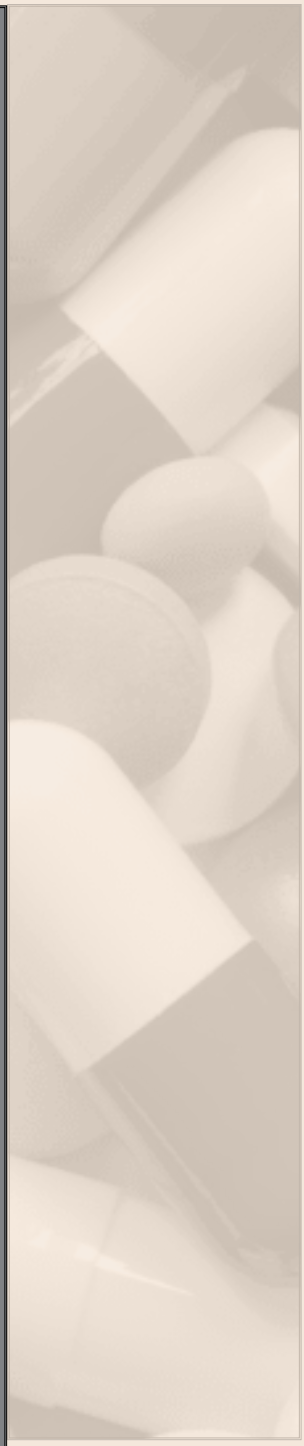
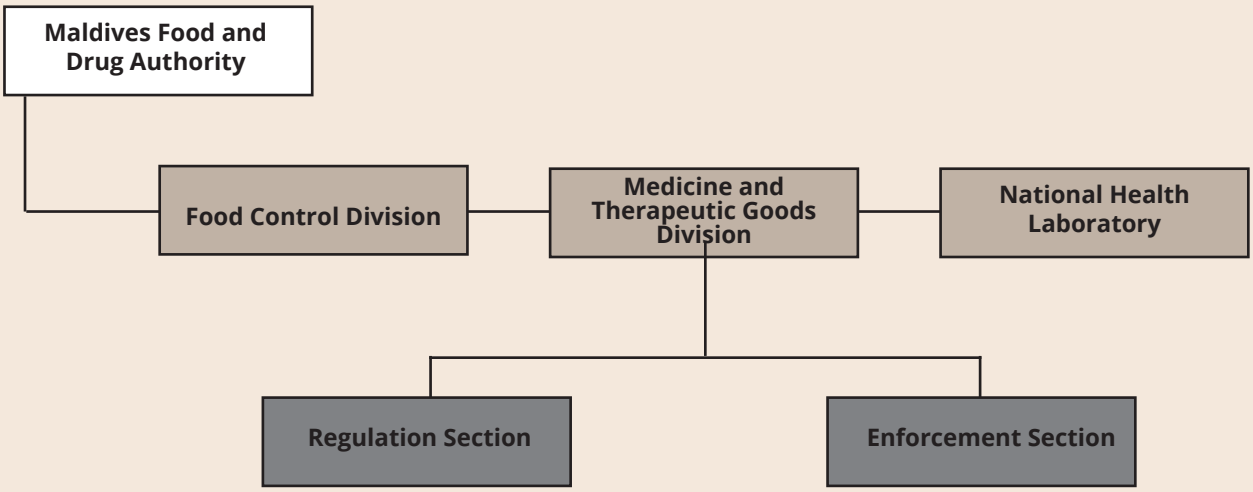
MTG NEWSLETTER 2021



MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTIC GOODS DIVISION



ABOUT MTG

Medicine and Therapeutic Goods Division (MFDA) is one of the three divisions of Maldives Food and Drug Authority.

The division is further divided into Regulation Section, Enforcement Section and Border Control Section.

