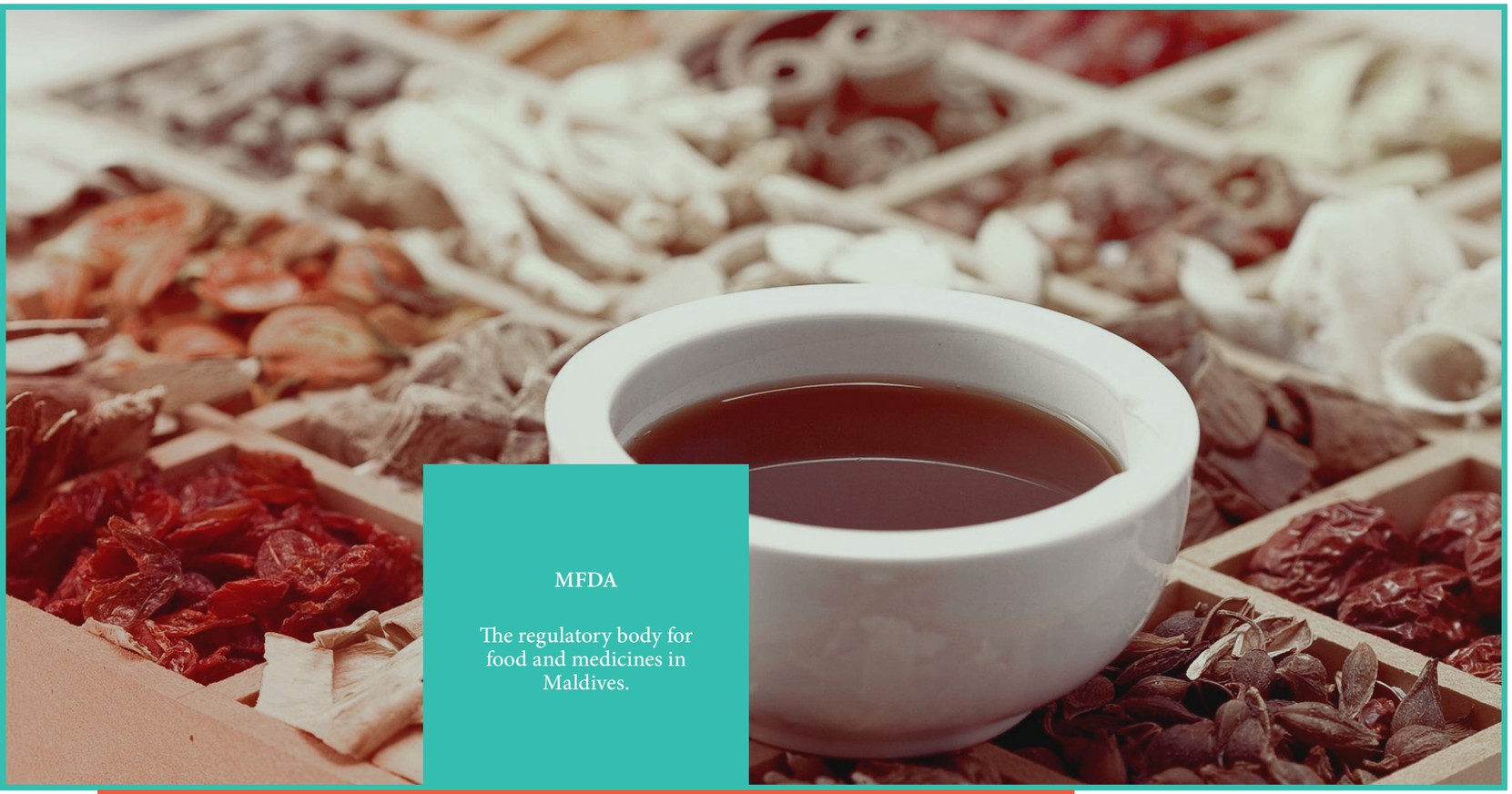
MALDIVES FOOD AND DRUG AUTHORITY

MEDICINE AND THERAPEUTIC GOODS

NEWSLETTER

2019



MFDA

The regulatory body for food and medicines in Maldives.

MTG

Authority under MFDA undertaking the regulatory tasks for pharmaceuticals and medical products.

