MEDICINES IN HEALTH CARE DELIVERY

MALDIVES

Situational Analysis:

26 May – 5 June 2014

Report prepared using the WHO/SEARO workbook tool for undertaking a situational analysis of medicines in health care delivery in low and middle income countries

July 2014

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1. ABBREVIATIONS

ABC	ABC analysis – method for measuring drug consumption
ADL	Approved Drug List
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
CCHDC	Centre for Health and Disease Control
CHW	Community Health Workers
CME	Continuing Medical Education
CPD	Continuing Professional Development
CPU	Central Procurement Unit
DIC	Drug Information Centre
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutics Committee
GDP	Good Dispensing Practice
GP	General Practitioner
EM	Essential Medicines
EDL	Essential Drug List
EML	Essential Medicines List
GPP	Good Prescribing Practice
HC	Health Centre
HOD	Head of Department
HPA	Health Protection Agency
HSD	Health Services Division
IGMH	Indira Gandhi Memorial Hospital

IPD	In-patient Department
MFDA	Maldives Food and Drug Administration
MOFT	Ministry of Finance and Treasury
MOHG	Ministry of Health and Gender
MVR	Maldivian Rufiyaa
NDP	National Drug Policy
NGO	Non-Governmental Organisation
NMP	National Medicines Policy
NSPA	National Social Protection Agency
OPD	Outpatient Department
OTC	Over-the-Counter
PHC	Primary Health Care
POM	Prescription-only medicine
PV	Pharmacovigilance
QA	Quality Assurance
RUM	Rational Use of Medicines
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
STO	State Trading Organisation
TOR	Terms of Reference
VEN	Vital, Essential, Non-essential – method for classifying drug importance
UNOPS	United Nations Office for Project Services
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Maldives during 26 May – 5 June 2014. The Terms of Reference were to examine medicines in health care delivery with respect to medicines supply, selection, use, regulation and policy. It was agreed that the WHO/SEARO workbook tool would be used and that a team of government officials, led by the Maldives Food and Drug Authority (MFDA), facilitated by WHO/SEARO would conduct the situational analysis.

The team members consisted of:

- Dr Shareefa Adman Malik, Director General, MFDA
- Dr Aisath Mohamed, Director Pharmaceuticals, MFDA
- Mohamed Fazeen, Pharmaceutical Officer, MFDA
- Dr Yusra Ali, Damana Veshi, MOHG
- Dr Kathleen A Holloway, Regional Advisor Essential Drugs & Other Medicines, WHO/SEARO

The programme involved meetings with all the major government departments and other stakeholders involved in the management of medicines and visits to health facilities in two regions. A detailed program can be seen in section 3. A one-day national stakeholder workshop was held on 5 June 2014 at which the findings were discussed and recommendations developed. The participants list can be seen in section 12. A presentation of the findings was given on behalf of the team by Dr Holloway, WHO/SEARO. Group work was done by participants to develop recommendations in the areas of medicines supply, selection, use, regulation and policy. The words “medicine” and “drug” are used interchangeably in this report.

2.2. Medicines Supply

The findings concerning drug supply and stock management are similar to other recent reviews by Eriksen in 2012 and UNOPS in 2013. Unstable government and the recent failed decentralization scheme involving regional health corporations have severely disrupted supplies of hospital injectables and consumables for IPD use. The lack of diploma pharmacists or advanced certificate pharmacists in any public health facility is a very serious infrastructural problem resulting in very poor stock management and stock-outs. Furthermore, there is no supervision of drug stock management from the central MOHG. In such circumstances it is not surprising that there have been stock-outs of medicines. However, private pharmacies are still supplying most of the OPD medicines needed, as seen by 85-95% of all prescribed drugs being dispensed in all facilities visited. Unfortunately, the serious financial difficulties of government have also undermined the Asandha insurance system such that some pharmacies have disengaged from the Asandha. As a result, some patients can no longer get free medicines even though covered by Asandha and other patients are getting their prescriptions copied out in the IGMH – which is unsafe – in order to use the Asandha system. Concerning recommendations made in the situational analysis in 2013, MFDA has now created a database of all drug imports and for the first time an ABC analysis and price analyses can be done once the data is cleaned. Unfortunately, recommendations to upgrade the central medical store, now the Health Supplies unit, have not been followed. Cost containment measures recommended for the Madhana insurance system have not been followed for the Asandha insurance system which is in severe financial stress.

While procurement and distribution of OPD medicines continues to be managed by the private sector, supply of hospital injectable drugs remains problematic. Government is deciding whether to request STO or CPU/Health supplies in MOHG to take this on. If STO is requested to this – and they are already expanding their island pharmacies - then more transparency and information sharing with MOHG concerning procurement, distribution and consumption will be needed. Furthermore, the regulation that does not allow private pharmacies to supply hospital injectable drugs would have to be refined to allow STO pharmacies to supply island hospitals directly. If CPU/Health supplies in MOHG is requested to do this, then a great deal of investment in infrastructure and human resources will be needed.

Recommendations were to:

- Employ one diploma pharmacist per region and one advanced certificate pharmacist per atoll hospital to manage drug stock and undertake quantification.
- Establish a unified electronic drug management information system from central level to hospital level, train/supervise the current store keepers to enter the data accurately, and monitor stock levels at both the central and hospital levels monthly.
- Establish SOPs for stock management, covering storage, receipt and distribution of goods, maintaining documentation, monitoring expiry of medicines and their destruction, and redistribution of medicines to avoid wastage.
- Establish SOPs for procurement to include: clear, transparent supplier criteria and product specifications; in-built quality assurance measures; and 2-stage tendering process.
- Develop a system for annual quantification based on accurate data of past consumption, taking into account stock-out and balance, and which may involve an annual national workshop.
- Establish a supervisory system and budget for undertaking supervision of stock management of all hospitals from the central MOHG, which may involve both the MFDA and the HSD.
- Make prompt payment by Ministry of Finance and Treasury (MOFT) to Asandha and all agencies involved in public sector procurement of medicines (whether STO or CPU or IGMH).
- Urgently reintroduce into Asandha more cost containment measures, such as limitation of reimbursement to the national EML and the MRP; and reintroduction of a maximum annual cap.
- Oblige suppliers in the public sector (STO and CPU) to share consumption and stock data with facility in-charges to aid stock management.
- Urgently upgrade the Health Supplies Unit if it is to continue to supply hospital injectable drugs and consumables.
- Refine the regulation on private pharmacies supplying hospital drugs so that they may supply hospitals directly, not through patients.

2.3. Medicines Selection

There is a national EML but it is not actively used or promoted. For the first time a prescription survey was done to estimate the % of prescribed drugs belonging to the national EML. About 25-30% of medicines in

the public sector and 40% of medicines in the private sector are non-EML medicines. The MFDA has now created a database of all national drug imports but the data needs cleaning and categorizing into EML and non-EML drugs before the % of drug imports that belong to the national EML can be estimated. The EML has been revised in 2013 but unfortunately the prescribers are still not sensitized. Once the cost of non-EML drugs imported into the country and the proportion of all drug costs that are due to non-EML drugs are known, it may be easier to sensitize policy makers of the need for a national EML. The hospital IPD list has not been revised recently and there is no list of oral medicines for doctors to prescribe in health centres with no private pharmacy. The list for Community Health Workers was revised in 2013 although the process is unclear. Supply and use of the CHW list for doctors to use in health centres without pharmacies would be better for most patients than use of the IPD hospital injectables unnecessarily.

Recommendations were to:

- Improve drug consumption data, including the MFDA database on drug importation, and also data from STO , CPU, and health facilities, which should be shared with the MOHG, in order to plan better.
- Implement the EML by: monitoring importation and use of EML medicines medicines (% of imported drugs/prescribed drugs belonging to the EML); reimbursement by Asandha of only EML medicines and sensitization of all doctors, especially new expatriates.
- Regularly revise the national EML and improve the selection process by: having written published criteria for selection; having a formal procedure to apply for new drug additions open to all prescribers; publishing reasons for additions and deletions to the EML; having wider representation of prescribers (specialists and general practitioners) including from the regions; and deleting unregistered and non-available medicines.
- Revise the hospital injectable drug list.
- Develop a list or oral drugs for Health Centres without a pharmacy.
- Revise the list of drugs for community health workers in islands where there is no doctor.

2.4. Medicines Use

Inappropriate, irrational use and overuse of medicines continues unchanged since 2011. Overuse of vitamins and injections is worse. Very few of the recommendations made in 2011 have been implemented. Thus there is no monitoring of prescribing, no clinical guidelines, no hospital DTCs, no CME on prescribing for doctors and no public education on prudent use of medicines. Recommendations have not been implemented partly because of political instability but mainly because a responsible unit in MOHG for these many functions has not yet been identified. However, some of the recommendations should not be too difficult to implement and are urgently needed.

Recommendations were to:

- Monitor drug use through:
    - Improved analysis of data from importers and port inspection;

- Prescription audit in all health facilities which could be done if a diploma pharmacist were employed in each regional hospital (as recommended under drug supply); and
- Some monitoring from the central MOHG, perhaps joint inspections by the MFDA and the Quality Assurance section/HSD.

- Develop, update and implement Standard Treatment Guidelines (STG) for the majority of common conditions, and which should be disseminated to every doctor, incorporated into CME/CPD and which should be done by HSD and MFDA jointly.
- Establish Drug and Therapeutic Committees (DTC) in the IGMH and all regional hospitals and require them to monitor drug use, encourage CPD, and report annually on activities to MOHG/MFDA;
- Establish continuing professional development (CPD) that incorporates prescription audit with feedback and ethics, and establish an orientation program on prescribing and the EML for new expatriate doctors.
- Establish a national Drug Information unit in MFDA to provide independent information for doctors.
- Organise public education through the HPA health education unit and the media, incorporating core pharmaceutical messages e.g. does my child need more than one drug? Antibiotics are not need for the common cold!

2.5. Medicines Regulation

The MFDA has made much progress in the last 3 years, having developed SOPs for most procedures, developed a database on drug imports and maintained annual inspections of all pharmacies. Unfortunately, there has been no progress with regard to improved pharmacovigilance or establishing a unit to monitor drug promotional activities – mainly due to lack of resources and staff dedicated for this. The problem of importation of unregistered drugs remains although a new system of temporary registration has now been started. A new Medicines Act giving the MFDA more authority and independence has still not been passed and this is a barrier to making more progress since such an Act is needed to implement regulations and introduce more control and punitive measures.

Recommendations were to:

- Establish a new Medicines Act required for implementing regulations and introducing more control and punitive measures.
- Strengthen the MFDA by increasing the budget and qualified and competent staff and increasing fees for drug registration, importation licenses, and pharmacy licenses to generate income and allowing the MFDA to retain some of the income generated.
- Improve the registration process and ensure stricter adherence to it by: ensuring that all products imported and sold are approved by the Pharmaceutical Board/MFDA; establishing a committee to review all prescriptions with unregistered products and publishing the number of unregistered products on prescription; deregistering all un-imported medicines; and ensuring that all suppliers are registered with the MFDA.

- Improve and clean the database on importation of pharmaceuticals so as to allow unit price comparisons for pharmaceuticals to calculate MRP on a regular basis.
- Follow up on the recommendations from the 2011 situational analysis which are still relevant:
    - Review the drug schedules to consider whether 3rd and 4th generation antibiotics may be limited to hospitals only, in order to prevent misuse in health centres and the private sector;
    - Improve ADR reporting by running a face-to-face sensitization campaign with all doctors, nurses, CHWs and pharmacists;
    - Establish a system of pre-approval of adverts for all medicines and a system to monitor all promotional activities.
- Refine the regulation on private pharmacies supplying hospital drugs so that they may supply hospitals directly, not through patients (see drug supply recommendations).

2.6. Medicines policy and coordination

The same problems of coordination within the different departments of the MOHG and between the MOHG and other Ministries were noted in the 2011 situational analysis. None of the recommendations from the 2011 situational analysis have been acted upon. This is not perhaps surprising given the political instability and huge structural changes that have been made and unmade in the health care delivery. Once political stability is achieved, serious consideration should be given to implementing the 2011 recommendations.

Recommendations were to:

- Establish a policy level statutory committee to: advise the president; develop coordinated medicines policy across all stakeholders; review and update the 2007 national drug policy; monitor and evaluate policy implementation; and which would require an executive unit(s) in MOHG (DGHS & MFDA) to do the committee's recommendations.
- Establish an extra unit in the MFDA responsible for promoting rational use of medicines, which would include monitoring of medicines use and coordination of policies to promote rational use of medicines, including:
    - Maintenance of the national EML, development of STGs, establishment of DTCs and monitoring their activities (in coordination with HSD), coordination of continuing medical education, establishment of a national Drug Information Centre, organization of public education (in liaison with HPA), etc.
    - Liaison with Faculty of Health Sciences to provide students to collect information needed by MOHG as part of their research studies.
- Generate MOHG income by raising fees for health professional licences and health facility licenses, as well as drug outlet and drug importation licences and drug registration (see drug regulation recommendations).

3. PROGRAMME AGENDA

Day	Date	Time	Places visited
1	26/5/14	Am	Meeting of assessment team and MFDA, MOHG, DGHS
		Pm	Meeting with CPU, Health supplies, Deputy Minister of Health & Gender
2	27/5/15	Am	Meeting with Medical & nursing councils and MBHS
		Pm	Visit to Hulhumale hospital & 2 pharmacies
3	28/5/14	Am	Meeting with Faculty Health Sciences, NSPA, Asandha,
		Pm	Visit ADK private hospital & pharmacy
4	29/5/14	Am	Visit to IGMH and the STO pharmacy serving the hospital
		Pm	Visit to STO and STO medicals
5	30/5/14	Am	Report reading and data analysis
		Pm	Free
6	31/5/14	Am	Visit to G DH atoll hospital and private pharmacy serving the hospital
		Pm	Visit to 2 health centres under the G DH atoll hospital and serving pharmacy
7	1/6/14	Am	Visit to GA Regional Hospital and STO pharmacy serving the hospital
		Pm	Visit to 1 health centre under the GA regional hospital
8	2/6/14	Am	Visit to K.Villingilli health centre and nearby private pharmacies
		Pm	Visit to sea and airports and private pharmacy Male
9	3/6/14	Am	Meeting with Minister of Health & Gender, Health Services Division, Quality Assurance Improvement Section
		Pm	Preparation for the workshop with the MFDA and the situational analysis team
10	4/6/14	Am	National workshop
		Pm	National workshop

4. MEDICINE SUPPLY

4.1 Responsible Agents/Departments

Function/ Organisation	MOHG	Other Agency	Name of Agency/MOHG Department
Selection	√		Maldives Food & Drug Administration coordinates the national EML
Quantification		√	Central Procurement Unit (CPU)/Health Services Division (HSD/MOHG) together with hospital manager for public inpatient injectables
Procurement	√	√	Central Procurement Unit (CPU)/MOHG; State Trading Organisation (STO); and private importers including ADK.
Pricing		√	Currently set by importers but MFDA is working with the Ministry of Economic Affairs to set a Maximum Retail Price
Storage	√	√	STO; Health Supplies/MOHG; other private importers & pharmacies
Distribution	√	√	STO; Health Supplies/MOHG; other private importers & pharmacies
Monitoring & evaluation	√		MFDA monitors controlled medicines, HSD/MOHG is supposed to monitor management of medicines in the public health facilities

4.2. Drug availability

There were no reports published on the availability of essential drugs in the last 5 years.