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. This includes :

1. Medicine registration
2. Approving medicines under clinician's request
3. Alternative and Dhivehi Beys registration
4. Medical device registration
5. Pre-authorization for medicines

MESSAGE FROM STATE MINISTER OF HEALTH
DR. SHAH ABDULLAH MAHIR

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

Our responsibilities can be divided into two key areas. Firstly, the regulation of all related to the import and distribution of pharmaceutical products. Secondly, the enforcement of these regulations through inspection and surveillance. To add further value to these areas, we strive to provide services that are accessible to all clients at their convenience. The division has made strides towards maintaining these values in 2021 and will continue to do so in the future.

The changing environment resulted in hurdles that could potentially risk the quality of our services. However our employees continue to focus on all of our corporate resources in order to provide professional services that meet customer requirements without any discriminations between clients.

I would like to convey my deepest gratitude for the staff for your dedication. For that, we humbly request for your continued support and patronage to help us fulfill our services.

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

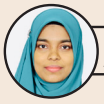
Aishath Jaleela
Director, Pharmaceuticals

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

ALERTS 2021

ALERT NO: 182-REG/23/2021/09 (15TH MARCH 2021) regarding WHO ALERT

Genuine Cytotec (Misoprostol) is used in labour induction among other uses.

Falsified products of Cytotec (Misoprostol) was reported to be wholesaled and used at patient level in multiple African Countries.

These batches were confirmed to be falsified after failing laboratory tests.

ALERT NO: 182-REG/23/2021/19 (01st December 2021)

An unauthorized IV Product (Ringer Lactate was found to be imported. This product was also identified to have quality issues.

The import and sale of this product is now banned in pharmacies.

PRESS RELEASES 2021

PRESS RELEASE NO: 182-REG/NB/2021/0004 PUBLISHED ON 28TH JANUARY 2021

MFDA approval given for Covishield Vaccine manufatured by Serum Institute of India.

PRESS RELEASE NO: 182-REG/CIR/2021/4 PUBLISHED ON 16TH JUNE 2021

MFDA approval given for Johnson Vaccine manufactured by Johnson & Johnson

PRESS RELEASE NO: 182-REG/CIR/2021/3 PUBLISHED ON 6TH JUNE 2021

MFDA approval given for Moderna Vaccine manufactured by Moderna Biotic Spain.

PRESS RELEASE NO: 2 (PR) 182-REG/182/2021/2 PUBLISHED ON 14TH MARCH 2021

MFDA approval given for Comirnaty Vaccine manufactured by Pfizer Bio and Tech.

PRESS RELEASE NO: 1 (PR) 182-REG/182/2021/1 PUBLISHED ON 14TH MARCH 2021

MFDA approval given for Sinopharm Vaccine manufactured by Beijing Institute for Biologic Products Company Ltd.

PRESS RELEASE NO: 5 (PR) 182-REG/182/2021/5 PUBLISHED ON 12TH MAY 2021

MFDA approval given for Sputnik Vaccine manufactured by Gamaleya National Center of Epidermology and Microbiology.

EFFECT OF FOOD ON MEDICATION

Food intake in relation to medicine intake is vital for medicine to work effectively. The body's response depends on the; timing, size, type and even the drink taken alongside the food.

Food intake prompts multiple pysiological mechanisms in the stomach. The resulting environment can affect the amount of medicine that is absorbed into the bloodstream through the stomach.

Food can create a physical barrier between the gut wall and prevent medicine from effectively absorbing into the bloodstream

Certainantibiotics,suchasphenoxymethylpenicillin (also known as penicillin V), are best taken on an empty stomach as they can be less effective after prolonged exposure to acidic conditions.

Food components may bind itselves to certain medcations which may lead to ineffectiveness

osteoporosis medicines risedronate and alendronate must be taken on an empty stomach with water only.

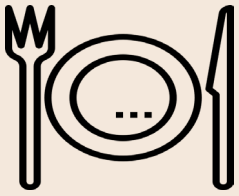
Mixing of certain medications with food can help reduce risk of side effects

Diabetes medicines such as gliclazide or glimepiride (belonging to the group of medicines known as sulfonylureas), for example, should be taken with food to reduce the risk of low blood sugar.