FCD

Authority under MFDA undertaking the regulatory tasks for food and food products.

NHL

Authority under MFDA undertaking the laboratary testings to ensure quality and safety of food and pharmaceuticals.

Contents

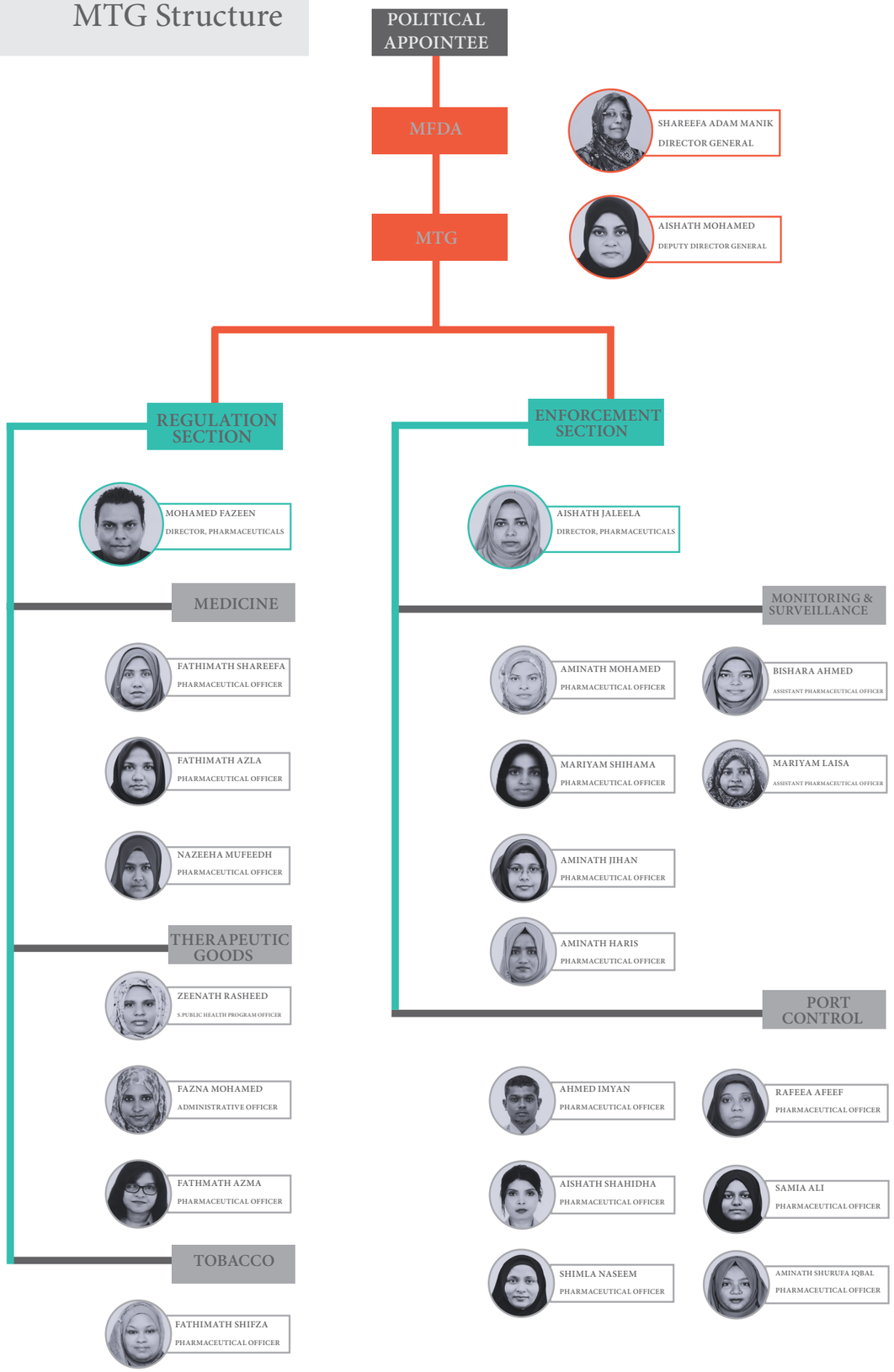
Director General's Message

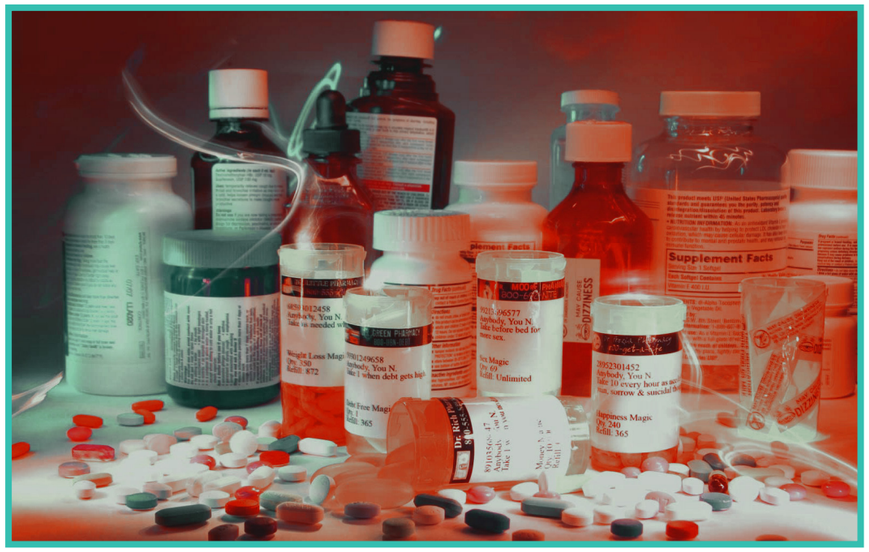
Since its establishment in 2006, Maldives Food and Drug Authority (MFDA), with its three main divisions, have worked towards ensuring the safety, quality and efficacy of food and medicine in the Maldives. Medicine and Therapeutic Goods Divsion (MTG) is one of our the main division responsible for regulating all medicines imported , distributed and sold in Maldives.

Building and maintaining a balanced regulatory system in Maldives has its own challenges. Maldives being geographically dispersed and the population being fully dependent on the provision of imported medicines, it is important to continuously improve our mechanisms. Hence, MTG has taken a vital step by getting certified for the ISO Standard 9001:2015 Quaity Management System. As of 2018, all the division's staff have been trained in conducting the processes and maintaining the documents and records according to the standards of the quality management system.

Taking this opportunity I would like to congratulate the MTG division on their path to a stronger and developed regulatory system to meet our mandate and also commend them for the reassurance of transparency to the general public.

MTG Structure





Welcome

About MTG

