MEDICINES IN HEALTH CARE DELIVERY

BHUTAN

Situational Analysis:

20 July -31 July 2015

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

October 2015

CONTENTS

1. ABBREVIATIONS

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
BHU	Basic Health Unit (primary care)
BMHC	Bhutan Medical and Health Council
BNF	Bhutan National Formulary
BoQ	Bill of Quantity
CME	Continuing Medical Education
CMS	Central Medical Store
DH	District Hospital
DHO	District Health Office
DIC	Drug Information Centre
DIGPY	Bhutan's Electronic drug inventory system
DMSHI	Department of Medical Supplies & Health Infrastructure
DMS	Department of Medical Services
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committees
DVED	Drugs, Vaccines and Equipment Division(prior to MOH reorganization)
DTMS	Department of Traditional Medicine Services
EDL	Essential Drug List
EDP	Essential Drug Program
EDL	Essential Drug List
EM	Essential Medicines
EML	Essential Medicines List
EMTD	Essential Medicines and Technology Division
GDMO	General Duty Medical Officer

GMP	Good Manufacturing Practice
HA	Health Assistant
HCDD	Health Care & Diagnostic Division
HOD	Head of Department
HRD	Human Resource Division
IPD	In-patient Department
INR	Indian Rupee
KGUMS	Khesar Gyalpo University of Medical Sciences
M&E	Monitoring & Evaluation
MO	Medical Officer
MOF	Ministry of Finance
MOH	Ministry of Health
MSH	Management Science for Health
MSO	Medicines Supply Organisation
MSDD	Medical Stores and Distribution Division
MSPD	Medical Supplies Procurement Division
MTC	Medicines & Therapeutics Committee
NDP	National Drug Policy
NF	National Formulary
NGO	Non-Governmental Organisation
NHP	National Health Policy
NMP	National Medicines Policy
NRH	National Referral Hospital
NTMH	National Traditional Medicine Hospital

Nu	Bhutanese Ngultrum
OPD	Outpatient Department
ORS	Oral Rehydration Solution
OTC	Over-the-Counter
PBPT	Problem-based Pharmacotherapy
PHC	Primary Health Care
PV	Pharmacovigilance
QA	Quality Assurance
RIHS	Royal Institute of Health Sciences
RUM	Rational Use of Medicines
RRH	Regional Referral Hospital
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
TRM	Traditional Medicines
USD	United States Dollar
VEN	Vital, Essential, Non-essential – method for classifying drug importance
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Bhutan during 20-31 July 2015. 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 Essential Medicines and Technology Division under the Department of Medical Services in the Ministry of Health, facilitated by WHO/SEARO, would conduct the situational analysis.

The team members consisted of:

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- Thinley,

  Jigme Dorji Wangchuk National Referral Hospital, Thimphu, Bhutan.

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  Drug Regulatory Authority, Bhutan.

- Dr Anita Kotwani,

  Technical Officer in Essential Drugs and Other Medicines, WHO/SEARO, New Delhi.

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. During the visits to public health facilities and private pharmacies, drug stores were visited to collect data on stock availability for 32 selected essential drugs and drug management, outpatient dispensaries were visited to do a prescription audit, wards were visited to review in-patient drug management, and staff were interviewed to identify health and health care factors affecting drug management.

A one-day national stakeholder workshop was held on 31 July 2015 where findings were discussed and recommendations developed. The participants list can be seen in section 12. The findings were presented 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

Virtually all medicine needs in Bhutan are met by the public sector. The Department of Medical Supplies and Infrastructure (DMSHI) manages procurement and distribution through the Procurement (MSPD) and Distribution (MSDD) divisions respectively. Annual procurement is done and annual requisitions (agreed centrally and based on health facility estimates) delivered to facilities through 3-4 consignments during the year. In addition, most hospitals make 4 or more additional (emergency) orders during the year. Availability of key essential drugs was 96-100% in all public facilities and complaints of stock-out were far fewer than in 2011. Strategies introduced since 2011 that have contributed to improved supply include re-introducing quantification based on average monthly consumption multiplied by 26 months, returning to annual tendering for each line item instead of 3-year tendering for lots, and greater flexibility by the Drug Regulatory Authority in issuing "No Objection" letters for the importation of small quantities of unregistered essential medicines. Furthermore, a well- functioning redistribution system between facilities for short-dated medicines was helping to keep stock-outs and expiry to a minimum. Restructuring within the MOH has occurred such that responsibility for drug procurement and distribution has been taken out of the Department of Medical Services (DMS) and put into a new Department of Medical Supplies and Infrastructure. Responsibility for quantification and the EML still remains with the DMS.

A new well-equipped central warehouse at Phuentsholing has been built since 2011 but some hospital stores are still short of space and poorly ventilated. Drug stores were generally well maintained though there is a shortage of pharmacists to manage them. The electronic logistic management information system, DIGPY, stopped functioning and the manual system now in place is difficult to manage. Procurement still relies on a one-envelope tendering system which may make it difficult for the procurement committee to follow all the technical product and supplier criteria needed to ensure timely procurement of good quality medicines.

Recommendations were to:

- Establish an harmonized, functional, sustainable electronic drug management information system, to monitor consumption, stock-out, expiry and for forecasting, which is necessary to improve quantification:
    - Start with national referral hospital, JDWNRH, referral hospitals and all district hospitals;
    - Employ good IT staff to manage and update the software centrally;
    - Employ a data-entry staff for electronic data management at each hospital;
    - Designate a budget every fiscal year for the maintenance and management of the software and the drug inventory data.
- Employ one pharmacist (B. Pharm degree) for each hospital to supervise the drug store, the outpatient (OPD) pharmacy, the inpatient (IPD) drug management and to supervise the pharmacy technicians.
- Improve district hospital stores with more space and proper shelves for better management of store and inventory:
    - Major structural changes to be done by MOH;
    - Minor small changes to be done by hospital administration.

- Establish a team from the DRA, DMSHI, DMS and JDWNRH to analyze all purchases done for non-registered medicines product, e.g.
    - Percentage of purchased products not registered;
    - Reasons underlying purchases of all such medicines.
- Establish a 2-envelope system for tendering and procuring Section B essential drugs (for which no suppliers or products are registered). Only those suppliers and product tenders that clear the technical qualifications criteria (which need to take into account the difficulties of obtaining documentation from manufacturers) would be eligible for opening of their price-bids.

2.3. Medicines Selection

The national 2012 Essential Medicines (Drug) List had recently been updated in 2014 for use in 2016 and in the meantime facilities were being supplied with EDL 2012 drugs. Compliance with the national EML is extremely good throughout the country with over 98-100% of all prescribed drugs belonging to the national EDL in all public health facilities. This is because of central public procurement which follows the EML. Some drugs meant for use at a higher level facility were found at lower level facilities mainly for the purpose of prescription refills, which could be dangerous if this is undertaken without regular review by a doctor and some review by the original prescriber.

The purchase of non-EML drugs on a named patient basis remains adhoc and not properly supervised by any national committee or hospital Drugs and Therapeutic Committee (DTC), though recommendation was made for this in 2011. The very frequent adhoc and unsupervised requests are resulting in inefficient purchase and extra procurement burden (as mentioned in chapter 4). Since some of the named patient drugs are actually on the national EML and some of the non-EML ones are used for chronic cases, there is scope for harmonizing the named patient non-EML list with the national EML and also rationalizing procurement of those non-EML medicines used for chronic cases. Some of the named-patients start their treatments in India, where there is a very large private sector, and this may account for a large number of named-patient products, which are often purchased by brand name and for which there may be many brands for the same medicine.

Recommendations were to:

- Continue to update and revise the national Essential Medicines List (EML) in a transparent manner to improve acceptance:
    - To include medicines for all levels of care and classify them by facility level, prescriber type and therapeutic class as is currently being done;
    - Have wide representation of specialists, pharmacologist, generalists and pharmacists, from the centre and from the districts.
- Review and harmonize the national EML with other non-EML lists which are used for procurement from Kolkata office, which will require:
    - Review of the named-patient list; ICU list (currently being done by the National Medicine Committee); haemodialysis list; any other non-EML list;

- Review of the named-patient guidelines (to ensure that procedures are transparent and efficiently followed in order to avoid unnecessary purchase of medicines outside the EML).

- Monitor compliance with the national EML, including compliance with level of use :
  - Through consumption analysis (which would be easier with an electronic logistic management information system, LMIS) and prescription audit;
  - To be done by DTCs in the national referral hospital, regional referral hospitals, district hospitals and centrally by EMTD/DMS/MOH and the National Drug Committee;
  - Focus on high-cost/low volume medicines.

- Ensure stricter adherence to the national EML by:
  - Program of educating prescribers (including new and in-service doctors) and dispensing pharmacists on the use of the national EML to be coordinated by the National Medicine Committee and EMTD/DMS/MOH.
  - Establishing a transparent system to review all requests for non-EML drugs including the named patient drugs:
    - Drug and Therapeutic Committees (DTC) in the national referral hospital, JDWNRH, and in each regional referral hospital to review all such requests;
    - National Medicine Committee to provide guidance on "reasonable" specialist medicines for non-EML purchase.

2.4. Medicines use

Medicine prescribing and dispensing and use remain similar to the previous situational analysis in 2011, apart from a possible slight increase in antibiotic use (though not with regard to antibiotic use in upper respiratory tract infections) and this may be a cause of worry and merits regular monitoring. Compared to many other low/middle income countries, prescribing in Bhutan is relatively good and this is due to the regular updating and implementation of the national Essential Medicines List (EML), Standard Treatment Guidelines (STGs) and Formulary and the absence of a private sector, where prescribing is generally worse and which can influence prescribing in the public sector. Unfortunately, despite previous recommendation in 2011, Hospital Drug and Therapeutic Committees remain largely non-functional and drug use and prescribing is rarely monitored. Although named-patient drugs are discussed on some occasions, unfortunately no committee reviews the use of named-patient drugs. Likewise, previous recommendations which are still pending include: development of a new orientation package for new doctors and continuing medical education programs for prescribers on rational use of medicines by the BHMC; carrying out national public education campaigns on the safe medicines use; and the establishment of a national Drug Information Centre.

Recommendations were to:

- Monitor medicine use - to be done by all hospitals Drug and Therapeutic Committees (DTCs) and centrally by the EMTD/DMS/MOH:

- ABC analysis of EML and non-EML consumption;
- Prescription audit following WHO indicator methodology and using diagnosis, which requires that out-patient registers have diagnosis and all the medicines prescribed, fully recorded;
- Identify specific inappropriate practices to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices;

- Implement the National Standard Treatment Guidelines (STGs) and National Formularies:
  - Continue to update and disseminate to all health facilities;
  - Develop secondary care national standard treatment guidelines to include the common conditions such as hypertension, diabetes, renal disease and emergency care;
  - Incorporate the STGs and National Formulary of Essential Medicines into continuing medical education (CME) for all prescribers (including the orientation course for new doctors) and undergraduate education of all medical pharmacy courses.

- Strengthen continuing medical education (CME):
  - Monitor and enforce the Bhutan Medical and Health Council credit system for CME;
  - Include prescription audit and feedback into CME;
  - Extend orientation course for all new doctors recruited in service to include the EML, STGs, national formulary, DTCs and drug supply system.

- Establish Drug and Therapeutic Committees (DTCs) in all referral and district hospitals:
  - To monitor drug use, encourage CME, and report annually on activities to the EMTD/MOH;
  - Pharmacists can act as DTC secretaries and implement DTC decisions.

- Undertake public education on the prudent and safe use of medicines:
  - Repeated (not just one day a year) public education campaigns which could be spread through all channels used by MOH, including Community Health Workers, and the mass media;
  - Include core pharmaceutical messages e.g. *No drugs or medicines are needed for mild cough and cold.*

- Establish a National Drug Information Centre:
  - To provide prescribers with independent information on all aspects of medicines, e.g. drug interaction, dose, treatment, medicine availability etc.;
  - Could be placed in the JDW National Referral Hospital or the Health Help Centre

2.5. Medicines Regulation

The Drug Regulatory Authority continues to develop. Promotion of registration of products so as to ensure access to essential medicines and avoidance of monopoly practices for products with few suppliers is an important activity. Since 2011, the DRA has introduced a new fast track registration process which has eased the problem of importing essential drugs that were not registered in the country at MOH request for emergencies and public health reasons. However, the DRA felt that the number of "No Objection" letters requested by MOH and the Jigme Dorji Wangchuck National Referral Hospital for emergencies and named patients is excessive and is undermining the DRA and that such requests could be reduced by better planning. Furthermore, frequent emergency requests result in tenders being given to suppliers of non-registered products even when there is a registered alternative because the local wholesaler cannot supply it within the time frame. Although the DRA stipulates that all fast track products should be registered with one of ten stringent regulatory authorities or be produced by a manufacturer with ten products already registered in Bhutan or be a WHO prequalified product, some people felt that clearer criteria for fast track registration, acceptable to both the DRA and the MOH, were needed. The DRA continues to develop SOPs for all processes and train its staff as best it is able with scarce resources, but there is still more need for training in dossier evaluation and GMP inspection. The Drug Testing Laboratory is being developed but is still not functional and this is a serious concern because of the delay in being able to test product quality, such delays sometimes leading to stock-outs.

Recommendations were to:

- Strengthen the National Drug testing Laboratory (NDTL) to be able to undertake regular samples for testing both registered and non-registered medicines:
    - Should be made fully functional at the earliest if necessary by reviewing the location of NDTL and if possible making it autonomous;
    - Should be strengthened in terms of human resources and equipment;
    - Establish minilab testing at the central drug store in Phuentsholing.
- Strengthen the abridged registration process:
    - Establish clear criteria for exemption of registration or abridged registration for procurement of medicines;
    - Will require collaboration between the MSPD/DMSHI/MOH, DMS/MOH, JDWNRH and the DRA;
    - Will require analysis of products granted exemption of registration and reasons underlying the exemption.
- Strengthen post-marketing surveillance:
    - Regular inspection of public health facilities;
    - Regular inspection of private retail pharmacies including whether they sell prescription-only medicines over-the-counter;
    - Regular quality testing of medicine samples.

2.6. Medicines Policy and Coordination

Since the last situational analysis in 2011, there has been increased investment in the procurement and distribution of medicines with the creation of a new Department of Medical Supplies and Health Infrastructure, including the building of a new warehouse in Phuentsholing. Furthermore, there has been some coordination to revise policies concerning quantification, procurement and fast-track registration which has resulted in more reliable drug supplies and few stock-outs. Nevertheless, some disagreements still exist between the MOH, the JDWNRH and the DRA concerning the number of "No objection" letters requested for importing unregistered drugs, so indicating an on-going need for coordination.

Greater inter-departmental and inter-ministerial coordination is needed to achieve certain functions but no clear coordinating mechanism has been set up. Thus, coordination is needed between: the Departments of Medical Services and Public Health (for public education campaigns on appropriate medicines use); the DMS, DMSHI, the Human Resource Division in MOH and the Royal Civil Service Commission to increase the number of pharmacists at district level (which is needed for better drug management and monitoring of use); the DMS/MOH, Khesar Gyalpo University of Medical Sciences of Bhutan, Ministry of Education and the Bhutan Medical and Health Council to ensure that pre-service and in-service training incorporates appropriate and safe prescribing. Coordination with MOF is needed for all activities to ensure appropriate budget.

Recommendations were to:

- Strengthen the following units/departments all of which require more pharmacists:
    - Department of Medical Services, DMS, (Essential Medicines and Technology Division [EMTD] and Health Care & Diagnostics Division [HCDD]);
    - Department of Medical Supplies & Health Infrastructure, DMSHI, (Medical Stores and Distribution Division [MSDD] and Medical Supplies Procurement Division [MSPD]);
    - Liaise with the Secretariat for Human Resources to increase the number of pharmacist posts in the hospitals and in DMS & DMSHI.
- Revise and make the national Drug Policy comprehensive:
    - Since new units and departments have been formed since the NDP was published in 2007;
    - Requires participation by all stakeholders to make the NDP comprehensive;
    - Should include monitoring indicators to monitor implementation.
- Institute a coordinating mechanism or forum under the chairmanship of the Minister of Health whereby the DMS, DMSHI and DRA and other relevant bodies can be brought together to resolve medicines-related issues.
- Support a strong national DRA.

3. PROGRAMME AGENDA

Day	Date	Time	Places visited
1	20.7.15 Monday	Am	Thimphu
		Pm	Meeting with core team
2	21.7.15 Tuesday	Am	Visit to WHO country office; Meeting & discussion with: Director General, Department of Medical Services, Secretary, Ministry of Health; and visit to JDW National Referral Hospital.
		Pm	Meeting with Director, Department of Medical Supplies & Health Infrastructure. Visit to Drug Controller office. Meeting and discussion with Drug Controller
3	22.7.15 Wednesday	Am	Travel to Chapcha. Visited Chapcha BHUII; Travel to Phuentsholing.
		Pm	Reached Phuentsholing and visited MSDD. Visited two retail pharmacies in Phuentsholing.
4	23.7.15 Thursday	Am	Travel to Samdrup Jongkhar.
		Pm	Reached Samdrup Jongkhar and visited one retail pharmacy
5	24.7.15 Friday	Am	Visit to Samdrup Jongkhar district hospital. Travel to Samdrupcholing
		Pm	Visited Samdrupcholing BHU I. Travel to PemaGatshel.
6	25.7.15 Saturday	Am	Visited Pema Gatshel District Hospital
		Pm	Visited Gompa singma BHU II facility in PemaGatshel district. Travel to Trashigang.
7	26.7.15 Sunday	Am	Visited Trashigang District Hospital. Travel to Monggar.
		Pm	Reached Monggar and visited one retail pharmacy.
8	27.7.15 Monday	Am	Visited Monggar Regional Referral Hospital.
		Pm	Visited Lingmethang BHU II. Travel to Bumthang. Team split into two halves (Teams 1 & 2)
9	28.7.15 Tuesday	Am	Team 1 visited Phobjikha BHU I and was then delayed overnight due to a landslide blocking the road
		Pm	Team 2 visited Punakha District Hospital & then travelled back to Thimphu.
10	29.7.15 Wednesday	Am	Team 1 travelled Punakha to Paro district and Team 2 from Thimpu to Haa district
		Pm	Team 1 visited Paro District Hospital and Team 2 visited Bali BHU I, Haa district.
11	30.7.15 Thursday	Am	Meetings with: Dean, Faculty of Traditional Medicine, Asst. Registrar, Bhutan Medical & Health Council, Medical Superintendent, National Traditional Hospital, Dean, Faculty of Nursing & Public Health. Visited two retail pharmacies.
		Pm	Compilation and preparation of report for workshop
12	31.7.15 Friday	Am	Workshop
		Pm	Workshop
13	01.8.15 Saturday	Am	No flight for Delhi
		Pm	
14	02.8.15	Am	Travelled back to Delhi

4. MEDICINE SUPPLY

4.1. Responsible Agents/Departments

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Selection	✓		Essential Medicines and Technology Division
Quantification	✓		Medical Supplies Management and Quantification Unit under the Health Care & Diagnostic Division, Department of Medical Services
Procurement	✓		Medical Supplies Procurement Division, Department of Medical Supplies & Health Infrastructure (DMSHI)
Pricing		✓	Drug Regulatory Authority (Autonomous)
Storage	✓		Medical Stores and Distribution Division (MSDD), DMSHI & Health facilities
Distribution	✓		Medical Stores and Distribution Division, DMSHI
Monitoring & evaluation	✓		Health Care & Diagnostic Division, Department of Medical Services

4.2. Drug availability

The situation analysis of 2011 and the health sector review of 2012 revealed that 2-3% of drugs were out of stock at district hospital level and below and 22% of drugs were out of stock at the national referral hospital, JDWNRH. Since only EML drugs were stocked at district level and below this meant that drug availability for EML drugs was 97-98% in district hospitals and BHUs but only about 80% in JDWNRH. At that time, there were many complaints of stock-outs for some drugs especially in the referral hospitals. Nevertheless, the percentage of prescribed drugs dispensed was 93-97% in all facilities except JDWNRH where it was 85%.

During this situational analysis, a survey was done of availability of key essential medicines in both public health facilities and private pharmacies. Table 4.2.1 show some data on stock availability and stock-out.

The % of key EML drugs available was based on a list of 32 drugs from the national EML, chosen by the team. Of these 32 drugs, only 23 were meant to be available at the BHU II level, staffed only by health assistants. The key essential medicines surveyed for availability consisted of:

BHU II

- Albendazole 400mg tab; Amoxycillin250mg tab; Atropine sulphate 1mg/ml inj; Cetirizine 10mg tab; Ciprofloxacin 0.3% eye/ear drop; Clotrimazole 1% ointment; Co-trimoxazole 400mg+80mg tab; Dexamethasone 4mg/ml inj; Diazepam 5mg tab; Diclofenac sodium 25mg/ml inj; Ferrous sulphate 60mg + folic acid 0.40mg tab; Gamma benzene hexachloride solution; Gentamicin 40mg/ml inj; Hydrochlorthiazide25mg tab; Metformin 500mg tab; Metronidazole 400mg tab; ORS packet; Oxytocin 5 unit/1ml inj; Paracetamol 500mg tab; Ranitidine 150mg tab; Ringer lactate 500ml inj; Salbutamol 4mg tab; Sodium chloride 0.9% 500ml inj.

Referral hospitals, District hospital and BHU I

- Amitriptyline 25mg tab; Atenolol 50mg tab; Ciprofloxacin 500mg tab; Enalapril 5mg tab; Frusemide 10mg/ml inj; Metronidazole5mg/ml inj; Prednisolone 5mg tab; Ranitidine 25mg/ml inj; Salbutamol respiratory solution 5mg/ml.