Food intake before certain medication can help reduce nausea and stomach upset

Diabetes medicines such as gliclazide or glimepiride (belonging to the group of medicines known as sulfonylureas), for example, should be taken with food to reduce the risk of low blood sugar.

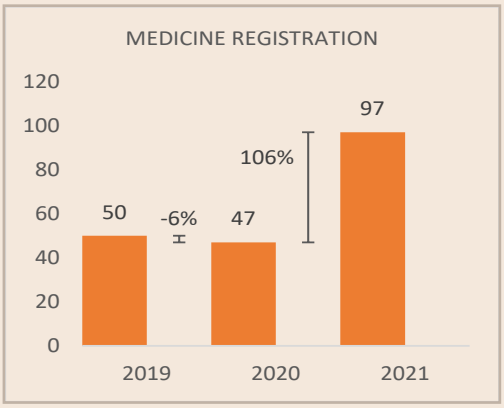
HOW TO TAKE MEDICINES EFFECTIVELY?

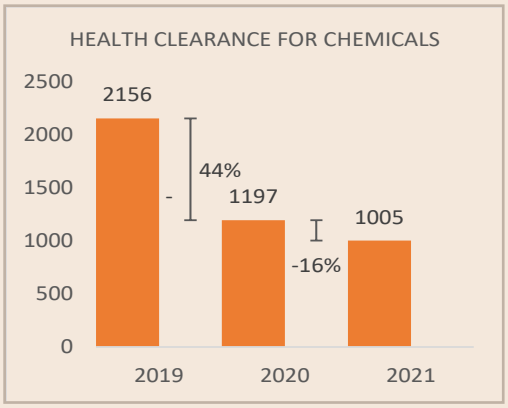
MEDICATION TIMINGS	LIQUID MEDICINES	FOOD AND WATER INTAKE
		
once a day: same time, once every 24 hrs, night or day as directed	Easier to use for children and adults	Unless advised otherwise, tablets or capusles should be taken with water
Twice a day: once every 12 hrs, eg: at 8am and at 8pm	Before use medicine should be shaked well to mix any medicine settled at the bottom	“Take with food” means medicine should be taken during the meal
Thrice a day: Once every 8 hrs, eg: at 6am, at 2pm and at 10pm	For accurate measurement of dosage, use a medicine cup, dropper or a syringe (as appropriate)	“After food” means medicine should be taken within half an hour of eating
four times a day: Once every 6 hrs, eg: at 6am, at 12pm, at 6pm and at 12am		“On an empty stomach” means no food has been taken in past two hrs and food should be taken at least half an hour after medication

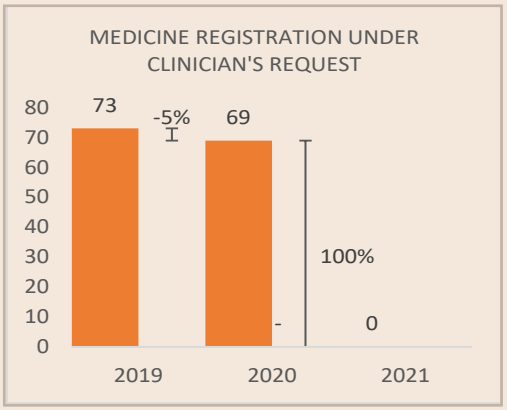
STATISTICS FOR MTG SERVICES

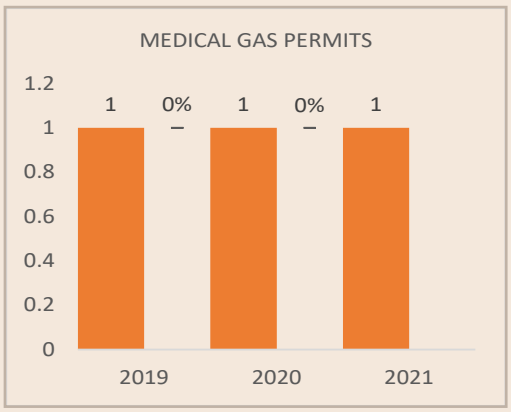
Regulation Section aims to ensure the safety, quality and efficacy of all medicines. In order to achieve its objectives, the section authorizes import of medicines, alternative medicines and traditional medicines (Dhivehi beys), medicine samples, medical devices and medical gases. It also monitors the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