The Medicine and Therapeutic Goods division (MTG) is the division under the Maldives Food and Drug Authority (MFDA), and is responsible for ensuring that medicine imported, distributed and sold in Maldives, adheres to the quality, efficacy and safety standards. Further work is being done by reviewing existing policies and procedures to strengthen the availability of safe, efficacious and quality medicines in Maldives. The MTG is divided further 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 incompliances for the following.

Our Services

Regulation

1. Medicine Registration
2. Alternate and Herbal Medicines Registration
3. Medicine Approvals Under Physician Requisition forms
4. Pre-Authorisation Approvals for Medicine Imports
5. Registration and Liscensing of Pharmacies and Medical Storage Facilities
6. Approval for Manufacturing and Sale of Medicine Gases
7. Medicine Devices Registration
8. Health clearance for Chemicals

Enforcement

1. Inspection of pharmacies and medical storage facilities
2. Pharmacovigilance
3. Post Market Surveillance
4. Monitoring Controlled Drugs
5. Port Control Male'
6. Medicine Import

Regulation Section

Medicine Registration

The objective of medicine registration is to ensure the quality and safety of all medicinal products imported and used in Maldives. The submission of the products dossiers initiates the process. Before the products are registered, the unit evaluates the dossiers and submits to the National Pharmaceutical Board for approval.

All approved and registered products are included in the Approved Drugs List (ADL) for pharmaceuticals. The list is updated on a monthly basis and published to the public.

In 2018, a total of 63 medicines were registered.

Alternative and Herbal Medicines Registration

The MTG also issues permit for import and sales of alternative and herbal medicines.