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

Public Referral Hospitals	JDWNRH	Monggar					Average
% EML/currently used items out of stock	4.6%	5.3%					4.9%
% key EML drugs available	96.9%	100%					98.4%
% prescribed drugs dispensed**	95.5%	96.7%					96.1%
Public District Hospitals	District hospital 1	District hospital 2	District hospital 3	District hospital 4	District hospital 5		Average
% EML/currently used items out of stock	1.4%	2.8%	1.4%	9.7%	4.5%		4.0%
% key EML drugs available	96.8%	100%	100%	84.3%	93.8%		95.0%
% prescribed drugs dispensed**	96.5%	100%	96.8%	100%	96.9%		98.0%
Basic Health Units I ***	BHUI 1	BHUI 2	BHUI 3				Average
% EML/currently used items out of stock**	2.8%	2.8%	1.0%				2.2%
% key EML drugs available	96.9%	93.8%	100%				96.9%
% prescribed drugs dispensed**	100%	100%	100%				100%
Basic Health Units II	BHUII 1	BHUII 2	BHUII 3				Average
% EML/currently used items out of stock	2.0%	1.0%	2.8%				1.9%
% key EML drugs available	91.3%	100%	91.3%				94.2%
% prescribed drugs dispensed**	100%	100%	100%				100%
Private pharmacies	Phuentsh-oling 1	Phuentsh-oling 2	Sandrup Jongkhar	Monggar	Thimphu 1	Thimphu 2	Average
% key EML drugs available	43.8%	43.8%	43.8%	36.7%	46.9%	43.8%	43.1%
% prescribed drugs dispensed**	80.0%	72.7%	96.7%	96.3%	100%	100%	91.0%

* 2 drugs (amitriptyline tab and furosemide inj) out of 9 surveyed for district hospital and BHU I (not for BHU II) were available

** From observing the dispensing process during the health facility survey (see section 6.4)

*** Basic health Unit Is have been upgraded from BHU IIs and should have a MBBS doctor and an EML list the same as for district hospitals

The availability of key essential medicines at all level of health facilities was good, being 94-98%. In particular, availability at the referral hospitals and JDWNRH had improved from the situation in 2011. The percentage of prescribed drugs dispensed was 96-100%. About 2-4% of items were out of stock – which is similar to the situation in 2011 for district level and below but a huge improvement with regard to JDWNRH. Availability of key essential medicines at the MSDD store at Phuentsholing was slightly lower at 88% with about 5% of items (including some non-EML ones regularly procured) out of stock. It was mentioned that stock-outs were due to having just distributed a large consignment of medicines and that they were still awaiting some items from the suppliers. Nevertheless, this would indicate that there is no buffer stock for some items.

Most health workers were happy with availability. There were only a few complaints of stock-out. At some BHUs it was mentioned that it is difficult to dispense medicines for children as they do not have a compounding room and the national EML has no syrups and very few preparations for the pediatric age group. Generally, liquid preparations for paediatric consumption were prepared in the hospital pharmacies and then dispensed to children. Some hospitals mentioned that for paediatric inpatients, parents often had to go to outside pharmacies to purchase syrups.

A common problem mentioned by staff was that often they received short-dated medicines from the MSDD and that it was difficult to redistribute these soon-to-expire medicines because the same batch had also been distributed to the other health facilities. In some hospitals it was mentioned that the some of the drugs were out-of-stock or in short supply because there had been many unplanned camps organised. Other reasons given for stock-out were that patient attendance had changed and prescribing patterns had changed due to new doctors working in the facilities.

The average availability of key medicines was much lower, at about 40%, at private retail pharmacies, since nearly all medicines were available at public facilities and they were catering to particular patients who either did not want to go to the hospital or required medicines not available on the EML e.g. paediatric syrups.

There was some very modest expiry of medicines at most health facilities – as would be expected in a mountainous country with difficult logistics and a supply system that is achieving over 95% availability of key essential medicines with few stock-outs.

4.3. Annual aggregate data of medicines distribution / consumption

Public sector procurement data for the fiscal year 2014-15 was collected from the Medical Supplies Procurement Division (MSPD) of the Department of Medical Supplies and Health Infrastructure (DMSHI) under the MOH. The Jigme Dorji Wangchuck National Referral Hospital (JDWNRH) has recently acquired the status of autonomy but the procurement of drug for this facility is done through DMSHI except for the emergency medicines and named patient medicines, where JDWNRH does the procurement directly through the Kolkata office.

Table4.3.1 shows national aggregate data on drug procurement of EML drugs by the MSPD for the year 2014-15. The data covers all EML medicines for the entire country including JDWNRH. It can be seen that the top 24 (7%) drugs cost 52% of the budget. About 18% of the budget was spent on antibiotics and 5% on vitamins. The medicine topping the list was purified vero cell rabies vaccine. These 24 medicines include two immune-suppressants which are used for graft rejection, three vitamins, five antibiotics and antacid and ranitidine. The total budget for EML medicines including that consumed by JDWNRH was Nu 111,413,076.

The table 4.3.2 compares data concerning the top 20 essential medicines by value for all public facilities (excluding JDWNRH) and for the JDWNRH. The top 20 essential medicines are different for the entire country and for the JDWNRH. The total amount spent on EML drugs was Nu 67,192,792 for all health facilities excluding the JDWNRH and Nu 44,220,284 in JDWNRH. Only 5 medicines were common between the top 20 drugs for all facilities (excluding JDWNRH) and the JDWNRH itself, these being: rabies vaccine, amoxicillin 250 mg, vitamin C, paracetamol 500mg and ranitidine 150mg.

In JDWNRH the number one EML medicine was mycophenolate mofetil which is an immunosuppressive agent and the top 20 EML drugs also included two other immunosuppressive agents, namely tacrolimus and cyclosporine. All three immunosuppressive agents were bought using the trade name of a company. The top 20 medicines also included two medicines for acidity/reflux, ranitidine and omeprazole, and methylcellulose eye drops. This analysis clearly indicates that the pattern of consumption of essential medicines, and the budget for the medicines, is very different for JDWNRH and all other facilities.

The top 20 medicines for the nation (excluding JDWNRH) consumed 55.9% of the budget with 22.65% on antibiotics and 6.2% on vitamins. For JDWNRH the top 20 essential medicines consumed 51.1% of the budget and for antibiotics consumption was 12.2% and for vitamins 3.0%.

Table 4.3.1: ABC analysis of top 24 items – national level for EML products

Source of data: DMSHI, Medical Supplies Procurement Division, MOH Year: 2014-15

Rank	Item Name (including strength& formulation)	Unit costs (Nu)	Monetary Value (Nu)	EML Yes/No
1	Purified Vero Cell Rabies Vaccine inj	248	11,571,680	Yes
2	Amoxycillin 250mg	0.78	6,188,520	Yes
3	Mycophenolate mofetil 500mg	60.00	5,094,000	Yes
4	Vitamin C 250mg tab	0.79	3,978,440	Yes
5	Human Albumin 20% 100ml	4,200.00	2,448,600	Yes
6	Retinol (Vit A) 200,000 unit	3.75	2,129,813	Yes
7	Paracetamol 500mg tab.	0.22	2,088,020	Yes
8	Antacid (Al+Mag Hydrox) tab	0.22	2,014,980	Yes
9	Ranitidine 150mg tab	0.32	2,014,144	Yes
10	Cycloserine 250mg tab	47.00	1,903,218	Yes
11	Normal Saline inj 500m	13.50	1,843,898	Yes
12	Ethyl Chloride spray with device100ml	423.00	1,706,805	Yes
13	Penicillin V 250mg tab	0.88	1,591,920	Yes
14	Chloramphenicol 1% 250mg eye applicaps	0.39	1,536,015	Yes
15	Spironolactone 25mg tab	1.58	1,282,960	Yes
16	Cloxacillin 250mg cap	0.79	1,216,600	Yes
17	Clotrimazole 1% oint, 15g	12.55	1,213,761	Yes
18	Ibuprofen 400mg tab	0.45	1,181,700	Yes
19	Cephazolin 500mg inj	17.50	1,153,005	Yes
20	Ringer lactate inj. 500ml	13.50	1,152,827	Yes
21	Metronidazole 5mg/ml inj 100ml	8.64	1,151,608	Yes
22	Vitamin B complex tab	0.13	1,100,060	Yes
23	Hydrocortisone 1% cream, 15g	23.74	1,051,445	Yes
24	Human Mixtard (neutral + isophane) 30: 70, 10ml	79.00	1,028,580	Yes
	% budget on top 24 medicines:	52%		
	% budget spent on antibiotics:	18%		
	% budget spent on vitamins:	5%		
	% budget spent on EML medicines:	100%		
	% budget supplied centrally:	100%		
	Per capita annual expenditure on essential medicines:	USD 2.38		

Table 4.3.2: ABC analysis of top 20 EML items for all national health facilities (excluding JDWNRH) and Jigme Dorji Wangchuck National Referral Hospital (JDWNRH)

Source of data: DMSHI, Procurement Division, MOH Year: 2014-15

Rank	National Health Facilities except JDWNRH		National Referral Hospital, JDWNRH	
	Item Name/Strength	Monetary Value Nu	Item Name/Strength	Monetary Value Nu
1	Purified Verro Cell Rabies Vaccine 0.5ml.	9,835,680	Mycophenolate mofetil 500mg cap (cellcept®)	5,094,000
2	Amoxycillin 250mg scored tab/cap.	4,689,360	Human Albumin 20%, 100ml	2,448,600
3	Vitamin C 250mg tab.	3,002,000	Cycloserine 250mg tab.	1,903,218
4	Retinol (Vitamin A) 200,000 unit cap.	1,875,000	Purified Verro Cell Rabies Vaccine 0.5ml with Diluent & 1ml disposable syringe.	1,736,000
5	Alum. hydroxide 250mg + Mag Hydroxide 400mg tab (Antacid)	1,750,760	Amoxycillin 250mg scored tab/cap.	1,499,160
6	Ethyl Chloride spray with devices (100ml)	1,607,400	Metronidazole 5mg/ml inj. 100ml	1,022,008
7	Paracetamol 500mg tab.	1,540,000	Vitamin C 250mg tab.	976,440
8	Ranitidine 150mg tab	1,487,360	Cephazolin 500mg/vial inj.	913,255
9	Penicillin V 250mg tab.	1,478,400	Sodium chloride 0.9% inj (500ml)	898,897
10	Chloramphenicol 1% 250mg eye applicaps	1,365,000	Isoflurane solution 250ml	690,900
11	Clotrimazole 1% oint., 15g	1,129,500	Compound solution of sodium lactate inj. (500ml)	679,768
12	Cloxacillin 250mg cap.	1,004,090	Tacrolimus 1mg tab (Pangraf ®)	628,614
13	Sodium chloride 0.9% inj (500ml)	945,000	Methylcellulose 0.3% eye drops, 10ml	601,731
14	Ibuprofen 400mg tab.	900,000	Omeprazole 20mg cap	565,600
15	Benzylpenicillin 3g (50lakh unit) inj.	875,000	Paracetamol 500mg tab.	548,020
16	Spironolactone 25mg tab	862,680	Ranitidine 150mg tab	526,784
17	Vitamin B complex tab.	845,000	Cyclosporin 100mg cap (Neoral ®)	501,320
18	Anti-snake venom serum inj. 10g	804,420	Ceftriaxone 1g/vial inj.	487,344
19	Ampicillin 500mg/vial inj	801,620	Cyclosporin 50mg cap (Neoral ®)	457,500
20	Theophylline 69mg + Etophylline 231mg	762,770	IV amino acid solution, 250ml.	438,360
	%budget on top 20 drugs	55.9%	% budget on top 20 drugs	51.1%
	% on ABs	22.6%	% on ABs	14.8%
	% budget on vitamins	6.2%	%budget on vitamins	3.7%
	% budget on EML drugs	100%	% budget on EML drugs	100%
	value of drugs supplied centrally	100%	% value of drugs supplied centrally	100%

Table 4.3.3 shows the top 20 items consumed by value at JDWNRH for EML (panel A) and for named-patient drugs which are mostly non-EML ones (panel B), respectively. The total JDWNRH budget was NU 59,168,067 of which budget Nu 44,220,284 (75%) was for EML (panel A) drugs and 14,947,783 (25%) was for named patient (panel B) drugs. Some of the named patient B drugs are also used in patients attending the other regional referral hospitals though the purchase is controlled by JDWNRH. In total, the JDWNRH EML drug consumption was 40% of the entire national EML budget. The total JDWNRH budget (EML and non-EML drugs) was 53% of the entire national budget (EML and non-EML drugs) and the named patient drugs consumed 13% of the entire national drug budget (EML and non-EML drugs).Thus drug consumption in JDWNRH for both essential and named patient drugs is very high in proportion to the whole country budget. This warrants investigation into whether all the medicines procured by JDWNRH are really necessary (are there cheaper alternatives?), and whether all procured medicines are procured at the best unit prices.

The top 20 named-patient medicines in JDWNRH (panel B table 4.3.3) included some EML drugs such as mycophenolate mofetil and tacrolimus but mostly consisted of non-EML drugs. Intravenous immunoglobulin tops the list, followed by two immune-suppressants, mycophenolate mofetil and tacrolimus in the same or different strengths from those mentioned in the EML. These two products were purchased by a variety of trade names of different pharmaceutical companies. Other products in the top 20 by value included imipenem (a reserve antibiotic), Hep B immunoglobulin and anti-cancer medicines. These top 20 named-patient medicines consumed about 57% of the JDWNRH named-patient budget.

Interestingly, in the named patient list there were many Calcium and Vitamin D preparations with different trade names, including: architrol, calcitrol, calciferol granules, calciriol granules, calcit, calcitriol, calcitrol Bio D3, cholecalciferol, osteocalcium, rocaltrol, sandocal, shelcal, etc. Procurement of so many different calcium preparations is likely to result in higher prices and greater expenditure than purchase of a few preparations.

Table 4.3.4 shows comparisons between the highest and lowest unit prices for some medicines in the named patient list. The table shows that there was a huge price variation in unit prices for some medicines. For example, the variation in unit price was: Nu 22,449 to Nu 23,810 per injection for Denosumab 120mg injection; Nu 4.45 to 61.93 per tab for Cilacar 10mg tabs; Nu 7,000 to Nu 8,800 per injection for Botox 100 IU injection. The highest unit price was 26% to 1291% higher than the lowest unit price. For some high priced medicines like Botox a 26% price variation may result in greatly increased absolute expenditure due to the volumes purchased.

On average, five purchases were made for each of over 400 products (range once to 32 times) in the last year. More than 20 purchases were made for the following drugs many of which are used for chronic, not emergency, cases - alendronate, azothiaprine, dorzolamide eye drops, filgrastim, gabapentin, hep B immunoglobulin, hydroxychloroquine, leflunomide, mycophenolic acid, tacrolimus, pregabalin, rocaltrol (calcitriol), shelcal (calcium + vitamin D), sildenafil, tacrograf, tamoxifen, tenofovir. Overall various products containing calcium and/or vitamin D were purchased 144 times – an average of nearly 3 preparations per week. Purchase of so many small amounts of the same product puts a much greater burden of work on the procurement unit and Kolkata office and will also lead to higher prices. It would seem that there is scope for rationalizing some of these purchases.

Table 4.3.3: ABC analysis of top 20 items – EML and additional procurement as named-patient for National Referral Hospital, JDWNRH

Source of data: DMSHI, Procurement Division, MOH& JDWNRH Year: 2014-15

Rank	National referral Hospital – JDWNRH for EML Panel A			National referral Hospital – JDWNRH for named-patient Panel B		
	Item Name/Strength	Monetary Value (Nu)	EML	Item Name/Strength	Monetary Value (Nu)	EML
1	Mycophenolate mofetil 500mg cap (cell cept®)	5094000	Yes	IVIG 5gram inj	1,390,741	No
2	Human albumin 20% 100ml	2,448,600	Yes	Mycophenolate mofetil (different strength and different trade names)	833,411	Yes & No
3	Cycloserine 250 mg tab	1,903,218	Yes	Tacrolimus (Different strengths & trade names)	739,147	Yes & No
4	Purified Verro Cell Rabies Vaccine	1,736,000	Yes	Imipenem 500mg Inj	736,720	No
5	Amoxycillin 250mg cap	1,499,160	Yes	Bevacizomab 100mg inj	359,149	No
6	Metronidazole inj	1,022,088	Yes	CAPD Solution (Baxter)	294,677	No
7	Vitamin C tab	976,440	Yes	Bosantan 62.5 mg	285,081	No
8	Cephazoline 500mg inj	913,255	Yes	Infliximab 100mg Inj	276,000	No
9	Sodium chloride 0.9% inj 500ml	898,897	Yes	Leuprolide 3.75 & 11.7mg inj.	252,642	No
10	Isoflurane Solution 250 ml	690,900	Yes	Hep B Immunoglobulin 100 IU Inj	250,556	No
11	Compound solution sodium lactate inj 500ml	679,768	Yes	Denosumab 120mg Inj	230,776	No
12	Tacrolimus 1mg tab (Pangraf)	628,614	Yes	Oxaliplatin 50 &100mg inj.	202,333	No
13	Methycellulose eye drops	601,731	Yes	Enoxaparin 60mg inj.	194,728	No
14	Omeprazole 20mg cap	565,600	Yes	Pemetrexed 500mg inj& 100 mg	176,556	No
15	Paracetamol 500mg tab	548,020	Yes	Gemcitabine 200mg inj& 1gm inj	158,7917	No
16	Ranitidine 150mg tab	526,784	Yes	Tocilizumab 560mg inj (and other strengths)	144,570	No
17	Cyclosporin 100mg cap (Neoral ®)	501320	Yes	Capectabine 500mg	138,613	No
18	Ceftriaxone 1g inj	487,344	Yes	Paclitaxel 260mg inj. &other strength	115,145	No
19	Cyclosporin 50mg cap (Neoral ®)	457,500	Yes	Filgrastim 300mg inj	108,880	No
20	IV Amino Acid Solution	438,360	Yes	Carboplatin 450mg inj	96,292	No
	%budget on top 20 drugs		51.1%	% budget on top 20 drugs		56.5%
	% budget on Antibiotics		14.8%	% on Antibiotics		4.9%
	% budget on vitamins		3.7%	% budget on vitamins		-
	% budget on EML drugs		100%	% budget on EML drugs		0%
	% value of drugs supplied centrally		100%	% value of drugs supplied centrally		100%

Table 4.3.4: Unit price comparisons between highest and lowest for few medicines procured as named-patient for National Referral Hospital, JDWNRH

Drug Name (include formulation & strength)	Highest unit price procured (Nu)	Lowest unit price procured (Nu)	% difference
Azathioprone 50mg	13.2	3.2	312.50
Bortezomib 2mg inj	2025	1610	25.78
Botox 100 IU inj.	8800	7000	25.71
Cabergoline 0.5mg	149.75	47.8	213.28
Calcirol Granules 60000 IU	24.65	7	252.14
Carboplatin 150mg inj	497	50.6	882.21
Cilacar 10mg	61.93	4.45	1291.69
Etoposide 100mg inj	101	15.86	536.82
Exemestane 25mg	55	29.99	83.39
Finasteride 5mg	9.37	3.3	183.94
Fludrocortisone 100mcg	8.49	4.63	83.37
Gliclazide 80mg	3.58	1.5	138.67
Hep B Immunoglobin 100 IU inj	2300	1446.46	59.01
Hydroxychloroquine 400mg	10.1	4.93	104.87
Ifosfamide with Mesna 1g inj	214.99	114	88.59
Imepenam 500mg inj	330	149	121.48
Leflunomide 20mg	16.09	3.6	346.94
Levetiracetam 500mg	14.3	3.9	266.67
Mycept 500mg	43.99	15.08	191.71
Shelcal 500mg	2.9	0.23	1160.87
Sidenafil 50mg	4.88	0.5	876.00
Surfactant 108mg inj	4179	2650	57.70
Tacrograf 0.25mg	24.17	5.7	324.04
Tadalafil 10mg	22.8	3.9	484.62
Tadalafil 20mg	22.8	3.28	595.12
Tamoxifen 20mg	4.25	1.5	183.33
Zoladronic acid 4mg inj	385	156.6	145.85

Table 4.3.5 provides a comparison of the procurement unit prices for the top 24 essential medicines by value of national Bhutan procurement with unit prices quoted in the MSH International Price Indicator Guide and as used in the same period by the Jawaharlal Institute of Postgraduate Medical Education (JIPMER) in Puducherry, India. Comparing the procurement prices between Bhutan and MSH, 14 products (shown in red color) had higher unit prices in the MSH international price guide and 8 medicines had higher unit prices (shown in red color) in Bhutan procurement. Procurement prices for Bhutan are less than in the MSH International price guide as Bhutan procures its medicines from India, which is well known for its low prices. While some medicines had similar or slightly lower unit prices in JIPMER in Puducherry, the unit prices for some drugs procured by Bhutan were lower, including antacid tablets, penicillin V tablets, chloramphenicol eye applicaps, cloxacillin tablets, ringer lactate infusion, hydrocortisone 1% cream and human mixtard (30:70) insulin.

Table 4.3.6 provides a comparison of procurement unit prices for the 32 medicines surveyed - for Bhutan, the National Capital Territory (NCT) of Delhi, and the JIPMER government hospital in Puducherry. Although for many drugs the lowest prices were generally found in Delhi State, there was in fact very little difference in the procurement prices between any of the three agencies. Only for a few medicines was the procurement price for Bhutan higher, e.g. diazepam, ORS packet, oxytocin, ranitidine injection and salbutamol respiratory solution. This result is not surprising since Bhutan procures almost all its medicines from India and the currency of Bhutan Ngultrum (Nu) is also aligned with the Indian currency, Indian Rupee (INR).Thus, comparison of procurement unit prices with two Indian states shows that Bhutan is procuring at competitive rates for many of its essential drugs.

