Pharmaceutical country profile





Socioeconomic



Population¹ 527 080 (2024)



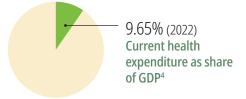


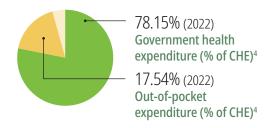


Spending on health

Current health expenditure (CHE)/capita (current US\$)⁴

US\$ 1150.69 (2022)







Spending on pharmaceuticals

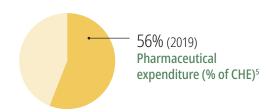
Government pharmaceutical expenditure

No data

Government pharmaceutical expenditure/capita

No data





Medical and pharmacy workforce

Medical doctors/ 10 000 population⁶

22.4 (2020)

Pharmacists/ 10 000 population⁶

7.01 (2020)

Pharmacy education accreditation⁷

Yes

Continuing professional development for pharmacists⁷

Partly

Pharmaceutical legislation and policy

2007 National Medicines Policy

2009 National Medication Practice Standards

2014 Health Services Act (Law No.29/2014);
Medicine Regulation No: R-46/2014

2015 Healthcare Professionals Act (13/2015)

2017-2021

National action plan for containment of AMR

2020 Guideline on Good Manufacturing Practices; Guideline of Good Reliance Practice for Regulation of Medicines

2021 🖕

Guidelines on Product Registration and Approval for Medicines

2022

Guideline on Regulation of Veterinary
Medicines Import and Pharmacy registration

2024

Guideline for Product Registration including Emergency Use Authorization V5; Guideline for Pre-Authorization Approval of Medicines V3; Guideline on Pharmaceutical Inspection V3; National Medication Practice Standard V2

2024-2029

National Action Plan for AMR

2024-2030

National Medicine Policy

2025

Guideline on Approving the Import of Medicines from Accredited Hospital V2; Guideline on Medicine Disposal V4

	Intellectual pro	perty rights
×	TRIPS flexibilities incorporated into the law	
X	TRIPS flexibilities utilized	No data

Rational use and antimicrobial resistance

% of market share of non-EML products

No data

WHO Global Antimicrobial Resistance and Use Surveillance System enrollment⁸: Yes, 2020

Total consumption of antibiotics:

No data

FDC sales in the	No doto
private market	No data

Number of antibiotics on the private market

	Total	AWaRe			Not
		Access	Watch	Reserve	recommended
Single drugs			No data		
FDCs			No data		



National Regulatory Authority²

Maldives Food and Drug Authority (MFDA)

Website: https://health.gov.mv/en/departments/maldives-food-and-drug-authority

Staff: No data

Annual budget: US\$ No data

Products regulated9

Medicines

☑ Biologicals

Medical devices

✓ Traditional medicines

Licensing of establishments¹⁰

Manufacturers Importers

Exporters

Wholesellers

Distributors

X Retailers

National Medicines Quality Control Laboratory⁷

1

ISO 17025 certified⁷

WHO prequalified⁷

Rational selection



Body responsible for selection of medical products¹¹

Maldives Food and Drug Authority (MFDA)

HTA used in the selection process

✓ NEML incorporated AWaRE list

✓ Medicines listed by level of care

Iraditional medicines included

National Essential Medicines List (number of active ingredient)¹²

2009 2013 2016 2018 2021 2023 428 medicines 438 medicines

National Medicines Formulary¹⁰

No data

National Essential Diagnostics List¹⁰: No data

Purchasing



Public sector

✓ Procurement^{7,10}: Centralized

Agency responsible for procurement: State Trading
Organization for public sector pharmacies, Ministry of Health
(for government health facilities in hospital use medicines)
Name of SH
(Aasandha)

LMIS used: No data

Frequency of tender: No data

Private sector

✓ Social Health Insurance

Name of SHI scheme¹³: Social Health Insurance Scheme

Population coverage: All Maldivians Number of products covered¹⁰: 3428

Pricing regulation

Pricing regulatory authority¹¹

Maldives Food and Drug Authority (MFDA)

Public sector

Tendering¹⁴: Yes

Private sector

Maximum retail price¹⁴: Yes (implementation not yet in place)

Number of price controlled products¹⁴: 3523 on reimbursement list





Market distribution

Estimated pharmaceutical market value

No data



Tertiary hospitals¹⁵: 4 Secondary hospitals: 14 PHC facilities: 165

Private

Manufacturers: None Importers: 73 Wholesellers/distributors: 76 Retail pharmacies: 453

Market exit



Legal provision for

- **Example 2** Cancellation of licences of pharmaceutical establishments
- **Exercise** Cancellation of marketing authorization of products
- Initiating product recalls and withdrawals

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