On discussion with government health workers, it was found that a few vials of injectable drugs, not generally on the MFDA list for hospital IPD injectable drugs, were reported out of stock by many facilities but some reported having all items and some said that if one item was out of stock they could use another. All OPD and oral drugs were supplied by private pharmacies. Adrenalin injection was reported out of stock by some facilities but a large quantity was found to be expiring in another facility. No formula or SOPs were followed for quantification and ordering was often done when items were out of stock. Drug stores were generally managed by administrative staff with a school-leaving level of education and no special training. Hospital managers did not give much support to the store keepers. In general there is poor management of medicines in the health facilities which needs to be addressed in order to ensure availability.

Table 4.2.1 show some data on stock availability and stock-out with regard to IPD medicines.

Table 4.2.1: Summary of EML* drug availability from observation and record review in the health facility surveys:

Public Referral Hospitals	Hospital 1	Hospital 2			Average
% EML items out of stock	0/25=0%	3/25=12%			6%
% key EML drugs available					
% prescribed drugs dispensed**	86.0%	85.8%			85.9%
Public District Hospitals	Dist. Hospital 1	Dist. Hospital 2			Average
% EML items out of stock	0/25=0%	5/25=20%			10%
% key EML drugs available					
% prescribed drugs dispensed**	95.2%	-			
Public primary health care centres	PHC 1	PHC 2	PHC 3	PHC 4	Average
% EML items out of stock	10/25=40%	5/25=20%	5/25=20%	1/25=4%	21%
% key EML drugs available					
% prescribed drugs dispensed**	86.6%	-	-	-	86.6%
Private pharmacies	Pharmacy 1 (in priv. hosp.)	Pharmacy 2 (STO)	Pharmacy 3 (priv. owner)		Average
% EML items out of stock	-	-	-		-
% key EML drugs available					
% prescribed drugs dispensed**	98.6%	95.5%	85.7%		93.3%

* Belonging to the national EML

** From prescription audit done during the health facility survey

% EML items out of stock refers to the hospital IPD injectable list which contains 25 medicines, including anaesthetic and other agents, which are not applicable to health centres. The % of prescribed drugs dispensed refers to OPD prescriptions which were reviewed in the private pharmacy serving the facility (either in the hospital compound or next door). STO pharmacies served IGMH, GA Regional Hospital and Villingilli/Male HC; Green pharmacy served Hulhumale HC; Radar pharmacy served GA Atoll hospital; and Dhandoo pharmacy served Dhandoo HC. No pharmacies served Mamendhoo and Hoandedhoo HCs.

In fact, each health facility had its own list of medicines for which a stock was kept for inpatients. Mostly they were injections which were poorly stored. A uniform list of medicines should be developed by MFDA/HSD depending on the inpatient requirements in line with the EML as categorized for different types of health facility.

4.3 Annual aggregate data of medicines distribution / consumption

Table 4.3.1 shows aggregate import data for the year 2013 from the newly established database operated by the Maldives Food and Drug Administration.

Table 4.3.1. ABC analysis of the top 24 items imported into Maldives in 2013

Source of data (government department/organization): MFDA/MOHG Database on imports;

Rank	Item Name/Strength	EML	Value ($)	% of total	Cumulative %
1	Salbutamol (mostly syrup)	√	1383118	12.70	12.70
2	Amoxy+Clavulinic acid (mostly tabs)	√	548044	5.03	17.73
3	Vitamins (Multivitamin & B Complex)		494784	4.54	22.28
4	Paracetamol	√	355743	3.27	25.55
5	Diclofenac	√	323390	2.97	28.51
6	Losarten	√	284887	2.62	31.13
7	Pantoprazole	√	246216	2.26	33.39
8	Atovastatin	√	197803	1.82	35.21
9	Efarvirenz	√	184800	1.70	36.91
10	Calcium	√	174097	1.60	38.50
11	Ranitidine	√	171236	1.57	40.08
12	Deferipone		157321	1.44	41.52
13	Desferioxamine	√	149730	1.38	42.90
14	Fluticasone		129050	1.19	44.08
15	Antacid	√	125241	1.15	45.23
16	Cefixime		119144	1.09	46.33
17	Levonorgestrel	√	110547	1.02	47.34
18	Cefuroxime	√	109372	1.00	48.35
19	Cetirizine	√	99297	0.91	49.26
20	Fexofenadine		87897	0.81	50.06
21	Amoxycillin	√	85772	0.79	50.85
22	Dextromethorphan		82634	0.76	51.61
23	Piroxicam		74077	0.68	52.29
24	Clopidogrel	√	73240	0.67	52.96
Totals: For all items - USD 10,889,297			5,767,440		52.96%

Import database not cleaned so ABC analysis by specific product (incl. formulation) could not be done.

Analysis of this 2013 annual importation data reveals:

- Annual per capita cost of medicines at importation: 36.42 USD (assuming a population of 298,968)
- Number of items on national EML: 321 APIs, 420 formulations;
- Number of top 24 items on EML: approx. 18;
- Total number of items on the national procurement list: >3000
- Total value of all items distributed (not just top 20) USD: 10,889,297
- % of total value due to antibiotics: 12%; vitamins (multivitamins and B Complex): 5%;
- % of total value of medicines that are not on the EML: 37%.

The top 10 causes of mortality in 2012 (Health Protection Agency 2012) were:

1. Heart Diseases
2. Cerebrovascular diseases (stroke)
3. Chronic lower respiratory diseases
4. Hypertension
5. Cancer
6. Accidental injuries
7. Diabetes Mellitus
8. Renal Failure
9. Perinatal cardiovascular & respiratory illness
10. Circulatory & respiratory symptoms & signs.

The top 10 communicable disease with greatest incidence in 2012 were:

1. Acute respiratory Infection
2. Viral fever
3. Acute Gastroenteritis/Diarrhoea
4. Conjunctivitis
5. Chicken Pox
6. Dengue fever/ DHF/ DSS
7. Food Poisoning
8. Hand foot and Mouth Disease
9. Scrub typhus
10. Mumps

Comparison of the top 20 drugs by value with the top 10 causes of mortality and the top 10 communicable diseases suggests that high expenditure on losartan, atorvastatin and clopidrogel for cardiovascular and cerebrovascular disease and amoxicillin, amoxicillin and clavulanic acid and salbutamol for respiratory disease may be very appropriate. However, the high expenditure on vitamin B Complex, multivitamins, omeprazole and pantoprazole, cetirizine and fexofenadine may not be justified by morbidity patterns. Furthermore, high expenditure on piroxicam which has a greater incidence of adverse drug reactions than other non-steroidal anti-inflammatory drugs may not be justified.

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

All medicines are imported and almost all drugs used, even in the public sector, are supplied by the private sector. All outpatient drugs are supplied to patients by private pharmacies. There are about 40 private importers, the major one being ADK that accounts for 44% of all drugs imported. The State Trading Organisation (STO) was formerly totally government-owned but now is a public-private parastatal with 17% private ownership and it imports nearly 2 million USD (17% of total imports) worth of drugs annually. Previously, the STO had a monopoly on importation of injectables for hospital inpatient use and controlled drugs but now a few other importers, such as ADK, are also able to import such items. The Central Procurement Unit (CPU) has recently been set up in the Health Services Division of the MOHG and is currently being supported by UNOPS. The CPU procures drugs for inpatient use, including controlled drugs, and the drugs are delivered to the Health Supplies Unit from where they are distributed to regional and atoll hospitals.

The STO operates an annual tendering system but the details were unclear. It was stated that they purchase from about 20 known suppliers in India, half of them wholesalers, but supplier criteria were unclear, none of the suppliers had been inspected on site and quality assurance testing does not seem to be built into procurement contracts. Evaluation of tenders is mostly manual. Emergency orders are made and the general lead time for medicines is 6 weeks and for medical equipment 3 months. STO is owed about 400 million MVR by MOFT, 70 million MVR by the Asandha insurance system and 90 million MVR by IGMH. This situation of very heavy debt and late payment will undermine the ability of STO to negotiate low drug prices and some people have accused to the STO of high prices. Furthermore, lack of foreign currency means that STO has actually has had to purchase some drugs locally from ADK. Although STO is partly privately owned, they must still follow government financial rules with regard to purchase and they still have a public sector focus. Previously, in 2011, they supplied only the Indira Gandhi Memorial Hospital (IGMH) and the Central Medical Store, but recently they have expanded pharmacies to nine islands, including 2 regional and atoll hospitals. There is a recent MOU in which they have agreed to expand their network of pharmacies to include all 12 regional and all atoll hospitals in the next 2 years. The STO infrastructure for procurement and distribution of medicines is quite well developed, having been established for many years. Thus, they have a well maintained warehouse and a drug logistic management information system that extends down to the level of the pharmacy. They employ about 160 staff, including approximately 10 staff per pharmacy, and are currently sponsoring about 15 students to study for the advanced certificate in pharmacy, which will later enable them to work as pharmacy assistants in pharmacies. Under current regulation, private pharmacies are not allowed to supply hospital injectable drugs so hospitals have to procure these themselves or get them through the MOHG/CPU.

The CPU under Health Services Division (HSD), MOHG, is only just set up and has been supported by UNOPS since September 2013. It was set up to take over procurement of hospital injectable drugs and inpatient consumables from the failed Regional Health Corporations and because, at that time, it was felt by government that STO could not take over supply of drugs to the islands. Unfortunately, progress has been slow and procurement limited due to lack of infrastructure in the Maldives and lack of foreign currency and, at the time of writing, the government was in the process of deciding whether procurement should be done for public sector use by the CPU or STO. So far, 850,000 USD (11 million MVR) of goods had been purchased (mostly consumables) by the CPU. Procurement for small amounts has been made from local suppliers and procurement of the first consignment of supplies in large amount was about to be received. The CPU/HSD has very limited infrastructure, with 5 MOHG (including one pharmacist) and 3 UNOPS (including one expatriate) staff.

4.4.2. Provincial/District/Hospital Drug Procurement

Private pharmacies supply all OPD drugs and hospitals usually buy hospital injectable drugs directly from STO or ADK. None of the facilities visited had purchased any injectable hospital drugs from the CPU. It is not clear if there is any tendering system but any purchase above 25,000 MVR requires central approval. Most purchases were below 25,000 MVR and made when there were already stock-outs or stock-outs about to happen. Funds for medicines purchase come out of the general budget for the hospital with no specific line item for medicines and it was unclear how much money was actually spent on medicines purchase (IPD injectables only). For the nine health facilities with an STO pharmacy, all drug supply is managed by STO and consumption information is not shared with the health facility in-charge.

4.5. Allocation of budget for medicines in the public sector

Drugs are not separately budgeted from the general hospital budgets. A cap of 100,000 MVR per person per year with Asandha has recently been removed. It is not clear how overall budgets for the hospitals are calculated and it was also mentioned, that if there was insufficient budget one could ask for more. One atoll hospital of 20 beds and 70 outpatients per day and covering 8 health centres in surrounding islands mentioned that they received a budget of 35 million MVR of which about 25% was spent on pharmaceuticals. A regional hospital stated that they had requested 108 million MVR but only received 48 million MVR.

4.6. Drug quantification in the public sector

No hospital or health facility had any standard system for undertaking quantification, ordering or stock management. Drugs were ordered when they were out of stock or about to be out of stock. There were no stock books, only inventory sheets which often did not record outgoing and incoming drugs or balance. In most facilities the inventory sheets only recorded what was considered the minimum number of units of a product that should be present and sometimes these did not match what was actually present. Therefore there was no way of knowing what stock was present. One hospital had its own electronic record of stock with records of outgoing and incoming drugs. However, the store-in-charge and computer were not based in the stock room and no physical reconciliation of stock with electronic recording had been done. In all health centres, there were an excessive number of injectables most of which were not used and thrown out on expiry. While IGMH and some people at central level complained of a stock out of adrenaline injections, 40 expired vials were found at a nearby health centre. There was no redistribution of stock between facilities nor could this be done easily with the present level of stock information. The CPU mentioned that quantification was very difficult because there is no consumption or stock data available.

STO manage quantification based on past consumption using its own electronic drug management information system. Even so, they complained that the IGMH made requests for certain products, which were difficult to procure, and then did not use some of these items when there was a change of doctor. A large amount of surgical suture was about to expire which had cost a considerable amount. Overall 6 million MVR of consumables expired last year.

4.7. Drug Management and Distribution in the public sector

4.7.1. National Public Sector Drug Distribution

Hospital IPD injectable drugs are distributed from the Health Supplies unit under the Administration Division in MOHG, according to requests from health facilities i.e. a ‘pull’ system operates. Often requests are made at the last minute when there is already a stock-out. There is no system of maintaining any buffer stock. The Health Supplies unit has a central electronic drug logistic management information system that is harmonized with that of the CPU and there is a liaison officer in the CPU to ensure smooth working relations with the Health Supplies unit. The infrastructure of the Health Supplies unit is very limited with no pharmacist and only 2 community health officers, 5 non-technical staff and 2 labourers. The store of the

Health Supplies unit was visited by the MFDA and WHO and was found to be totally unsuitable to store medicines in terms of both size and infrastructure. The store was totally inadequate and chaotic, with a leaking roof, inadequate temperature control, and boxes lying scattered in the courtyard to such an extent that a new walk-in cooler donated by WHO had been buried. The only exceptions to this chaos were 2 rooms where injectable drugs and other medical consumables supplied by UNOPS were being stored, but even these rooms had insufficient space to cater to all the medicines procured by CPU/UNOPS. On review of the electronic drug management system, it was found that many of the 626 items on the supply list were out of stock and that many nearby health facilities were ordering small amounts daily, even 1 bottle of 5% dextrose or normal saline at a time. Further away island facilities were generally making orders weekly although the island facilities visited stated that they had not made any orders to the Health Supplies unit, and that they only made purchases from STO or ADK monthly. At the time of the visit, UNOPS was trying to establish a monthly ordering schedule to supply the island hospitals. Unfortunately, there is insufficient information on past consumption within the electronic drug logistic management information system to undertake accurate quantification. OPD drugs are supplied by the private sector.

4.7.2. Provincial / District Drug Distribution and Management

The regional and atoll hospitals visited purchased hospital injectable drugs from ADK or STO and distributed these drugs to the health centres (HCs) in their catchment area according to their demand. No ordering schedule or SOPs were followed for when and how much to order. No facilities visited had ordered from the CPU. It was mentioned by HCs that what was ordered was not always supplied. All facility staff (hospital and store managers) stated that they had never received any supervision of stock management in the past 2 years. Sometimes expired drugs were stored with non-expired ones and different drugs were stored in the same box. OPD drugs are supplied by the private sector.