Table 4.3.5: Comparative procurement prices of top 24 items – national level for EML products with external price indicator of MSH and Puducherry, India procurement prices

Rank	Item Name (including strength & formulation)	Unit pricein Bhutan procurement in (USD)*	Unit price JIPMER Hospital (Puducherry) procurement (USD) #	Unit price in MSH International price indicator guide (USD)
1	Purified Vero Cell Rabies inj	3.82	2.39	15.6334
2	Amoxycillin 250mg	0.01	0.01	0.0207
3	Mycophenolate mofetil 500mg	0.92	0.15	0.3521
4	Vitamin C 250mg tab	0.01	-	0.0071
5	Human Albumin 20% 100ml	0.6461	NA	0.5632/ml
6	Retinol (Vit A) 200,000 unit	0.06	NA	0.0558
7	Paracetamol 500mg tab.	0.003	0.0039	0.0051
8	Antacid (Al+MagHydrox) tab	0.003	0.0051	0.0039
9	Ranitidine 150mg tab	0.0049	NA	0.0204
10	Cycloserine 250mg tab	0.72	0.38	0.4887
11	Sodium chloride 0.9% inj 500ml	0.21	0.23	0.0010/ml (0.05/500 ml)
12	Ethyl Chloride spray with device100ml	6.51	NA	NA
13	Penicillin V 250mg tab	0.01	0.02	0.0200
14	Chloramphenicol 1% 250mg eye applicaps	0.01	0.02	NA
15	Spironolactone 25mg tab	0.02	0.02	0.0597
16	Cloxacillin 250mg cap	0.01	0.02	0.0217
17	Clotrimazole 1% oint, 15g	0.19	0.14	0.0575/g (0.8625/15 g)
18	Ibuprofen 400mg tab	0.01	0.01	0.0148
19	Cephazolin 500mg inj	0.27	NA	0.5412/vial
20	Ringer lactate inj. 500ml	0.21	0.26	0.0007/ml (0.35/500 ml)
21	Metronidazole 5mg/ml inj 100ml	0.13	0.12	0.0045/ml (0.45/100 ml)
22	Vitamin B complex tabs	0.002	0.002	0.0052
23	Hydrocortisone 1% cream, 15g	0.37	0.69	0.0529/g (0.078/15 g)
24	Human Mixtard (neutral + isophane) 30: 70, 10ml	1.22	1.45	0.3603/ml (3.603/10ml)

*1 USD = 65 Bhutanese Ngultrum; #1 USD = 64.97 Indian Rupees

Table 4.3.6: Comparative procurement prices of 32 EML products surveyed in Bhutan with procurement price of NCT, Delhi and Puducherry, India procurement prices

S. No.	Medicine name and Strength	Procurement price (Nu) per unit for Bhutan	Procurement price (INR) per unit for Delhi State	Procurement price (INR) per unit for Puducherry	Remarks
1	Albendazole 400mg tab	0.85	0.81	2.23	Lowest for Delhi State
2	Amoxycillin 250mg tab	0.78	0.89	0.8739	Lowest for Bhutan
3	Atropine sulphate 1mg/ml inj	1.88	NA	NA	Different strength available for 2 procurement agencies
4	Cetirizine 10mg tab	0.11	NA	0.149	Lowest for Bhutan
5	Ciprofloxacin 0.3% eye/ear drop	1.04/ml	0.62/ml	1.16/ml	Lowest for Delhi State
6	Clotrimazole 1% ointment	0.83/gm	0.35/gm	0.602/gm	Lowest for Delhi State
7	Co-trimoxazole (400mg+80mg) tab	0.57	0.54	0.5090	Lowest for Puducherry
8	Dexamethasone 4mg/ml inj	1.96/ml	1.95/ml	2.3008/ml	Lowest for Delhi State
9	Diazepam 5mg tab	0.24	0.16	0.1140	Lowest for Puducherry
10	Diclofenac sodium 25mg/ml inj	2.50	NA	1.71/3ml (0.57/ml)	Lowest for Puducherry
11	Ferrous sulphate 60mg + folic acid 0.40mg tab	0.06	NA	NA	
12	Gamma benzene hexachloride solution 100ml	14.85	NA	NA	
13	Gentamicin 40mg/ml inj 2ml	3.80	3.96	3.42/2ml	Lowest for Puducherry
14	Hydrochlorthiazide 25mg tab	0.14	NA	0.1820	Lowest for Puducherry
15	Metformin 500mg tab	0.21	0.21	0.21	Same for all three
16	Metronidazole 400mg tab	0.47	0.45	0.5980	Lowest for Delhi State
17	Oral rehydration solution (ORS) packet	2.65	2.43	2.52/packet	Lowest for Delhi State
18	Oxytocin 5 unit/1ml inj	7.69	1.66	3.10/ml	Lowest for Delhi State
19	Paracetamol 500mg tab	0.22	0.22	0.2520	Puducherry is higher
20	Ranitidine 150mg tab	0.32	0.24	NA	Lowest for Delhi State
21	Ringer lactate inj 500ml	19.56	16.60	17.01/500 ml (0.03402/ml)	Lowest for Delhi State
22	Salbutamol 4mg tab	0.13	0.104	0.1409	Lowest for Delhi State
23	Sodium chloride 0.9% inj 500ml	13.50	13.95	14.81/500 ml (0.02962/ml)	Lowest for Bhutan
24	Amitriptyline 25mg tab	0.25	0.18	0.2221	Lowest for Delhi State
25	Atenolol 50mg tab	0.18	NA	0.1178 (25 mg)	Lowest for Puducherry
26	Ciprofloxacin 500mg tab	1.51	1.397	1.529	Lowest for Delhi State
27	Enalapril 5mg tab	0.15	NA	0.126	Lowest for Puducherry
28	Frusemide 10mg/ml inj	0.31	1.87	2.28/2ml (1.14/ml)	Lowest for Bhutan
29	Metronidazole 5mg/ml inj	8.64	7.35	7.60/100 ml (0.0760/ml)	Lowest for Delhi State
30	Prednisolone 5mg tab	NA	0.58	0.38	Lowest for Puducherry
31	Ranitidine 25mg/ml inj	3.01	NA	1.31/2 ml (0.655/ml)	Lowest for Puducherry
32	Salbutamol respiratory solution 5mg/ml	11.73	6.75	8.85/15 ml (0.59/ml)	Lowest for Delhi State

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

The Medical Supplies Procurement Division (MSPD) under the Department of Medical Supplies and Infrastructure (DMSHI), MOH, is the central pubic procuring agency for all the medical supplies. This division replaced the Drugs, Vaccines and Equipment Division (DVED) in the Department of Medical Services (DMS) which existed in 2011. The quantities procured by the MSPD are based on the BoQ (Bill of Quantity) prepared by Health Care and Diagnostics Division (HCDD) under DMS. The BoQ is prepared by the HCDD through compilation of all the quantities needed as estimated by the health facilities across the country. The HCDD also monitors stock through a manual reporting system whereby all health facilities are required to report stock-outs on a monthly basis.

By end of January the annual quantity needed is sent by all the health facilities to the HCDD, where quantities are compiled and then these quantities are sent to the MSPD for procurement. Currently there is no cap to spending, but from 2016 the budget, based on the estimated amounts of drugs needed, will be agreed by the DMS and DMSHI and submitted to the Ministry of Finance for approval by March each year.

Tendering is done annually based on an International tendering process whereby only the suppliers registered with the MSPD and Drug Regulatory Authority (DRA)are allowed to participate. The previous attempt in 2011-2012 to encourage local Bhutanese wholesalers by introducing 3-year tendering for lots (groups of drugs) and higher default penalties was abandoned due to lack of wholesalers willing to bid as they were unable to make long-term agreements with stable prices with manufacturers for the small quantities required. The MSPD seeks the list of registered medicines from the DRA every year prior to annual tendering. However, the suppliers registered with the autonomous DRA only cover 263 out of the 367 essential medicines. Those medicines which have registered suppliers are classified as Section A drugs and the remaining 104 medicines are classified as Section B drugs. For section A only those suppliers which have registered the medicines are eligible to quote but for section B any suppliers registered with DRA can submit their tenders. Invitation to tender for all the essential medicines is floated in the Bhutanese newspapers, put on the MOH and DMSHI websites and also the registered suppliers with MSPD are notified through the facsimile.

The quotations are invited in a one-envelope system where technical specifications and prices are quoted together. A committee consisting of Pharmacists and Pharmacy Technicians from JDWNRH but not any other regional hospitals (though this is planned for the next tendering) evaluates the tender based on the past performance of the supplier and the quality history of the quoted products. The delivery period is usually 90 days after the placement of purchase orders but due to complaints of not being able to supply in the delivery deadline, the delivery period has been extended to 120 days from 2015. An additional 60 days is given for the delivery of narcotics and psychotropic substances, since the import and export of these medicines is strictly regulated strictly internationally.

As per Medicines Regulations 2012, only Bhutanese and foreign manufacturers can register pharmaceutical products in Bhutan. Since the volume of medicines procured is low, only Bhutanese wholesalers participate in the tender. Foreign manufacturers who have registered their medicines with the DRA, though allowed to participate in the tenders, do not do so. All the medicines supplied by wholesalers are, in turn, procured from Indian manufacturers. Only a few suppliers are registered with the DRA, but since 2011-2012, the DRA has introduced more flexibility concerning the issue of “No-objection” letters for the importation of small quantities of essential medicines that are not registered (despite effort to encourage wholesalers to register them). Even so, for the year 2014-15, out of 367 essential medicines, 295 medicines were quoted

by Bhutanese wholesalers but no quotes were received for 72 medicines. For these 72 medicines, tenders were invited through the Kolkata office after obtaining “no objection” or exemption letters from the DRA. From those drugs quoted for and given purchase orders in the 2014 annual tender, around 16 medicines have not been received due to supplier default.

The procured medicines are received at the MSDD (Medical Store& Distribution Division) which has its office and central warehouse at Phuentsholing. A committee of experts (pharmacists from different referral hospitals) visits the MSDD warehouse and physically checks all the batches of medicines before they are sent for distribution to health facilities. If there is doubt for any medicine on physical verification, the manufacturers are contacted and the sample may be sent for quality testing. Also the DRA sends random samples for quality testing. The supplies of JDWNRH also come to this warehouse first and before being sent to the hospital.

4.4.2. Provincial/District/Health facility Drug Procurement

No district or regional referral hospital does any procurement. In order to treat patients needing drugs which are not available at the level of health facility available locally, the drugs are requested from the nearest higher-level health facility (Form III) or on a named-patient (Form II) basis. If necessary, such patients are referred to the next level facility or to the national referral hospital, JDWNRH

All additional supply or emergency medicines for all the health facilities, except for the JDWNRH, are procured through DMSHI by the Kolkata office, India. As the volumes are usually very small, the local suppliers are not able to deliver the products within 2-3 weeks. Therefore, all such procurement is done by the Kolkata office which invites tenders.

The JDWNRH does its own additional and emergency procurement through the Kolkata office. Recently, the amount of additional medicines ordered has increased. JDWNRH recently procured 2million Nu worth of medicines through the Kolkata office. It was stated that the reason for this was that, with the diagnostic facilities made readily available to all levels of health facility, the consumption of medicines for non-communicable disease, especially diabetes and hypertension, has increased drastically. As a result, the order for additional procurement of medicines for non-communicable disease (NCD) was made to the Kolkata via the Health Liaison Officer. However, the emergency medicines included those for both communicable diseases and non-communicable diseases.

4.5. Allocation of budget for medicines in the public sector

The budget for the procurement is prepared by the MSPD based on the total amount spent on the medicines in the previous year with 10-15% increase and submitted to the Ministry of Finance for approval at the end of every financial year. As such there is no cap on the funds. From 2014, the Bhutan Health Trust Fund (BHTF) has started funding the budget for medicines and vaccines and the funds are being released to the Division on quarterly basis. However, the Trust Fund only funds EML drugs and there is currently a problem on how to fund the named-patient drugs. While some named-patient medicines are not on the EML because they may not be critically important, others are critically needed but are not on the EML due to reasons of low volume.

4.6. Drug quantification in the public sector

All the health facilities send their annual requirement to HCDD/DMS, in January (in December from 2016) based on the formula:

Annual Requirement = Last year's average monthly consumption x 26 months MINUS expected December Balance

> Where expected December balance = the physical quantity that can be consumed before expiry plus quantity of the product that is in the pipeline from the MSDD to the health facilities

This quantification formula was reinstated following an attempt in 2010-2012 to use a formula based on last year's average consumption multiplied by 12 months (instead of 26 months) which failed due to lack of buffer stock to tide over supplies during periods when suppliers delivered late or defaulted. Drug quantification for all health facilities is taught to all the staff including the BHU II in-charges. The quantification is based on the past consumption method.

Compilation of all the health facility indents is done manually by the Health Care and Diagnostic Division (HCDD) under the Department of Medical Services (DMS). Since compilation is done manually, errors may be made with regard to quantities needed by individual facilities and overall for the whole country.

At the central level, buffer stock amounts are calculated based on the VEN system, where 30%of the annual estimated quantities needed are kept for Vital, 20% for Essential and 10% for Necessary drugs. Since there were problems with the buffer stock getting expired at the MSDD, from 2014 some quantities have been deducted from this estimation based on the past stock trends of medicines at MSDD.

There was previously an electronic drug inventory management system, DIGPY, which is no longer used due to the problems with the software. The MSPD has got permission to develop a new online system and it is proposed that the new system be a web- enabled inventory system. The budget for the new system has been approved for the coming financial year and a feasibility study is being currently under process.

4.7. Drug Management and Distribution in the public sector

4.7.1. Drug Storage and Distribution at the central national level

The Medical Store and Distribution Division (MSDD) under DMSHI is located at Phuentsholing, where there is a large new, well equipped warehouse, with good shelving and cold storage facilities. This division replaces the Medical Supplies Depot under DVED which existed in 2011. The warehouse was well kept. The MSDD receives medicines and equipment directly from suppliers as procured by the MSPD in Thimphu. The MSDD then distributes the received medicines to all the health facilities across the country based on the Distribution Order prepared by HCDD/DMS.

After the receipt of medicines from suppliers, a quality inspection (QI) committee, formed of pharmacists and Pharmacy Technician from JDWNRH and other referral and district hospitals and a representative from HCDD/DMS, undertakes a visual quality inspection of the medicines received from suppliers. Unsatisfactory products are rejected at the MSDD and returned to the suppliers. Once quality inspection is completed, medicines are repacked as per the Distribution Order (taking into account current stock levels and the amounts of drugs received from suppliers) and distribution starts. The MSDD store issues notes (packing

slip) to all facilities for delivery. Upon delivery, the health facilities count the number of cases and return a form verifying the delivery of the correct number of cases through the driver back to the MSDD. A yellow copy of the packing slip is returned to the MSDD at a later date once the contents of the delivery are verified and accepted by the health facility.

Distribution to health facilities is theoretically done annually and the distribution orders are prepared by the HCDD based on the indents made by the respective health facilities during the quantification process. However, the amounts needed cannot be delivered to each health facility in one go for various reasons.

Firstly, if there have been errors in quantification process then these errors will be passed on in the amounts distributed. Many hospitals have underestimated their annual requirements and make 2-3 additional orders on top of the annual indent request. Secondly, although the main supply of medicines is received by the MSDD in Phuentsholing during October - December, often only 30-40% of drugs are received on time, the rest being received in 3-4 deliveries later in the year. Thus, the annual indent for health facilities often has to be distributed over 3-4 deliveries, there not being the stock available in the main warehouse to deliver the whole year's estimated need. Thirdly, the MSDD has only 10 vehicles and so distribution cannot be done in one go. Ten vehicles are not enough and they have not previously been able to purchase more vehicles due to a government suspension on purchase. However, for the new financial year, government has approved the budget to procure 3 additional large trucks and one medium truck (two of which had arrived shortly after the situational analysis).

In order to overcome the distribution problems and reduce the likelihood of patients suffering from stock-out, distribution is first done to JDWNRH and the other regional referral hospitals and thereafter to farthest/remote areas. For the health facilities with no accessibility to motor roads, the medicines are dropped at an agreed location for the health facilities to collect themselves. All logistic management inventory control is done manually and is time consuming. Another strategy used to avoid stock-outs at health facilities, and avoid needing time to deliver extra stock in emergencies, is to keep some buffer stock in the District Hospitals (based on the quantities estimated for the respective Dzongkhags).Despite these efforts to avoid stock-outs, most hospitals also make 4 or more additional (emergency) orders during the year over and above the 3-4 deliveries they receive with regard to their annual requisition.

4.7.2. Drug Storage and distribution at the Provincial/District level (including redistribution)

At district hospitals, the stores were well kept though the common complaint was of space. At some district hospital there was no space for keeping lab reagents and equipment (non-medicines). At BHUs many stores did not have proper ventilation and storage space was very small. Although all health facilities had fridges (even kerosene ones in areas without electricity) at some places storage for vaccines was insufficient and sometimes there was no temperature monitoring system.

Usually the expired medicines were stored separately but occasionally a few expired drugs were also found on the shelves with un-expired medicines. There was also difficulty for destroying expired drugs as there were no clear guidelines issued by MOH.

Pharmacy technicians generally managed the stores except in BHUIIs where the health assistant did this. In referral hospitals there was a pharmacist to oversee the pharmacy technicians. Generally, the medicines were stored alphabetically. A common complaint was a shortage of staff for managing the stores.

Re-distribution of medicines within districts was commonly practiced and sometimes medicines were also redistributed between districts and referral hospitals. The store in-charges generally push for the

redistribution of short-expiry medicines, sending them to other health facilities which have a shortage. For BHUs, short-dated stock is generally sent back to the concerned district hospital. However, redistribution between hospitals also occurs. Either the hospital store in-charge has already received a request from another hospital about the need for extra stock or, in some cases, the hospital store in-charge phones around to find facilities needing extra stock. The redistribution system was working well but in many places no vehicle was available for redistribution in which case collection of medicines was a challenge.

For inpatients, nurses usually maintain the ward store and inventory. There was generally a small room for storing drugs. In one hospital some ward drugs were stored in the ward kitchen area. A stock book was not maintained, only a request sheet, so there was no record of actual stock amounts. In the ward they have a trolley with small containers for medicines which the nurses refill from the main container. From the trolley individual small plastic medicine dispensers were used to dispense drugs to individual patients. The stores were generally well kept but there was not sufficient space for good storage. Pharmacy technicians and pharmacists did not usually supervise ward management of medicines.

4.7.3. Pharmaceutical Human Resources

The drug stores at all levels of health facility are managed by Pharmacy technicians, except at the BHU II level, where there are no pharmacy technicians and where the Health Assistant (basic prescriber) who is the prescriber and dispenser, is usually in charge of the store.

In general, there is shortage of pharmacists in the DMS, including the HCDD, EMTD and hospitals. Although the procurement division (MSPD) within DMSHI has a pharmacist who looks after the entire procurement process, there are no pharmacists at distribution division (MSDD) based in Phuentsholing. At MSDD, it is mainly pharmacy technicians who look after the warehouse and manage the logistics.

At national referral hospital, JDWNRH, there were five pharmacists and 37 pharmacy technicians. At the regional referral hospital in Monggar there was one pharmacist and five pharmacy technicians and at Trashigang hospital there was one pharmacist and three pharmacy technicians. At other district hospitals and BHU Is stock management, redistribution, OPD etc. was managed by pharmacy technicians. At the BHU IIs, there were generally only health Assistants (2-3) who managed everything including dispensing and store management.

The sanctioned posts of pharmacy technicians are usually filled up to 70-80%. Only a few unfilled posts were observed in the facilities visited. However, at district level, the number of sanctioned posts for pharmacists is very low and for pharmacy technicians insufficient. Thus, there are often no pharmacists at district hospitals to supervise pharmacy technicians and the management of medicines in the store, the OPD and in the inpatient wards. Since no pharmacy technicians went to supervise drug management in the wards, it is not certain that this aspect of drug management is taught or included in their job description.

4.7.4. Traditional Medicine

Traditional medicine practitioners are available, under one roof with allopathic practitioners, at public facilities mainly at BHU Is, district hospitals and regional referral hospitals but not at BHU IIs and the national referral hospital, JDWNRH. There is also a separate hospital for traditional medicines, the National Traditional Hospital in Thimphu, where about 300-350 OPD patients visit daily. Traditional medicines are supplied, from the MSPD store in Thimphu (since the humidity in the MSDD warehouse in Phuentsholing is

too high) to all the health facilities, where traditional medicine is practiced. In addition, there is only one private retail pharmacy in Thimphu for traditional medicines. All traditional medicine units whether in allopathic facilities or separate are headed by a Traditional Prescriber.

Most district hospitals had 2 traditional practitioners (one for prescribing and the other for dispensing) and saw about 10-20 patients daily including some old patients coming for follow up treatment. Some of the larger hospitals saw more patients. Paro district hospitals had 5 traditional practitioners (including "Menpa" nurses and "Drungtsho" physicians) and saw about 30-40 patients daily. Paro district hospital had 5 traditional practitioners and Monggar Regional Referral Hospital had four traditional practitioners. Some BHU I facilities had only one traditional practitioner and saw less than 10 patients daily.

Bhutan has an essential medicine list for traditional medicines as well as allopathic medicines. There are 94 traditional medicines on the list. These traditional medicines are also procured centrally by the MSPD and distributed by the MSPD. Traditional medicines were generally stored in the same stores and managed by the same store in-charges as for allopathic medicines although in some health facilities due to staff shortages, the store was managed by traditional medicine staff. However, the traditional medicine outpatient dispensary was always managed by a traditional medicine practitioner.

Menjong Sorig Pharmaceuticals (MSP) under the Department of Traditional Medical Services (DTMS), MOH, manufactures all the traditional medicines used by the health facilities. Since the MSP has to pay to the villagers for the raw materials used in the production of medicines, the MSPD procures the medicines from the MSP and they are supplied to the health facilities based on their requests.

4.8. Patient Flow in the Health Facilities

In Bhutan, the government provides all the health services completely free, with no registration fees, inpatient fees or fees for diagnostic tests or drugs. Only cosmetics in dental procedures are charged for at around 50% of the actual cost of the items.

The patients are required to register at the reception where they are segregated into old or new cases and where the prescription form with a registration number, and the chamber number of the physician that they need to visit, is written. Once the doctor or health assistant has prescribed medicines, the patients go to the pharmacy counter and give their prescription which is then dispensed.

The national referral hospital, JDWNRH, is a 350 bedded hospital, staffed by more than 20 general and 60 specialist doctors, and seeing about 1000 OPD patients both new and old per day. OPD registers with diagnosis were not kept at this hospital. Monggar regional referral hospital is a 150-bedded hospital, staffed by 5 general and 14 specialist doctors, and seeing about 300 OPD patients per day. There was an MBBS doctor and a clinical officer working in the OPD. OPD registers with diagnosis and treatment were maintained by the prescribers though complete details of diagnosis and prescription were sometimes omitted.

Other district hospitals have 20-40 beds, are staffed by 2-5 doctors, mostly generalists, and see about 100-400 OPD patients daily. Usually in these hospitals, there were always Health Assistants and one doctor in the OPD though sometimes all the doctors were on the ward or dealing with emergencies. BHU I facilities have 10 beds, are staffed by one generalist doctor and health assistants, and see about50-150 OPD patients daily. There was not a doctor on site in all the BHU I facilities visited. The OPD is run by a doctor (if available) or a Health Assistant or (if the latter is not available) by another health worker as seen in one facility visited where the doctor was away and the Health Assistant fully occupied in an immunization clinic. BHU II facilities have 2-5 beds, are staffed by health assistants and see 2-20 OPD patients daily.

The OPD registers were reasonably well maintained though not always complete in district hospitals and BHU I facilities but always completely filled in BHU II facilities.

4.9. Insurance

There is no medical insurance in Bhutan.

There is some medical insurance for the corporate employees. Although civil servants and the general public are not health insured, 1% of the income of civil servants is deducted by the government as a health contribution.

4.10. Drug Manufacturing

There are no government-owned or private pharmaceutical formulation manufacturing companies except for one government-owned manufacturing unit for traditional (herbal) medicines. Any quality testing must be done in the national Drug testing Lab in Bhutan or at another private lab in Nepal. There is one private API manufacturing company in Phuentsholing.

4.11. Drug Management in the private sector

Six private retail pharmacies were surveyed, two in Thimphu, two in Phuentsholing, and one each in Monggar and SamdrupJongkhar. Usually the retail pharmacy owner was not qualified as a pharmacy assistant/technician, but usually employed pharmacy assistant and untrained pharmacy assistants for the shop.

In all pharmacies, medicines and cosmetics were stored separately except in one. Some were following therapeutic class for storing, while others were storing medicines by formulation, but usually it was a mix of both. Some, but not all, of the pharmacies had a good labelling system on the shelves.

The approximate number of patients daily was 30-200 in Thimphu and 40-110 in Phuentsholing but only up to 20 patients per day in the more remote areas of Monggar and Samdrup Jongkhar. Similarly the daily sales for these retail pharmacies ranged from Nu 3000 where attendance was low to Nu 70,000 where attendance was high. Thus the economic viability of private retail pharmacies in the more remote areas is questionable.

