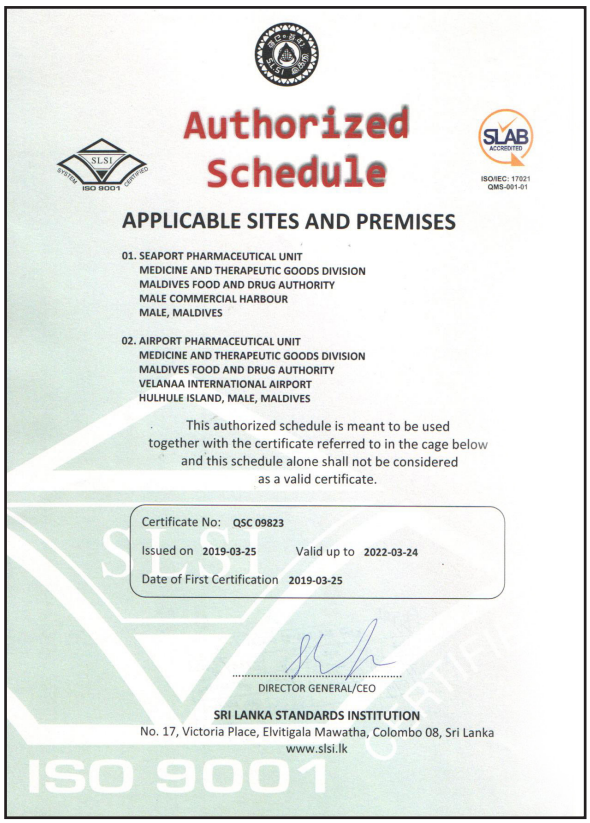
SAMAALU PROGRAM

Through this TV program we were able to spread more awareness regarding Anti-Microbial Resistance in 2020 and our goal is to continue raising awareness in the same manner in the following years.

ACHEIVEMENTS 2019-2020

ISO 9001:2015 CERTIFICATION

MTG successfully sustained all services within the requirements of ISO 9001:2015 Quality Management System. The division first received certification on 23rd March 2019 and passed the first surveillance audit in 2020.



Authorized Schedule

APPLICABLE SITES AND PREMISES

01. SEAPORT PHARMACEUTICAL UNIT
MEDICINE AND THERAPEUTIC GOODS DIVISION
MALDIVES FOOD AND DRUG AUTHORITY
MALE COMMERCIAL HARBOUR
MALE, MALDIVES

02. AIRPORT PHARMACEUTICAL UNIT
MEDICINE AND THERAPEUTIC GOODS DIVISION
MALDIVES FOOD AND DRUG AUTHORITY
VELANAA INTERNATIONAL AIRPORT
HULHULE ISLAND, MALE, MALDIVES

This authorized schedule is meant to be used together with the certificate referred to in the cage below and this schedule alone shall not be considered as a valid certificate.

Certificate No: QSC 09823
Issued on 2019-03-25 Valid up to 2022-03-24
Date of First Certification 2019-03-25

DIRECTOR GENERAL/CEO

SRI LANKA STANDARDS INSTITUTION
No. 17, Victoria Place, Elvitigala Mawatha, Colombo 08, Sri Lanka
www.slsi.lk

Certificate of Conformity

The Sri Lanka Standards Institution
Certifies that the Quality Management System of

MEDICINE AND THERAPEUTIC GOODS DIVISION OF MALDIVES FOOD AND DRUG AUTHORITY
MINISTRY OF HEALTH, ROASHANEE BUILDING, SOSUN MAGU, MALE,
MALDIVES

has been assessed and approved in accordance with
the requirements of ISO 9001: 2015/ SLS ISO 9001: 2015

Certificate No: QSC 09823
This certificate issued on 2019-03-25 is valid up to 2022-03-24
Date of first certification 2019-03-25

SCOPE OF CERTIFICATION

ALL ACTIVITIES OF REGULATION OF MEDICINES AND MEDICAL DEVICES IMPORTED, DISTRIBUTED, SOLD, MANUFACTURED AND USED IN THE MALDIVES IN COMPLIANCE WITH THE NATIONAL AND INTERNATIONAL STATUTORY AND REGULATORY REQUIREMENTS, ISSUANCE OF HEALTH CLEARANCE FOR CHEMICALS

This approval is subject to the continued satisfactory operation of the organization's Quality Management System. This certificate is also applicable to the sites and premises described in the authorized schedule bearing the same number and date as in this certificate.

DIRECTOR GENERAL/CEO

SRI LANKA STANDARDS INSTITUTION
No. 17, Victoria Place, Elvitigala Mawatha, Colombo 08, Sri Lanka
www.slsi.lk

LAUNCH OF ONLINE SERVICES

Through 'Dhirithi Portal' launched by MFDA, the following services are provided online as of 2020.

1. Medicine Importer Registration
2. Medicine Registration
3. Pharmacy and Warehouse Registration
4. Import Permit for Sample Medicines
5. Pre-authorization

In addition to this 'Health clearance of Chemicals is also provided online through 'Makudi Portal' (MNDF).

MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTIC GOODS DIVISION

CONTACT US

MTG Hotline : 7200321
Pharmacy Registration : 3314308
Pharmaceutical Product Registration : 3014322
Chemical Health Clearance : 3014322, Ext 246
Medical Device Registration : 3014322, Ext 246
Medical Oxygen : 3014322, Ext 246
Alternative/Herbal Medicine : 3014322, Ext 246
ControlledDrugs : 3014322, Ext 263
PharmacyInspection : 3014322, Ext 264
E-Mail : mtg@Health.gov.mv
Complaints : aicommfda@health.gov.mv
Website : www.mfda.gov.mv