4.7.3. Within Health Facility Drug Distribution and Management

All wards in all hospitals and health centres had injectable drugs, in much greater variety than the MFDA hospital inpatient drug list. Hospital nurses kept the inventory sheets with the minimum amounts of injectables needed and restocked the wards daily. In one health centre, one nurse reported giving only one injection per week and most injections had to be disposed of on expiry. In a health centre without a pharmacy, the doctor felt constrained to use the injectables instead of oral medication, even though it may be inappropriate. All facility staff (store managers and nurses) stated that they had never received any supervision of stock management in the past 2 years. Sometimes expired drugs were stored with non-expired ones and often different drugs were stored in the same box. It was mentioned by some nurses in island hospitals that dealing with quality issues was difficult. One nurse mentioned that nasogastric tubes without caps and endotracheal tubes without inflator cuffs had been received. However, when she mentioned this to the storekeeper, nothing had happened and so she had to use the substandard stock or go without. On further enquiry it was found that the store keeper would report to the procurement unit in the hospital, who would report to the manager and that the process was so lengthy and unclear that it was uncertain if any complaint would ever reach the supplier.

4.8. Patient Flow in the Health Facilities

Patients registered and were referred to the outpatient department or the emergency room depending on severity as decided by the patient and/or by the registration staff. In the IGMH a nurse triaged patients to go to the emergency room or GPs or OPD. After seeing the doctor in OPD, patients took their prescriptions to the private pharmacy either within the hospital compound or nearby. If patients were admitted, hospital injectables could be given but all other medicines had to be bought from a private pharmacy by relatives and administered in the ward. More than 90% of all patients were covered by Asandha.

The prescriptions had details of the patient, the health facility, diagnosis and medicines prescribed and so were good sources of information for prescription audit. Although details of the prescription are entered into the Asandha computer portal in the nearby pharmacy, duplicate prescriptions are also retained in the pharmacy to send to Asandha for reimbursement. Foreigners are not entitled to Asandha coverage and must pay cash in public health facilities – 200 MVR for a consultation with a specialist or 100 MVR for a consultation with a generalist, 120 MRV per bed per day, and all treatment costs. If a national does not have an Asandha ID card s/he must also pay a fees – usually half that paid by foreigners. The fees in the private ADK hospital were higher being 800-900 MVR/ day for a private single room, 300 MVR /day for a bed in a 10-bedded ward, 200 MVR per specialist consultation and 100 MVR per non-specialist consultation.

Most doctors saw about 30 patients a day although busy GPs saw up to 50 patients a day in IGMH. In most pharmacies, there was sufficient staff such that patients did not have to wait long. Even so, patient-dispenser interaction time was generally less than 1 minute with little explanation to patients on how to take their medicines. Apart from IGMH, where many beds were occupied, in most of the other hospitals visited there were many empty beds.

4.9. Insurance

The National Social Protection Agency (NSPA) was formed in 2008 and the Health Insurance Act passed in 2009 when Allied Insurance, owned by STO, was contracted to run the Madhana Insurance system, which covered about 20% of the population in 2010-2011. At that time, annual premiums and copayments were required and the benefit package was limited. Even so, the Madhana system was in financial difficulty and had been unable to implement some cost containment measures such as limiting reimbursement to the national EML or even an expanded EML. From 2012, the Asandha Insurance system was established which covers all the population and which requires no premiums from patients, being funded through central taxation. As with the previous Madhana system, the Asandha system is run by Allied Health Insurance, while Asandha private limited supervises implementation and NSPA sets policy. The NSPA Board has a chief appointed by the President with members from the NSPA, Ministry of Finance, independent organisations and the stock exchange but it was mentioned that it has not been functional. Patients can only get free treatment if they go to registered health facilities and pharmacies and have their consultation and treatment entered electronically into an Asandha electronic portal operating in registered facilities and pharmacies. Pharmacists also keep a copy of the bills to send to the Insurance system in order to get reimbursement.

The Asandha system currently has no cost containment measures, reimbursing all medicines (even outside the approved drug list) in all quantities. It even reimburses travel expenses to reach the hospital. Recently, a maximum cap of 100,000 MVR per patient per year, split between charges for medicines, hospital

admission and evacuation, had been removed. Since this removal costs have escalated greatly – from 70 million MVR in 2013 to an estimated 1.3 billion MVR in 2014. However, there are plans to limit reimbursement to drugs on the approved drug list only (> 3000 items) and to limit reimbursement to a maximum retail price (MRP) currently being developed by the Maldives Food and Drug Administration (MFDA) in collaboration with the Ministry of Economic Development. This MRP is likely to reduce prices by 50%. Generic substitution is allowed so limiting reimbursement to the MRP could save much money.

Unfortunately the Asandha is in serious financial difficulty and owed millions of MVR by the government, resulting in a 120 day delay in reimbursing pharmacies. As a result many private pharmacies, including ADK, have disengaged from the Asandha system. In such circumstances, patients have to pay for their medicines. In Male, patients are circumventing this problem by getting their treatment from private clinics and pharmacies and then going to the IGMH to get their consultation and treatment copied into the Asandha portals in the IGMH and attached STO pharmacy respectively. Often the patient does not attend him or herself but sends a family member. Thus, one doctor is copying about 150 prescriptions per day for patients he does not see, which is unsafe and ethically incorrect. Despite this problem, most patients seen in the public health facilities visited, even in the islands, received their medicines through the Asandha system.

4.10. Drug Manufacturing

No drugs manufactured in Maldives.

4.11. Progress / changes / problems in drug supply since last situational analysis

The findings concerning drug supply and stock management are similar to other recent reviews by Eriksen in 2012 and UNOPS in 2013. Unstable government and the recent failed decentralization scheme involving regional health corporations have severely disrupted supplies of hospital injectables and consumables for IPD use. The lack of diploma pharmacists or advanced certificate pharmacists in any public health facility is a very serious infrastructural problem resulting in very poor stock management and stock-outs. Furthermore, there is no supervision of drug stock management from the central MOHG. In such circumstances it is not surprising that there have been stock-outs of medicines. However, private pharmacies are still supplying most of the OPD medicines needed, as seen by 85-95% of all prescribed drugs being dispensed in all facilities visited. Unfortunately, the serious financial difficulties of government have also undermined the Asandha insurance system such that some pharmacies have disengaged from the Asandha. As a result, some patients can no longer get free medicines even though covered by Asandha and other patients are getting their prescriptions copied out in the IGMH – which is unsafe – in order to use the Asandha system.

Concerning recommendations made in the situational analysis in 2013, MFDA has now created a database of all drug imports and for the first time an ABC analysis and price analyses can be done once the data is cleaned. Unfortunately, recommendations to upgrade the central medical store, now the Health Supplies unit, have not been followed. Cost containment measures recommended for the Madhana insurance system have not been followed for the Asandha insurance system which is in severe financial stress.

While procurement and distribution of OPD medicines continues to be managed by the private sector, supply of hospital injectable drugs remains problematic. Government is deciding whether to request STO or

CPU/Health supplies in MOHG to take this on. If STO is requested to this – and they are already expanding their island pharmacies - then more transparency and information sharing with MOHG concerning procurement, distribution and consumption will be needed. Furthermore, the regulation that does not allow private pharmacies to supply hospital injectable drugs would have to be refined to allow STO pharmacies to supply island hospitals directly. If CPU/Health supplies in MOHG is requested to do this, then a great deal of investment in infrastructure and human resources will be needed.

4.12. Medicines Supply: Recommendations

- Employ one diploma pharmacist per region and one advanced certificate pharmacist per atoll hospital to manage drug stock and undertake quantification.
- Establish a unified electronic drug management information system from central level to hospital level, train/supervise the current store keepers to enter the data accurately, and monitor stock levels at both the central and hospital levels monthly.
- Establish SOPs for stock management to cover: storage, receipt and distribution of goods, maintaining documentation, monitoring expiry of medicines and their destruction, and redistribution of medicines to avoid wastage.
- Establish SOPs for procurement to include: clear, transparent supplier criteria and product specifications; in-built quality assurance measures; and 2-stage tendering process.
- Develop a system for annual quantification based on accurate data of past consumption, taking into account stock-out and balance, and which may involve an annual national workshop.
- Establish a supervisory system and budget for undertaking supervision of stock management of all hospitals from the central MOHG, which may involve both the MFDA and the HSD.
- Ministry of Finance and Treasury (MOFT) to promptly pay Asandha and all agencies involved in public sector medicines procurement (whether STO or CPU or IGMH).
- Asandha to introduce urgently more cost containment measures, e.g.
    - Limitation of reimbursement to the national EML and the MRP;
    - Reintroduction of a maximum annual cap.
- Oblige suppliers in the public sector (STO and CPU) to share consumption and stock data with facility in-charges to aid stock management.
- Urgently upgrade the Health Supplies Unit if it is to continue to supply hospital injectable drugs and consumables.
- Refine the regulation on private pharmacies supplying hospital drugs so that they may supply hospitals directly, not through patients.

5. MEDICINE SELECTION

5.1. National Essential Medicines List (EML)

From review of the national EML:

- Responsible government department or agency: Maldives Food and Drug Administration (MFDA)
- Date of publication of latest EML: 2013
- Previous publication date: 2009
- Number of active pharmaceutical ingredients (APIs): 326
- Number of formulations for all APIs: 510
- Number of products (incl. all brand names & formulations) on Approved Drug List: >3000
- Categories by level of use: Primary care - 136 drugs, Secondary care – 88 drugs , Tertiary care – 20 drugs, Specialist use – 57 drugs, National programs (e.g. TB, HIV, malaria) – 53 drugs
    - P, S, T: denotes that the drugs must be available at Primary, Secondary and Tertiary levels respectively i.e. all levels of health care, including health centers, atoll hospitals, regional hospitals and Tertiary hospitals (IGMH and ADK)
    - S: denotes that the drugs must be available at secondary levels i.e. atoll and regional hospitals but not at primary care facilities
    - T: denotes that the drugs must be available at the tertiary level i.e. the Indhira Gandhi memorial hospital (IGMH) and ADK hospital, but not at other hospitals or primary care facilities
    - Sp: denotes that the drugs are for use by specialists only and should therefore be available where the concerned specialist is available and used under the specialist's instruction or guidance.
    - NP: denotes that the medicines is used for the National programs like TB, malaria etc. These medicines should be available as required by the national programs, in public health units at all levels of health care.
- Number of persons involved in drafting the latest EML:
    - Core team: 10 specialists from different areas
    - Experts: 10 core team experts as above, plus 4 additional experts
- Consistency with national STGs? No National STGs for most common conditions

5.2. Other Medicine Lists

Central procurement

The Approved Drug List (of registered drugs) and unregistered drugs are procured. STO procures whatever IGMH requests and this, in turn, depends on the requests of individual doctors. There is no concept of having or following an essential medicines list or hospital formulary. Only the IGMH Medical Superintendent mentioned that some doctor requests were inappropriate. The Central Procurement Unit (CPU) procures hospital injectable drugs and of 125 injectable drug items on the CPU procurement list, 31 (24%) are not on the national EML.

Hospital

Hospitals are only supposed purchase 25 injectable drugs from the hospital IPD list produced by the MFDA. However, all the health facilities visited developed their own hospital lists of sometimes more than 50 injectable drugs. These lists varied from one facility to another even within the same atoll and were developed by nurses compiling lists from whatever doctors asked for. Most doctors had not heard of the national EML.

Primary health care

There is a list of 63 medicines for use by community health workers in islands where there is no doctor. This list was updated in 2013 but the process used to do update it, and whether the few prescribing CHWs are using it, is unknown.

Insurance

The Approved Drug List (of registered drugs) and unregistered drugs are reimbursed by Asandha but from September 2014 this will limited to the Approved Drug List.

5.3. Development / updating of national EML

The national EML of 2013 was developed by a core team of 10 experts in collaboration with the MFDA. The national EML has been endorsed by the Minister of Health and the Pharmaceutical Board. The process with regards to selection criteria, sources of evidence, conflict of interest, transparency and budget is unclear. Between 2009 and 2013, 65 medicines were deleted and 64 medicines added. Two meetings with the core experts were held, during which various additions and deletions were made and then the revised list was sent for comment to national programs and other specialists. Following this, the draft revised EML was compared with equivalent lists used in other countries as well as the WHO model EML and then finalized during two further meetings with the core experts and sent again to specialists for comment. All deleted items were added to the Approved Drug List so that the availability of these products would not be hindered.

The status of the hospital injectable drug list and when it was developed is unclear. Some items such as 25% dextrose, 50% dextrose, 5% dextrose, normal saline, ringer lactate, which one might think important for a hospital to stock are not actually on the hospital list, so patients must purchase these from the pharmacy.

Many of the drugs are being supplied inappropriately to primary health care centres. There is an urgent need to have a list of oral medicines for use in health centres without pharmacies. Commonly stocked non-EML injectables (even in health centres) - all listed under brand names - included avil, buscopan, paracetamol, diclofenac, emeset, perinorm, phenergan, stemetil, rantac, pantoprazole, ceftriaxone, ciplox, gentamycin, ampliclox, ampicillin, augmentin, metrogil, eptoin, hydrocortisone, betnesol, bricanyl, derifphylline, polybion, neurobion, vitamin K, xylocaine, heparin, lasix, inderal, and nifedipine.

The CHW drug list was updated in 2013 but there is no information on the process and who was involved.

Unfortunately, nobody appears to be following the national EML, Asandha and IGMH appear to be resistant to following the EML and few health workers have even heard of it. Thus it appears that dissemination of the EML, and sensitization on its use, appear to have been inadequate and possibly undermined by the political situation.

As in 2011, there are still some medicines on the national EML that are not registered, particularly with regard to the hospital injectable drugs.

5.4. Implementation of the national EML

The national EML was distributed to all health facilities via the HSD/MOHG. However, no national EML was seen in any facility and nobody appeared to be using it. Thus the national EML is not actively implemented by prescribers, health facilities or the Asandha. Most health professionals were not aware of the EML and if they were, they regarded it as a list of the minimum list of medicines that must be present in all facilities, rather than as the maximum list. Even 31 (24%) out of 125 hospital medicines supplied by the CPU/MOHG were not on the EML.

Since virtually all prescribing is done by expatriate doctors, some form of training and introduction to the EML is needed but so far there has been no training so it is not surprising that nobody knows of it. The Faculty of Health Sciences does train Community Health Workers, nurses, diploma pharmacists and pharmacy assistants but even they do not appear to be familiar with the national EML.

There are no previous reports on EML implementation. It appears that neither the % of EML drugs available nor the % of drugs prescribed that belong to the EML has ever been measured. Consumption data were not available at regional/ hospital level, but implementation of the EML was reviewed during the health facility survey by observing stock availability and doing a prescription audit at health facilities.

Prescription review during the situational analysis showed that in public sector OPD about 70-75% of all drugs prescribed belonged to the national EML and in the private sector OPD about 60%, i.e. about 25-30% of drugs used in the public sector and 40% used in the private sector are non-EML drugs. ABC analysis of import data showed that 18 out of the top 24 drugs by value imported into Maldives in 2013 belonged to the national EML. Of the CPU procurement list, 76% of the items belong to the national EML.

Table 5.4.1 shows some indicators relating to implementation of the EML.