Only about 10% of the patients come with a prescription, since most patients get their medicines free from the health facilities. Many of the prescriptions are for paediatric syrups which are not supplied by the public health facilities. In the capital city, Thimphu, the two retail pharmacies stocked about 125 and 250 products, respectively, and got their medicines from 7-9 suppliers. Retail pharmacies in the other three towns stocked only 52-100 products which they got from 4-6 suppliers.

Usually the medicines were dispensed in strips or bottles and sometimes in an envelope. Instructions were given verbally but no label was printed or handwritten for patients. However, in one pharmacy, the staff started to put medicines into an envelope and write the dose frequency and duration due to the presence of team members. The time for dispenser-patient interaction was 1-2 minutes.

4.12. **Summary status including progress, changes and problems** in drug supply since the last situational analysis

Virtually all medicine needs in Bhutan are met by the public sector. The Department of Medical Supplies and Health Infrastructure (DMSHI) manages procurement and distribution through the Procurement (MSPD) and Distribution (MSDD) divisions respectively. Annual procurement is done and annual requisitions (agreed centrally and based on health facility estimates) delivered to facilities through 3-4 consignments during the year. In addition, most hospitals make 4 or more additional (emergency) orders during the year. Availability of key essential drugs was 96-100% in all public facilities and complaints of stock-out were far fewer than in 2011. Strategies introduced since 2011 that have contributed to improved supply include re-introducing quantification based on average monthly consumption multiplied by 26 months, returning to annual tendering for each line item instead of 3-year tendering for lots, and greater flexibility by the Drug Regulatory Authority in issuing "No Objection" letters for the importation of small quantities of unregistered essential medicines. Furthermore, a well- functioning redistribution system between facilities for short-dated medicines was helping to keep stock-outs and expiry to a minimum. Restructuring within the MOH has occurred such that responsibility for drug procurement and distribution has been taken out of the Department of Medical Services (DMS) and put into a new Department of Medical Supplies and Health Infrastructure. Responsibility for quantification and the EML still remains with the DMS.

A new well-equipped central warehouse at Phuentsholing has been built since 2011 but some hospital stores are still short of space and poorly ventilated. Drug stores were generally well maintained though there is a shortage of pharmacists to manage them. The electronic logistic management information system, DIGPY, stopped functioning and the manual system now in place is difficult to manage. Procurement still relies on a one-envelope tendering system which may make it difficult for the procurement committee to follow all the technical product and supplier criteria needed to ensure timely procurement of good quality medicines.

4.13. Medicines Supply: Recommendations

- Establish an harmonized, functional, sustainable electronic drug management information system, to monitor consumption, stock-out, expiry and for forecasting, which is necessary to improve quantification:
    - Start with national referral hospital, JDWNRH, referral hospitals and all district hospitals;
    - Employ good IT staff to manage and update the software centrally;
    - Employ a data-entry staff for electronic data management at each hospital;
    - Designate a budget every fiscal year for the maintenance and management of the software and the drug inventory data.
- Employ one pharmacist (B. Pharm degree) for each hospital to supervise the drug store, the outpatient (OPD) pharmacy, the inpatient (IPD) drug management and to supervise the pharmacy technicians.

- Improve district hospital stores with more space and proper shelves for better management of store and inventory:
    - Major structural changes to be done by MOH;
    - Minor small changes to be done by hospital administration.
- Establish a team from the DRA, DMSHI, DMS and JDWNRH to analyze all purchases done for non-registered medicines product, e.g.
    - Percentage of purchased products not registered;
    - Reasons underlying purchases of all such medicines.
- Establish a 2-envelope system for tendering and procuring Section B essential drugs (for which no suppliers or products are registered). Only those suppliers and product tenders that clear the technical qualifications criteria (which need to take into account the difficulties of obtaining documentation from manufacturers) would be eligible for opening of their price-bids.

5. MEDICINE SELECTION

5.1. National Essential Medicines (Drug)List (EML)

- Responsible government department or agency: Essential Medicines & Technology Division (EMTD) under the Department of Medical Services (DMS)
- Date of publication of latest EML: EDL 2012 was in use during the situational analysis survey. The EML 2014 has been finalized and will be used for medicine procurement for the year 2015-16.
- Previous publication dates:2009;2011;2012
- Number of active pharmaceutical ingredients (API) in EML 2012: 264 excluding vaccines, immunoglobulins and insulins
- Number of formulations for all APIs:367 for NRH; 324 for RH; 213 for DH and 106 for BHU
- Number of traditional medicine products: 94 for NTMH; 84 for RRH; 69 for DH and 42 for BHU
- Categories by level of use:
    - EDL 2012 is categorized by facility type - for national referral hospital (NRH), referral hospital (RH), district hospital (DH) and basic health unit (BHU)
    - Medicines are also categorized as VEN (Vital, Essential, or Necessary) for each level of health care. Of a total of 367 medicines, 108 are classified as Vital, 217 as essential and 42 as necessary. These VEN classifications are made by the EMTD in consultation with the NRH and are used in the quantification of buffer stock
- Number of persons involved in drafting the 2012 EDL:
    - Core team: Editors – 6, including 4 staff members of the Essential Medicines and Technology Division (EMTD) under DMS) and 2 pharmacists from JDWNRH.
    - Experts: 13
    - Advisory Committee: consists of members of the National Medicine Committee (see section 5.3).
- Specialties represented:
    - Major specialties: 11
    - General practice: 2
- Geographic representation of experts?
    - All experts were from JDWNRH, Thimphu, except one, Medical Superintendent from Gelephu Hospital
- Consistency with national STGs? Yes

5.2. Other Medicine Lists

5.2.1. Central level

Non- EML lists include the following: Named-Patients, Intensive Care Unit (ICU), Haemodialysis. The Named-Patient List contains specific medicines for individual patient as prescribed at JDWNRH or one of the other referral hospitals by one of the specialist doctors. The JDWNRH arranges purchase of all these drugs (even for the regional referral hospital patients) through Kolkata office. The drugs on the named patient list are not reviewed or approved by any committee but just procured as they are prescribed for individual patients week by week.

5.2.2. Province/District

Other lists with EML drugs include the following: School Health Program list and the Monastic Body List (which are the same) and also the Voluntary Health Workers list. These lists contain about 11 essential medicines and the medicines but the Voluntary Health Workers List is different from the other two lists.

5.2.3. Hospital

Regional referral hospitals can ask for some specific medicine for a specific case. The request for named-patient medicines are sent to national referral hospital for procurement.

5.3. Development / updating of the national EML

The Essential Medicines & Technology Division (EMTD) under the Department of Medical Services (DMS) is responsible for maintaining the national essential medicines (drug) list. The latest list, EML 2014 was reviewed and finalized in 2015 and contains 381 formulations and will be used for procurement for 2015-16. However, the 2015 EML had not been printed and distributed and the 2012 EDL was being used at the time of the situational analysis, hence descriptions of the EML refer to the 2012 version.

The EML was reviewed by the National Medicines Committee which acts as the advisory body to the Ministry of Health. The National Medicines Committee has about 25-30 members comprising the following members:

- One representative (medical doctor) each from all Clinical Departments of the JDWNRH
- One representative from Nursing Services of the JDWNRH
- One representative (Pharmacist) from the Pharmacy Department of the JDWNRH
- One representative from Department of Medical Services (DMS)
- One representative from Department of Public Health (DPH)
- One representative from Department of Medical Supplies & Health Infrastructure (DMSHI)
- One District Health (DHO) representative
- One Medical Officer from the District
- One Health Assistant representative.

Various doctors may request changes to the EML submitting their reasons and justification on a specific form. Once all the proposals for the changes in the EML are received by the EMTD as per the prescribed form, the forms are compiled and shared with the Pharmacy Department of JDWNRH. With the support of the Pharmacy Department, the required literature search is conducted and a core team of 5-8 people comprising some doctors and pharmacists, who are members of the National Medicine Committee, meet to review the proposals. Some recommendations are then drawn up as preliminary discussion points for the main meeting of the National Medicine Committee

Thirteen 13 expert members, all doctors, and 6 editors (including 2 pharmacists from JDWNRH and 1 doctor from EMTD/DMS) contributed to the 2012 EDL. Only one expert (from Gelephu) was from outside JDWNRH in Thimphu and it is not clear if any generalists were included. The Medical Specialist of JDWNRH was the Chairman for the National Drug Committee (NDC).

The criteria for selection of essential drugs are based on the national drug policy as follows:

- Therapeutic need
- Relevance to national morbidity and mortality pattern
- Safety, quality and efficacy
- Cost effectiveness
- Ease and safety in administration and dispensing
- Usefulness in more than one condition
- Likelihood of patient compliance
- Training and experience of the prescribers
- Treatment facilities in the country
- Selection of essential drugs by generic name or International Non-proprietary Name (INN) only.
- When several drugs are available with the same indication, or when two or more drugs are therapeutically equivalent, the pharmaceutical product and dosage form that provides the most favorable benefit/risk ratio shall be selected.
- Fixed ratio combinations to be acceptable if one or more of the following criteria are met:
    - The clinical condition justifies the use of more than one drug;
    - The therapeutic effects of the combination are greater than the sum of effects of each drug;
    - The cost of the combination product is less than the total cost of the individual products;
    - In case of selection of traditional medicines, besides all the criteria that are relevant, other conditions such as availability of raw material, use of endangered species and legally prohibited materials should be considered.

The source of evidence is mostly from the literature, WHO websites, drug formularies, procurement data, clinical guidelines, etc.

Proposals for addition and deletion should be submitted to the Committee through the EMTD/DMS. The process is fairly transparent. Although all proposals should be reviewed and compiled by a group of experts organized by the EMTD prior to review by the National Committee meeting, there are times when the proponent (generally a clinician) is member of the Committee and therefore has the opportunity to present the case in the meeting. However, even if this occurs, the decisions are based on the views of the majority. The budget for the Committee meetings is provided by the government through program support.

During the 2011 situational analysis, a detailed review by WHO of the 2009 EDL used at the time was done. Some recommendations at that time have been incorporated in the 2012 EDL, namely, the deletion of fentanyl patches and the inclusion of carbamazepine. However, lithium carbonate, a commonly used cost-effective drug for bipolar conditions was still not included.

5.4. Implementation of the EML

The National Medicines Policy 2007 of Bhutan states that medicines supplied in the public sector shall belong to the national EDL, through the Essential Drug Program (now taken over by the EMTD/DMS).

Implementation of the national EDL 2012 was good throughout the country. Copies of the 2012 EDL booklet, as well as the 2014 national standard treatment guidelines and the 2012 national formulary of essential medicines, were available in almost all the health facilities. The 2012 EDL is also available on the MOH website. The EDL 2012 was used by the procurement agency, DMSHI, for government procurement.

Only the JDWNRH and the regional referral hospitals have any possibility to get non-EML medicines for specific patients on a “Named-Patient” basis. Generally supply of essential medicines to facilities followed the recommendations of the EDL with regard to what drugs may be used at what levels. However, there were some exceptions. It was observed that at one of the BHU IIs visited there were two drugs available, amitriptyline tab and furosemide injection, which were only meant for BHU I. At some district hospitals visited, there were drugs available that were only meant for use at the regional referral hospitals or the JDWNRH. This generally happened because patients were initially prescribed these drugs at the higher level hospitals and then came back to the district hospital for prescription refills. In some cases the prescriptions were refilled without the patient being seen by any doctor for years! Often the patient was not seen by the original prescriber and some subsequent prescribers were unaware that the pharmacy departments were refilling these prescriptions – so resulting in a situation where no prescriber knew about all the medicines a patient may be taking.

The national EML, STGs and National Formulary are included in the training of undergraduate diploma courses for Health Assistants and Pharmacy Technicians. However, doctors have all been trained abroad, where they have not received such training, though some receive an orientation course on first coming to Bhutan, when these documents are introduced. Some prescribers felt that the orientation course was insufficient and did not give sufficient focus to the national EDL, STGs, and formulary. Generally the Health Assistants, Clinical Officers and General Duty Medical Officers found the EDL, STGs and formulary very useful.

Table 5.4.1 shows some data on EML implementation.

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

Public Referral Hospitals	JDWNRH	Monggar					Average
% key EML items available*	96.9%	100.0%					98.4%
% prescribed drugs belonging to the EML**	92.6%	98.9%					95.8%
Public District Hospitals	District hospital 1	District hospital 2	District hospital 3	District hospital 4	District hospital 5		Average
% key EML items available*	96.8	100.0%	100.0%	84.3%	93.8%		95.0%
% prescribed drugs belonging to the EML**	100.0%	98.4%	98.8%	100.0%	96.9%		98.8%
BHU I	BHUI 1	BHUI 2	BHUI 3		--		Average
% key EML items available*	96.9%	93.8%	100.0%				96.9%
% prescribed drugs belonging to the EML**	100.0%	100.0%	100.0%				100.0%
BHU II	BHUII 1	BHUII 2	BHUII 3				Average
% key EML items available*	91.35	100.0%	91.3%				94.2%
% prescribed drugs belonging to the EML**	100.0%	100.0%	100.0%				100.0%
Private pharmacies	1	2	3	4	5	6	Average
% key EML items available*	43.8%	43.8%	36.7%	46.9%	43.8%	43.8%	43.1%
% prescribed drugs belonging to the EML**	53.3%	36.6%	74.1%	53.6%	38.2	40.0%	49.3%

* Belonging to the national EML or the provincial / hospital formulary in decentralized systems – please see the same indicator recorded in table 4.2.1.

** From prescription audit done during the health facility surveys – please see the same indicator recorded in table 6.3.1.

Table 5.4.1 shows that more than 96% drugs prescribed were from national EML. Compliance with EML was good as the supply of medicines is based on procurement of only EML medicines (apart from the named patient drugs). By contrast, compliance with the EML was much lower in private retail pharmacies, where many fewer key essential drugs were stocked. This is as expected because all patients are getting their medicines free from the public facilities and private retail pharmacies mainly exist to sell medicines that patients cannot get free from the public facilities. In particular, they often stock paediatric medicines in syrup form because these are not on the EML and available in public facilities. One pharmacy patient in Thimphu mentioned that she did not like to wait a long time in the public hospital and could not be sure of seeing the correct doctor so she bought her medicines from the pharmacy. Some specialist doctors mentioned the difficulty of getting higher-end antibiotics and other non-EML drugs on time through the named patient drug purchases, so they stored the balance of these drugs from named patients who had discontinued such drugs (perhaps through death) and then used the drugs for new patients.

5.5. Summary status including progress, changes and problems in drug selection since last situational analysis

The national 2012 Essential Medicines (Drug) List had recently been updated in 2014 for use in 2016 and in the meantime facilities were being supplied with EDL 2012 drugs. Compliance with the national EML is extremely good throughout the country with over 98-100% of all prescribed drugs belonging to the national EDL in all public health facilities. This is because of central public procurement which follows the EML. Some drugs meant for use at a higher level facility were found at lower level facilities mainly for the purpose of prescription refills, which could be dangerous if this is undertaken without regular review by a doctor and some review by the original prescriber.

The purchase of non-EML drugs on a named patient basis remains adhoc and unsupervised by any national committee or hospital Drugs and Therapeutic Committee (DTC), though recommendation was made for this in 2011. The very frequent adhoc and unsupervised requests are resulting in inefficient purchase and extra procurement burden (as mentioned in chapter 4). Since some of the named patient drugs are actually on the national EML and some of the non-EML ones are used for chronic cases, there is scope for harmonizing the named patient non-EML list with the national EML and also rationalizing procurement of those non-EML medicines used for chronic cases. Some of the named-patients start their treatments in India, where there is a very large private sector, and this may account for a large number of named-patient products, which are often purchased by brand name and for which there may be many brands for the same medicine.

5.6. Drug Selection: Recommendations

- Continue to update and revise the national Essential Medicines List (EML) in a transparent manner to improve acceptance:
    - To include medicines for all levels of care and classify them by facility level, prescriber type and therapeutic class as is being done currently;
    - Have wide representation of specialists, pharmacologist, generalists and pharmacists, from the districts as well as the centre.
- Review and harmonize the national EML with other non-EML lists which are used for procurement from Kolkata office, which will require:
    - Review of the named-patient list; the ICU list (currently being done by the National Medicine Committee); haemodialysis list; any other non-EML list;
    - Review of the named-patient guidelines (to ensure that procedures are transparent and efficiently followed in order to avoid unnecessary purchase of medicines outside the EML).
- Monitor compliance with the national EML, including compliance with level of use :
    - Through consumption analysis (which would be easier with an electronic logistic management information system, LMIS) and prescription audit;
    - To be done by DTCs in the national referral hospital, regional referral hospitals, district hospitals and centrally by EMTD/DMS/MOH and the National Medicine Committee;

- Focus on high-cost/low volume medicines.

- Ensure stricter adherence to the national EML by:
  - Program of educating prescribers (including new and in-service doctors) and dispensing pharmacists on the use of the national EML to be coordinated by the National Medicine Committee and EMTD/DMS/MOH.
  - Establishing a transparent system to review all requests for non-EML drugs including the named patient drugs:
    - Drug and Therapeutic Committees (DTC) in the national referral hospital, JDWNRH, and in each regional referral hospital to review all such requests;
    - National Medicine committee to provide guidance on “reasonable” specialist medicines for non-EML purchase.

6. MEDICINE USE

6.1. Responsible Agents/Departments

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Monitoring medicines use in hospitals	✓		EMTD/DMS/MOH
Monitoring medicines use in primary care	✓		EMTD/DMS/MOH
Development of national STGs	✓		EMTD/DMS/MOH
Development of national formulary	✓	✓	National Drug Formulary of Essential Medicines, EMTD/DMS National Drug Formulary of Bhutan, DRA
Drug Information Centre	x		No drug information centre
Provision of independent drug information	x	x	-
Monitoring Hospital DTCs	✓		EMTD/DMS/MOH
Monitoring Hospital quality of care	✓		Quality Assurance and Standardisation Division, Secretariat, MOH
Monitoring DTCs in provinces/districts	✓		EMTD/DMS/MOH
Undergraduate education for health professionals		✓	Khesar Gyallpo University of Medical Sciences of Bhutan (KGUMSB)
Continuing medical education for health professionals	✓	✓	Bhutan Medical and Health Council (BMHC) and MOH
Public education on medicines use	✓		EMTD/DMS/MOH on public education for medicines received from public sector; DRA for public education received from retail pharmacies including not selling antibiotics without prescription; Health Promotion Division under Department of Public Health, MOH for community education.
Implementing generic policies	✓	✓	EMTD/DMS/MOH

6.2. Past prescription surveys

Table 6.2.1 shows the results of prescription surveys done in recent years. MOH did a survey in five health facilities including JDWNRH in 2014 and a prescription survey was done during the first situational analysis in 2011. MOH mentioned that they were concerned about the prescription selection process and whether the best or worst prescriptions had been selected. They also mentioned that analysis had been difficult and no feedback had been given to the health facilities. The sampling frame for the MOH surveys was not clearly defined though sample sizes were adequate and it was not clear whether sampling had been according to prescriber type. The majority of prescriptions were written by health assistants in the BHU I, medical officers in the district hospitals, and specialists and medical officers in the referral hospitals.

Table 6.2.1: Reports of medicines use surveys done in the last 10 years

Indicators	MOH Survey 2014			Situational Analysis 2011			
Year of survey*	BHU 1	DH	RH	BHU	DH	RH	Private pharmacy
No. facilities	1	2	2	2	3	2	3
Public / private	Public	Public	Public	Public	Public	Public	Private
Average number of drugs per patient	3	3	2.5	1.9	2.5	2.6	1.5
% patients prescribed antibiotics	29%	44%	26%	34%	33%	31%	17%
% patients prescribed injections	8%	5%	2%	8%	NA	NA	0%
% drugs prescribed by generic name	95%	84%	88%	100%	92%	77%	22%
% prescribed drugs belonging to the EML	99%	97%	97%	100%	97%	96%	53%
% patients prescribed vitamins	NA	NA	NA	29%	42%	28%	17%
% URTI patients prescribed antibiotics	NA	NA	NA	54%		NA	NA
% diarrhoea cases treated with AB	NA	NA	NA	44%		NA	NA
Average cost per prescription (Nu)	NA	NA	NA	NA	NA	NA	163.67

* Year of survey refers to the year the survey was done not the publication date of the report;
RH = Referral hospital; DH = district hospital; BHU = Basic Health Unit (primary care) – BHUs in 2011 were staffed by Health Assistants and BHU 1 in 2014 is a BHU upgraded to have a doctor present.
AB=antibiotics; URTI=Upper respiratory tract infection; EML=essential medicines list; STG=Standard Treatment Guidelines.

6.3. Current prescribing practices

A prescription survey in public facilities was done by reviewing 30 consecutive prescriptions from prescribers on the day of the visit to each facility. Prescription data was collected for general /primary health care patients as far as possible. In hospitals, data was not collected for specialist clinics but did include some patients from general medicine and paediatric clinics. Where possible, in the larger hospitals, prescriptions were examined prospectively as patients came to the OPD pharmacy after consultation with OPD doctors. However, for some facilities the data could not be collected for the day of the visit because either there were not many patients during the visit (for BHU II) or the OPD hours were over by the time team visited the facility. In these two circumstances data was collected for the last 30 patients from the OPD registers which were usually well maintained with diagnosis and drugs prescribed.

In some hospitals, patients that were prescribed only injections (and no oral drugs) went directly to the injection room and did not come to the OPD pharmacy for dispensing of the injection - particularly with regard to tetanus toxoid and anti-rabies injections for dog bites. In these circumstances, the % of cases receiving an injection had to be calculated by dividing the number of injections given that day (from the injection register and excluding childhood immunization) by the total number of outpatients. However, in BHUs prescribing data was generally collected from the OPD registers where, injections were generally recorded.

Finally, the OPD registers were also examined to identify the last 30 patients coming to the facility with an upper respiratory tract infection (including cough, cold, sore-throat, runny nose or earache) and a note made of whether an antibiotic had been prescribed or not.

In the private pharmacies, there were no registers or record-keeping of individual sales to patients, apart from in two pharmacies where a record of prescription-only drug sales was kept. Data was collected by standing near the dispensing counter and observing the retailer and the patient during the sale of medicines. At two retail pharmacies only seven and 11 patients, respectively, could be surveyed, the patient load being very low. At the other retail pharmacies 23, 26, 29 and 30 purchases were observed, respectively. Since most sales were over-the-counter, the % of drugs prescribed by generic name could not be estimated. Due to lack of diagnostic information, the % of upper respiratory tract infections sold antibiotics could not be calculated.

Traditional medicines were dispensed at a different pharmacy by a traditional medicine dispenser in those public facilities offering traditional medicine services. In the private sector, patients go to the traditional practitioner and traditional medicine pharmacy, and traditional medicines were not dispensed from the retail pharmacies visited. No data was collected on the prescribing or dispensing of traditional medicines.

The results of the prescription survey done during this situational analysis are shown below in table 6.3.1.