The permitted medicines are shared to the public through the Alternative and Herbal Medicines List. The list is updated a monthly basis.

In 2018, a total of 55 alternative and herbal medicines were registered.

Medicine Approval Under Clinician Requisition Form

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

In 2018, a total of 36 medicines were given approval.

Pre-Authorisation Approvals for Medicine Imports

Pre-authorization is given to ensure medicines required for treatments are always available in the market. The permit is issued to prevent shortage of supply and stock out of essential medicines.

In 2018, a total of 1098 pre-authorizations were issued.

Registration & Liscensing of Pharmacies & Medical Storage

PHARMACIES IN 2018	*WAREHOUSES IN 2018*
NEW 27	NEW 10
TOTAL 357	TOTAL 37

The registration and licensing unit issues operating licenses for pharmacies and medical storage facilities according to the Medicine Regulation 2014/R-46 and 2015/R-49. The registration and licenses are issued after the pharmacies are inspected and its assured they are in compliance with the standards in the medicine regulations.

Approval for Manufacturing & Sale of Medical Gases

The MTG inspects the manufacturing plants of medical gases such as oxygen and issues permits for its use in and plants for such gases.

In 2018, no new medical gas plants were granted permisssion from the Medicine and Therapeutics Goods Division.

In 2018, no new plants were registered for medical gases.

Regulation of Medicine 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… Medical devices and importers are registered on voluntary basis through applications.

In 2018, a total of 10 medical devices were registered.

HEALTH CLEARANCES FOR CHEMICALS 2018

2045

Health Clearance for Chemicals

To facilitate chemical imports, which could have potential health effects on the public, a health assessment from the MFDA is required. MFDA issues the clearance permits for these chemicals.

Enforcement Section

Inspection of Pharmacies & Medical Storage Facilties

The inspectorate consists of 3 pharmaceutical inspectors who conduct scheduled routine inspections, follow up inspections and spot inspections in pharmacies, medical storage facilities and institutions in Maldives.

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

Inspection are also conducted when, renewing permits issued to existing registered pharmacies and medical storage facilities, and to issue permits for newly operating pharmacies and medical storage facilities.

MALE'	
1ST HALF 2018	2ND HALF 2018
102 PHARMACIES	95 PHARMACIES
18 WAREHOUSES	22 WAREHOUSES

ATOLLS	
1ST HALF 2018	2ND HALF 2018
50 PHARMACIES	26 PHARMACIES
03 WAREHOUSES	0 WAREHOUSES

Pharmacovigilance

Pharmacovigilance system is vital to a pharmaceutical market. The public may face harm from registered pharmaceutical products even though they may have been utilized in the recommended manner by qualified health professionals. 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.

The Maldives took its first step towards this in 2011, when it successfully became a provisional member of the WHO PIDM (Programme for International Drug Monitoring). All health facilities operating in Maldives have been provided with the relevant forms required for reporting ADRs. Still in its early stages of implementation, Maldives officially became the 125th member of WHO PIDM after completing the requirements for membership and the training of one MFDA staff in pharmacovigilance. As a result Maldives gained access to Vigibase® giving way to receive to receive medicinal safety data and early information about potential hazards based on the data entered throughout the world by the members of WHO PIDM.

In 2018, no ADR reportings were recieved from the public.

Monitoring Controlled Drugs

Controlled drugs are narcotics and psychotropic substances used for medical purposes. The MTG reports to the International Narcotics Board (INCB) on the statistics on the status of controlled drugs imported and used in Maldives at the specified itervals annually.

Controlled drugs can be imported to the Maldives with the import license issued by the MTG.

Importers for controlled medicines are designated by MFDA. The MTG issues purchase authorizations to registered pharmacies that meet the required conditions.

	PURCHASE AUTHORISATIONS 2018	IMPORT LICENSE 2018
PSYCHOTROPICS	348	41
NARCOTICS	170	32

Port Control Male'

This main purpose of this section is to ensure the quality, efficacy and safety of medicines and other medical products imported into the Maldives through both the airport and seaports. The pharmaceutical port units collaborates with other government agencies such as MACL, 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. The MTG inspectors stationed at the ports are responsible of inspecting the shipments and evaluating whether the imported product can be released for use in the Maldives.

The MTG will take 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.