Table 5.4.1: EML use from observation and record review in the health facility surveys

Public Referral Hospitals	Hospital 1	Hospital 2			Average
% EML items out of stock*	0/25=0%	3/25=12%			6%
% items that are non-EML					
% prescribed drugs belonging to the EML**	75.0%	76.1%			75.6%
EML available in pharmacy? Yes/No	No	No			0%
Public District Hospitals	Dist. Hospital 1	Dist. Hospital 2			Average
% EML items out of stock*	0/25=0%	5/25=20%			10%
% items that are non-EML					
% prescribed drugs belonging to the EML**	72.6%	72.2%			72.4%
EML available in pharmacy? Yes/No	No	No			0%
Public primary health care centre	PHC 1	PHC 2	PHC 3	PHC 4	Average
% EML items out of stock*	10/25=40%	5/25=20%	5/25=20%	1/25=4%	21%
% items that are non-EML					
% prescribed drugs belonging to the EML**	54.6%	69.7%	83.0%	70.7%	69.5%
EML available in pharmacy? Yes/No	No	No	No	No	0%
Private pharmacies	Pharmacy 1 (in priv. hosp.)	Pharmacy 2 (STO)	Pharmacy 3 (priv. owner)		Average
% EML items out of stock*	-	-	-		-
% items that are non-EML					
% prescribed drugs belonging to the EML**	52.4%	76.1%	55.2%		61.2%
EML available? Yes/No	No	No	No		0%

* Belonging to the national EML – please see also the section on drug supply under drug availability

** From prescription audit done during the health facility surveys

5.5. **Progress / changes / problems** in drug selection since last situational analysis

There is a national EML but it is not actively used or promoted. For the first time a prescription survey was done to estimate the % of prescribed drugs belonging to the national EML. About 25-30% of medicines prescribed in the public sector and 40% of medicines prescribed in the private sector are non-EML medicines. The MFDA has now created a database of all national drug imports but the data needs cleaning and categorizing into EML and non-EML drugs before the % of drug imports that belong to the national EML can be estimated. The EML has been revised in 2013 but unfortunately the prescribers are still not sensitized. Once the cost of non-EML drugs imported into the country and the proportion of all drug costs that are due to non-EML drugs are known, it may be easier to sensitize policy makers of the need for a national EML. The hospital IPD list has not been revised recently and there is no list of oral medicines for doctors to prescribe in health centres with no private pharmacy. The list for Community Health Workers was revised in 2013 although the process is unclear. Supply and use of the CHW list for doctors to use in health centres without pharmacies would be better for most patients than use of the IPD hospital injectables unnecessarily.

5.6. Drug Selection: Recommendations

- Improve drug consumption data, including the MFDA database on drug importation, and also data from STO, CPU, and health facilities, which should be shared with the MOHG, in order to plan better.
- Implement the EML by:
    - monitoring importation and use of EML medicines (% of imported drugs/prescribed drugs belonging to the EML);
    - reimbursement by Asandha of only EML medicines and
    - sensitization of all doctors, especially new expatriates.
- Regularly revise the national EML and improve the selection process by:
    - having written published criteria for selection;
    - having a formal procedure to apply for new drug additions open to all prescribers;
    - publishing reasons for additions and deletions to the EML;
    - having wider representation of prescribers (specialists and general practitioners) including from the regions; and
    - deleting unregistered and non-available medicines.
- Revise the hospital injectable drug list.
- Develop a list or oral drugs for Health Centres without a pharmacy.
- Revise the list of drugs for community health workers in islands where there is no doctor.

6. MEDICINE USE

6.1. Responsible Agents/Departments

Function/ Organisation	MOHG	Other Agency	Name of Agency/MOHG Department
Monitoring medicines use in hospitals	?		MFDA monitors controlled drugs and Health Services Division (HSD) is supposed to, but does not, monitor drug use
Monitoring medicines use in Primary care	?		MFDA monitors controlled drugs and Health Services Division (HSD) is supposed to, but does not, monitor drug use
Development of national STGs	√		Health Services Division (HSD) but no national STGs
Development of national formulary	√		MFDA maintains an Approved List of registered drugs but there is no national formulary manual
National Drug Information Centre	√		MFDA wants to start a National Drug Information Centre
Provision of independent drug information			No independent drug information is provided officially. Doctors may search online for information
Monitoring Hospital DTCs	√		HSD has responsibility, but there are no DTCs
Monitoring Hospital quality of care	√		Quality Assurance Improvement Section, HSD, but no monitoring
Monitoring DTCs in provinces/districts	√		Quality Assurance Improvement Section, HSD, but no DTCs
Undergraduate education for health professionals		√	Faculty of Health Sciences, University of Maldives
Continuing medical education for health professionals	√	√	Faculty of Health Sciences runs some post graduate courses and refresher training courses (at MOHG request) for nurses & paramedics
Public education on medicines use	√		Centre for Community Health Disease Control (CCHDC) and Health Protection Agency do public education, but no public education on prudent use of medicines yet done.
Implementing generic policies			No generic policies, although MFDA has developed a concept paper on generic policy for inclusion in the national medicines policy

6.2. Past prescription surveys

Only one previous prescription survey done in the last 10 years was identified – the one done during the situational analysis of 2011, results shown in table 6.2.1.

Table 6.2.1: Results of situational analysis prescription survey done in 2011

Indicators	Holloway KA. Pharmaceuticals in Health Care Delivery: Situational analysis. WHO/SEARO, 2011.
Year of survey*	2011
Facility type	2 public hospitals; 3 primary healthcare centres (PHC); 3 private hospitals/clinics
Public / private	5 public facilities and 3 private ones
Average number of drugs per patient	Public Hospital: 3.4; public PHC 3.0; Private hospital/clinic: 3.2
% patients prescribed antibiotics	Public Hospital: 43%; public PHC 35%; Private hospital/clinic: 26%
% patients prescribed injections	Public Hospital: 9%; public PHC 8%; Private hospital;/clinic: 4%
% drugs prescribed by generic name	Public Hospital: 3%; public PHC 2%; Private hospital;/clinic: 0%
% prescribed drugs belonging to the EML	-
% URTI patients prescribed antibiotics	-
Average cost per prescription (MVR)	Public Hospital: 269; public PHC 99; Private hospital/clinic: 166 MVR

* Year of survey refers to the year the survey was done not the publication date of the report;

6.3. Current prescribing practices

A prescription survey was done reviewing 30 prescriptions from general practitioners on the day of the visit to each facility. Care was taken to select only primary care type cases in the hospitals. In addition, 30 prescriptions for upper respiratory tract infection were reviewed. Data was collected from both prescriptions in the nearby pharmacy serving the facility and also from the outpatient registers. In some facilities data was collected from both the patient register and prescriptions in the nearby pharmacy, in which case an average was calculated for each indicator for prescribing in that facility. The prescriptions generally recorded both diagnosis and medicines. Most OPD patient registers also recorded both diagnosis and medicines but not in IGMH.

Table 6.3.1 shows the results of the prescription survey done during this situational analysis.

Table 6.3.1: Results of the 2013 situational analysis prescription survey

Public referral hospitals	Hospital 1	Hospital 2			Average
Average number of drugs per patient	3.13	3.77			3.45
% patients prescribed antibiotics	25.0	43.3			34.2
% patients prescribed injections	6.3	10.0			8.2
% patients prescribed vitamins	31.3	73.3			52.3
% drugs prescribed by generic name	24.0	21.2			22.6
% prescribed drugs belonging to the EML	75.0	76.1			75.6
% URTI patients prescribed antibiotics	27.3	61.5			44.4
Average cost per prescription	168.31	155.48			161.90
% patients prescribed analgesics	56.3	36.7			46.5
Public district hospitals	Dist. Hospital 1	Dist. Hospital 2			Average
Average number of drugs per patient	2.59•	3.91•			3.25
% patients prescribed antibiotics	6.9•	23.3			15.1
% patients prescribed injections	8.8•	16.9•			12.9
% patients prescribed vitamins	20.6•	30.0			25.3
% drugs prescribed by generic name	37.0	24.1			30.6
% prescribed drugs belonging to the EML	72.8•	72.2			72.5
% URTI patients prescribed antibiotics	5.0	63.3			34.2
Average cost per prescription	88.68	96.55			92.62
% patients prescribed analgesics	60.0	56.7			58.4
Public primary health care centres	PHC 1	PHC 2	PHC 3	PHC 4	Average
Average number of drugs per patient	3.23	2.97	3.13	2.73	3.02
% patients prescribed antibiotics	16.7	33.3	23.3	23.3	24.2
% patients prescribed injections	10.0	33.3	20.0	6.7	17.5
% patients prescribed vitamins	53.3	30.0	56.7	46.7	46.7
% drugs prescribed by generic name	8.2	32.6	12.8	13.4	16.8
% prescribed drugs belonging to the EML	54.6	69.7	83.0	70.7	69.5
% URTI patients prescribed antibiotics	31.3	53.3	44.7	63.3	48.2
Average cost per prescription	60.59	-	-	127.32	93.96
% patients prescribed analgesics	53.3	56.7	40.0	46.7	49.2
Private-for-profit pharmacies	Pharmacy 1 (in priv. hosp.)	Pharmacy 2 (STO)	Pharmacy 3 (priv. owner)		Average
Average number of drugs per patient	3.86	3.1	2.56		3.17
% patients prescribed antibiotics	64.9	39.3	29.3		44.5
% patients prescribed injections	8.1	17.9	0		8.7
% patients prescribed vitamins	32.4	17.9	19.5		23.3
% drugs prescribed by generic name	2.8	15.9	0		6.2
% prescribed drugs belonging to the EML	52.4	76.1	55.2		61.2
% URTI patients prescribed antibiotics	50	-	58.3		54.2
Average cost per prescription	166.78	165.57	102.03		144.79
% patients prescribed analgesics	-	-	39.0		39.0

•data calculated from both the patient register and the pharmacy in the hospital compound

Overall patients received three or more medicines on average per consultation and most prescribing was by brand name in all types of facility, the same as in 2011. Public sector prescribing in the islands tended to include more antibiotics, injections and vitamins in comparison with Male. In the private sector there was greater use of antibiotics and non-EML drugs and less prescribing by generic name in comparison with the public sector. Non-EML medicines constituted about 25-30% of medicines in the public sector and 40% of medicines in the private sector. In the public sector, while use of antibiotics appeared to have decreased slightly, use of vitamins and injections had increased in comparison with 2011. Medicine costs per prescription remained similar to 2011 levels. Antibiotic use for upper respiratory tract infections was 34% - 48% in the public sector and 54% in the private sector and this is high considering most of these infections were coughs and colds not requiring any antibiotic at all.

About half of all patients received an analgesic, mostly paracetamol. Since paracetamol and diclofenac account for the 4th and 5th highest amount by value of medicines imported, it may be reasonable to see if all this analgesic use is warranted, particularly since every patient is receiving on average more than three medicines.

These results indicate widely differing prescribing patterns between facilities and considerable inappropriate prescribing, worse in the private sector and in the islands with overuse of injections, antibiotics and vitamins. While antibiotic use has not increased, injection and vitamin use has, and is inappropriately high particularly in primary care facilities. The third highest expenditure on medicines (ABC analysis of import data 2013) was for multivitamins and vitamin B Complex so this represents a huge waste of resources.

On discussion with prescribers, most hospital general practitioners saw about 25-35 patients per day although the IGMH general practitioners said they saw up to 50 patients per day and specialists said they saw about 20 patients per day. In some health centres with no pharmacies only 5 or less patients per day came. Thus most doctors are not overworked and have time to undertake appropriate prescribing.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

All OPD dispensing was done by private pharmacies and none in any public health facility.

6.4.2. Health Facility Inpatients (wards)

Hospital injectable medicines were generally kept in an emergency trolley. Sometimes controlled drugs were also in the trolley, which was not locked. Generally each ward had about 5 vials of each injection type stored in the open plastic packing “trays” generally used inside the cardboard packing that vials are packed in when coming from the factory. Sometimes, the vials in their plastic “trays” were stored in an orderly manner on the emergency tray but sometimes the “trays” were all piled one on top of another in a box. Expired vials were sometimes observed stored side by side non-expired ones. Other medicines, oral and injectable, which were purchased by patients from the pharmacy were stored in separate boxes, one for each patient. If a patient required a drug from the emergency tray, then after use, a request would be

made to replace it from the hospital store. However, the inventory sheets did not always record in the incoming and outgoing vials.

6.4.3. Private pharmacies

Private pharmacies did all dispensing for public OPD prescriptions. Even though there appeared to be sufficient staff, most patient-dispenser interaction time was less than one minute with minimal instruction given to patients. Most observed OPD dispensing was done by private pharmacies which had computer systems with portals linking directly to Asandha system. Prescriptions were kept to send to Asandha. For those pharmacies that were not serving Asandha patients, prescriptions were not kept. Some pharmacies may not have a computer in which case a prescription audit could only be done by observing patients as they come to get their medicines.

All pharmacies visited had a registered pharmacist present and most had good storage of medicines. One island pharmacy was closed down during the field visit because of poor storage conditions although it was already in the process of closing down.

No proper labelling was used. Slips of paper on which dosing instructions were written were stapled to most strip packs of tablets or capsules or instructions were written on the bottle.

6.5. Policies to promote rational use of medicines

6.5.1. Monitoring and supervision of prescribing/dispensing

No monitoring, prescription audit or drug utilization review has been or is being done. The Quality Assurance Section in HSD/MOHG is in charge of quality of services which should include stock management of medicines as well as prescribing, but no inspection had been organized to any island facility since 2006 due to lack of budget. Previous to that joint inspections with the MFDA had been done and it was suggested that perhaps future joint inspections could be organized.

6.5.2. Standard Treatment Guidelines (STGs)

There are no national standard treatment guidelines covering the majority of conditions. There are a few guidelines for the vertical disease control programs.

6.5.3. National Formulary

There is no national formulary manual.

6.5.4. Drug Information Centre

There is no national drug information centre.

6.5.5. Independent drug information

Independent drug information is not distributed by MOHG. Some individual doctors used the internet to search for information. Some doctors in Male are visited by medical representatives who have been known to give free samples of unregistered medicines.

6.5.6. Drug and Therapeutics Committees

There are no Drug and Therapeutic Committees and most doctors did not understand the need for them since private pharmacies supply all the medicines. Even when discussing the problems of stock-outs for inpatient injectable drugs few doctors had thought about how they might ease the supply chain management problems by all of them agreeing on a common list instead of having a greatly expanded list based on each individual doctor's preference.

6.5.7. Undergraduate education on medicines use

There is no medical school in Maldives so all doctors are trained overseas, most of them expatriate. Thus there is no medical faculty to teach prescribing principles at undergraduate or postgraduate level.

The Faculty of Health Sciences, University of Male, runs the following courses:

Nursing: Enrolled nurse – 1 year; Diploma nurse – 3 years; these courses can be followed up with a further 2 years for Bachelor of Nursing; and various postgraduate specialty nursing courses exist e.g. midwifery. A diploma nurse receives 40 hours pharmacology training but is not allowed to prescribe except on standing orders.

Community primary health care workers: advanced certificate, which can be followed up with various courses e.g. health management. Community health workers are taught to prescribe using a limited list of drugs but they are doing very little prescribing since doctors have taken over this function even in remote islands. Furthermore, the status of the limited list of medicines for them to use is uncertain. Most of the CHWs get jobs under the CCHDC or HPA to undertake public health activities such as vaccination maternal child health and many later go into hospital management.