Table 6.3.1: Results of prescription audit from health facility survey

Public referral hospitals	JDWNRH	Monggar				Average
Average number of drugs per patient	2.52%	3.07%				2.8
% patients prescribed antibiotics	38.5%	60.0%				49.3%
% patients prescribed injections	5.0%	3.3%				4.2%
% patients prescribed Vitamins	11.7%	46.7%				29.2%
% drugs prescribed by generic name	70.1%	85.9%				78.0%
% prescribed drugs belonging to the EML	92.6%	98.9%				95.8%
% URTI patients prescribed antibiotics	-	36.7%				36.7%
Public district hospitals	1	2	3	4	5	Average
Average number of drugs per patient	2.37%	2.6	2.8	2.4	2.17	2.50
% patients prescribed antibiotics	45.0%	37.9%	66.7%	36.7%	23.3%	41.9%
% patients prescribed injections	0.0%	4.1%	1.7%	0.0%	0.0%	2.9%
% patients prescribed vitamins	21.3%	27.4%	30.0%	36.7%	20.0%	27.1%
% drugs prescribed by generic name	95.7%	96.9%	95.1%	95.8%	92.3%	95.2%
% prescribed drugs belonging to the EML	100.0%	98.4%	98.8%	100.0%	96.9%	98.8%
% URTI patients prescribed antibiotics	43.3%	30.0%	53.3%	30.0%	53.3%	42.0%
BHU I (primary care unit with doctor)	1	2	3			Average
Average number of drugs per patient	2.53	1.8	2.5			2.3
% patients prescribed antibiotics	53.3%	26.7%	40.0%			40.0%
% patients prescribed injections	5.1%	10.0%	0.0%			7.6%
% patients prescribed vitamins	30.0%	10.0%	6.7%			15.6%
% drugs prescribed by generic name	90.8%	98.2%	81.1%			90.0%
% prescribed drugs belonging to the EML	100.0%	100.0%	100.0%			100.0%
% URTI patients prescribed antibiotics	23.3%	16.7%	46.7%			28.9%
BHU II (primary care unit without doctor)	1	2	3			Average
Average number of drugs per patient	2.0	1.7	1.9			1.9
% patients prescribed antibiotics	33.3%	33.3%	33.3%			33.3
% patients prescribed injections	3.3%	3.3%	6.7%			4.4
% patients prescribed vitamins	23.3%	30.0%	10.0%			21.1
% drugs prescribed by generic name	88.3%	96.1%	100.0%			94.8
% prescribed drugs belonging to the EML	100.0%	100.0%	100.0%			100.0%
% URTI patients prescribed antibiotics	26.7%	26.7%	23.3%			25.6%

Table 6.3.2 on prescribing consolidation sheet continued

Private-for-profit pharmacies	1	2	3	4	5	6	Average
Average number of drugs per patient	1.36	1.57	1.15	1.23	1.37	1.2	1.31
% patients prescribed antibiotics	9.1%	0.0%	30.8%	13.0%	6.7	3.4	10.5%
% patients prescribed injections	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
% patients prescribed vitamins	9.1%	14.3%	0.0%	13.0%	10.0%	6.9%	8.9%
% prescribed drugs belonging to the EML	53.3%	36.6%	40.0%	74.1%	53.6%	38.2%	49.3%
Average cost per prescription (Nu)	53.72	36.21	56.54	40.38	24.54	46.22	59.60

The prescribing survey in the public sector shows that as the level of health facility increases so does the average number of drugs prescribed per patient increase and also the percentage of patients prescribed antibiotics. Thus the average number of drugs per patient was 2.8 for referral hospitals, 2.5 for district hospital, 2.3for BHUI and 1.9 for BHU II. Similarly, the percentage of patients receiving an antibiotic was 49.3% in referral hospitals, 41.9% in district hospitals, 40.0% in BHU I and 33.3% in BHU II. Higher use at higher level facilities may be expected since cases coming to the higher level facilities are more complex than those coming to lower level facilities even though effort was made to include only primary care cases in the survey. The percentage of patients receiving an injection was reasonably low at 10% or less in all facilities but further comment cannot be made as injection use could not be measured sufficiently accurately as previously mentioned. The percentage of patients prescribed vitamins was quite high in all facilities ranging from 15.6% in BHU IIs to 29.2% in referral hospitals. The percentage of drugs prescribed by generic name was, as expected, lowest at 78% in the referral hospitals, but above 90% in all other facility types. The percentage of prescribed drugs belonging to the EML was very high in all public facilities, being 95-98% in hospitals and 100% in BHUs.

These public sector prescribing indicators show similar results to the situational analysis of 2011, although overall antibiotic use appears to have increased slightly. The results are also similar to what was found in the MOH survey of 2014 with the exception of higher average number of drugs per patient in the MOH survey, this difference possibly being due to different prescription sampling in the MOH survey. The percentage of upper respiratory tract infection (URTI) cases treated with antibiotics was lowest in the BHUs (25.6%-28.9%), compared to the district hospitals (42.0%) and referral hospital (36.7%). While, these results appear to show an improvement from the 2011 situational analysis, the sample size in 2011 was insufficient to make a comparison. Although most cases of URTI are viral, not requiring antibiotics, and the prescribing results do indicate overuse of antibiotics, the prescribing is very good in comparison with what is observed in most other low/middle income countries.

The prescription survey in the private retail pharmacies showed that average number of drugs purchased per patient was 1.3 and that 10.5% bought antibiotics and 9%bought vitamins. This lower use is not surprising since most purchases were over-the-counter with no prescription for minor ailments. Not surprisingly, only 49.3% of the purchased medicines were from EML since shops were selling those non-EML medicines that patients cannot get free from the public health facilities. On average each patient spent Nu59.60 per purchase, which is lower than what was seen in 2011, but this is because smaller pharmacies in the more remote Eastern Region were included in the sample of shops.

Some common examples of inappropriate prescribing were observed across all public health facilities. For example, almost all cases of common cold were prescribed paracetamol. For upper respiratory conditions and other simple conditions more than three medicines were often prescribed, e.g. paracetamol, an antihistamine and vitamin B Complex, as well as an antibiotic sometimes. Antacid and ranitidine were commonly prescribed often without any gastro-intestinal symptoms and often in order to prevent possible side-effects from non-steroidal anti-inflammatory drugs such as ibuprofen. A very important and worrying observation made at a district hospital was that patients were getting their prescriptions re-filled every three months for medicines that had been prescribed at the national referral hospital three or more years ago without being seen by the specialist doctor who had originally prescribed the drugs or sometimes without being seen by any doctor. Some of these prescriptions were for drugs not designated for use at the district hospital by the national EML.

In the JDWNRH, the OPD prescribers met were MBBS doctors from General Duty Medical Officer (GDMO) cadre, all of whom had done MBBS from other countries e.g., Sri Lanka and India. They mentioned seeing about 50-80 patients per day and that they were not able to write the diagnosis and treatment in the OPD registers because of heavy patient load. One doctor mentioned that she writes about one extra medicine for about three patients in every ten patients for purchase from outside. A copy of the national Standard Treatment Guidelines (STGs) was available and all mentioned usually receiving one lecture in the hospital per week, so providing an update. In regional referral hospital, Monggar, on the day of the visit, two Clinical Officers (non-MBBS) were present in the general OPD, no STG was available but the National Formulary of Essential Medicines was available. They mentioned seeing about 20-70 patients per day and that they did not always write diagnosis and treatment in the OPD registers although sometimes they wrote the disease codes for certain diseases for which they were sure of the codes. One of the two prescribers interviewed mentioned generally writing separate prescriptions for combination products for outside purchase in the case of some diseases such as fungal infection. One of the prescribers had attended three continuing medical education (CME) sessions in the last one year.

In district hospitals, a mixture of Medical Officer (MO) and Health Assistant (HA) were present in the OPD on the day of the visit. Generally only the national formulary of essential medicines was available but not the STGs. Each prescriber saw about 30-60 patients per day and generally diagnosis and treatment were written in the OPD registers particularly by the HA, though less so by the MO. At one hospital visited after the OPD hours, an emergency clinic was being run by the HA who was recording all diagnoses and treatments in the register. This HA had the national formulary of essential medicines available but not the national STG in the consulting room and mentioned seeing about 50 patients per day in the emergency room and that he had not received any CMEs in the last one year. One of the senior Pharmacy technicians in a district hospital stated, "*There is a lot of irrational prescribing by doctors but it is very difficult to give any feedback*".

At one of the BHUI visited, one HA and one doctor were attending the OPD and at another BHU I a pharmacy technician was attending patients as the HA was busy in the immunization clinic. At the BHU IIs visited, only Health Assistants (HAs) were available as expected. Prescribers generally saw 20-40 patients per day in BHU Is and 10-25 patients per day in BHU IIs. Generally the OPD registers were well filled in with diagnosis and treatment and most staff mentioned receiving some form of CME in the last year. One of the doctors at a BHU I said, "*There should be prescribing orientation for new prescribers*".

Thus, overall, most prescribers appeared to have adequate time to see patients and access to either the national formulary of essential medicines or the national standard treatment guidelines. The district hospital health assistants and clinical officers appeared to have the heaviest OPD duty and least access to CME.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

An effort was made to observe dispensing in all health facilities in order to observe the quality of the process and to record the percentage of prescribed drugs dispensed. It was assumed that all the prescribed drugs, whether non-EML drugs to be purchased from an outside pharmacy or EML drugs to be dispensed from the health facility, were recorded on the same prescription form (and not two separate forms), as most doctors and pharmacists stated this was the case. However, a few referral hospital doctors stated that they prescribed drugs for outside purchase on separate forms. Where dispensing could not be directly observed, the percentage of prescribed drugs dispensed was estimated by examining the OPD registers for that day and asking the staff to report for each drug whether or not it had been dispensed based on whether the drug was in the EDL (and thus supplied) and whether it was in stock (or not). In view of these methodological problems the high percentage of prescribed drugs dispensed shown in table 4.2.1 (see section 4.2) may be an over-estimate, particularly in the referral hospitals.

At national, regional referral hospitals, district hospitals and BHU Is, qualified pharmacy technicians do the dispensing. Dispensing registers are maintained, loose tablets are counted by hand and the medicines are dispensed in a plastic envelop. These envelopes have handwritten labels that contain the drug generic name, strength, dosing frequency and sometimes (but not always) the duration of treatment. At the JDWNRH, they used self-adhesive printed labels for pasting onto the bottles of oral liquids. Generally, the dispenser-patient interaction was 1-2 minutes (excluding making the envelope and placing the medicines inside them). In consultation with doctor, the pharmacist could do therapeutic substitution in case of stock-outs.

At BHU IIs, the dispensing is done, and the dispensing information maintained in the OPD register by the prescriber present, which is the HA. Dispensing was only observed at one BHUII where loose tablets were counted by hand and given to the patient in a plastic envelop with the drug generic name, strength, dosing frequency and duration written. Dispenser-patient interaction was about 3-4 minutes.

Liquid preparations for children are prepared in all referral and some district hospital pharmacies even though no liquid preparations or syrups are mentioned in the 2012 EDL, using solid formulations of medicines that are in the EDL. A few ointments are also prepared in the hospital pharmacies. Despite this, some private retail pharmacies mentioned that a substantial proportion of their clients are children with prescriptions for syrups and liquid preparations.

All the OPD pharmacy technicians interviewed at referral and district hospitals mentioned that they have a huge patient work load and that more staff is needed.

6.4.2. Health Facility Inpatients (wards)

In the wards, doctors prescribe the medicine in the patient record history form and nurses fill in the individual patient dispensing charts and sign for each drug on the chart once it is dispensed. There is a dispensing trolley with small containers labelled with the name of medicine and from these containers the medicines are dispensed to patients. The main stock is generally kept in one or more small rooms in the ward. Oral medicines, injections and intravenous fluids are sometimes stored in separate rooms in the hospital wards. The trolley drug stock is re-filled from time to time, the few remaining left over tablets being taken out and put back on top of the new tablets so as to avoid expired tablets ending up at the bottom of the containers. There are no stock books in the wards, only requisition forms which are used for ordering more medicines from the store. Narcotic agents were kept under lock and key.

The Chief Nurse manages the store and look after the medicines. There is no pharmacist who looks after or manages the drug store in the wards. It was observed that First-expired, First-out (FEFO) was not always followed in the wards.

Often syrups for children are prescribed and these must be purchased outside from private retail pharmacies as they are not available. One hospital nurse stated, *"Almost all pediatric patients have to buy syrups from a private pharmacy".*

6.4.3. Private retail pharmacies

Dispensing at private retail pharmacies was generally done, or supervised, by a qualified pharmacy assistant who has passed the DRA's basic competency examination. Medicines were dispensed as strips or in bottle containers and generally no packing or labelling was done. However, at one pharmacy shop, during the time of data collection, medicines were put into a brown envelope. The dispenser-patient interaction was 1-2 minutes. No records were maintained at any shop except at two where the sale of prescription-only drugs was recorded.

Out of 16 antibiotics dispensed at the six shops surveyed, 12 were without prescription. Out of these 12 antibiotics, 9 were antibiotic ointments, one was antibiotic eye drops, one was co-trimoxazole tablets and one was amoxicillin tablets.

Medicines and cosmetics were stored separately. Medicines were generally neatly stored but not always alphabetically or therapeutically. At some pharmacies some non-medicine supply was stored on the floor.

6.5. Policies to promote rational use of medicines

6.5.1. Monitoring and supervision of prescribing/dispensing by supervisors

The Essential Medicines and Technology Division has done adhoc intermittent prescribing surveys in the past using the standard WHO/INRUD primary care indicators, the most recent survey being in 5 health facilities in 2014. However, the sampling method in facilities was not standardized and was generally left to the pharmacy technician and may have involved biased selection towards better or worse prescriptions. This may have influenced the outcome, since prescriptions for acute cases may have more antibiotics and

for chronic cases greater number of medicines. It was mentioned that data had not always been analysed and that often it was not shared, nor feedback given to the health facilities and prescribers. Drug consumption studies using ABC or DDD analysis are not done routinely and drug utilization review or other in-depth prescription audit has not been done. There are -graduate pharmacists in referral hospitals where dispensing and prescribing may easily, and should be, monitored.

6.5.2. Standard Treatment Guidelines (STGs)

The National STGs are published by EMTD/DMS/ MOH. The first edition was published in 2009 and the latest fourth edition in 2014. The national STGs were developed in consultation with various stakeholders, including clinicians of JDWNRH, pharmacists, General Duty Medical Officer (GDMO) representatives, Health Assistant (HA) representatives and Royal Institute of Health Services (RIHS) - now Faculty of Nursing and Public Health - representatives. The STGs mainly cover the common illnesses at primary care and are prepared keeping in mind the national EDL. The STG booklet has been distributed to all public health facilities and is also available on the web. Copies of the STG booklet were found in the OPD of all the BHUs visited and all HAs and Clinical Officers mentioned using the STGs. However, doctors at hospitals generally did not have copy of the STGs or use it. In those facilities also offering traditional medicine services, a copy of a national STG booklet for traditional medicines was found in the OPD.

6.5.3. National Formulary

There is a National Formulary of Essential Drugs 2012, published by EMTD, and distributed free of charge to all health facilities. It was available at all BHU II, BHU I, and district hospitals visited. This formulary is also available on the web. The National Formulary of Essential Drugs is used during training of Pharmacy technicians and Nurses. During the survey it was found with Health Assistants at BHU II and BHUI and also with Clinical Officers at district hospitals but not always with doctors.

There is also a National Formulary of Bhutan 2014, produced by the National Drug Regulatory Authority, which includes not only EML drugs but all the drugs registered in Bhutan including veterinary products. This formulary is updated every year by the DRA and contains about 1000 drugs. The non-EML drugs in this formulary include ointments, syrups and liquids, and combination products (not for antibiotics). The national formulary is only available on purchase for Nu 65 (which covers the printing costs).The National Formulary of Bhutan must be purchased and is aimed at private pharmacy retailers, not being supplied by the DMS or used in any training for public sector health workers. It is not clear to what extent the National Formulary of Bhutan is used.

6.5.4. Drug information Centre

There is no Drug Information Center in the country. There used to be one information center for drugs in JDWNRH but now it is not functioning.

6.5.5. Independent drug information.

No medical representatives are allowed in public facilities (though for most facilities there are no representatives who would wish to visit, there being no private prescribing).

At district hospitals and referral hospitals prescribers have access to internet but not generally at BHUs. There are national STGS but they are for primary care and not secondary care. All doctors (whether Bhutanese or foreign) have got their degrees from outside Bhutan, and so have been using different sources of information, often old textbooks or foreign guidelines. There is a short orientation course run by the MOH for new doctors but the orientation on the national EML, formulary and STGs is very limited.

6.5.6. Drug and Therapeutics Committees

The Drugs and Therapeutics Committee (DTC) was established in the national JDWNRH about 10 years ago but it is not functional at the moment. The last meeting was held about one and a half years ago. Similarly in the regional referral hospital surveyed, the DTC was established but not quite functional. Prescription audit and presentation of the results had not been done in any forum.

There is no check or approval by the DTC or any other committee for the named-patient medicines. This was clear from data provided by JDWNRH showing that the same medicine is procured by different trade names and generic medicines are not always procured e.g. multiple trade names for the same calcium preparations. For quite a few of the medicines there was huge price difference for different products with the same medicine, strength and formulation (See Table 4.3.4).

Recently a circular was sent from EMTD/DMS/MOH to all hospitals asking them to establish a functional DTC and some hospitals mentioned that they were trying to form or revive their DTCs. Two district hospitals had formed a DTC in June 2015 with the pharmacist or pharmacy technician as Secretary and the medical officer as Chairman. However, the proper functioning of DTC is still to be started and it is not clear whether all concerned staff know what a DTC should do.

A functional DTC (as determined by the activities undertaken) could be one of the criteria for accreditation for teaching/referral hospital status by the Bhutan Medical and Health Council.

6.5.7. Undergraduate education on medicines use

Currently, no doctors or pharmacists are trained in Bhutan, though a Medical School has just started and will be producing doctors in the future.

Khesar Gyalpo University of Medical Sciences has three functional faculties:

1. Faculty of Nursing & Public Health (formerly called as Royal Institute for Health Sciences)
2. Faculty of Traditional Medicine
3. Post-graduate Medical Education Centre (further described under section 6.5.8 on CME)

The Faculty of Nursing & Public health offers 3 year diploma courses after 12th grade of schooling. The diploma courses are in: General Nursing & Midwifery; Community Health (Health Assistants); and Medical Technicians in various subjects including pharmacy, X-Ray, laboratory, dental, and dental hygiene. Earlier

the diploma courses were for two years but now all diplomas are for three years. The Diploma courses for medical technician in ENT, eye and orthopaedics have been stopped as doctors are now being recruited for these specialties.

In the pharmacy course, first year students are taught in college and the curricula includes the National EML, STGs and Formulary. Second year students visit the hospital mainly in the OPD and third year students visit IPD and the store for supply management. In the curriculum there is one chapter on traditional pharmacy and the students also visit the traditional hospital. The outline for the course is provided by the University and the curriculum is developed by the in-service pharmacists and discussed in meetings taking into consideration the University guidelines. In the health Assistant course, students are taught about the national EML, STGs and formulary and are attached to the community for one month and during that period they go to a BHU II. Clinical Officers training involves an extra one year on top of the Health Assistant training and also includes prescribing using the national STGs, formulary and EML.

The faculty of traditional medicines offers a diploma course of three years and a degree course of five years in traditional medicines. The courses are taught in the Bhutanese language. The traditional medicine department also has a national EML and STGs, which the students are taught and the students visit the National Hospital for Traditional Medicines for training. At the end of the courses, there is an internship of three months for the diploma course and of six months for the bachelor course. The curriculum does not include teaching of modern medicine or allopathic medicine. The institute is autonomous under the University whereas the hospital of traditional medicine and the traditional medicine manufacturing unit are under the MOH.

6.5.8. Continuing Medical Education on medicines use

Continuing medical educations is usually in the form of training courses organized by the MOH for various vertical programs. These trainings are attended by BHU II and BHU I prescribers. Occasionally doctors and other health professionals (including traditional medicine practitioners) visit other countries for training/workshops or for conferences. All doctors practicing in Bhutan, whether Bhutanese or foreign, have obtained their degrees from other countries and so the MOH organizes a 3-day orientation course for them on first arrival. However, often they do not get much orientation on the national EML, STGs and national formulary and it was mentioned by some doctors that the orientation course should be extended.

The Post-graduate Medical Education Centre of Khesar Gyalpo University of Medical Sciences offers post-graduate medical courses in the specialties of Medicine, Surgery, Gynaecology & Obstetrics, Pediatrics and Anesthesia. The courses are for four years and the university has collaboration with some of the well-recognized institutes in other neighboring countries. Training is done for resident doctors, who work in the JDWNRH under the supervision of the respective specialists.

The Bhutan Medical and Health Council (BHMC) is the professional regulatory body for regulating the professional practice of all Medical and Health professionals and ensuring the quality of medical education and training (whether pre-service or in-service) in the country. The BMHC regulations came into force in 2005 and the latest guidelines on continuing medical education were published in 2009 by BHMC. As per the BMHC all the registered medical and health professionals including doctors, dentists, traditional prescribers, pharmacy professional, nurses, etc. need to accrue a minimum of 30 credits in five years for renewal of their registration. Registration of all health professionals by the BMHC is for five years at which time a renewal fee must be paid. The BMHC has not been strict until now with regard to credits for re-

registration but they mentioned that soon they will start to enforce this rule stringently (although they mentioned this also in 2011).

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

Irrational use of medicines was blamed on patient demand by many prescribers. However, there have been no national programs for public education through various mass media. The MOH has had some posters printed on medicine use which have been posted in the health facilities. Also the MOH has prepared a video tape on prudent use of antibiotics which they are planning to launch on TV during 'Antibiotic awareness week' in November 2015. Unlike in other countries, the private sector for purchase of medicine is very small and so there is very little commercial advertising.

All MOH hospitals have a Community Health Unit (CHU) which undertakes some routine services, including family planning, antenatal care, childhood vaccination and cervical smears. Also they propagate specific public health messages, e.g. hygiene, according requests by the MOH vertical programs. Likewise, all BHUs have outreach programs that go to various villages regularly every week or month. Unfortunately, these programs have not generally included messages on the safe and appropriate use of medicines.

6.5.10. Generic Policies

There is a generic prescription policy which encourages doctors to prescribe by generic name. Generic substitution by pharmacists and Pharmacy Technicians is allowed in JDWNRH and referral hospitals in consultation with the doctor. If necessary, therapeutic substitution is also done in consultation with the doctor.