In 2018, 6,249,733 medicines were imported through seaport and 14,283,974 were cleared through airport.

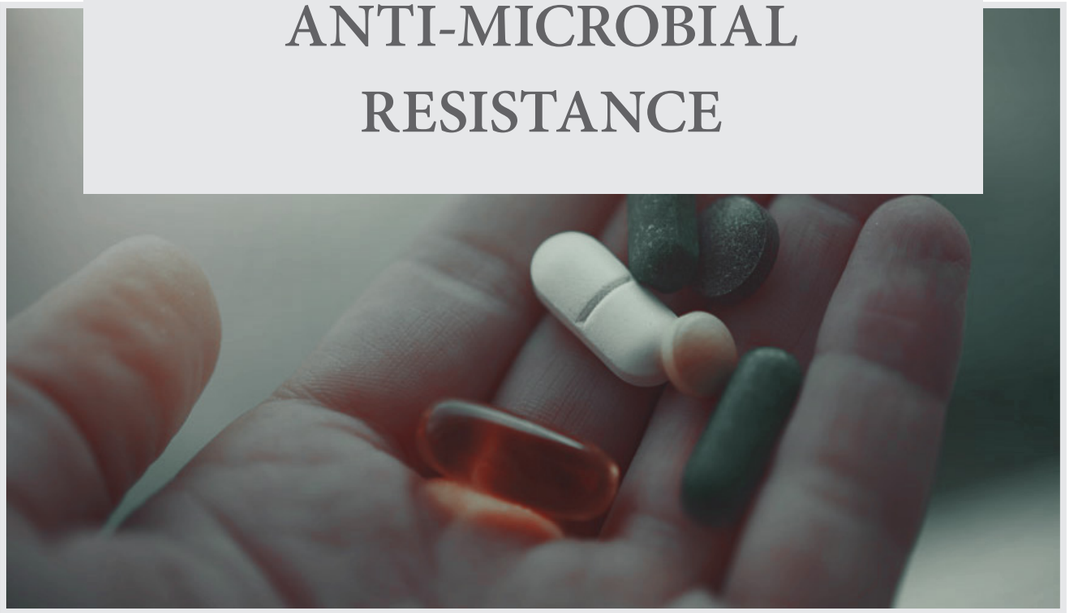
Medicine Import

The prerequisit for medicine import lisence is a registered medicine storage facility in accordance to the medicine regulatory standards.

TOP 20 MOST IMPORTED MEDICINES 2018

#	Generic Name	Brand Name/Dosage form / Strength
1	PARACETAMOL	PANADOL / TABLET / 500MG
2	MEFANAMIC ACID	MEFNAC DS / TABLET / 500 MG
3	VITAMIN	NEUROBION FORTE / TABLET / 10 MG +10 MG +3MG + 15 MCG 45 MG + 50 MG
4	METFORMIN	GLUCOPHAGE / TABLET / 500 MG
5	PANTAPRAZOLE	PANTAZ / TABLET / 40MG
6	PHENYRAMINE	AVIL / INJECTION / 22.75 MG / ML
7	METOPROLOL	METOLAR / TABLET / 25MG
8	FOLIC ACID	FOLIC ACID / TABLET / 5 MG BP
9	ATORVASTATIN	ATORIN - 10 / TABLET / 10MG
10	FOLIC ACID	AXCEL FOLIC ACID / TABLET / 5 MG
11	DOMPERIDONE AND PANTAPRAZOLE	DOMPAN OD / TABLET / 30 MG(IN SR FORM) (BP) + 40 MG (USP)
12	CALCIUM AND VITAMIN D	MILICAL TABLETS / TABLET / 1000 MG(USP) + 200 IU(USP)
13	AMLODIPINE	STAMLO 5 / TABLET / 5MG
14	VITAMIN B COMPLEX	BECOSULES / CAPSULE / 50MG+25 MG + 10 MG +15 MCG +100 MG +25 MG +1 MG +150 MG + 5 MG
15	PREDNISOLONE	WYSOLONE / DISPERIBLE TABLET / 10 MG
16	FLUNARAZINE	FLUDAC / CAPSULE / 20MG
17	ACETY SALICYLIC ACID	ECOSPRIN 75 / EXTENDED RELEASE TABLET / 75MG
18	RANITIDINE	ZYNOL / TABLET / 150 MG USP
19	CALCIUM AND VITAMIN D	SHELCAL / TABLET / 500 MG + 250IU
20	MULTIVITAMIN	R.B. TONE / CAPSULE / 200 MG (BP) + 38 MG(BP)+ 124 MCG(BP)+ 3 MG(BP)+2.5 MG (BP) +1 MG(BP)+ 2.5 MG(BP) + 23 MG(BP) + 150 MG(BP)