Pharmacy: Advanced certificate (to become a pharmacy assistant) – 1 year; Diploma (to become a pharmacist) – 2 years. A new Bachelor of Pharmacy 3-year course is about to start. These students are taught about stock management, pharmacy law and good pharmacy practice. They get about 150 hours on pharmacy law including practical sessions. The MFDA asked if some of these students could be assigned to the MFDA for short assignments. Unfortunately, some diploma pharmacists are unable to find jobs in the public sector on qualifying even though there is a great need for their services in running hospital pharmaceutical services. The STO is sponsoring some advanced certificate level students whom they hope will work in their expanding system of island pharmacies.

6.5.8. Continuing Medical Education on medicines use

Continuing medical education (CME) is absent or extremely adhoc for most doctors. In IGMH medical seminars are organized for junior doctors by senior doctors and some specialists go to international conferences. In some of the regional and atoll hospitals, some doctors meet to discuss cases occasionally. Outside of Male there is no formal CME though some doctors get prescribing information on-line. There is no accreditation system nor any orientation program for new doctors although this has been suggested previously.

Refresher training is sometimes organized for nurses and CHWs by the Faculty of Health Sciences upon request of MOHG.

An orientation program and examination for new expatriate pharmacists is organized by the MFDA with the Faculty of Health Sciences marking the examination. However, there is no CME for pharmacists.

The Medical and Nursing Councils are mainly concerned with vetting the qualifications of new doctors and nurses, respectively, coming to work in the Maldives, issuing licences and investigating a few negligence cases every year. The Maldives Board of Health Sciences governs all health professionals, including pharmacists, but with the exception of doctors, nurses and dentists. Like the councils, they are mostly concerned with vetting foreigners' qualifications, licensing and investigating negligence cases. The Nursing council and Maldives Board of Health Sciences are also involved in setting standards and curricula content in the Faculty of Health Sciences.

6.5.9. Public Education on the safe and prudent use of medicines

A program on antibiotic awareness was recently done in collaboration with the HPA. Currently messages on purchasing medicines and antibiotic awareness are being given through the internet of the Ministry of Health. Awareness messages on antibiotics, in the form of pamphlets, were also sent to pharmacies, clinics and IGMH to be made available to the patients/public. However, no wider public education campaigns on prudent use of medicines, involving the media, have been done.

Public education messages in the past have generally been on traditional maternal and child care run by the CHW program under Health Protection Agency (HPA) and the vertical disease programs run by the Centre for Community Health Disease Control (CCHDC). The recent decentralization initiative with Regional Health Corporations severely disrupted community health services which came under the control of the hospitals. Although this system is now disbanded and CHW programs are again run by the Health Protection Agency and the CCHDC, some functions (e.g. vaccination and antenatal care) have been taken over by hospitals, partly due to patient demand for doctors and specialists. Many of the CHWs thus go into management. Some people said that there are now no longer community services. Nevertheless patient demand for medicines is high and prescription-only drugs can be bought easily without prescription so there is a need for a public education campaign on appropriate use of medicines.

6.5.10. Generic Policies

Generic substitution is allowed and has been sometimes done to reduce medicine costs. However, with the abolition of the annual per capita expenditure cap in Asandha, there is no incentive for insured patients to have lower costing brands. Almost all prescribing is by brand name. MFDA has developed a concept paper on generic policy for inclusion in the national medicines policy.

6.6. Progress / changes / problems in medicines use since last situational analysis

Inappropriate, irrational use and overuse of medicines continues unchanged since 2011. Overuse of vitamins and injections is worse. Very few of the recommendations made in 2011 have been implemented. Thus there is no monitoring of prescribing, no clinical guidelines, no hospital DTCs, no CME on prescribing for doctors and no public education on prudent use of medicines. Recommendations have not been implemented partly because of political instability but mainly because a responsible unit in MOHG for these many functions has not yet been identified. However, some of the recommendations should not be too difficult to implement and are urgently needed.

6.7. Medicines use: Recommendations

- Monitor drug use through:
    - Improved analysis of data from importers and port inspection;
    - Prescription audit in all health facilities, which could be done by a diploma pharmacist employed in each regional hospital (as recommended under drug supply);
    - Some monitoring from the central MOHG, perhaps joint inspections by the MFDA and the Quality Assurance section/HSD.
- Develop, update and implement Standard Treatment Guidelines (STG) for the majority of common conditions, which should be:
    - Disseminated to every doctor;
    - Incorporated into CME/CPD;
    - Done by HSD and MFDA jointly.
- Establish Drug and Therapeutic Committees (DTC) in the IGMH and all regional hospitals and require them to monitor drug use, encourage CPD, and report annually on activities to MOHG/MFDA:
    - a program may be started in the IGMH immediately and then extended to all the regional hospitals;
    - HSD and MFDA may work jointly on this.

- Establish continuing professional development (CPD)/continuing medical education (CME) that:
    - incorporates prescription audit with feedback and ethics;
    - includes an orientation an orientation program on prescribing and the EML for new expatriate doctors;
    - may be facilitated by the Maldives Medical Association, Maldives Medical Council and a credit system for CME, incorporation of prescription audit and feedback and ethics into CPD.
- Establish a national Drug Information unit in MFDA to provide independent information for doctors.
- Organise Public Education:
    - Through the HPA health education unit and the media;
    - Incorporating core pharmaceutical messages e.g. does my child need more than one drug? Antibiotics are not need for the common cold!

6. MEDICINE REGULATION

7.1. Responsible Agents/Departments

Regulatory function	DRA	Other Agency	DRA/MOHG department/Name of Agency
Drug Schedules	√		MFDA/MOHG
Licensing & Inspection of drug outlets	√		MFDA/MOHG
Drug registration	√		MFDA/MOHG
Pharmacovigilance	√		MFDA/MOHG
Drug quality testing	√		National Health Laboratory/MFDA/MOHG
Drug promotion	√		MFDA/MOHG – but not done
Drug pricing	√		MFDA/MOHG – in collaboration with Ministry of Economic Development
Health professional licensing/accreditation		√	Medical Council, Nursing Council, Maldives Board of Health Sciences, all under MOHG
Health facility/hospital licensing/accreditation		√	Quality Assurance Improvement Section, HSD, MOHG

7.2. Pharmaceutical sector

From discussion with national drug regulatory authority

- Number of products on the market: 3109 products in the Approved Drug List (ADL);
- Number of manufacturers: 0;
- Number of wholesaler outlets: 15;
- Number of retailer outlets: 198 (79 in Male and 119 in the islands);
- Number of blood outlets: 2 (one in IGMH and the other run by Maldives Blood Services).

Table 7.3.1 summarises the medicines legislation.

7.3. Current Medicines Legislation[1] (key documentation)

Table 7.3.1: Summary of medicines legislation

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
Medicines Act – law on import to, and sales of, medicines in Maldives	1994
Redrafted Medicines Act pending since 2006	

b) Coverage: *indicate with Y (Yes) or N (No)*

Area / Activity Covered?	Y/N	Document Name
Establishment & functioning of National MRA	Y	MFDA assigned and established by a presidential decree with a mandate
Medicines marketing authorisation	Y	The mandate plus medicines regulation cover marketing authorization and how products should be gazetted
Medicines scheduling	Y	Regulation
Licensing of medicines handling premises, personnel & practices	Y	Mandate and medicines regulation
Licensing of prescribers	Y	HSD
Mandatory CME for prescriber licence renewal	Y	HSD
Licensing of pharmaceutical personnel	Y	MBHS
Mandatory CME for pharmacy licence renewal	N	MBHS/MFDA
Regulatory inspections/ enforcement activities	Y	MFDA: Mandate and Regulation
Medicines quality	Y	MFDA: Mandate and Regulation
Medicines packaging & labelling	Y	MFDA: Mandate and Regulation
Medicines promotion	Y	MFDA: Mandate and Regulation
Post-market surveillance/ pharmacovigilance	Y	MFDA: Mandate and Regulation
Collection of fees	Y	MFDA: Mandate and Regulation
Clinical trials	N	Clinical trials not done
Generic substitution	Y	MFDA Regulation – that generic substitution cannot be done – although it is done
TRIPS-related issues	N	Ministry of Economic Development deals with TRIPS and IP issues
Transparency & accountability[2]	N	
Banning of unsafe medicines	Y	MFDA: mandate and regulation

[1] Medicines regulation issues may be covered in more than one law and may have multiple associated regulations, so ensure that all relevant documentation is identified & obtained for review.
[2] Includes provisions for the MRA to define and publish its policies and procedures, publicly account for its decisions, conduct and actions, and follow a regulatory code of conduct.

7.4. National Regulatory Authority for medical products

- Name of National Drug Regulatory Authority: Medicine and Therapeutic Good Division, Maldives Food and Drug Administration (MFDA)

- Total number of technical staff:
    - 5 pharmacists (diploma);
    - 8 pharmacy assistants (advanced certificate);
    - 2 senior public health program officers;
    - 2 non-technical staff.

- Website address: http://www.mfda.gov.mv

- Number of quality-control (drug testing) laboratories: 1 (National Health Laboratory)

- Annual Report of MFDA 2013 (in local language)

- Budget: MVR 15,134,659

- Written SOPs for the following key regulatory procedures?

Key procedure	Written SOP? (Yes/No)	SOP Seen? (Yes/No)
Product dossier evaluation	Yes	English, Dhivehi
Registration of medicines	Yes	English, Dhivehi
Inspection of manufacturing premises	Yes	Dhivehi - only for herbal medicines
Inspection of retail premises	Yes	Dhivehi
Sampling for Quality Control testing	Yes (guideline)	English
Medical product recall or withdrawal	Draft	English

- Position in hierarchy of government structure (e.g. under MOHG or independent)? Under MOHG

- Decentralised capacity?
    - There are no branch offices and inspection of island pharmacies is outsourced to island CHWs at the request of the MFDA, at least once a year, using a checklist.

7.5. Drug Schedules

There are 3 schedules – over-the-counter medicines (OTC), prescription-only medicines (POM) and controlled medicines including narcotics. In practice both OTC and POM drugs, but not controlled drugs, can be easily bought over-the-counter. Ordinary shops can sell OTC drugs but only pharmacies staffed by a pharmacy assistant can sell POM drugs. Pharmacies are not allowed to sell controlled drugs or injectables on the hospital IPD list. No pharmacist has been punished for selling POM drugs without prescription. It is not clear when the drug schedules were last revised.

The following categories exist in the Approved Drug List (ADL) of registered drugs all of which have had completed dossier evaluation:

1) Over the counter(OTC): 222 products
2) Prescription only medicine: 2494 products
3) Hospital use only: 161 products
4) Hospital and institutional use only: 10 products
5) Controlled drugs (psychotropic and Narcotics): 110 products
6) National program: 112 products.

7.6. Regulation and inspection of drug outlets

All pharmacies are inspected annually. The MFDA registers pharmacies according to set criteria and documentation and regularly updates the list. The MFDA has 5 pharmaceutical officers who inspect the 79 pharmacies in Male (as well as doing other routine work), but CHWs generally inspect the 119 island pharmacies at the request of the MFDA, which has no budget and insufficient staff to visit all island pharmacies. A checklist is used and pharmacies are regularly closed down for poor stock management or absence of license – including one pharmacy during the field visit of this situational analysis. There is no limit to the number of pharmacies that may be opened, only what the market will bear, and so the density in Male is high. However, the more pharmacies are opened the greater the inspection workload. In the first half of 2014, 63 pharmacies have been inspected by the MFDA and 55 pharmacies by island CHWs. By the end of 2013 there were total of 312 pharmacies (94 in Male' region and 218 in islands) but 114 pharmacies were removed during an updating of the list of licensed pharmacies at the beginning of 2014, mostly because they had already closed down but some because they had been found to be non-compliant with the regulations.

A major function of the MFDA is inspection and clearance of imported pharmaceuticals at the sea and airports where there are 5 full-time dedicated inspectors. Since 2011, responsibility for food inspection has been transferred from the MFDA to the HPA. A set procedure with checklist is used. The system is unchanged since 2011. "All imports should officially be registered and all the papers, including the import license, bill of laden, certificate of origin and invoice, should be in order. The importer must inform the customs 24 hours in advance of the goods arriving. Once all goods have arrived and the papers checked, then an inspection team is assembled consisting of the national security officer, a customs officer, the MFDA inspectors and the importer. The container is then opened in everyone's presence and a random selection of 5% of the cartons examined and contents checked. In each carton opened, a further 5 % of the contents (bottles, packets) are visually inspected to check the drug name, batch, expiry date, company name, dosage and strength and whether there has been any damage e.g. leakage. If any problem is found,

more bottles/packets and cartons are checked." (Holloway KA 2011). In 2013, of 21470138 amount of medicines (3087676.1 kg) released into the market, 648847 (3%) was permanently held by the MFDA for destruction due to various reasons such as degradation or wrong documentation (MFDA annual report 2013). There was no analysis of the reasons for failure and goods being permanently held and it was difficult to follow the paper trail on decisions with regard to temporary holding by the MFDA. It is not clear how unregistered products and controlled drugs are dealt with at the ports.

Since 2011, the MFDA have kept a database of details on all pharmaceuticals imported. The database needs some cleaning and would benefit from having 'drop-down' menus developed for data-entry to avoid spelling errors. Nevertheless, the database has now allowed ABC analysis of total drugs imported in 2013 and can be used to analyse unit prices, expiry dates, and volume of business by importer for the very first time.

7.7. Drug Registration

The Pharmaceutical Board decides upon, and is responsible for registering drugs and the Medicines Regulation Unit (of one staff) within the Medicine and Therapeutics Division of the MFDA evaluates the dossiers. In 2013, 204 dossiers were received for evaluation, of which 162 were evaluated and 2 subjected to further evaluation (MFDA annual report 2013). All registered products must be registered with a stringent regulatory authority such as the USA, UK, Canada, Australia, and Thailand. Most drugs registered in India and Sri Lanka also gain acceptance in Maldives, even though some may be of substandard quality. There are now written SOPs and also a process for temporary registration for new products. If a product passes temporary registration 3 times, it will be added to the ADL.

Despite some progress, there are still unregistered drugs entering the country. While the market is too small to attract wholesalers or manufacturers to register some lesser used medicines, there are more than 20 brands for some of the commonly used products, which was felt to be too much but the Board has no way of limiting registration of different brands of drugs already on the market if the quality of the concerned new brand is satisfactory. Wholesalers do not have any incentive to register little used products not only because of the small market but also because after all the work of registering a drug they do not have the sole importation rights. MFDA is discussing with the Ministry of Economic Development how to change this and give the importer who registers a drug sole importation rights for at least 1 year. The registration fee is very small – 350 MVR – which goes straight to the Treasury.

7.8. Pharmacovigilance

The Monitoring and Surveillance Unit (1 staff) in the Medicine and Therapeutics Division of the MFDA is in charge of pharmacovigilance and covers ADR monitoring, unexpected lack of efficacy, quality defects and medication errors. Unfortunately, despite some announcement in the gazette, doctors have not been sensitized in a face to face manner and only one ADR has been reported in the last 3 years (and only 3 ADRs before that). It was mentioned that all the ADRs so far reported have, in fact, been fact side-effects. The MFDA is an associate member of the WHOCC/Uppsala Global ADR reporting network. SOPs are currently being drafted. In addition 5 products have been recalled in the past 3 years due to low quality.