6.6. Summary status including progress / changes / problems in medicines use since last situational analysis

Medicine prescribing and dispensing and use remain similar to the previous situational analysis in 2011, apart from a possible slight increase in antibiotic use (though not with regard to antibiotic use in upper respiratory tract infections) and this may be a cause of worry and merits regular monitoring. Compared to many other low/middle income countries, prescribing in Bhutan is relatively good and this is due to the regular updating and implementation of the national Essential Medicines List (EML), Standard Treatment Guidelines (STGs) and Formulary and the absence of a private sector, where prescribing is generally worse and which can influence prescribing in the public sector. Unfortunately, despite previous recommendation in 2011, hospital Drug and Therapeutic Committees remain largely non-functional and drug use and prescribing is rarely monitored. Although named-patient drugs are discussed on some occasions, unfortunately no committee reviews the use of named-patient drugs. Likewise, previous recommendations which are still pending include: development of a new orientation package for new doctors and continuing medical education programs for prescribers on rational use of medicines by the BHMC; carrying out national public education campaigns on the safe medicines use; and the establishment of a national Drug Information Centre.

6.7. Medicines use: Recommendations

- Monitor medicine use - to be done by all hospitals Drug and Therapeutic Committees (DTCs) and centrally by the EMTD/DMS/MOH:
    - ABC analysis of EML and non-EML consumption;
    - Prescription audit following WHO indicator methodology and using diagnosis, which requires that out-patient registers have diagnosis and all the medicines prescribed, fully recorded;
    - Identify specific inappropriate practices to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices;
- Implement the National Standard Treatment Guidelines (STGs) and National Formularies:
    - Continue to update and disseminate to all health facilities;
    - Develop secondary care national standard treatment guidelines to include the common conditions such as hypertension, diabetes, renal disease and emergency care;
    - Incorporate the STGs and National Formulary of Essential Medicines into continuing medical education (CME) for all prescribers (including the orientation course for new doctors) and undergraduate education of all medical pharmacy courses.
- Strengthen continuing medical education (CME):
    - Monitor and enforce the Bhutan Medical and Health Council credit system for CME;
    - Include prescription audit and feedback into CME;
    - Extend orientation course for all new doctors recruited in service to include the EML, STGs, national formulary, DTCs and drug supply system.
- Establish Drug and Therapeutic Committees (DTCs) in all referral and district hospitals:
    - To monitor drug use, encourage CME, and report annually on activities to the EMTD/MOH;
    - Pharmacists can act as DTC secretaries and implement DTC decisions.
- Undertake public education on the prudent and safe use of medicines:
    - Repeated (not just one day a year) public education campaigns which could be spread through all channels used by MOH, including Community Health Workers, and the mass media;
    - Include core pharmaceutical messages e.g. *No drugs or medicines are needed for mild cough and cold.*
- Establish a National Drug Information Centre:
    - To provide prescribers with independent information on all aspects of medicines, e.g. drug interaction, dose, treatment, medicine availability etc.;
    - Could be placed in the JDW National Referral Hospital or the Health Help Centre.

7. MEDICINE REGULATION

7.1.Responsible Agents/Departments

Regulatory function	DRA	Other Agency	DRA/MOH department/Name of Agency
Drug Schedules	✓		DRA
Licensing &Inspection of drug outlets	✓		DRA
Drug registration	✓		DRA
Pharmacovigilance	✓		DRA
Drug quality testing	✓		DRA
Drug promotion	✓		DRA
Drug pricing	✓		DRA
Health professional licensing/accreditation	✓	✓	DRA licenses private pharmacy assistants and BMHC licenses all other health facilities
Health facility/hospital licensing/accreditation	✓	✓	Private pharmacies are issued licences by the Department of Trade based on technical authorization issued by the DRA. Public facilities do not need a licence. Private diagnostic centres are licensed by the Ministry of Economic Affairs based on technical clearance by the MOH.

7.2. Pharmaceutical sector

From discussion with national drug regulatory authority

- Number of products on the market:
  - Allopathic: 1051 products
  - Traditional: 71 products
- Number of manufacturers:
  - Allopathic: 0 (Bhutan has 1 operational API manufacturing firm)
  - Traditional: 1
- Number of wholesaler outlets: 18
- Number of retailer outlets:
  - Allopathic: 45
  - Traditional: 1
- Number of blood outlets: 0
- Enforcement of regulations in last fiscal year::
  - Prosecutions:13firms for late renewal of Technical Authorization and 2 persons for late renewal of Competent Person certificate
  - Value of fines: 68,300(for 13 firms)+ 8000/-(for 2 persons)
  - Number of people imprisoned: 0

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

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
Medicines Act of the Kingdom of Bhutan	2003
Bhutan Medicines Rules and Regulation (BMRR)	2012

b) Coverage:

Area / Activity Covered?	Y/N	Document Name
Establishment & functioning of National Drug Regulatory Authority	Y	Medicines Act of the Kingdom of Bhutan 2003
Medicines marketing authorization	Y	BMRR 2012
Medicines scheduling	Y	BMRR 2012
Licensing of medicines handling premises, personnel & practices	Y	BMRR 2012
Licensing of prescribers	Y	Medical and Health Council Act, 2002, Kingdom of Bhutan, BMHC
Mandatory CME for prescriber licence renewal	Y	BMHC
Licensing of pharmaceutical personnel	Y	BMHC
Mandatory CME for pharmacy licence renewal	Y	BMHC
Regulatory inspections/ enforcement activities	Y	Medicines Act and BMRR 2012
Medicines quality	Y	BMRR 2012
Medicines packaging & labelling	Y	BMRR 2012
Medicines promotion	N	There is no law for medicine promotion
Post-market surveillance/ pharmacovigilance	Y	BMRR 2012
Collection of fees	Y	BMRR 2012
Clinical trials	N	There is no law for clinical trials although there is a Research Ethical Board which may cover clinical trials
Generic substitution	Y	Registration Guidelines for medicinal products
TRIPS-related issues	N	
Transparency & accountability[2]	Y	
Banning of unsafe medicines	Y	

[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 Drug Regulatory Authority 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: Drug Regulatory Authority of Bhutan
- Total number of technical staff: 16
    - Number of posts: No fixed numbers of posts, but three new chief regulatory officer posts, recently agreed, are not filled. Technical positions are for pharmacists.
- Total number of non-technical staff:
    - Number of posts: No fixed numbers of posts, but one human resource officer has been proposed but not recruited and there are finance, general and IT staff.
- Website address: www.dra.gov.bt
- Number of quality-control (drug testing) laboratories: one public health lab that is not yet fully functional so samples are sent to two labs outside the country
- Annual report of activities: DRA Annual report is briefly presented to the Bhutan Medicines Board but no report has been printed or uploaded yet to the website the annual reports until now
- Annual Budget last fiscal year: Nu. 15.237 million
- Written SOPs for the following key regulatory procedures?

Key procedure	Written SOP? (Yes/No)	Details/language
Product dossier evaluation	Yes	English
Registration of medicines	Yes	English
Inspection of manufacturing premises	Yes	English
Inspection of retail premises	Yes	English
Sampling for Quality Control testing	Yes	English
Medical product recall or withdrawal	Yes	English

- Position in hierarchy of government structure: Autonomous, reporting directly to the Medicines Board constituted by Parliament and chaired by the Minister of Health.
- Decentralised capacity?
    - Number of branch offices: One branch office in Phuentsholing
    - Number of staff in each office: : Proposed to have three staffs (last year only one staff was sent to the branch office and the person was stationed there for three months)
    - Functions of branch offices:

      -Inspection and verification of the consignments before their release.

      -inspection of pharmacies and hospital in Phuntsholing
    - Functions outsourced to public health authorities:

      None

7.4.1. Technical committees to advise the drug regulatory authority

- The Medicines Board constituted by Parliament and chaired by the Minister of Health, overseas all the functions of the DRA. The Drug Controller is the Member Secretary and other Members come from the Ministry of Agriculture, the Medical and Health Council, the Ministry of Economic Affairs and the Bhutan Chamber of Commerce.

- Drug Technical Advisory Committee (DTAC): consists of technical experts from the Ministry of Health and the Ministry of Agriculture and Forests for veterinary products.

- Blood Technical Advisory Committee (BTAC): includes experts from hospitals and MOH to advise the DRA on matters related to blood and blood products (this committee is formed in line with the blood regulation 2015)

- Committee for Registration of Medicinal Products: includes external experts besides the DRA staff and is involved in the evaluation and approval of product dossiers for registration.

- Product Recall Committee: meets as and when a product needs to be recalled from the market based on post marketing surveillance, which comprises the following persons:

    a. Drug Controller, DRA as Chairman
    b. Head of Pharmacy Department, JDWNR Hospital(in case of Human Medicines)
    c. Principal Veterinary Officer/Chief Livestock Officer from Drug Technical Advisory Committee (in case of Veterinary Medicines)
    d. Chief Regulatory Officer, Inspection Division, DRA
    e. Chief Regulatory Officer, Registration Division, DRA
    f. Chief Regulatory Officer, Post Marketing Control Division, DRA(as Member Secretary

7.4.2. Regulation of Traditional Medicine

Traditional medicinal products are regulated similarly like that of allopathic products. The DRA does not have different regulations for traditional medicines. However, the documents required for registration of such products with the DRA may be less than the allopathic products. Traditional medicines of Bhutan are called as gSo-ba-Rig-pa.

7.5. Drug Schedules

As per the Bhutan Medicines Rules and Regulations, 2012, medicinal products in Bhutan are classified into six schedules according to the risk for the customers and the degree of complexity of storage.

Schedule A

- Schedule A1 : Pharmacy-Only Medicines
- Schedule A2 : General Sale List (Over the Counter)

Schedule B: Prescription Only Medicines

Schedule C: Controlled drugs

- Schedule C1 : Controlled Narcotic drugs
- Schedule C2 : Controlled Psychotropic substances

Schedule D: Traditional Medicines and Herbal Products

- Schedule D1 : Non Prescription Traditional Medicines and Herbal Products
- Schedule D2: Prescription Traditional Medicines and Herbal Products

Schedule E: Medicinal Products for Veterinary use

- Schedule E1 : Non Prescription Veterinary Medicines
- Schedule E2 : Prescription Veterinary Medicines

Schedule F: Vaccines, Biologicals and Special Products

As mentioned previously, the survey conducted at private retail pharmacies showed that out of 16 antibiotics purchased, 12 were without prescriptions. Out of these 12 antibiotic preparations, 9 preparations were ointments containing an antibiotic, one was antibiotic eye drops, one was co-trimoxazole tablets and one was amoxicillin tablets. All of these preparations of antibiotics are prescription only drugs. The sales of other groups of prescription–only drugs without prescription was not observed during the situational analysis and it is not possible to comment whether such drugs could can be bought without prescription.

7.6. Regulation and inspection of drug outlets

The Inspection Division of the DRA is responsible for monitoring regulatory compliance by the pharmacies and health facilities in the country. The DRA has five drug inspectors and one regulatory officer in the division to carry out various types of inspections related to medicinal products. Last year, 107 facilities were inspected, including 10 manufacturers abroad for GMP compliance. Each retail outlet is inspected at least annually.

There are 10 SOPs used by the inspection division, including procedures for drug inspection in both wholesale and retail outlets, GMP inspection and vaccines lot release. The pharmacy outlets are licensed by the Department of Trade, under the Ministry of Economic Affairs, based on a technical authorization issued by the registration division, DRA. Technical authorization is issued only after verification of the proposed site or premises by the inspection division. Retail and wholesale outlet licenses must be renewed annually. As for initial licensing, re-licensing is done by the Department of Trade based on technical authorization issued by the DRA.

Professionals operating drug outlets are licensed by the DRA after they have passed the competency examination conducted by the DRA. The minimum qualification required for opening a pharmacy retail outlet is a certificate in pharmacy, hence no professionals other than pharmacists or pharmacy technicians of diploma or certificate-level can operate private pharmacies. There is only one private retail pharmacy for traditional medicines in Bhutan but the inspection procedure is same as that for the allopathic outlets. The DRA office also involves external officials in their inspection team as and when required, for example during the GMP inspection of manufacturing firms and inspection of blood establishments.

7.7. Drug Registration

The Registration Division of the DRA is responsible for registration of medicinal products as well as the issuance of licenses (authorizations) for the manufacture, sale and distribution of medicinal products. This division is also responsible for registration of competent persons, wholesalers and retailers, and issuance of licences for the import and export of medicinal products. The division consists of 1 Senior Regulatory Officer, 2 Regulatory Officers, 1 Assistant Regulatory Officer, 1 Senior Drug Inspector and 1 Administrative assistant. The annual budget allocated for all the activities related to the division for the fiscal year 2015-16 is about 1.33 million ngultrum.

All the work in the division is carried out according to written Standard Operating Procedures (SOPs) as listed below:

- SOP for Receiving Product Dossier and Sample
- SOP for Pre-evaluation of Product Dossier
- SOP to convene Product Registration Committee Meeting
- SOP for Technical Evaluation of Product Dossier
- SOP for Communicating and Receiving Missing Documents
- SOP for Registration and Renewal of Certificate for Competent Person
- SOP for Issuing Import Authorization for Named Patient Use and Medicines for Personal Use
- SOP for Issuing Import Authorization for Sale of Medicinal Products by Wholesale, Retail and Distribution by Government Agencies

The following SOPs are under development:

- SOP for Issuing Registration Certificates
- SOP for Renewal of Registration Certificates
- SOP for Processing Post Registration Changes to Medicinal Products
- SOP for Transfer of Market Authorization Holders

The total number of medicinal products approved for registration in the last 3 years until 16th July 2015 is 1122. Bhutan has only 1 API manufacturing firm.

The process for the approval of registration of medicinal products follows a systematic procedure. It begins with the receipt of the product dossier (drug master file) and product sample. Then the dossier and sample are subjected to a pre-evaluation process whereby the general documents required by the Guidelines for Registration of Medicinal Products 2013 are evaluated. After the dossier passes the pre-evaluation, it will be put up to the Registration Committee for technical evaluation. In the technical evaluation process, different parts such as Product Profile, Quality Profile and Pharmacological Profile are assessed by experts designated for each part. After technical evaluation of each part, the expert(s) for each part will give recommendations to the chairperson of the committee who will provide the final decision whether the product is approved for registration or whether more documents or clarifications are required from the applicant, based upon the recommendations of the committee. If the product is approved for registration, then the registration division will prepare a registration certificate and issue it to the applicant. However, if the product requires additional documents or clarifications, the registration division will communicate this to the applicant.

The following are the categories of medicines currently regulated in Bhutan:

i. Human allopathic medicines

ii. gSo-ba-rig-pa medicines (Traditional medicines)

iii. Veterinary allopathic medicines

iv. Biologics and Biotechnology Products

v. Complimentary medicines

vi. Medical gas

vii. Active pharmaceutical ingredients for extemporaneous preparation

viii. Antiseptics/skin disinfectants

ix. Medicines falling under General Sale List (GSL) of BMRR 2012.

The Committee for Registration of Medicinal Product consists of the following members:

- Clinical Pharmacists from the JDWNRH as Pharmacology Experts;
- Pharmacist from the Drug Testing Lab, within the Public Health Laboratory, as the Quality Expert;
- Veterinary Officer from National Animal Hospital as the Expert in Veterinary Medicines;
- Head of Quality Control from Menjong Sorig Pharmaceuticals as the Expert in Traditional Medicines;

- Regulatory Officers from Registration, Inspection and Post-Marketing Control Divisions of the DRA as Committee members;

- Head of Registration Division as the Member Secretary.

Registration lasts 3 years and must then be renewed. The registration fee is - 1500Nu with an extra 150Nu processing fee for each item but the income goes straight to the MOF and is not kept by the DRA. The fee is quite small, as there is little incentive for manufacturers or their representatives (wholesalers) to register products since the market is very small and some product sales may not cover the time taken to collect the dossiers of documents for registration purposes or the fees.

As for the situational analysis in 2011, there are still a number of medicines on the EML for which there is no registered product, and which must be imported after getting a "No Objection" letter from the DRA. Since 2011, there is a new fast track registration process, incorporated into the Bhutan Medicine Rules and Regulations (2012), which allows for fast-track registration and temporary registration when requested by relevant government agencies, especially for products required in emergencies, disease outbreaks or for named patients. Such products must be registered with one of ten stringent national regulatory authorities of produced by a manufacturer who already has ten other products registered in Bhutan or is a WHO prequalified product. The DRA felt that too many "No Objection" letters were being requested by JDWNRH and the MOH and also that MOH tenders were sometimes given for non-registered products when there was a registered alternative available due to reasons of low price. This happens particularly in emergency orders when the local wholesaler with the registered product is not able to supply the requested quantity within the short time frame requested and so the order is given to another supplier of a non-registered product. Such a situation acts as a disincentive to local wholesalers to register certain products. The DRA felt that such situations could be minimized by better quantification and rationalisation of named patient drugs by the JDWNRH.

7.8. Pharmacovigilance

As per the Bhutan Medicines Rules and Regulation 2012, National Pharmacovigilance Centre should be set up at the DRA. Currently the Post-Marketing Control Division under the DRA is responsible for Pharmacovigilance, functioning with only 2 staff. However, this division must not only cover ADR monitoring, but also report on lack of efficacy and quality defects, control of false advertisements, and provision of drug information including the National Formulary of Bhutan.

Referral Hospitals act as Regional Pharmacovigilance Centres and District Hospitals send ADR reports from their own and lower facilities to the regional hospital. As per the regulation, the National Veterinary Hospital is the Pharmacovigilance Centre for Veterinary medicines and the Traditional Hospital is the Pharmacovigilance Centre for Traditional Medicines. For Human medicines, the hospitals are actively collaborating with the DRA, but the collaboration with Veterinary Hospital and Traditional Hospital is poor with few ADRs being reported.

Written SOPs exist for product recall and all decisions about product recall are made by the Product Recall Committee. Since 2011, the DRA has become an Associate Member of the Pharmacovigilance Monitoring

Centre run by the WHO Collaborating Centre in Uppsala, Sweden. A total of 39 ADRs have so far been reported and been entered into the Vigiflow reporting system.

Table 7.8.1: Number of Adverse Drug Reactions reported at national level in the last 5 years

Year	2011	2012	Till 2013	2014	2015	Total
No. ADRs	?	?	14	10	15	30

7.9. Drug Promotion

Drug promotion is rare in Bhutan and only occurs in the large border towns and in Thimphu, where drug representatives have been known to give out free samples of unregistered drugs to doctors. The DRA is the only agency mandated to monitor drug promotion and the Post-Marketing Control Division within the DRA is responsible for monitoring drug promotion. They give Pre/ Post approval of adverts and monitor access of pharmaceutical representative to health professionals in public facilities. So far, the DRA has not received any pharmaceutical adverts to approve or disapprove, nor has it had to stop any inappropriate advertising of allopathic medicines though it has had to do so for traditional medicines.

7.10. Drug Price controls

The Registration Division of the DRA regulates the price of all the medicinal products that are registered in Bhutan. The price structure must be submitted at the time of registration of the medicinal product, containing the price from the manufacturer to the wholesaler, from the wholesaler to the retailer and the maximum retail price (MRP). After registration, the price will be checked when the wholesalers applies for import authorization of the medicinal products. If the price structure in the proforma invoice does not match the initial submission, the import authorization will not be approved. In such a case, the applicant has to apply for post-registration changes to the price before importation of the products.

Mostly the drugs are imported from India, where all medicines are printed with an MRP (maximum retail price) which is also the MRP followed in Bhutan.

7.11. Drug Testing Laboratories

The National Drug Testing Laboratory, which is within the National Public Health Laboratory under the Department of Public Health, is not fully equipped and functional as yet, though it has 3 staff. The DRA has signed an agreement with two Drug Testing Laboratories outside country, Zest Laboratory Pvt. Ltd. in Nepal and SGS Life Science Pvt. Ltd. in India, as appellant Laboratories. All the samples are sent for quality analysis to these two labs. In the last one year 80 samples were sent for testing and six non-compliant batches were recalled.

Table 7.11.1 shows the number of samples tested and the failure rate. Overall, in the last 5 years, 23 (8.4%) samples out 275 have failed to meet quality standards on testing. Premarketing testing has not so far been done. Post-market samples are collected randomly upon receipt of complaints or for products suspected for quality failure, from the market and from the MSDD warehouse at Phuentsholing and sent for testing to examine the quality of medicines.

Table 7.11.1: Drug quality testing results for the last 5 years

Year	Samples received		Samples tested		Samples found to be substandard	
	Pre-market authorisation	Post-market authorisation	Pre-market authorisation	Post-market authorisation	Pre-market authorisation	Post-market authorisation
2011		46		40		7
2012		68		69		5
2013		40		48		7
2014		40		48		0
2015		69		70		4

7.12. Licensing and accreditation of health professionals

Registration, licensing and accreditation of all health professionals, including practitioners of modern medicine, practitioners of traditional medicine, dentists, nurses, pharmacists and paramedics is done by one body, the Bhutan Medical and Health Council (BMHC). The registration fee for health professional is Nu.1000, Nu.700 and Nu.500 for degree, diploma and certificate holder professionals, respectively. Registration has to be renewed every five years. The DRA licenses retailers and wholesalers once they have passed a competency exam that they conduct.

7.13. Licensing and accreditation of health facilities and pharmacies

The Registration Division of the DRA issues technical authorizations for licenses to be issued by the Department of Trade, under the Ministry of Economic Affairs, to private pharmacies, both wholesale and retail. Technical authorization is based on a site visit to check the adequacy of the premises and staff. The authorization is valid for 1 year after which it needs to be renewed.

Public facilities do not need licenses, health facilities being established and/or upgraded as per the Government. Licensing and registration of teaching institutes is done by the BMHC, who also conduct site visits to check the adequacy of the facilities, faculty, equipment, etc.

There are currently no private hospitals although there are some diagnostic centres in the border towns and in Thimphu. Proposals to establish diagnostic centres are scrutinized by a Committee at MOH and a license awarded to operate. The QASD does some adhoc inspections of the centres for the quality and precision of the tests provided. The licences to private diagnostic centres (lab and X-ray) are issued by the Ministry of Economic Affairs based on the technical clearance granted by the Ministry of Health. The Essential Medicines & Technology Division in consultation with the relevant experts screens the application for the clearance.

7.14. Summary status including progress / changes / problems in medicines regulation since last situational analysis

The Drug Regulatory Authority continues to develop. Promotion of registration of products so as to ensure access to essential medicines and avoidance of monopoly practices for products with few suppliers is an important activity. Since 2011, the DRA has introduced a new fast track registration process which has eased the problem of importing essential drugs that were not registered in the country at MOH request for emergencies and public health reasons. However, the DRA felt that the number of "No Objection" letters requested by MOH and the Jigme Dorji Wangchuk National Referral Hospital for emergencies and named patients is excessive and is undermining the DRA and that such requests could be reduced by better planning. Furthermore, frequent emergency requests result in tenders being given to suppliers of non-registered products even when there is a registered alternative because the local wholesaler cannot supply it within the time frame. Although the DRA stipulates that all fast tract products should be registered with one of ten stringent regulatory authorities or be produced by a manufacturer with ten products already registered in Bhutan or be a WHO prequalified product, some people felt that clearer criteria for fast track registration, acceptable to both the DRA and the MOH, were needed.