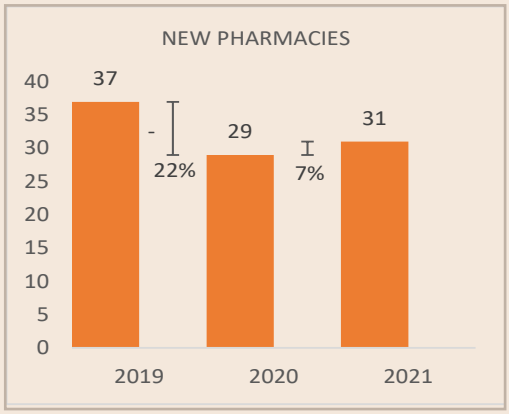
All services provided through this section conforms to the rules and regulations stated in Medicine Regulation (2014/R46) ,Medicine Regulation (2016/R49) and Health Services Act (2015/29).

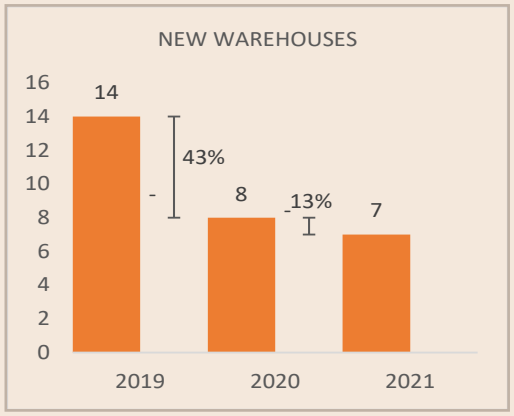






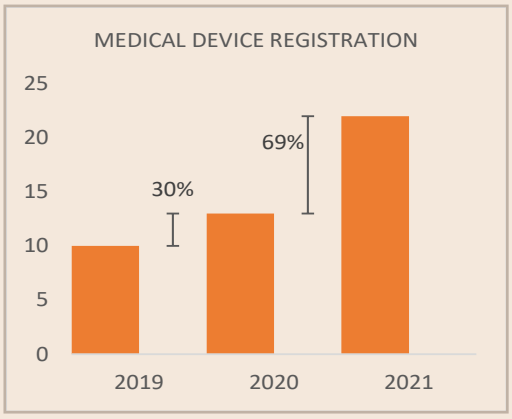


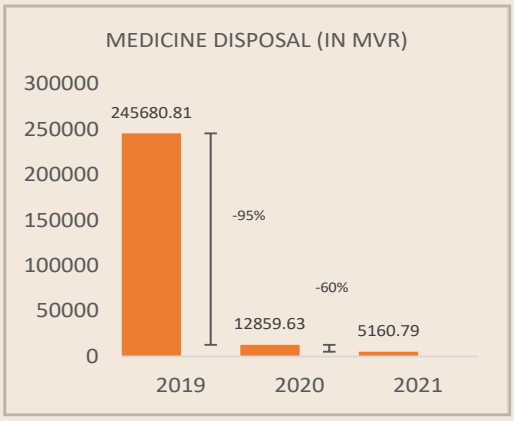


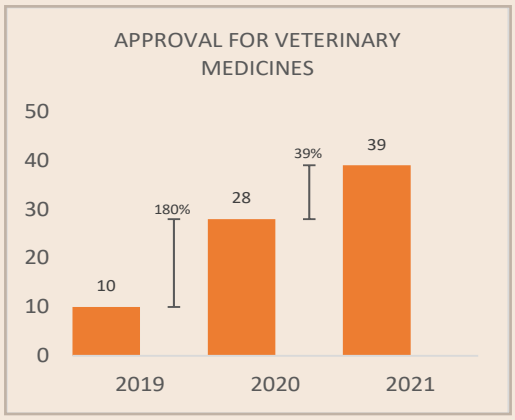


Total pharmacies as of 2021 are 424

Total warehouses as of 2021 are 60







REGULATION OF NUTRACEUTICALS

Nutraceuticals can be defined as naturrally occuring products that are said to provide medical or health benefits .