ANTI-MICROBIAL RESISTANCE



Antimicrobial resistance (AMR) threatens the effective prevention and treatment of infections caused by microorganisms, resulting in prolonged illness, disability and death.
Various efforts are taken in order to tackle the global health threat in combating the antimicrobial resistance.

- WHO Consultant visited to give information on stewardship program for health professionals working in IGMH, ADK Hospital. Draft of National Antimicrobial Stewardship Program was prepared
- Antimicrobial Resistance Awareness sessions were conducted in different organizations throughout the year. These include Fenaka Corporation Limited, Ministry of Environment and Energy, State Trading Organization, Maldives Water and Sewerage Company, L Atoll Thauleemee marukaz, Hamadhu Bin Khaleefa Al Saanee School
- Draft of AMR Regulation and National Antimicrobial Resistance Containment policy was prepared
- Learning Out comes for educational materials to be incorporated in the curriculum of Primary, Secondary, Higher Secondary schools and courses conducted for health Professionals, had been finalized and sent to Ministry of Education.
- Member of Technical Subcommittee (TSC) AMR program participated in "Towards one health approach to antibiotic resistance" , training program held in Faculty of veterinary science, Chulalongkorn University held from 24th – 28th June 2018.
- National focal point for AMR and members of TSC Committees participated in "Inter country meeting to review implementation of national action plan in antimicrobial resistance" conducted by WHO Regional Office for south East Asia held at Bangkok, Thailand from 23rd to 25th July 2018.

World Antibiotic Awareness Week 2018

12th – 18th November 2018

To mark the World Antibiotic Awareness Week, WHO Maldives, Maldives Food and Drug Authority, Indira Gandhi Memorial Hospital, ADK Hospital and committees of AMR Program, organized activities aimed to increase awareness on safe use and protecting the effectiveness of antibiotic.

Activities Conducted

- On Monday 12th November, World antibiotic awareness week celebration initiated with staffs of Ministry of Health wearing shades of green color, carried props with Antimicrobial Resistance messages. Badges of antibiotic awareness messages were worn by staffs.
- Director, Pharmaceutical provided information about Awareness week activities through "Rahkaavethibiyya Dhathureh" on "Dhivehi Raajeyge Adu" and "Baahjaveri Hedhuneh" program.

Pledge to Save Lives

Pledging event was conducted in IG MH, ADK Hospital and Atoll Hospitals throughout the week. Staffs in respective organizations and visitors pledged their actions to combat antibiotic resistance

Developed Awareness Materials

- 300 AMR posters were printed and distribution to Hospitals, Clinics, Schools, offices, have been initiated.
- Staffs of MFDA developed over 100 props which conveyed different messages. Photos were taken with the props and uploaded on Facebook, Twitter to spread the awareness through social media.
- -WHO AMR animated Video clip (Amala's story: how to prevent antimicrobial resistance) was dubbed in local language (Dhivehi) and telecasted through national TV Channel throughout the week. Video clips of AMR awareness and posters published in WHO Website were shown in reception areas of all Health care facilities.

Awareness Sessions

- A Refresher session for IGMH Hospital staffs were conducted on 13th November reminding nurses, doctors about the global threat and encourage best practices in healthcare facility
- Awareness session for the staffs of Ministry of Fisheries and Agriculture were conducted on 21st November, providing detailed information on preventing antimicrobial resistance in agriculture and veterinary sector.
- Staffs of Maldives Food and Drug Authority, Indira Gandhi Memorial Hospital, Maldives National University were trained to conduct awareness sessions to the public. 12 groups were allocated to different areas of Male' and Hulhumale where interactive awareness sessions were planned.
- A series of awareness sessions were planned to conduct in Addu atoll for staffs of hospitals.