The DRA continues to develop SOPs for all processes and train its staff as best it is able with scarce resources, but there is still more need for training in dossier evaluation and GMP inspection. The Drug Testing Laboratory is being developed but is still not functional and this is a serious concern because of the delay in being able to test product quality, such delays sometimes leading to stock-outs.

7.15. Medicines regulation: Recommendations

- Strengthen the National Drug testing Laboratory (NDTL) to be able to undertake regular samples for testing both registered and non-registered medicines:
    - Should be made fully functional at the earliest if necessary by reviewing the location of NDTL and if possible making it autonomous;
    - Should be strengthened in terms of human resources and equipment;
    - Establish minilab testing at the central drug store in Phuentsholing.

- Strengthen the abridged registration process:
    - Establish clear criteria for exemption of registration or abridged registration for procurement of medicines;
    - Will require collaboration between the MSPD/DMSHI/MOH, DMS/MOH, JDWNRH and the DRA;
    - Will require analysis of products granted exemption of registration and reasons underlying the exemption.
- Strengthen post-marketing surveillance:
    - Regular inspection of public health facilities;
    - Regular inspection of private retail pharmacies including whether they sell prescription-only medicines over-the-counter;
    - Regular quality testing of medicine samples.

8. MEDICINE POLICY AND COORDINATION

8.1. National Medicines Policy

The National Drug (Medicines) Policy 2007 has five main aims:

- To ensure the accessibility, availability and affordability of essential drugs to all citizens.
- To ensure the safety, efficacy and quality of drugs
- To promote good dispensing practices, prescribing practices and rational use of drugs.
- To promote efficient supply management system.
- To promote the development of local pharmaceutical industry and local production of essential drugs.

The following aspects are covered in the policy: Selection; Quantification; Storage; Distribution; Financing; Quality Assurance; Advertisement and Promotion; Local Manufacturing; Rational use; Disposal; Pharmacovigilance; Intellectual property rights; Emerging diseases; Human Resources; Research and Development.

The national drug policy (NDP) is to a large extent implemented, with the exception of point (v) on the manufacturing of allopathic drugs which may not be possible due to due to the relatively small amounts actually needed. The NDP has been implemented because there has been, and is, political will to do so and achieve Gross National Happiness, and because a unit, the Essential Drugs Program (EDP),has been identified and responsible for implementation of the national EDL, STGs, Formulary, training on rational use of medicines and supply management.

The NDP mentions guidelines for implementation by the respective agencies, which would require mechanisms for coordination and collaboration, and also the need for appropriate monitoring and evaluation of systems in order to measure the effectiveness of the policy, identify possible problems and take corrective measures. The NDP states that the EDP and the Drugs, Vaccines and Equipment Division (DVED) would take the lead role in implementation and that the Department of Medical Services (DMS),would be the Focal Agency for the promotion of inter and intra-sectoral collaboration and co-operation. Unfortunately, the implementation plan received insufficient budget and the EDP has become weakened in recent years due to under-funding.

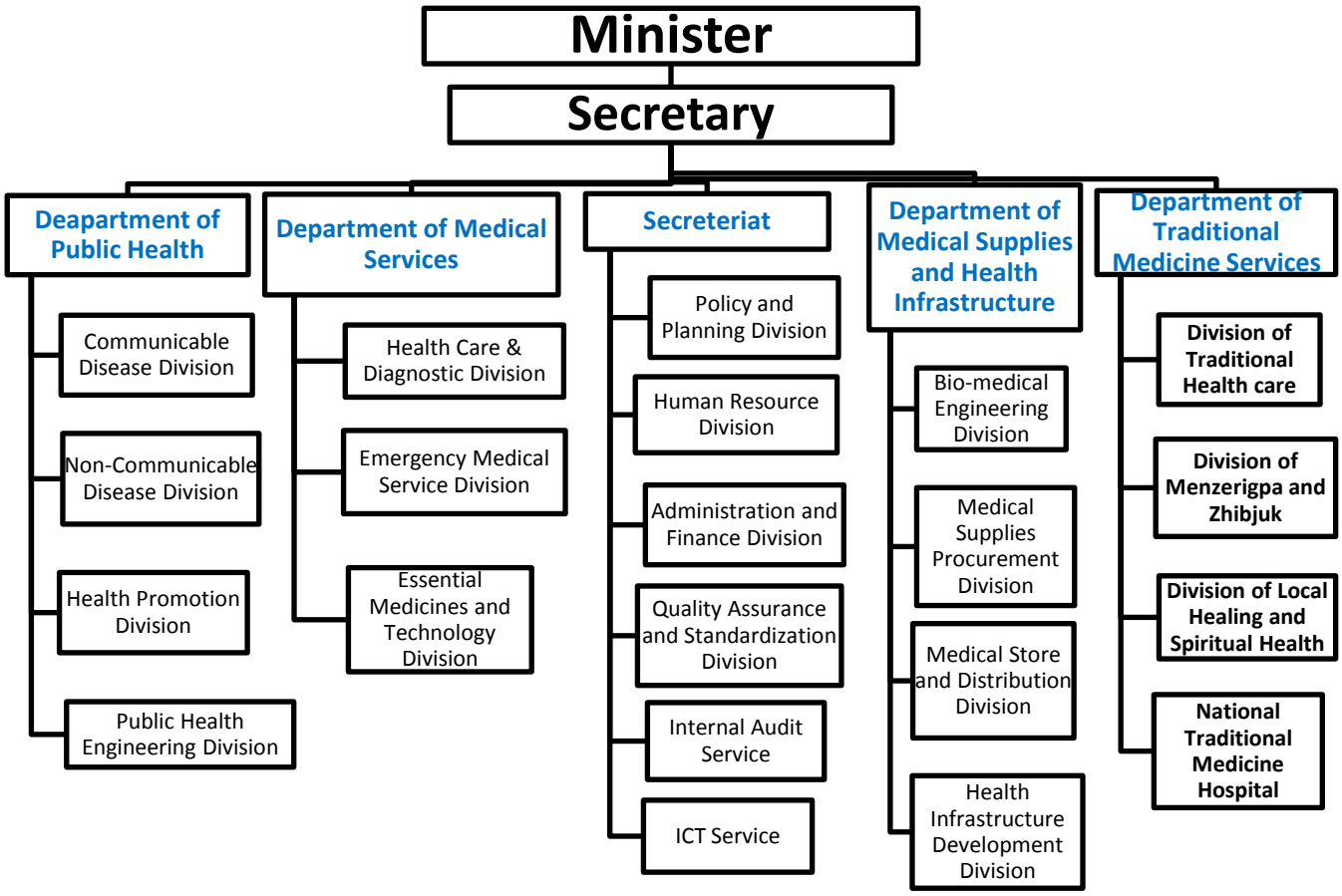
This resulted in a stock-out crisis in 2011-2012, following which the MOH was reorganized. The DVED (formally responsible for quantification, distribution and procurement) is no longer under the Department of Medical Services but is now under the new Department of Medical Supplies and Health Infrastructure (DMSHI) and its function divided between a procurement division and a stores and distribution division in DMSHI. However, responsibility for quantification remains with the Department of Medical Services (DMS) under the Health Care and Diagnostic Division and the Essential Drug Program is now subsumed in the Essential Medicines and Health Technology Division also under the DMS. Thus, the NDP, and it implementation plan, need updating and also budget allocation for monitoring implementation.

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

Policy	Implementation status
National Medicines/Drug Policy (NMP/NDP)	Official NMP document 2007, with many aspects implemented but some aspects not implemented.
National Essential Medicines List (EML)	National EML 2014 currently being implemented fully and updated EML 2015 to be implemented from 2016
National Standard Treatment Guidelines (STGs)	National STGs 2014 distributed to all district facilities and used extensively by paramedical staff but less by doctors
National Formulary manual	National Formulary of Essential Drugs 2012 (covering only EML drugs) found in all health facilities and National Formulary of Bhutan 2014 (covering all registered products) not generally found in health facilities.
National government unit dedicated to promoting rational use of medicines	Essential Medicines and Technology Division (EMTD) within the Department of Medical Services
Monitoring medicines use	Adhoc monitoring by EMTD/DMS/MOH
Drug and Therapeutic Committees (DTCs)	DTCs present in some hospitals but not functional
National Drug Information Centre (DIC)	No national DIC
Generic Policies	Generic prescribing encouraged and generic substitution by pharmacists permitted
Health insurance	No health insurance
Payment for medicines by patients	No fees or payments in the public sector
Provider revenue from medicines	No provider revenue from medicines in the public sector
Undergraduate training on pharmacology & prescribing	Some training on prescribing, the EML, the STGs to paramedical professionals and now also to new medical undergraduates.
CME training on pharmacology & prescribing	Some training on antibiotics to health professionals but generally very little on prescribing
Public education on medicines use	Some posters at health facilities but no public education campaign by the mass media
Pharmacovigilance	New unit in DRA has started monitoring ADRs and become an Associate Member of the WHO Upsalla Monitoring Centre
Regulation of drug promotion	Unit in the DRA responsible for monitoring drug promotion but few activities undertaken due to the low presence of the private sector
National strategy to contain Antimicrobial Resistance	Under draft
Over-the-counter availability of prescription-only medicines including antibiotics	Some OTC availability of antibiotics but very low due to the very small private sector.

8.3. Coordination of medicines-related policies within the Ministry of Health

8.3.1. Ministry of Health Organogram



The MOH has seen a few changes since 2011. The Bhutan Health Trust Fund was previously under the Secretariat within the MOH but has now been made autonomous and is thus not reflected in the MOH organogram. The Drug, Vaccines and Equipment Division (DVED), previously under the Department of Medical Services (DMS) and responsible for procurement and distribution, has been replaced by the new Department of Medical Supplies and Health Infrastructure (DMSHI) under which there are Medical Supplies Procurement Division (responsible for procurement) and a Medical Stores and Distribution Division (responsible for storage and distribution). The DMS, while losing responsibility for procurement and distribution, has retained responsibility for quantification and forecasting need, done by the Health Care and Diagnostic Division (HCDD), and implementation of essential drug policies such as the EML and STGs, done by the Essential Medicines and Technology Division (EMTD), under which is subsumed the former EDP.

The Department of Public Health is responsible for the disease control programs, health promotion and public education and the Public Health Laboratory under which is the new Drug Testing Laboratory, as yet not functional. However, the Public Health Laboratory may be shifted or become autonomous as per a new organogram.

8.3.2. Coordination within the Ministry of Health

Different departments within the MOH undertake different functions as follows:

- Quantification and forecasting of essential medicines is done by the Healthcare & Diagnostic Division (HCDD) under the Department of Medical Services (DMS) although quantification and forecasting of medicines for the vertical disease control programmes, including TB, HIV/AIDS, vaccines, is done by the Department of Public Health.
- Procurement of medicines is done by the Medical Supplies Procurement Division (MSPD) under the Department of Medical Supplies and Infrastructure (DMSHI) in Thimphu.
- Annual procurement of essential medicines, for the JDWNRH is done by the hospital itself albeit through DMSHI, whereas, procurement of additional/emergency and named-patient drugs is done by the JDWNRH directly with the Kolkata office without going through DMSHI.
- Storage and distribution is done by the Medical Stores and Distribution Division (MSDD) under the DMSHI but based in Phuentsholing.
- Maintaining the national EML, STGs, Formulary of Essential medicines, encouraging DTCs and monitoring medicines use is done by the Essential Medicines and Technology Division (EMTD) under the DMS.
- Public education is the responsibility of the Department of Public Health, MOH, though no specific public education campaigns on medicines use have been undertaken.
- Traditional medicines services are under the Department of Traditional Medicine Services, although ensuring the quality of such medicines rests with the DRA.

It is unclear what specific strategies and mechanisms exist for coordination between all the MOH Departments and Divisions. As and when the functions are carried out by various Departments, meetings are called from time to time to discuss the issues of common interest. Previously in 2011, when the DMS was responsible for most aspects of drug management (excluding quality assurance), i.e. procurement, distribution, quantification and setting standards through the national EML, STGs and DTCs, the DG of the Department of Medical Services held regular meetings, sometimes weekly, for all the staff in his department. Unfortunately, these meetings excluded various bodies outside the MOH, including the DRA (responsible for drug quality assurance), RIHS (responsible for training health workers) and the Health Council of Bhutan (responsible for licensing professionals), so some issues could not be easily resolved. Nevertheless there was opportunity to discuss overlapping issues with regard to supply chain management and medicines selection and use. The stock-out problems in 2011 were not due lack of communication within the DMS/MOH but rather between the MOH and other bodies such as the MOF, the DRA, etc. and lack of investment in the former EDP and DVED. Now that the responsibility for supply chain management rests between two departments in the MOH, there is clearly a need for regular meetings between DMS and DMSHI as well as with the Department of Public Health responsible for public education and quantification of drugs for the disease control programmes.

8.4. Other Ministries with medicines-related functions

Other Ministries, apart from the Ministry of Health, involved in medicines-related policies include:

- Bhutan Health Trust Fund
    - responsible for funding for the purchase of essential drugs for the entire country.
- Ministry of Finance
    - responsible for financial support for the named patient drugs.
    - the parent agency for all procurement officials.
    - the custodian of any laws and Acts concerning procurement and financial matters.
- Ministry of Economic Affairs
    - responsible for issuance of licenses for all retail and wholesale suppliers.
    -
- Khesar Gyalpo University of Medical Sciences
    - trains all the health professionals
    - finalizes the syllabus for various health professional courses in consultation with the Ministry of Education.
- Bhutan Medical and Health Council
    - Responsible for licensing and re-licensing health professionals and for setting standards with regard to CME for re-licensing.
- Royal Civil Service
    - responsible for the recruitment of health professional staff.
- Bhutan Narcotics Control Agency (BNCA)
    - responsible for the issuance of import permits for the narcotic and psychotropic substances based upon import authorization issued from the DRA
- Drug Regulatory Authority
    - Responsible for ensuring the quality of medicines and which is independent of the MOH but reports to a Medical Board appointed by parliament and chaired by the Minister of Health.
    - Organizes the testing of drug samples sending them to private labs in India and Nepal, since the new Drug Testing Laboratory, under the MOH's Public Health Laboratory, is not yet functional.

Coordination between the MOH and other Ministries with regard to pharmaceuticals is sometimes not well managed due to lack of a coordinating unit. In particular, coordination is needed between the DMS, DMSHI and the DRA to keep to a minimum the number unregistered products imported into the country which could pose a quality risk. Coordination is also required between the MOH, MOF and the DRA with regard to procurement since the procurement of registered essential medicines can only be done from suppliers registered with the DRA. Furthermore, ensuring quality through supplier and product quality criteria may result in having to accept higher unit prices for some medicines. Coordination between the MOH and

University of Medical Education, the Ministry of Education and the Royal Civil Service is needed to ensure that health professionals are appropriately trained and appointed, respectively, in order to meet the needs of the health care system and ensure appropriate use of medicines.

8.5. **Summary status including progress / changes / problems** in medicines policy since last situational analysis

Since the last situational analysis in 2011, there has been increased investment in the procurement and distribution of medicines with the creation of a new Department of Medical Supplies and Health Infrastructure, including the building of a new warehouse in Phuentosholing. Furthermore, there has been some coordination to revise policies concerning quantification, procurement and fast-track registration which has resulted in more reliable drug supplies and few stock-outs. Nevertheless, some disagreements still exist between the MOH, the JDWNRH and the DRA concerning the number of "No objection" letters requested for importing unregistered drugs, so indicating an on-going need for coordination.

Greater inter-departmental and inter-ministerial coordination is needed to achieve certain functions but no clear coordinating mechanism has been set up. Thus, coordination is needed between: the Departments of Medical Services and Public Health for public education campaigns on appropriate medicines use; the DMS, DMSHI, the Human Resource Division in MOH and the Royal Civil Service Commission to increase the number of pharmacists at district level (which is needed for better drug management and monitoring of use; the DMS/MOH, Khesar Gyalpo University of Medical Sciences of Bhutan, Ministry of Education and the Bhutan Medical and Health Council to ensure that pre-service and in-service training incorporates appropriate and safe prescribing. Coordination with MOF is needed for all activities to ensure appropriate budget.

8.6. Medicines policy and coordination: Recommendations

- Strengthen the following units/departments all of which require more pharmacists:
    - Department of Medical Services, DMS, (Essential Medicines and Technology Division [EMTD] and Health Care & Diagnostics Division [HCDD]);
    - Department of Medical Supplies & Health Infrastructure, DMSHI, (Medical Stores and Distribution Division [MSDD]and Medical Supplies Procurement Division [MSPD]);
    - Liaise with the Secretariat for Human Resources to increase the number of pharmacist posts in the hospitals and in DMS & DMSHI.
- Revise and make the national Drug Policy comprehensive:
    - Since new units and departments have been formed since the NDP was published in 2007;
    - Requires participation by all stakeholders to make the NDP comprehensive;
    - Should include monitoring indicators to monitor implementation.

- Institute a coordinating mechanism or forum under the chairmanship of the Minister of Health whereby the DMS, DMSHI and DRA and other relevant bodies can be brought together to resolve medicines-related issues.

- Support a strong national DRA.

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10. PERSONS MET DURING THE SITUATIONAL ANALYSIS

	Name	Designation and Affiliation
1	Dr. Dorji wangchuk	Secretary, Ministry of Health, Thimphu
2	Dr. UgenDophu	Director General, Department of Medical Services, MoH, Thimphu
3	Mr. SonamJamtsho	Director, Dept. of Medical Supplies & Health Infrastructure, MoH, Thimphu
4	Mr. Sonam Dorji	Drug Controller, Drug Regulatory Authority, Thimphu
5	Dr. Chencho Dorji	Dean, Faculty of Nursing & Public Health, Thimphu
6	Mr. Dorji Wangchuk	Dean, Faculty of Traditional Medicine, Thimphu
7	Dr. Karma Gaylek	M S, National Traditional Medicine Hospital, Thimphu
8	Mr. Nima Sangay	Asst. Registrar, Bhutan Medical & Health Council, Thimphu
9.	Ms. Sangay Yagkey	Senior HR Officer, JDWNRH, Thimphu
10.	Mr. BirkhaBhadur	Store In-Charge, JDWNRH, Thimphu
11.	Mr. SonamJamthso	Store In-Charge (Drugs), JDWNRH, Thimphu
12.	Mr. Yeshi Dorji	Officiating Chief procurement Officer, Medical Stores & Distribution Division, Phuentsholing
13	Mr. TsheringDhandup	Pharmacy technician, Drug Section In-charge, Medical Stores & Distribution Division, Phuentsholing
14	Mr. RinzinChhophet	Health Assistant, In-Charge, Chapcha BHU II
15	Mr. SonamNamo	Health Assistant, Chapcha BHU II
16	Mr. Shiv Kumar Sharma	Namsey, Retail Pharmacy Owner, Phuentsholing
17	Ms. SharmilaGurnug	Namsey, Retail Pharmacy, Phuentsholing
18	Mrs. Ratna Maya	TCC Pharmacy, Pharmacy Asstt. Phuentsholing
19	Mr. Bothevkartik???	TCC Pharmacy, Pharmacy Asstt. Phuentsholing
20	Mr. H. K. Galley	Lakhi Pharmacy, Pharmacy Technician, SamdrupJongkhar
21	Mr. Sangay Tshedup	Officiating Asstt District Health Officer, SamdrupCholing, BHU I
22	Dr. Ugen Thinley	GDMO, Samdrupcholing, BHU I
23	Mr. Dawa	Pharmacy technician, SamdrupCholing, BHU I
24	Mr. Durga Prasad	Staff Nurse II, SamdrupCholing, BHU I
25	Mr. TsheringPenjor	Asst. Administrative Officer, SamdrupJongkhar Hospital
26	Dr. Sangay Wanggchuk	GDMO, SamdrupJongkhar Hospital
27	Dr. KezangWangdi	GDMO, SamdrupJongkhar Hospital
28	Mr. Dorji Rinzin	Ward In-charge, GNM, SamdrupJongkhar Hospital
29	Mr.Lal BhadurSunwar	Pharmacy technician, Drug Store, SamdrupJongkhar Hospital
30	Mr. Dorji Chendup	Administrative Officer, PemaGatshel Hospital
31	Dr. Kinzang Dorji	Medical Officer, PemaGatshel Hospital

32	Mr. YeshiWangdi	Health Assistant, PemaGatshel Hospital
33	Mr. Jigme	Nurse In-Charge, PemaGatshel Hospital
34	Mrs. Kelzang Pelden	Medical Store In-Charge, PemaGatshel Hospital
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45	Mr. DawaGyeltshen	Pharmacy Technician, Monggar Regional Referral Hospital, Mongar
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47	Mr. Sangay Choden	Health Assistant, Lingmethang BHU II, Mongar
48	Ms. RinzinWangdi	Health Assistant, Lingmethang BHU II, Mongar
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50	Mr. B. N.Sharma,	Administrative Officer, Punakha District Hospital, Punakha
51	Mr. Indra Bdr. Ghalley	Pharmacy technician (Store In-charge), Punakha District Hospital, Punakha
52	Mr. Phub Dorji	Pharmacy technician,Phobjikha BHU I, Wangdue
53	Mr. Kelzang	Staff Nurse, , ,Phobjikha BHU I, Wangdue
54	Dr. PemaTenzin	CMO,Bali BHU I, Haa
55	Mr. Sangay Lethro	Pharmacy technician, Bali BHU I, Haa
56	Mr. SonamZangmo	Pharmacy technician, Bali BHU I, Haa
57	Mrs. TandinWangmo	Health Assistant, , Bali BHU I, Haa
58	Mr. Changla	Eye Technician, Bali BHU I, Haa
59	Mr. Dorjee	Dy Chief Administrative officer, Paro district hospital
60	Mrs. Zangmo	Pharmacy Technician,Paro district hospital
61	Mr. KezangDawa	Pharmacy Technician, Paro district hospital
62	Ms. Hema Devi Chhetri	Pharmacy Asst. Kuenphen Retail Pharmacy, Thimphu
63	Mr. Nima Chodon	Pharmacy Asst. Norling Retail Pharmacy, Thimphu

11. PARTICIPANTS OF THE STAKEHOLDER WORKSHOP

	Name	Designation and Affiliation
1	Dr Ornella	WR, WHO-Bhutan
2	SonamJamtsho	Director, DMSHI
3	Karma Yeshi	Sr. Administrative Officer, Monggar
4	Dr. Chabilal Adhikari	CMO, Paro
5	TsheringChoden	Pharmacist, Monggar
6	TsheringDuba	Pharmacist, Trashigang
7	DawaGyeltshen	Program Officer, BHTF
8	Dr. D.B. Subba	Medical Specialist, JDWNRH
9	ChakchuTshering	Offtg. CPO, MSDD
10	Pema Wangchuk	Sr. Procurement, MSPD
11	Zangmo	Sr. Pharmacy Technician, Paro
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13	DendupPenjor	Sr. Research Officer, MSDD
14	ManbirMongar	Assistant Procurement Officer, MSDD
15	Sherab Tenzin	Dy. Chief Pharmacist, DTMS
16	Thinley Dorji	sMenpa, DTMS
17	Wangchen Norbu	Sr. Human Resource Officer, HRD
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19	GyemTshering	Regulatory Officer, DRA
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30	Dr. Kathleen Holloway	RA, EDM, WHO-SEARO
31	Dr. Anita Kotwani	TIP, EDM, WHO-SEARO

12. WORKSHOP SLIDE PRESENTATION

Medicines in Health Care Delivery in Bhutan

Situational Analysis: 20-30 July 2015

Dr Kathleen Holloway, WHO/SEARO
Kinga Jamphel, EMTD/DMS/MOH
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Ugyen Tashi, MSPD/DMSHI/MOH
Thinley, JDWNRH
Pelden Chejor, DRA
Dr Anita Kotwani, WHO/SEARO

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 main activities, who will do them, and in what time frame

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 conduct a rapid assessment of medicines in health care delivery covering drug supply, selection, use, regulation and policy,
  - In liaison with national counterparts nominated by the MOH;
  - Taking into account progress made since the last situational analysis done in 2011
- To report on the findings and develop an action plan in a workshop of government officials and other stakeholders.