- Micro-nutrients
- Dietary Supplements
- Functional Foods
- Polyphenols
- Terpenoids
- Glucosinolates
- Terpenoids

Nutraceuticals are not included under Medicine Regulation. However, as of 1st March 2022 Nutraceuticals which include vitamins and minerals (natural or synthetic) or any product that claims to enhance a specifc bodily function is to be regulated under MFDA.

WHAT IS THE IMPORTANCE OF REGULATING NUTRACEUTICALS?

Nutraceuticals has a growing market among all ages groups of the population. Even though these products are extensively used, there is a lack of clear information on the effectivenes of the products, and the safety in using them.

Althoug these prodcuts may be percieved as safe for use, it may not be suitable for all individuals. Susceptible individuals may face adverse effects. Nutraceuticals can be made up of active ingredients which can lead to elevated blood pressure, racing or irregular heartbeat, headache, dizziness or digestive problems.

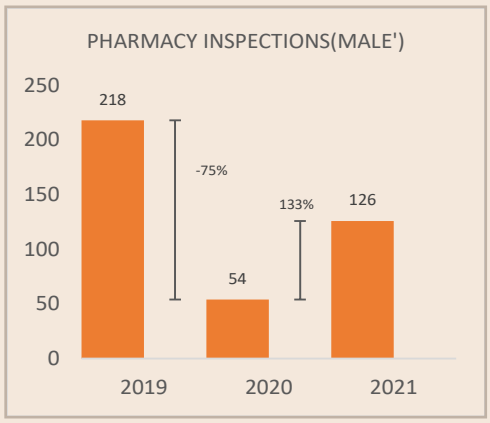
Hence, our regulatory authority aims to work towards ensuring the safety and efficacy of these products. As of 1st March 2022, "Guideline on Registration of Nutraceuticals" has been published and as per the guideline the following types of products will be regulated under MFDA.

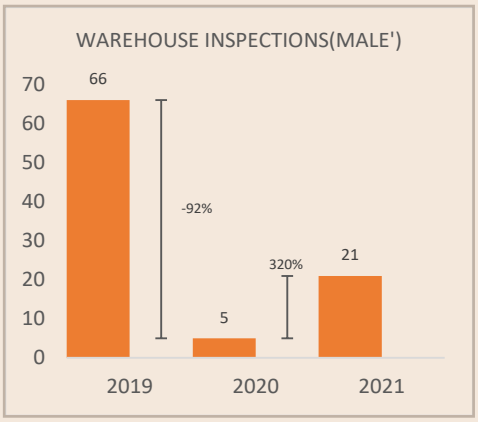
"Products containing vitamins, and minerals (natural & synthetic) with physiological process or specific claims to maintain or enhance a specific body function or structure."

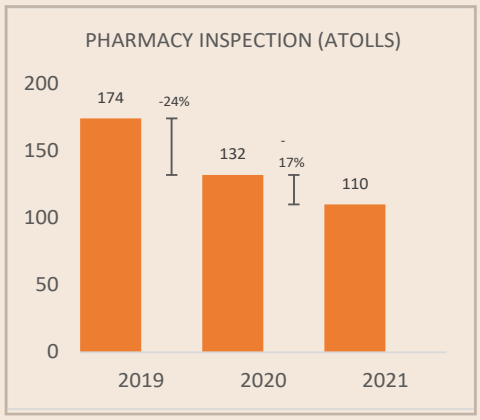
Enforcement Section is responsible for ensuring the safety, quality and efficacy of medicinal products after it is in the market for consumption. It ensures public safety by monitoring products defects and adverse drug reactions, inspection of facilities and conducting public awareness programs.