Awareness Through Social Media

Posted Informative messages, posters, Animated video clips, related to AMR in Facebook, Twitter, throughout the week.

Panel Discussions

- Panel discussion took place on 15th November at MNU Auditorium which was telecasted on PSM. The Panel members were Dr Aminath Shafia, Director General, Ministry of Fisheries and Agriculture, Dr Ahmed Shaheed, Consultant in internal Medicine, IGMH, Dr Nazla Musthafa, Consultant in Pediatrics, Medica Hospital.
- Doctors highlighted the burden of the global threat, discussed what causes Antibiotic Resistance, Noted the critical issues in Antibiotic Resistance control, the role of the public, health sector and agriculture, veterinary sector in preventing antibiotic resistance.

AMR Information by Doctors

Dr Niyasha Ibrahim, Senior consultant in Pediatrics, and Dr. Moosa Murad, Consultant in Internal Medicine gave information on "Raaje Miadu". Focusing mainly on the importance of appropriate antibiotic prescribing and use.

Future Activities

1. Awareness sessions in schools.
2. Spot inspections on pharmacies in the Capital and Hulhumale planned , aimed to advocate the proper use of antibiotics and to scrutinize whether pharmacies sell antibiotics without prescription.
3. Identification and Inspection of Petshops for antibiotics.
4. International consultancy to develop an AMR communication Plan.
5. Local Consultancy to develop IPC Guidelines
6. Establishing and antibiotic residue testing mechanism in NHL , MFDA.

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

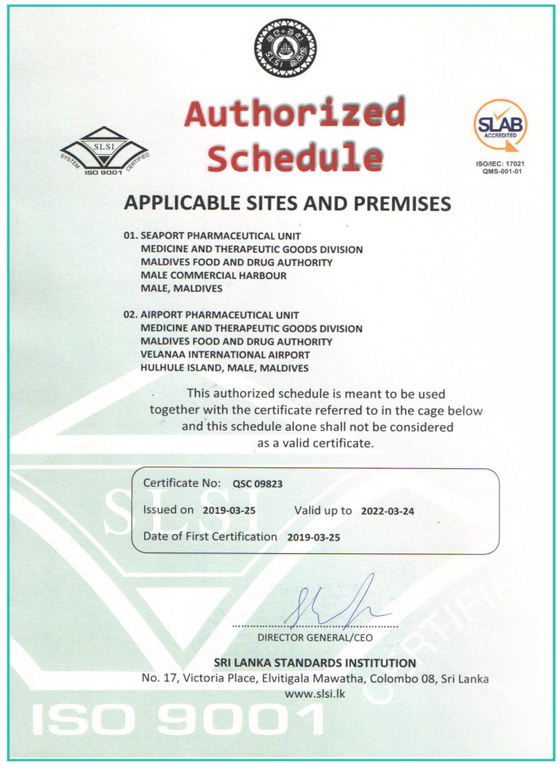
SCOPE OF CERTIFICATION

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



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

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No. 17, Victoria Place, Elvitigala Mawatha, Colombo 08, Sri Lanka
www.slsi.lk

Goals achieved in 2018

- The division has successfully achieved the certifcation for ISO 9001:2015 Quality Managment System.
- At the end of 2018,Symposium Dhivehi and Alternative Medciines was held which is an essential first step towards reaching the goals of establishing a seperate regulatory system for these medicines.

Future Goals

1. Maintain and improve the current quality management system.
2. To enhance the medicine regulatory system and to establish a transparent system, all the documentations are to be reviewed and finalized by an expert committee.
3. To further develop the pharmacovigilance mechanism aand to enhance Adverse Drug Reaction (ADR) reporting System.
4. To strengthen the medical devices regulatory system.

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

Contact us:

Hotline : 3014316

Pharmacy Registration : 3314308

Pharmaceutical Product Registration : 3314308

Chemical Health Clearance : 3014322, Ext 246

Medical Device Registration : 3014322, Ext 246

Medical Oxygen : 3014322, Ext 246

Alternative/ Herbal Medicine : 3014322, Ext 246

Controlled Drugs : 3014322, Ext 263

Pharmacy Inspection : 3014322, Ext 264

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