7.9. Drug Promotion

There is no monitoring of drug promotional activities and no designated unit or assigned staff. Outside Male, there is very little drug promotion but within Male drug representatives do visit doctors and have been known to give out free samples of unregistered drugs. Pre-approval of adverts for OTC medicines is required and should be done by the MFDA. The Health Promotion Unit within the Health Protection Agency has some role in monitoring this although the exact relationship between the HPA and MFDA over this is unclear.

7.10. Drug Price controls

Although the Ministry of Economic Development has a price control mechanism established by Presidential Decree, nobody follows it and there is not penalty for not following it. Therefore, currently, prices are set by manufacturers and importers. However, the MFDA is working with the Ministry of Economic Development to set a Maximum Retail Price. The IGMH negotiates with STO through an MOU concerning the prices it pays for drugs and consumables. According to limited price comparisons done in 2013, some imported drugs have unit costs at importation below the international reference prices which calls into question the quality of such drugs (UNOPS 2013). Many drugs have a mark-up of over 100% from import cost price to the price used in sales to patients.

7.11. Drug Testing Laboratories

There is one drug testing laboratory, the National Health Laboratory, which has tested 46 samples so far in 2014, with no substandard medicines detected. Two staff work in the laboratory. There are SOPs for all procedures, including sampling, and a quality manual. Key procedures are computerized.

In 2013, the following quality problems were found, although not through the laboratory, leading to a recall of the products:

- IV Fluids of Baxter Company were found to have foreign particles in the fluids, found to be due to fungus growth; this was later found to be caused by damage to the plastic bottles while in transit, as the company had used bottles suitable for domestic consumption rather than export, which requires stronger bottles.
- Ultop injections 40mg of Labon laboratory had a change in colour.
- Dinaprostone gel (primigin) had complaints from health facilities of low effectiveness.
- Cotem – 2 batches – due to a WHO analysis report that showed absence of API.
- Tyno 120mg cough syrup – due to a WHO alert that showed the product was contaminated with dextromethaphine; (The product is not in the ADL but can be imported).

7.12. Licensing and accreditation of health professionals

The Maldives Medical Council (MMC) licenses doctors, the Maldives Nursing Council (MNC) licenses nurses and the Maldives Board of Health Sciences (MBHS) licenses all other health professionals, including pharmacists. All the councils and the Board are under the MOHG and are not independent. The annual registration fee for all expatriates is MVR 150 per year and for Maldivians MVR 150 once only. All monies received go to the treasury so there is very little money to reimburse the time of members investigating the qualifications of expatriate professionals seeking employment. It was also mentioned that communication concerning negligence cases is poor between hospitals so a person dismissed in one hospital has been able to find employment in another. All the councils are mainly concerned with licensing and there is no system of accreditation for any professional.

7.13. Licensing and accreditation of health facilities and pharmacies

Private pharmacies are granted licenses by the MFDA and private clinics and hospitals by the Quality Assurance Section in the Health Services Division, according to set criteria. In the case of private clinics the criteria cover things such as physical structure, staffing, fees, water and sanitation but not drug management. The MFDA is quite strict in enforcing compliance, ensuring that every pharmacy is visited once per year in order to retain its license. The Quality Assurance Section in the Health Services Division stated that they had no budget for undertaking supervisory visits or inspections, which they had not been able to do outside of Male since 2006, so it is unclear how well they can enforce compliance with quality criteria, particularly in private facilities outside of Male. For public sector facilities, there appears to be no need for licenses, there is no system of accreditation, and supervisory visits are not generally undertaken to check for quality of services.

7.14. **Progress / changes / problems** in medicines regulation since last situational analysis

The MFDA has made much progress in the last 3 years, having developed SOPs for most procedures, developed a database on drug imports and maintained annual inspections of all pharmacies. Unfortunately, there has been no progress with regard to improved pharmacovigilance or establishing a unit to monitor drug promotional activities – mainly due to lack of resources and staff dedicated for this. The problem of importation of unregistered drugs remains although a new system of temporary registration has now been started. A new Medicines Act giving the MFDA more authority and independence has still not been passed and this is a barrier to making more progress since such an Act is needed to implement regulations and introduce more control and punitive measures.

Specific actions taken by the MFDA include:

- Redrafting of the Medicine Act (in process);
- Recruitment of three advanced-level pharmacy staff although 5 more staff are still needed to do medicine regulatory and enforcement tasks;
- Setting a pharmacy diploma as the minimum entry criteria to do regulatory work;
- Submission of a proposal to have one MFDA contract staff at each atoll to conduct pharmacy inspections even though island level CHWs are inspecting the pharmacies and reporting to MFDA;
- Drafting of criteria for reviewing registration of me-too drugs (in process);
- Discussion between MFDA, NSPA and Asandha concerning options to minimize medicines imported for individual prescriptions;
- Pre-authorization by MFDA before importation for all hospital-use medicines – which requires evaluation of the product as well as the manufacturer;
- Development of minimum criteria for one year's registration for those products not yet included in the ADL;
- Formation of a subcommittee, pharmaceutical panel, of the pharmaceutical board;
- Review and implementation of a marketing authorization form;
- Finalization and implementation of a list of reference countries;
- Decision to evaluate all products (including previously inherited products that had not been approved by the Board) and submit them to pharmaceutical board for approval and incorporation into the ADL;
- SOPs for all procedures drafted with some at the final stage and some finalized;
- Mandate and operating procedures for pharmaceutical board established and endorsed by president's office;
- Sensitization programs on ADR reporting via the focal point assigned to IGMH conducted;
- Identification of OTC medicines in the ADL, and development of an OTC list (in process) which will be distributed to all pharmacies;
- Identification of all hospital-use items and inclusion in the ADL, with a requirement that all these products get pre-authorization prior to importation – which will require evaluation of the product and manufacturer by MFDA staff.

7.15. Medicines regulation: Recommendations

- Establish a new Medicines Act required for implementing regulations and introducing more control and punitive measures.
- Strengthen the MFDA by:
    - Increasing the budget and qualified and competent staff;
    - Increasing fees for drug registration, importation licenses, and pharmacy licenses to generate income and allowing the MFDA to retain some of the income generated.
- Improve the registration process and ensure stricter adherence to it by:
    - ensuring that all products imported and sold are approved by the Pharmaceutical Board/MFDA;
    - establishing a committee to review all prescriptions with unregistered products and publishing the number of unregistered products on prescription;
    - de-registering all un-imported medicines; and
    - ensuring that all suppliers are registered with the MFDA.
- Improve and clean the database on importation of pharmaceuticals so as to allow unit price comparisons for pharmaceuticals to calculate MRP on a regular basis.
- Follow up on the recommendations from the 2011 situational analysis which are still relevant:
    - Review the drug schedules to consider whether 3rd and 4th generation antibiotics may be limited to hospitals only, in order to prevent misuse in health centres and the private sector;
    - Improve ADR reporting by running a face-to-face sensitization campaign with all doctors, nurses, CHWs and pharmacists;
    - Establish a system of pre-approval of adverts for all medicines and a system to monitor all promotional activities.
- Refine the regulation on private pharmacies supplying hospital drugs so that they may supply hospitals directly, not through patients (see drug supply recommendations).

8. MEDICINE POLICY AND COORDINATION

8.1. National Medicines Policy

A National Medicines Policy (NMP) document was published in 2007 (MOHG 2007) just before the new constitution of 2008. The NMP described a full set of pharmaceutical polices, with an emphasis on full government involvement in the provision of health care, for example, by recommending a central procurement and supply system and drug price controls. The NMP (2007) had 3 main aims, which were:

i. To ensure that all medicines authorized, imported or locally manufactured, distributed and sold in the Maldives are effective, safe and of good quality.
ii. To ensure that adequate quantities of quality Essential Medicines, based on the needs of the population, are available at affordable cost at all times to the entire population.
iii. To promote rational use of medicines.

There was no national medicines policy implementation plan or budget and now the national medicines policy is being revised.

The decentralised health structure of Health Corporations established in 2010 and disbanded in 2012, severely disrupted and fragmented the medicines supply chain and indeed the authority of MOHG to develop and implement policy in accordance with the NMP or any other central policy. Since the disbandment of the Health Corporation system, the role of MOHG in developing and implementing health policy has been reasserted. Nevertheless, many things with regard to pharmaceuticals were in a state of flux at the time of writing. Thus, government had yet to decide whether drug supply would be managed be STO or CPU/MOHG/UNOPS. Whatever decision is made there is a need for a pharmacist in each region to supervise stock management, monitor consumption and introduce good pharmaceutical care. There are plans to revise the NMP but this has not yet started. Much will depend on what legislation, currently pending in parliament, is passed.

Table 8.2.1 summarises medicines policies in place to promote rational use of medicines.

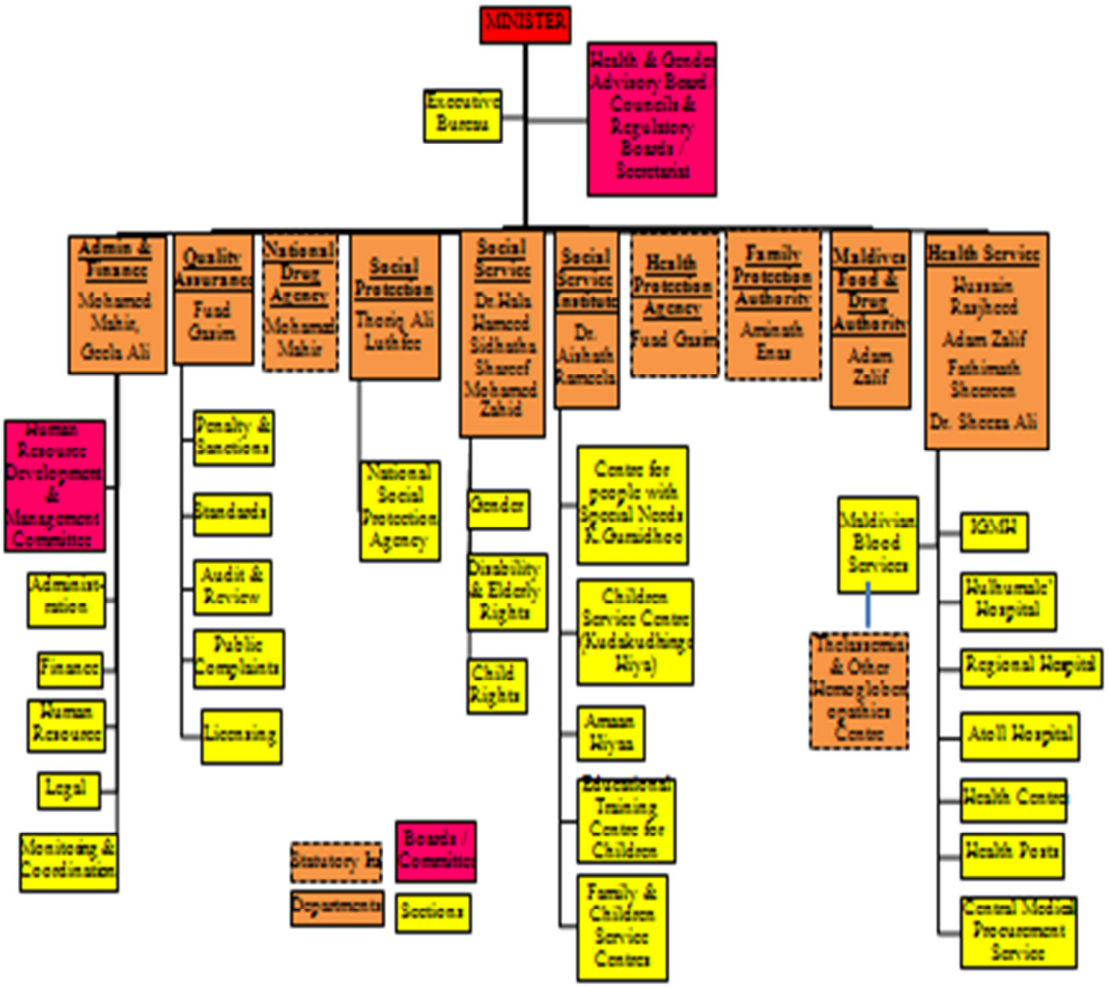
8.2. Summary of medicines policies in place to promote rational use of medicines

Table 8.2.1: Policies in place to promote rational use of medicines

Policy	Implementation status
National Medicines Policy (NMP)	Official document published and endorsed in 2007 but the new constitution in 2008 and health structure in 2010-12 went in a direction contrary to the NMP. Now NMP is to be revised.
National Essential Medicines List (EML)	National List 2013 exists but nobody is using it
National Standard Treatment Guidelines (STGs)	No national STGs (apart from some STGs for the vertical disease control programs)
National Formulary manual	None
National government unit dedicated to promoting rational use of medicines	None
Monitoring medicines use	No monitoring of medicines use
Drug and Therapeutic Committees (DTCs)	No DTCs in any hospital or at the national level
National Drug Information Centre (DIC)	None
Generic Policies	Generic substitution in the public sector although it is officially illegal
Health insurance	Public health insurance does cover all the population.
Payment for medicines by patients	All medicines must be paid for either out of pocket or through insurance reimbursement.
Pricing policies	No pricing policies used in either the public or private sectors
Provider revenue from medicines	Never used to pay salaries in the public sector
Undergraduate training on pharmacology & prescribing	There is no medical training but the national EML and prescribing are part of the CHW curricula
CME training on pharmacology & prescribing	Very little CME in Male and none outside Male
Public education on medicines use	No wide public education campaigns involving the media on prudent use of medicines ever done
Pharmacovigilance	Only 4 ADRs ever reported to the MFDA
Regulation of drug promotion	Drug promotion not monitored or regulated
National strategy to contain Antimicrobial Resistance	No national strategy and antibiotics frequently available over-the-counter with prescription
Over-the-counter availability of prescription-only medicines including antibiotics	OTC and POM drug schedules exist but POM including antibiotics may be bought over-the-counter without a prescription

8.3. Coordination of medicines-related policies within the MOHG

8.3.1. Ministry of Health and Gender Organogram



Departments within the MOHG with medicines-related functions include:

- Maldives Food and Drug Agency (MFDA) – regulation of medicines and medical products;
- Health Services Division (HSD) – regulation of public health facilities;
- Health Protection Agency – organization of public education;
- Administration and Finance – management of human resources and budget;
- Social Protection – management of Asandha reimbursement of medicines;
- Quality Assurance – management of health professional licences, including pharmacists and doctors.

8.3.2. Coordination of medicines policy during recent decentralization and recentralization

Many lessons have been learnt from government restructuring and the decentralisation of health care during 2009 – 2012. In this restructuring seven Regional Health Corporations were established to run health care, financed by MOFT, with MOHG having regulatory/policy role only. This policy fragmented Health services, disrupted drug supply and did not work. The health promotion units under MOHG/CCHDC were moved into separate premises and their antenatal and vaccine work taken over by corporations. This policy undermined health education work of these units and did not work.