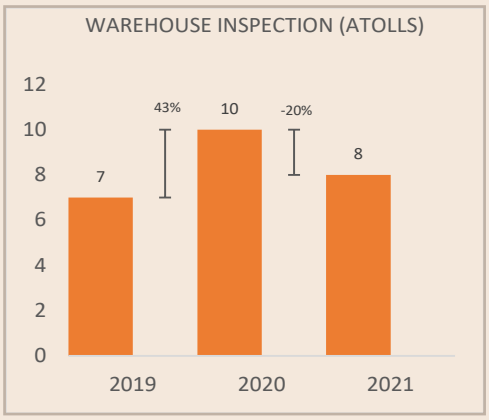
Enforcement Section monitors regulatory compliance and compliance to the standards (both national and international adopted standards).

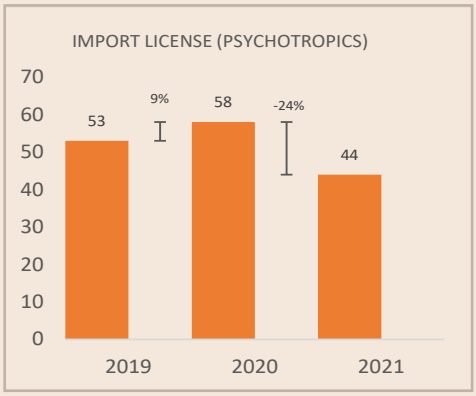
Inspectors empowered by the Health Services Act (2015/29) medicine regulation (2014/R-46) and medicine Regulation (2016/R-49) inspects premises where any medicinal products are being manufactured, dispensed, distributed, stocked or offered for sale.