While disbandment of the decentralised health corporation system has given back MOHG its coordinating and policy forming role, there are still serious gaps. Following the new constitution in 2008, a new Public Health Act was passed in 2010, covering communicable diseases, vaccination, food safety, but a new Medicines Act, Food Act, Health Professionals Act, Health Services Act and an overarching Health Act is still needed. Another gap is the almost total lack of qualified pharmaceutical human resources for supply chain management in public sector, leading to very serious problems in stock management and quantification. There are a number of problem policies which require coordination between different departments within the MOHG but there is no coordinating mechanism to manage decisions on these matters.

Problem policies requiring coordination between different departments within the MOHG include:

- Island HCs without pharmacies need PHC drugs, not hospital ones, and a mechanism to receive them from supervising hospitals and this requires intervention from HSD and the Administration Section in MOHG as well as MFDA.
- Supply of hospital injectable IPD drugs currently requires coordinated action by the CPU (under HSD/MOHG supported by UNOPS) and the Health Supplies (under Administration Division/MOHG) as well hospital staff (under both the HSD and Administration Division of MOHG).
- Public education on the prudent use of medicines is urgently needed and requires intervention by the HPA as well as HSD and MFDA.
- National STGs, DTCs, CME, and monitoring of prescribing are all needed and require intervention by HSD as well as MFDA.
- Medicines management is a critical part of quality of care in both public and private health care facilities and ensuring this will require intervention by both the MFDA and the QAD/HSD.
- Good communication between hospitals and the central level MOHG is required to ensure that a health professional dismissed in one hospital does not find employment in another one.

8.4. Other Ministries with medicines-related functions

Other Ministries involved in medicines-related policies include:

- Ministry of Finance and Treasury – provides budget for:
    - human resources and medicines in MOHG;
    - reimbursement of medicines and treatment by Asandha;
    - public sector medicines supplied by STO.

- Ministry of Economic Development – sets rules for:
    - Medicines prices and mark-ups;
    - Importation of medicines, licensing of importers, drug outlets, registration of medicines, etc. which may not always serve the public health interest.
- Ministry of Education – sets training programs and curricula for health professionals:
    - All health professionals excluding doctors through the Faculty of Health Sciences;
    - May not give the same importance to some topics as would the MOHG in determining health service delivery needs.
- Public Services Commission (human resources): decides on the number of posts in MOHG:
    - May not assign posts as MOHG needs e.g. there are no posts for pharmacists in the public sector in the regional and atoll hospitals or even in the MOHG outside the MFDA.

Coordination between the MOHG and other Ministries with regard to pharmaceuticals does not appear to be well managed due to lack of a coordinating unit. Problem policies, requiring intervention by other ministries, include:

- Lack of incentive for importers to register drugs due to small market and no exclusive rights to import after registration but the Ministry of Economic Development does not want to grant any exclusive rights even for temporary time periods.
- Excessive number of pharmacies in Male' but the number cannot be limited as the Ministry of Economic Development does not want to limit competition.
- Lack of private pharmacies to serve the island hospitals – this may change as STO is now expanding its island pharmacies but there will still be a need for drug procurement and distribution data to be shared with MOHG and facilities, which should be possible since STO is 85% publically owned
- Slow payment by Ministry of Finance and Treasury (MOFT) to:
    - Asandha, so resulting in disengagement of pharmacies;
    - STO, so resulting in delayed procurement & higher prices;
    - IGMH, so resulting in late payment to STO.
- Lack of pharmacists in the human resource plan but without them, quantification and efficient procurement sufficiently in advance cannot be done. Faculty of Health Sciences is producing pharmacists but they cannot find employment in the public sector and intervention by government civil service is required to create the posts.
- Ensuring health worker's undergraduate training meets the needs of MOHG requires coordination between the Faculty of Health Sciences, Ministry of Education, and the MOHG; currently there appears to be good cooperation between the MFDA and those training pharmacists and pharmacy assistants.

8.5. **Progress / changes / problems** in medicines policy since last situational analysis

The same problems of coordination within the different departments of the MOHG and between the MOHG and other Ministries were noted in the 2011 situational analysis. None of the recommendations from the 2011 situational analysis have been acted upon. This is not perhaps surprising given the political instability and huge structural changes that have been made and unmade in the health care delivery. Once political stability is achieved, serious consideration should be given to implementing the 2011 recommendations.

8.6. Medicines policy & coordination: Recommendations

- Establish a Policy level statutory committee to advise the president and:
    - to develop coordinated medicines policy across all stakeholders including MOFT, Asandha, HSD, MFDA, Dept. of Economic Development, Ministry of Education and Faculty of Health Sciences;
    - to review and update the 2007 national drug policy;
    - to monitor and evaluate policy implementation; and
    - which would need an executive unit(s) in MOHG (DGHS & MFDA) to do the committee's recommendations.
- Establish an extra unit in the MFDA responsible for promoting rational use of medicines, which would include monitoring of medicines use and coordination of policies to promote rational use of medicines, including:
    - Maintenance of the national EML, development of STGs, establishment of DTCs and monitoring their activities (in coordination with HSD), coordination of continuing medical education, establishment of a national Drug Information Centre, organization of public education (in liaison with HPA), etc.
    - Liaison with Faculty of Health Sciences to provide students to collect information needed by MOHG as part of their research studies.
- Generate MOHG income by raising fees for health professional licences and health facility licenses, as well as drug outlet and drug importation licences and drug registration (see drug regulation recommendations).

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10 . PERSONS MET DURING THE SITUATIONAL ANALYSIS

	Name	Designation and Affiliation
1	Dr.Mariyam Shakeela	Minister of Health
2	Col.Retired Mohamed Nazim	Acting Minister of Health
3	Ms. Geela Ali	Permanent Secretary of Health
4	Dr. Sheeza Ali	DG Health Services
5	Dr Shareefa Adam Manik	DG MFDA
6	Aisath Mohammed	Director MFDA
7	Mohammed Fazeen	Pharmaceutical Officer, MFDA
8	Ubeydulla Thoufeeq	CPU/HSD/Head
9	Ali Akhthamy	CPU/UNOPS/Financial Mgt Analyst
10	Ahmed Misbah	CPU/UNOPS/Help desk & Administrator
11	Aisath Shelna	CPU/Laboratory technologist
12	Ahmed Fazeen	CPU/Logistics Assistant
13	Masood Prasana	CPU/Procurement Assistant
14	Dave Terpestra	UNOPS
15	Mohammed Mazin	Health Supplies/Administrator
16	Sinan Hassan	Health Supplies/Assistant Manager
17	Ahmed Naseem	Health Supplies/Community Health Officer
18	Ashiyath Rasheep	President Nursing Council
19	Husna Ibrahim	Member Nursing Council
20	Hafsa Ali	Member Nursing Council
21	Fathimath Haleem	Member Nursing Council
22	Maryam Nasrath	Member Nursing Council
23	Dr Adam Khaleel	Member Medical Council
24	F Nasheeda Mohammed	Deputy Director, Regulatory Boards & Councils Secretariat
25	Dr Aisath Malifooza	Registrar, Maldives Board of Health Sciences
26	Thooma Adam	Maldives Board of Health Sciences
27	Mariam Shabeen	Matron, Hulhumale Hospital
28	Dr Mohammed Arifum Rahman	Doctor, Hulhumale Hospital
29	Dr Moosa Manik Ibrahim	Chief Doctor, Hulhumale Hospital
30	Mr Hussain Habib	Green pharmacy in Hulhumale Hospital
31	Hussain Sobaah	STO, Assistant General Manager
32	Imad	STO, Manager of pharmacies
33	Abdulla Wisham	STO, Manager of warehouse

	Name	Designation and Affiliation
34	Hamdhoon Faaiz	STO, Planning officer
35	Asiya Ibrahim	Faculty Health Sciences, Head of Nursing
36	Aisath Ahmed Didi	Faculty Health Sciences, Head of Wellness
37	Muthaau Shaheen	Faculty of Health Sciences, Head Public Health
38	Fathmath Sahudha	NSPA, Director
39	Mohamed Ismail Fulhu	NSPA, Project Director
40	Aminath Zeeniya	Asandha, Medical Director
41	Niyaz Mohamed	Asandha, General Manager, claims administration department
42	Khadhaja Mohamed	Asandha, Senior Officer, claims administration
43	Ismail Azzam	World Bank, Project Coordinator
44	Dr Faisal Saeed	ADK hosp, medicolegal &quality assurance
45	Mariyam Nasrath	ADK hospital, Director Nursing
46	Haneefa Abdul Gadin	ADK hospital, Coordinator operations
47	Dr Abdulla Niyaf	ADK hospital, Chief medical officer
48	Mohamed Ali G	ADK hospital, pharmacist
49	Vino Justus	ADK hospital, storekeeper
50	Ahmed Imyan	MFDA, airport
51	Ibrahim Waheed Haassan	MFDA, airport
52	Aisath Jaleela	MFDA, seaport
53	Fathimath Limya	Quality Assurance Section, Asst. Director
54	Hassan Riyaz	Assistant Director, HSD/MOHG
55	Suresh Kumar	IMC private pharmacy
56	Vijay Balaji	Doctor, Villingili HC
57	Mohamed Haneef	Doctor, Villingili HC
58	Fathimath Shizna	Nurse, Villingili HC
59	Aisath Shamla	Store keeper, Villingili HC
60		Pharmacist, STO pharmacy, Villingili
61		Pharmacist, Point pharmacy, Villingili
62	Dr Mohammad Adnam Arshad	Doctor, Hoandedhu HC
63	Mrs Anumal David	Nurse, Hoandedhu HC
64	Bineethe PS	Nurse, Hoandedhu HC
65	Ifasha Shareef	Nurse, Hoandedhu HC
66	Abdal Muhainin	Asst. Manager, Hoandedhu HC
67	Mohamed Fauzee	Deputy Manager, GA Atoll hospital
68	Dr Nathanial	Anaesthetist, GA Atoll hospital
69	Dr Assad Bilal	Surgeon, GA Atoll hospital

	Name	Designation and Affiliation
70	Ahumeena Mohamed	Administrator, GA Atoll hospital
71	Aishath Jumana	Public Relations, GA Atoll hospital
72	Afriza Anees	Chief nurse, GA Atoll hospital
73	Fathuheena Jameel	Medical Records, GA Atoll hospital
74	Mr Rajan	Radar Pharmacy, near GA Atoll hospital
75	Dr Rauf Kamal	Community health officer, Dhaandoo HC
76	Dr Gnana Prakash	Doctor, Dhaandoo HC
77	Aisath Shafeeza	Administrator, Dhaandoo HC
78	Nishan Chandran	Dhaandoo pharmacy (ahmed latheef)
79	Dr Ammar Ahmed	Doctor, Mamendhoo HC
80	Mr Mohamed Nasheed	Administrator, Mamendhoo HC
81	Dr Mohammed Imran	Doctor, GDh Regional hospital
82	Dr Rajesh	Doctor, GDh Regional hospital
83	Dr Jagmohan Singh Rana	Doctor, GDh Regional hospital
84	Dr Akshaya Kumar	Doctor, GDh Regional hospital
85	Dr Mohammad Shafi Khan	Doctor, GDh Regional hospital
86	Dr Khushi Mohammad	Doctor, GDh Regional hospital
87	Dr Nasir Awan	Doctor, GDh Regional hospital
88	Dr Faisal Malik	Doctor, GDh Regional hospital
89	Abdulla Rasheed	GDh Regional hospital
90	Ahmed Shameem	GDh Regional hospital
91	Riyaza Abdulla	GDh Regional hospital
92	Azmeela Hassan	GDh Regional hospital
93	Zimma Rasheed	GDh Regional hospital
94		Pharmacist, STO Pharmacy, GDh Regional Hosp
95	Dr Ali Latheef	Head of Medicine, IGMH
96	Dr Ahmed Migdhaadh	Consultant physician, IGMH
97	Dr Aminath Zeyba Ahmed	Emergency physician, IGMH
98	Dr Mohamed Habeeb	Deputy Executive Officer, IGMH
99	Ms Bishara Ahmed	STO pharmacy chief, IGMH
100	Adam Shabeeb	Finance Officer, IGMH
101	Zeenath Ali Habib	Procurement & media officer, IGMH
102	Dr Yusra Ali	DHAMANA VESHI

10. PARTICIPANTS OF THE STAKEHOLDER WORKSHOP

	Name	Designation and Affiliation
1	Abdulla Wisham	STO
2	Hamdoon Faiz	STO
3	Dr Fathmath Nadhiya	PVT SECTOR
4	Nazha Ibrahim	MALDIVES CUSTOM SERVICE
5	Dr Rizana Abdul Gafoor	IGMH
6	Dr Ali Latheef	IGMH
7	Fathmath Lamya	MOHG/QA
8	Asma Ibrahim	MOHG/HPA
9	Dr Mohamed Ashraf	SENEHIYA, MNDF
10	Manoj Madhavan	ADK COMPANY
11	Mohamed Muzammil	ADK COMPANY
12	Aminath Saeed	MEDICA
13	Aminath Zeeniya	AASANDHA
14	Dr Abdulla Niyaf	ADK HOSPITAL
15	Faisal Saeed	ADK HOSPITAL
16	Ahmed Migdad	IGMH
17	A. Maumoon	LIFE SUPPORT
18	Aishath Ibrahim	NDA
19	Dr Ali Mafaz Rasheed	MNDF
20	Abdulla Sunah	IGMH
21	Mariyam Nazima	IGMH
22	Fathmath Shahuda	NSPA
23	Haneefa Abdul Gadhir	ADK HOSPITAL
24	Abdulla Imad	STO
25	Dr Yusra Ali	DHAMANA VESHI
26	Shareefa Adam Manik	MFDA
27	Aishath Mohamed	MFDA
28	Mohamed Fazeen	MFDA
29	Aishath Ibrahim	MFDA
30	Aishath Jaleela	MFDA
31	Fathmath Shareefa	MFDA
32	Fathmath Shifza	MFDA
33	Aminath Mohamed	MFDA

12. SLIDE PRESENTATION AT STAKEHOLDER WORKSHOP

Medicines in health care delivery in Maldives:

Situational analysis: 26 May – 5 June 2014

Dr Kathleen Holloway, WHO/SEARO
Ms Shareefa Adam Manik, MFDA
Ms Aishath Mohamed, MFDA
Mr Mohamed Fazeen, MFDA,
Dr Yusra Ali, MO/Dhamanveshi

Agenda of the workshop

AM

- Presentation by situational analysis team with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
  - include practical steps and the human and financial resources needed

PM

- Presentation of group work with plenary discussion and finalization of recommendations
  - Road map for MOH, stakeholders and WHO to follow

Terms of Reference

- To meet with senior officials of MOHG & MFDA in Maldives;
- To conduct a rapid assessment of medicines in health care delivery with a focus on drug supply and medicines use in liaison with national counterparts from the MOHG;
- To report on the findings in a workshop to government officials and other stakeholders;
- To discuss with MOHG and MFDA future WHO technical support.