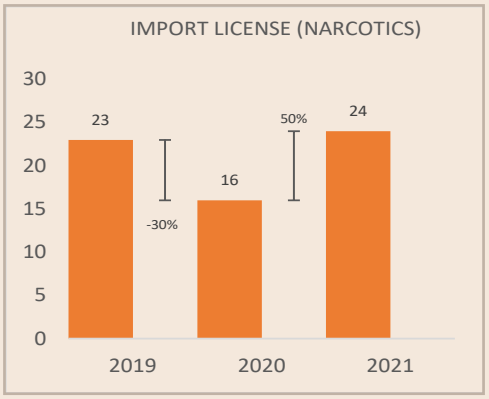


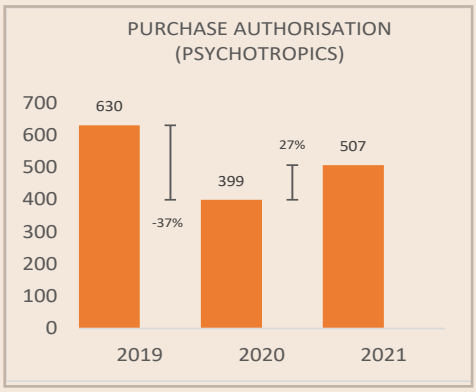


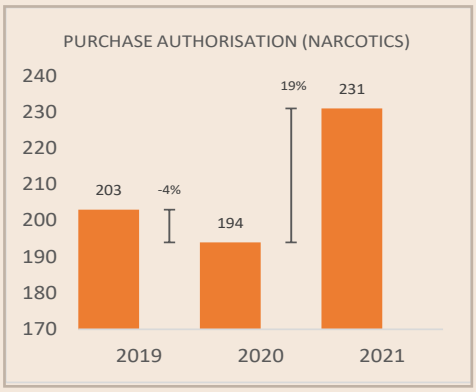


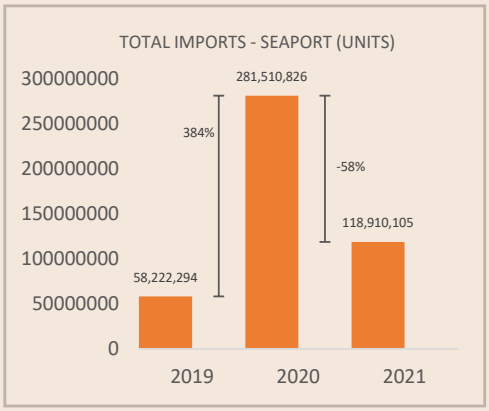


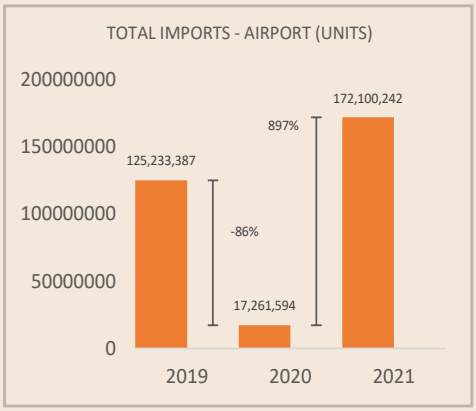

IMPORT LICENSE (PSYCHOTROPICS)
70
60
50
40
30
20
10
0
53
9%
58
-24%
44
2019
2020
2021


IMPORT LICENSE (NARCOTICS)
30
25
20
15
10
5
0
23
-30%
16
50%
24
2019
2020
2021


PURCHASE AUTHORISATION (PSYCHOTROPICS)
700
600
500
400
300
200
100
0
630
-37%
399
27%
507
2019
2020
2021


PURCHASE AUTHORISATION (NARCOTICS)
240
230
220
210
200
190
180
170
203
-4%
194
19%
231
2019
2020
2021


TOTAL IMPORTS - SEAPORT (UNITS)
300000000
250000000
200000000
150000000
100000000
50000000
0
58,222,294
384%
281,510,826
-58%
118,910,105
2019
2020
2021


TOTAL IMPORTS - AIRPORT (UNITS)
200000000
150000000
100000000
50000000
0
125,233,387
-86%
17,261,594
897%
172,100,242
2019
2020
2021

THE IMPORTANCE OF PHARMACOVIGILANCE

Pharmacovigilance (PV) relates to the activities of detecting, assessing, understanding and preventing adverse effects or any medicine related problems. Pharmaceutical products can include:

- Vaccines
- Medical Devices
- Biologics
- Blood Products
- Herbal Medicines
- Complementary Medicines
- Traditional Medicines

ADVERSE DRUG EVENTS

Adverse Drug Events (ADE) is any unexpected medical occurences when treating a patient with a pharmaceutical product.

ADVERSE DRUG REACTIONS

Adverse Drug Reactions (ADR) any unintended or harmful reactions that occur at the use of a medicine at normal dosage used in treatment.

Through collected ADE and ADR reports and analysing them, pharmacovigilance aims to:

- monitor and detect medicine safety, effectiveness and quality problems through passive and active surveillance of adverse events.

- assessing the safety, quality, effectiveness and risk/ benefit of pharmaceutical products

HOW TO REPORT?

As per as the "Guideline for Pharmacovigilance and ADR reporting", ADR's and ADE's can be reported through the "ADR Reporting Form".

WHO CAN REPORT?

1. Doctors
2. Nurses
3. Pharmacists
4. Community Health Workers
5. Patients
6. General consumers

WHAT CAN BE REPORTED?

1. ADRs (severe and non-severe)
2. Product quality
3. Medication errors
4. Therapeutic ineffectiveness
5. Abuse
6.

TOP 21 MEDICINE IMPORTS FOR 2021

#	Product Name	Dosage Form	Strength	Quantity (Units)
1	WYSOLONE	Disperible Tablet	10 mg	21,767,195
2	LIMCEE	Tablet	500 mg	10,021,400
3	PANADOL	Tablet	500 mg	8,951,486
4	ATORIN-10	Tablet	10 mg	5,478,630
5	ECOSPRIN 75	Extended Release Tablet	75 mg	5,059,104
6	DOPAN OD	Tablet	40 mg	4,345,900
7	MELMET 500	Tablet	500 mg	4,338,260
8	NEUROBION FORTE	Tablet	10 mg + 10 mg + 3 mg + 15 mcg + 45 mg + 50 mg	3,899,850
9	PANTAZ	Tablet	40 mg	3,600,975
10	TELMED 40	Tablet	40 mg IP	3,298,380
11	GALVUS MET	Tablet (Film Coated)	50 mg + 1000 mg	3,256,500
12	MILICAL	Tablet	1000 mg(USP) + 200 IU(USP)	2,765,380
13	MEFNAC DS	Tablet	500 mg	2,609,820
14	R.B TONE	Capsules	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)	2,484,872
15	BECOSULES	Capsules	50MG+25 MG + 10 MG +15 MCG +100 MG +25 MG +1 MG +150 MG + 5 MG	2,483,313
16	ZYLORIC	Tablet	100 mg	2,394,040
17	ALLERCET	Tablet	10 mg BP	2,379,400
18	AMODEP	Tablet	5mg	2,177,094
19	CRESTAT	Tablet	10 mg	2,096,825
20	NEUROBION FORTE	Tablet	10mg + 3mg + 15mcg + 100mg + 50mg	1,963,530
21	VAZORTAN 50	Tablet	50 mg USP	1,957,140

Disclaimer: The data and information in the data set provided here are intended to show the quantity of medicines imported within the year 2021 only. The information is not appropriate for application in creating medicine consumption patterns.

JOIN THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE!

What are Antimicrobials?

Antimicrobials include antibiotice, antivirals, antifungals and antiparasitics, which are vital for the prevention and treatment of infections in humans, animals and plants.

Antimicrobial Resistance (AMR)

Resistance to these medicines stems from the misuse and overuse of antimicrobials.

Antimicrobials become ineffective in treating infections and this increases the risk of disease spread, severe illnesses and even death.

Hence, Antimicrobial Resistance is identified as one of the top 10 global public health threats facing humanity by WHO.

WAYS TO REDUCE ANTIMICROBIAL RESISTANCE

- **Only use Antimicrobials when prescribed by a doctor**
- **Never share prescribed Antimicrobials**
- **Complete the prescribed quantity of antibiotics**
- **Help spread the message on risks of AMR**

World Antimicrobial Awareness Week (WAAW)

To participate in WHO's"Go Blue" Campaign, Roashanee Building was lit up in blue lights and government employees in Male' wore blue on the first day of the week.

An awareness session was held for media channels on Antimicrobial Resistance.

An information session regarding AMR stewardship program was held on 18th November 2021 with 56 health care workers in attendance. This included doctors, nurses and employees in hospital quality management.

AMR awareness session was held for pharmacists working in Male'. A total of 96 pharmacies were inspected.

On 27th October 2021, spot inspections were conducted in Greater Male' Region.

To celebrate the week "AMR Virtual Run" was held throughout the week. A total of 500 people participated in this event including doctors, nurses and workers in related fields along with the general public.

On 27th October 2021, spot inspections were conducted in Greater Male' Region.

1. Noncompliances identified and actions taken during the spot inspections:
2. 15 pharmacies issues antibiotics without prescription
3. Pharmacists selling antibiotics against regulations were fined

Awareness session for the following parties were conducted in HDh.Vaikaradhoo"

1. Grade 10 students and teachers.
2. Employees in island's government offices
3. Farmers and general public

An orientation program for AMR stewardship program was held in L.Gan

1. Under this program an inspection was conducted on the chemicals used by farmers
2. AMR awareness session for farmers and general public.
3. Infection Prevention and Control Training Session for L.Gan Regional Hospital nurses

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