Mission: 26 May – 4 June, 2014

- 26 May: MOHG, DGHS, MFDA, CPU, Health supplies, Deputy Minister of Health & Gender
- 27 May: Medical & nursing councils, MBHS, Hulhumale hospital & 2 pharmacies
- 28 May: Faculty Health Sciences, NSPA, Asandha, ADK hospital & pharmacy;
- 29 May: IGMH, STO, STO medicals
- 31 May – 1 June: Visit to GA and G DH atoll – regional & atoll hospitals, health centres and pharmacies
- 2 June: K.Villingilli health centre and pharmacies, sea and airports, private pharmacy Male
- 3 June: Minister of Health & Gender, Health Services Division, Quality Assurance Improvement Section
- 4 June: workshop

Objectives of the workshop

- Review the situational analysis findings
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems
- Develop plan to implement recommendations

Mission findings

- Extensive health care system, with substantial infrastructure, trained health care personnel and good health indicators, but…
- Many areas of progress since last situational analysis but political instability and the decentralisation initiative have had serious impact on the pharmaceutical sector, but….
- Sufficient resources and capacity to address the problems

National Drug Policy

- Formulated 1999, endorsed 2006, published 2007
  - review started in 2014
- Objectives:
  - Ensure all medicines are effective, safe & of good quality
  - Ensure essential medicines are available at affordable costs to all
  - Promote rational use of medicines
- Implementation
  - Insufficient legislation and regulation to ensure all medicines are safe, effective and of good quality
  - Lack of public sector involvement in public sector drug supply
  - No program to monitor or promote rational use
- Political instability in recent years
  - Decentralisation to regional health corporations & recentralisation
  - Decommissioning central procurement & re-commissioning
  - Uncertain roles for MOH/CPU, STO; public sector vs private

Procurement: CPU/UNOPS

- Central procurement unit (CPU), set up in 2013, responsible for procurement, severely under-resourced
  - only 5 staff, with one pharmacist
  - No LMIS or information on consumption from the regions/atolls
- Health supplies store, formerly Central Medical Store, is inadequate
  - Only 9 staff (incl. labourers), no pharmacists, no LMIS, very poor store conditions & inadequate stock management
- Link between CPU & Health Supplies unclear
  - Liaison officer in CPU works with Health Supplies
  - No clear lines of authority between CPU, Health Supplies, and health facilities
- UNOPS contracted to support the CPU
  - Progress slow due to lack of in-country infrastructure

Drug supply

- National Medicines Policy recommends "centralized procurement & supply system … to economize expenditure … and ensure availability … to all levels of health care" but
- Most medicines supply done by the private sector apart from hospital injections which are supplied by MOH/CPU or purchased directly by hospitals from STO/ADK
- Only the Approved Drug List (3000 items) is followed, not the EML (420 items)
- Prices are set by the importers with fixed mark-ups, so prices may be high
- No information on medicine consumption for planning, quantification or forecasting
- No qualified staff/infrastructure for managing medicines in public facilities

Health facility stock management poor (1)

- No pharmacists employed by MOHG in any public health facility
- School-leavers running hospital stores & doing quantification by guesswork, with minimal admin support
- No SOPs followed for stock management
- Inadequate stock records which often do not match stock
- Some Male' facilities order daily, 1-2 units of an item when there is a stock-out & most facilities in regions order weekly
  - Health Supplies, with the help of UNOPS, trying to start 3-monthly ordering system

Procurement: STO

- STO (83% government owned) supplies about half the drugs
- Operates one pharmacy in IGMH with prices fixed by an MOU between STO & IGMH
- Recently established 9 pharmacies in regions/atolls & plans to expand to all 19 regional hospitals and atoll hospitals
- Supplies controlled drugs & "hospital" injectable drugs to health facilities and unregistered drug on prescription to patients
- Supplies about MVR 300 million annually, MVR110 million to IGMH
- Owed MVR >470 million by government & Asandha
- Well organised central store with about 150 staff, incl. pharmacists and currently sponsoring 19 advanced certificate-level students
- Procures from about 20 known suppliers after tendering but supplier criteria unclear & manufacturing sites not inspected
- Manages its own pharmacies & has not previously shared stock or consumption information with local health staff

Health facility stock management poor (2)

- Poor medicine storage conditions in health facilities and some pharmacies
- Expired drugs sometimes stored with unexpired ones
- Little re-distribution of drugs
  - Stock-out of adrenaline in many facilities but 40 vials of expired adrenaline found in another facility
  - Health Centres seeing 5 patients /day are supplied with hospital injections which they cannot use & must throw out on expiry
- No system to report poor quality items
- No supervision or inspection from the centre

Asandha Insurance (1)

- Covers all the population, run by Allied insurance, & started in 2012
- Paid for by taxes through MOFT, no patient premiums
- Computer system links insurance system to pharmacies
- Benefit package covers OPD & IPD expenses including drugs, recently up to an annual maximum of MVR100 000 per year, split between charges for medicines, hospital admission, evacuation
- Owed millions by government & unable to pay re-imbursement to pharmacies, leading to many pharmacies withdrawing from Asandha
  - 150 patients/day come to IGMH to get their prescriptions from elsewhere copied & entered into the Asandha portal – patient safety!

Drug Selection

- 2013 EML of 420 items, 326 API, but not followed:
  - Chosen by expert group, approved by Pharmaceutical Board and endorsed by Minister
  - Some drugs on the EML are not registered and/or unavailable
  - Role of EML unclear
- Only Approved Drug List of 3000 items followed; EML not accepted by Asandha
- Hospital list of injections for use in IPD not followed, every hospital & Health Centre following its own list, developed through doctor request
- Regulation that pharmacies cannot supply injections from the hospital drug list may limit availability if CPU/STO supply fails

Asandha Insurance (2)

- Limited cost-containment measures & pay-outs increasing since maximum limit abandoned
- All approved list drugs covered & also some drugs outside the list, but Asandha will introduce a limit for the approved drug list only (>3000 drug products)
- Asandha want to pay according to a new Maximum Retail Price under development with MFDA for drugs - not any price - in order to keep costs down
- Generic substitution is now practiced & helps to lower prices.

Annual drug consumption in 2013

	Drug name	Cost USD		Drug name	Cost USD
1	Salbutamol	1383118	13	Desferioxamine	149730
2	Amoxy+Clavulinic	548044	14	Fluticaseone	129050
3	Vitamins	494784	15	Antacid	125241
4	Paracetamol	355743	16	Cefixime	119144
5	Diclofenac	323390	17	Levonorgestrel	110547
6	Losarten	284887	18	Cefuroxime	109372
7	Pantoprazole	246216	19	Cetrizine	99297
8	Atovastatin	197803	20	Fexofenadine	87897
9	Efarvirenz	184800	21	Amoxycillin	85772
10	Calcium	174097	22	Dextromethorphan	82634
11	Ranitidine	171236	23	Piroxicam	74077
12	Deferipone	157321	24	Clopidogrel	73240

Top 25 drugs (1%) cost 53% budget. Antibiotics cost 12% & vitamins cost 5%

Recommendations

- Employ one diploma pharmacist per region & one advanced certificate pharmacist per atoll hospital to manage drug stock and undertake quantification
- Establish an LMIS & train/supervise the current store keepers to enter the data accurately
- Establish SOPs for stock management
- Establish SOPs for procurement including
  - clear, transparent supplier criteria & product specifications
  - 2-stage tendering process
- MOFT to promptly pay for Asandha and medicines procurement (whether STO or CPU)
- Oblige suppliers (STO or CPU) to share consumption & stock data with facility in-charges to aid stock mgt.

Drug selection: recommendations

- Improve drug consumption data to plan better
  - Data from newly started MFDA import database
  - Improve data & analysis for other info e.g. Unit price
  - Require importers & health facilities to share consumption data
- Implement the EML
  - Improve the selection process for the national EML
    - Wider representation of medical specialties and general practitioners including regions.
    - Delete unregistered and non-available drugs
  - Revise the hospital injectable drug list & develop a list or oral drugs for Health Centres without a pharmacy
  - Monitor % of drugs prescribed that belong to EML
  - Asandha only to reimburse EML drugs
  - Sensitize all doctors, especially new expatriates
- Refine regulation on pharmacies supplying hospital drugs

Prescribing Survey

Data collected from private pharmacy shop bills & patient registers

Health facility	Public Hosp (n=4)	Public HC (n=4)	Private Hosp/clinic (n=3)
Av.no.drugs/Px	3.35	3.02	3.17
% Px with AB	25%	24%	45%
% PX with INJ	11%	18%	7%
% Px with VIT	39%	47%	23%
% Generic drugs	27%	18%	6%
% EML drugs	74%	70%	61%
% URTI with AB	39%	48%	51%
Av.cost/Px (R)	127.26	93.96	144.79

Drug use: recommendations

- Monitor drug use
  - Improved analysis on data from importers and port inspection, prescription audit
- Implement Standard Treatment Guidelines (STG)
  - Development, updating, dissemination to every doctor, incorporation into CPD
- Establish Drug and Therapeutic Committees (DTC)
  - to monitor drug use, encourage CPD, and report annually on activities to MOHG/MFDA
- Establish continuing professional development (CPD)
  - MMA, MMC, credit system, incorporation of prescription audit and feedback and ethics into CPD
- Establish a national Drug Information unit in MFDA
  - To provide independent information for doctors
- Organise Public Education
  - Core pharmaceutical messages e.g. does my child need more than one drug? through HPA health education unit and media

Prescribing survey (2)

- Hospital compared to health centre (HC) prescribing
  - prescribing for general patients includes more drugs and more costly drugs in hospitals than in HC
- Health centres with & without pharmacies
  - Health centres without pharmacies prescribe more injections to provide patients with some treatment in the absence of oral drugs
- Regions/atolls vs Male in public sector
  - Prescribing is better in Male than in region/atolls
- Private compared to public sector
  - Private sector may prescribe less quantity but it is more expensive than the public sector
- Treatment of URTI in one hospital
  - 4 drugs/patient; 43% received Abs, 43% received vitamins

Drug Regulation (1)

- MFDA in charge of drug regulation
- Very old Act from 1970s which is insufficient and does not allow MFDA to enforce regulations or exact penalties
  - New Act being redrafted.
  - New regulation passed by parliament, to be gazetted
- Size of the sector
  - 188 pharmacies for 385 000+ people, including 79 pharmacies for 100 000 people in Male
  - About 18 importers (11 major)
  - 3009 products in the Approved Drug List
- Staffing
  - 5 pharmacists, 8 pharmacy assistants, 2 Senior public health programme officers, 2 non technical staff, for all regulatory activities, so difficult to manage all activities
  - Staff supplemented with non-pharmacists to carry out inspections, e.g. CHWs to inspect island pharmacies

Drug Use

- No monitoring of drug use
- Few prescribers know of the EML or use any STGs or other sources of independent drug information
- Regular pharmaceutical representative visits reported by doctors in Male but not elsewhere
- Very little Continuing Professional Development
  - Adhoc for Maldivian doctors
  - Virtually none for expat doctors outside Male'
  - Some refresher trainings for CHWs but not on prescribing
- CHW prescribers underused
- No public education on proper use of medicines despite public education units (under HPA) in every hospital/HC
- Pharmacist-patient interaction time often < 1 minute

Drug Regulation (2)

- Pharmaceutical Board decides upon drug registration based on written process.
  - Drugs must be registered in UK, USA, Canada, Australia, Sri Lanka, Thailand, Malaysia, Japan, Singapore, EU
  - More than 20 brands of same generic e.g. paracetamol, amoxycillin
- Inspection of pharmacies well done by MFDA staff but insufficient budget and staff to do regular inspection
- Pharmacists mostly present in pharmacies but prescription-only drugs available OTC
- Laboratory has limited capacity to monitor and ensure adequate quality – 46 samples tested in 2014
- Inadequate monitoring of drug promotional activities
- ADR reporting form but only 4 ADRs ever reported due to lack of sensitization of prescribers
- All SOPs now in place

Drug regulation: recommendations

- New Medicines Act required
  - to implement regulations and introduce more control and punitive measures
- Strengthen the MFDA
  - Increase budget and qualified and competent staff
  - Raise fees for drug registration and institute higher fees for import licences, pharmacy licences in order to generate income
  - Develop monitoring of promotional activities
  - Institute a sensitization campaign with face-to-face meetings with doctors and nurses to improve ADR reporting
- Stricter adherence to the registration process
  - All products imported and sold and covered by should be approved by the Pharmaceutical Board/MFDA
  - Number of unregistered products on prescription that are imported should be published & a committee set up to review the prescriptions

Problem policies

- Lack of incentive for importers to register drugs due to small market and no exclusive rights to import after registration
- Excessive number of pharmacies in Male' but cannot limit the number due to Ministry of economic development
- Previously – lack of service pharmacies & transaction info from STO even though it is 85% publically owned – changing?
- Previously, slow payment by Ministry of Finance to:
  - Asandha, so resulting in disengagement of pharmacies
  - STO, so resulting in delayed procurement & higher prices
  - IGMH, so resulting in late payment to STO
- Pharmacists are not in the human resource plan but without them, quantification & efficient procurement sufficiently in advance cannot be done
- Island HCs without pharmacies need PHC drugs, not hospital ones, & a mechanism to receive them from supervising hosps.

Structure and Coordination

Lessons learnt from restructuring (2009 – 2012)

- 7 Regional Health Corporations to run health care, financed by MOFT, with MOHG having regulatory/policy role only
  - Fragmented Health services, disrupted drug supply & did not work
- Health promotion units under MOH/CCHDC moved into separate premises & their ANC & vaccine work taken over by corporations
  - Undermined health education work of these units & did not work

Current gaps

- Inadequate qualified pharmaceutical human resources for supply chain management in public sector
  - Serious problems in stock management & quantification
- No coordinating mechanism between government departments for pharmaceutical policy formulation
  - Drug supply, regulation and use undermined

Health Structure: recommendations

- Establish a Policy level statutory committee to develop coordinated policy and advise the president:
  - Executive in MOH (DGHS & MFDA) to do committee recommendations
  - To undertake coordinated policy formulation, monitoring & evaluation
  - To ensure coordination between all stakeholders including MOFT, Asandha, HSD, MFDA, Dept. of Economic Development, Ministry of Education and Faculty of Health Sciences.
- Establish extra unit in MFDA responsible for rational use of drugs:
  - EML, STGs, DTCs, monitor use, CPD, MIC, public education in liaison with HSD, QAD, HPA, etc.
  - Liaison with Faculty of Health Sciences to provide students to collect information needed by MOH as part of their research studies
- Generate MOHG income by raising fees – licences, registration
  - Drug registration & licences for importing, health workers & facilities.

Health Care Regulation

- New Acts required since new constitution
  - Public Health Act passed 2010, covering communicable diseases, vaccination, food safety, but…
  - Medicines Act, Food Act, Health Professionals Act, Health Services Act and an overarching Health Act needed
- Medical Council, Nursing Council, Board Health Sciences
  - Licence doctors, nurses, CHWs, pharmacists
  - Very little recompense for the work of assessing applications from expatriate professionals.
  - Fees are limited, go to the treasury & can only be raised by MOFT
  - Health Facilities/HSD do not inform other facilities about dismissed health staff so these staff can find employment in another island
- Quality Assurance Division (QAD)
  - Mandated to supervises quality of care, No inspections since 2008. disrupted lack of budget and health corporation policy.
  - Licences private clinics (58 Male') but lack budget to visit facilities

Group work

- Each group to draft recommendations with practical steps including
  - What will you do?
  - Who will do it?
  - How many staff?
  - Budget?
- Groups
  - Drug supply and selection
  - Promoting rational drug use
  - Drug regulation
  - National structure and drug policy