Mission 21-30 July, 2015

- 20 July: met core team
- 21 July: visits to WHO country office & JDWNRH and meetings with Secretary of Health, DG Dept. Medical Services, Director Medical Supplies & Health Infrastructure, Drug Controller DRA
- 22 July: visits to Chapcha BHU II, MSDD Phuentsholing & two retail pharmacies in Phuentsholing
- 23 July: travel to Samdrup Jongkhar & visit to one retail pharmacy
- 24 July: visits to Samdrup Jongkhar District Hospital, Samdrup Choeling BHU I & travel to Pema Gatshel
- 25 July: visits to Pema Gatshel District Hospital, Gonpasingma BHU II & travel to Trashigang
- 26 July: visit to Trashigang District Hospital, travel to Monggar & visit to one retail pharmacy
- 27 July: visits to Monggar Regional Referral Hospital, Lingmethang BHU II & travel to Bumthang
- 28 July: visits to Phobjikha BHU I & Punakha District Hospital
- 29 July: visits to Paro District Hospital & Bali BHU I in Haa District
- 30 July: visits to 2 pharmacies, Faculties of TRM & NPH, BMHC, NTMH
- 31 July: workshop

Objectives of the workshop

- Review the situational analysis findings
- Identify the main priority problems to be addressed, in 5 areas:
  - Drug supply, Drug selection, Drug use, Drug regulation, Drug policy
- Formulate recommendations to resolve / address the priority problems in each area to include:
  - What activity?
  - Who will do it?
  - Timeline?

Methods

- 2-week data collection using WHO/SEARO situational analysis tool
- Interviews with concerned government officials & stakeholders & document review
- Visits to public health facilities & private pharmacies
  - Stock-check for availability of 32 selected essential drugs, stock-out, expired drugs, storage conditions, quality-failed stock, etc.
  - OPD prescription survey for WHO indicators
  - In-patient drug management
  - Drug consumption
  - Health system & health care factors

Mission findings

- Extensive health care system, with substantial infrastructure, trained hardworking health care personnel and good health indicators, and…
- Some good areas of progress since last situational analysis in 2011, but some problems remain in all areas of drug management.
- Many of the problems can be addressed by existing resources and capacity.

Selected key essential medicines to measure drug availability

- BHU II
  - Amoxycillin tab; atropine inj; cetirizine tab; ciprofloxacin eye/ear drop; clotrimazole ointment; cotrimoxazole tab; dexamethasone inj; diazepam inj; diclofenac inj; ferrous + folic tab; gamma benzene hexachloride solution; gentamicin inj; hydrochlorthiazide; metformin tab; normal saline; ORS; oxytocin inj; paracetamol tab; ranitidine tab; ringer lactate; salbutamol tab;
- District hospital & BHU I
  - amitriptyline tab; atenolol tab; ciprofloxacin tab; enalapril tab; furosemide inj; metronidazole inj; prednisolone tab; ranitidine inj; salbutamol respiratory solution

Drug Supply

- Drugs supplied to all public facilities by DMSHI (MSPD & MSDD) through "push" system according to quantification done by DMS/HCDD
- Budget proposed by DMSHI based on quantification & agreed with MOF
- Quantification based on past average monthly consumption x 26 months minus stock balance
- Annual drug indent delivered from MSDD Phuentsholing - should be annually but often delivered in 2-3 consignments due to non-arrival of drugs from suppliers
- Additional orders made by most hospitals 2-3 times per year
- Very good system of re-distribution of short-dated drugs between facilities to avoid expiry and stock-out
- Manual stock management system
- Some stock-out complaints from hospitals
- JDWNRH has its own budget for procurement through MSPD
- Named patient drugs procured by JDWNRH through Kolkata office
- Non-quoted EML & additional EML drugs procured through Kolkata office

Drug Availability

- **Situational analysis 2015**
  - Availability of 32 key EML drugs: 99% in regional referral hospitals, 95% in district hospitals, 96% in BHUs, 88% at MSDD in Phuentsholing, 42% in private pharmacies
  - % items out of stock: 4-5% in hospitals & MSDD Phuentsholing, 2% in BHUs
  - Alternative drugs available for many non-available items
  - % prescribed drugs dispensed in public facilities: 94-100%
  - Only few complaints from facilities of stock-out for some drugs
- **Situational analysis 2011**
  - Drug availability: 90% in hospitals & BHUs, ≈ 80% in JDWNRH
  - % prescribed drugs dispensed 95% in all facilities except JDWNRH where it was 85%
  - Many complaints of stock-out for some drugs in referral hosps

Drug Supply since 2011

- New Department of Medical Supplies & Health Infrastructure (containing MSPD & MSDD) to replace DVED & MSD
- New warehouse at Phuentsholing with much better storage capacity
- Quantification kept under the Department Medical Services & changed back to the old system of monthly consumption x 26 months (instead of 15 months) minus balance
- 3-year contract tendering abandoned & reverted to one year tendering
- Greater flexibility of DRA issuing exemptions for purchase of non-registered drugs (e.g. abridged registration, no-objection letters), but still no consensus between DRA, MOH & JDWNRH about the degree to which this is happening & the criteria followed
- Fewer complaints of stock-out, but additional orders still happening due to quantification difficulties in hospitals occurring due to changing prescribing, unplanned camps, increased demand
- DIGPY LMIS abandoned due to software issues & outdated non web-based system & lack of in-house IT capacity

Drug Procurement (1)

- All government drugs from foreign manufacturers (mainly Indian) procured by MSPD/DMSHI
  - Quantities based on Bill of Quantity prepared by HCDD/DMS
- Annual international tender where only suppliers registered with MSPD are allowed to participate
  - One envelope system where technical and price criteria are evaluated simultaneously
  - Evaluation Committee: pharmacists & pharmacy technicians from JDWNRH & other hospitals
  - Tender Selection Committee decides on the basis of price, past supplier performance & product quality history
- Delivery time extended from 90 to 120 days this year due to non-delivery (because of low volume)

Procurement (2)

- Procurement of EML drugs for annual tendering must follow open tendering according to MOF rules
- EML (2012) drugs (367 drugs) divided into 2 lists
  - section A (263 drugs), registered with the DRA
  - section B (104 drugs), not registered with DRA
- Quotes were not available for 82 drugs from section B, so they were purchased through Kolkata office after receiving "No Objection Letters" (exemption) from DRA
- Named patient drugs & additional drugs purchased from Kolkata office
  - still requires tendering but might not be from registered suppliers, since the quantities are generally small & local registered suppliers cannot supply within a short duration, but recently....
- Additional drugs (many on EML) worth 2 million Ngultrum were purchased from Kolkata by JDWNRH

Drug supply: possible solutions

- Establish electronic inventory management system for centre & all district hospitals for better stock mgt. & forecasting
  - MOH now starting the process but will require connectivity
- Employ one pharmacist per hospital to supervise the drug store, OPD, IPD drug management & pharmacy technicians
- Improve district hospital stores - space, shelving,
- Review the MSPD tendering system for technical criteria & consider establishing a 2-bid system at least for section B drugs
- Analyse all purchases of non registered products, e.g.
  - % of purchased products not registered?
  - Reasons underlying the purchases?
  - To be done by team of DRA, DMSHI, DMS & JDWNRH

Stock Management

- Stock management good in most facilities, but
  - A few stores and wards not following FEFO
  - Some expired items occasionally stored with unexpired ones
- No electronic LMIS so monitoring of stock difficult
- Under-estimation of quantities in a few hospitals
  - due to unplanned camps, using different quantification formula, changing patient attendance, changing prescribing patterns
- District hospital in-patient ward drug management not supervised by pharmacist
  - no ward stock book & no pharmacist monitoring of ward stock
- District hospital drug stores managed by pharmacy technician, with no supervision from a pharmacist
- Lack of storage space in many of the health facilities visited

Drug selection

- **National EML 2012**
  - 367 drugs divided by 4 levels of care (BHU II, BHU I & district hospital, referral hospitals, and JDWNRH)
  - 94 traditional medical products divided by same 4 levels of care
  - New EML 2014 approved and 2015 procurement in process
  - Other lists: named patient, ICU, haemodialysis (non-EML) and VHW, school health program (EML)
- **Implementation of EML**
  - MSPD follows the EML but JDWNRH procures some non-EML drugs
  - OPD prescribing survey: ≥96% drugs prescribed are EML ones
  - Occasionally higher facility drugs found at lower levels e.g. for refilling higher level prescriptions sometimes without clinical review
  - JDWNRH and regional referral hospital specialists are able to request non-EML drugs for purchase via JDWNRH on a named patient basis and these drugs are purchased directly through Kolkata, but no effective review by national EDL committee/DTC

Problem of drug supply

- Small market so manufacturers/suppliers not interested to register their products
  - No quotes for some EML drugs
  - Few drugs are quality tested based on receiving a complaint or based on DRA risk-based priority list for recently registered products - so many quality problems may remain undetected
  - Many DRA exemptions for additional & named patient drugs
  - Fewer additional orders would lead to less exemptions
- Quantification made difficult by unplanned camps, changing prescribing patterns & case loads
- Named patient drugs (>50 cases/week) ordered weekly by JDWNRH but no effective review system (e.g. DTC)
- Difficult logistics for distributing drugs
- No electronic LMIS for real-time monitoring of stock

Top EML drugs by value supplied by MSPD in 2014-15

	Drug name	Nu		Drug name	Nu
1	Purified Verro Cell Rabies	11571680	13	Penicillin V 250mg tab	1591920
2	Amoxycillin 250mg	6188520	14	Chloramphenicol 1% 250mg eye	1536015
3	Mycophenolate mofetil 500mg	5094000	15	Spironolactone 25mg tab	1282960
4	Vitamin C 250mg tab	3978440	16	Cloxacillin 250mg cap	1216600
5	Human Albumin 20% 100ml	2448600	17	Clotrimazole 1% oint, 15g	1213761
6	Retinol (Vit A) 200,000 unit	2129813	18	Ibuprofen 400mg tab	1181700
7	Paracetamol 500mg tab.	2088020	19	Cephazolin 500mg inj	1153005
8	Antacid (Al+Mag Hydrox) tab	2014980	20	Ringer lactate inj. 500ml	1152827
9	Ranitidine 150mg tab	2014144	21	Metronidazole 5mg/ml inj 100ml	1151608
10	Cycloserine 250mg tab	1903218	22	Vitamin B complex tab	1100060
11	N.Saline inj 500ml	1843898	23	Hydrocortisone 1% cream, 15g	1051445
12	Ethyl Chloride spray 100ml	1706805	24	Human Mixtard insulin, 10ml	1028580

Top 24 (7%) items cost 52% budget, antibiotics 18%, vitamins 5%.

Top EML drugs by value supplied by JDW in 2014-15

	Drug name	Nu		Drug name	Nu
1	Mycophenolate mofetil 500 & 250 mg cap (cellcept)	5,436,000	11	Compound Solution Sodium lactate inj 500ml	679,768
2	Human albumin 20% 100ml	2,448,600	12	Tacrolimus 1mg tab (Pangraf)	628,614
3	Cycloserine 250 mg tab	1,903,218	13	Methycellulose eye drops	601,731
4	Amoxycillin 250mg cap	1,499,160	14	Omeprazole 20mg cap	565,600
5	Rabies vaccine inj	1,736,000	15	Paracetamol 500mg tab	548,020
6	Metronidazole inj	1,022,088	16	Ranitidine 150mg tab	526,784
7	Vitamin C tab	976,440	17	Ceftriaxone 1g inj	487,344
8	Cephazoline 500mg inj	913,255	18	IV Amino Acid Solution 250ml	438,360
9	Normal Saline 500ml	898,897	19	Spironolactone 25mg tab	420,280
10	Isoflurane Soln 250 ml	690,900	20	Salbutamol inhaler	403,256

Drug use (1)

- Monitoring of drug use weak with little feedback to prescriber
  - OPD patient records & registers record diagnosis & drug treatment
  - IPD patient records and individual patient dispensing sheets record diagnosis & treatment, so ....
  - Drug use monitoring could easily be done by DTCs & pharmacists, but
  - Analysis & follow-up required in MOH
- Hospital Drug & Therapeutic Committees (DTCs) exist in some hospitals, but often not meeting or functional
  - Should be a criteria for accreditation for teaching/ref hosp. status
  - Should evaluate named patient drugs
- National Standard Treatment Guidelines (STGs)
  - Regularly updated & distributed to all hospitals but mainly used by Health Assistants & Assistant Clinical Officers, not doctors
  - Most consulting rooms had the STGs

JDWNRH: Named Patient Medicines: some facts

Various brands of Calcium

- Calcitrol (Bio D3)
- Calciriol granules 60000IU
- Calciriol granules 60000IU
- Calcit 0.25mcg
- Calcitriol 0.25mcg
- Calcitriol Granules 60000U
- Calcitrol Bio D3
- Cinacalcit 30mg
- Osteocalcium
- Shelcal 500 mg

Huge variation in price

- Denosumab 120mg Inj
  - 22449.00
  - 23810.00
- Cilacar 10mg
  - 04.45
  - 61.93
- Botox 100 IU Inj
  - 7000.00
  - 8800.00

More quantities of Cellcept (Mycophenolate mofetil) **ordered**

Drug use (2)

- Independent drug information
  - no functional national Drug Information Centre
- Undergraduate medical education
  - All doctors trained abroad with very varying degrees of training on prescribing but inadequate focus on prescribing during internship / orientation in Bhutan
  - Prescribing principles taught to HAs using STGs, BNF
- CME regular for BHU staff and JDWNRH staff, but rarer for hospital staff, and not much on prescribing
  - MOH vertical disease control programs for government staff
  - Occasional CME for specialists through conferences
  - New system whereby every health worker will need 30 credits every 5 years to get re-licensed, due to start in 2012 but delayed due to inability of many staff to meet the requirement
  - VHWs, school/monastery drug use not supervised

Drug selection: possible solutions

- Continue to update regularly the national EML in a transparent manner with wide representation
- Harmonize national EML with other lists e.g. named patient, ICU, haemodialysis lists
  - Easier purchase in Kolkata should not be a criteria for keeping other non-EML lists
  - Review the named patient guidelines
- Monitor EML compliance regarding level of use
  - Would be much easier with electronic LMIS
  - Focus on high-cost / low volume drugs
- Stricter adherence to EML
  - Referral hosp DTCs to judge all non-EML drug requests
  - National EML committee to provide guidance on "reasonable" specialist drugs for non-EML purchase

Drug use indicator survey

Drug use indicator	Ref hos n=2	Dist hos n=5	BHU I n=3	BHU II n=3	Retailer n=6
Av.no.drugs/patient	2.8	2.5	2.3	1.9	1.3
% patients given ABs	49.3	41.9	40.0	33.3	10.5*
% patients given INJs	4.2	2.9	7.6	4.4	0
% patients given VITs	29.2	27.1	15.6	21.1	8.9
% generic drugs	78.0	95.2	90.0	94.8	-
% EDL drugs	95.8	98.8	100	100	49.3
% URTI cases given ABs	36.7	42.0	28.9	25.6	-
% drugs dispensed	96.1	98.0	96.9	94.2	91.0
Av.cost/Px (Nu)	-	-	-	-	59.60

*75% without prescription

Past MOH prescription surveys

- MOH had done surveys in the past, but
  - not effectively analysed them & inadequate feedback given
  - not sure of sample selection (some hospitals selecting the best prescriptions and some the worst)
- Cannot mix chronic and acute cases in prescription survey in hospitals because
  - Chronic case prescriptions have more items and fewer antibiotics than acute case prescriptions
- % patients prescribed injections cannot be measured from the OPD register because injections are not always recorded in it
- % drugs dispensed cannot be measured accurately without observing the dispensing process

Possible solutions for improving use

- Monitor & analyse drug use & give feedback
  - ABC analysis, prescription audit - by DTCs & MOH
- Standard Treatment Guidelines and National Formulary
  - Continue to update & disseminate & incorporate into CME
- Establish functional hospital DTCs
  - to monitor drug use, encourage CME, and report annually on activities to MOH
- Continuing Medical Education (CME)
  - Bhutan Medical Council credit system for CME should incorporate prescription audit and feedback
  - Extend orientation course for all new doctors – include EDL, STGs
- Public Education
  - Core pharmaceutical messages e.g. *mild coughs & colds do not need any drugs* through all channels used by MOH and the media
- Establish Drug Information Centre
  - Could be placed in JDWNRH, DRA or Health Help Centre

Examples of inappropriate prescribing & dispensing in public facilities

- Almost every case of common cold is prescribed paracetamol
- Repeat prescriptions issued in some district hospitals on the basis of one referral hospital prescription - for years without any clinical review (form 3)
- >3 medicines often prescribed for simple conditions
  - Paracetamol, anti-allergic, vitamin BC &/or C
- Many patients prescribed antacids for non-GI conditions & as "analgesic prophylaxis"
- Often patient-dispenser interaction time was less than one minute with no checking that the patient understood the dosing instructions

Drug regulation (1)

- **National Drug Regulatory Authority (DRA) executes:**
  - Medicines Act of the Kingdom of Bhutan 2003
  - Bhutan Medicines Rules & Regulations 2012
  - DRA is autonomous & independent of MOH
- **DRA manages a sector consisting of:**
  - 1,051 allopathic products & 71 TRM products
  - 1 TRM manufacturing unit & 1 API manufacturing firm
  - 18 wholesalers, 46 allopathic retail shops, 1 TRM retail shop
- **DRA staffing**
  - 16 technical staff & one branch office in Phuentsholing during peak drug receiving time at MSDD
- **SOPs/Checklists**
  - Extensive set of SOPs for most procedures
- **Regulation enforcement in 2014**
  - 107 inspections, including 10 GMP inspections in India
  - Fines worth Nu 76,300 for various offences (e.g. late TA renewals)

Health worker views

- **Nurse**
  - *Almost all paediatric patients have to buy syrups from outside pharmacies*
- **Pharmacy Technician**
  - *There is a lot of irrational prescribing by doctors but it is very difficult to give any feedback*
- **BHU I Doctor**
  - *There should prescribing orientation for new prescribers*
- **Store-in-charge**
  - *We receive very short-dated drugs from MSDD*
- **Pharmacy shop patient**
  - *I don't like to go to the hospital because of the long wait & difficulty to see the correct doctor*

Drug regulation (2)

- **National Drug Quality Assurance Laboratory**
  - one drug testing lab under Department of Public Health (not DRA) with 3 staff but not adequately equipped
  - Testing agreement between DRA & Zest Lab Ltd in Nepal & SGS Life Science Lab in India
  - 80 samples tested in 2014 and 6 (non-compliant) batches recalled
- **Drug Schedules**
  - A1: pharmacy-only medicines; A2: General sales list (OTC)
  - B: prescription-only medicines
  - C1: controlled narcotic drugs; C2: controlled psychotropic substance
  - D: traditional medicines (D1: OTC; D2: prescription-only)
  - E: veterinary medicines (E1: OTC; E2: prescription-only)
  - F: vaccines & biologicals
- **Drug Price Controls**
  - Price structure submitted at registration. Prices follow India MRP

Drug Regulation (3)

- **Drug Registration**
  - All products pre-evaluated by DRA staff and then evaluated by Registration Committee for approval or rejection
  - Separate guidelines for old and new molecules
  - Fast track/ abridged registration for products registered with 10 stringent NRAs, products from manufacturers with 10 other products already registered in Bhutan, WHO/PQ for vaccines
  - Trying to be strict as too many exemptions will compromise quality & weaken the DRA
- **Adhoc monitoring of drug promotion**
  - Pre-approval of drug labels, package inserts and adverts required
- **Adverse Drug Reaction Monitoring**
  - 39 ADRs reported from referral & district hospitals during 2013-2015 & reported to WHO/Upsalla

Coordination and management

- Under MOH, there are 4 departments & 1 secretariat
  - Dept. Medical Services, Dept. of Medical Supplies & Health Infrastructure, Dept. Public Health, Dept. Traditional Medicine Services; Secretariat (incl. Human Resources, Planning, Finance)
- Under Dept Medical Services, there are 2 divisions including HCDD (responsible for quantification & drug supply monitoring) & EMTD (responsible for STGs, EDL)
- Under Dept Medical Supplies & Health Infrastructure, there is MSPD (responsible for procurement) & MSDD (responsible for distribution)
- The DRA is independent of the MOH and reports to the Bhutan Medicines Board
  - Communication, and collaboration are sub-optimal
  - Need for collaboration between different "drug" departments in MOH and DRA

Drug regulation: possible solutions

- Strengthen the national drug testing lab
  - In order to be able to undertake regular sample testing of both registered and unregistered products
  - Minilab at Phuentsholing to test samples?
- Establish clear criteria for exemption of registration or abridged registration such that procurement of medicines is not compromised but at the same time exemptions are minimized
  - Will require collaboration between the MSPD, JDWNRH, DMS/MOH and the DRA
  - Will require analysis of products granted exemption and reasons underlying the exemption.

Possible solutions for coordinating structure and national policy

- Strengthen the following units / departments all of which require pharmacists
  - DMS (EMTD & HCDD), DMSHI (MSDD & MSPD)
  - Institute a coordinating mechanism under the MOH whereby the DMS, DMSHI and DRA can be brought together to resolve issues
  - Possibly through the Medicines Board of which the Minister of Health is the chairman
- Liaise with the Secretariat for Human Resources to increase the number of pharmacist posts in the DMS, DMSHI & hospitals
- Revise the NDP to include monitoring indicators for implementation & monitor implementation
- Support a strong DRA

National Drug Policy

- National Drug Policy, latest edition published in 2007
- Comprehensive set of policies to be implemented mainly by DMSHI, DMS & DRA
- Mentions development of human resources but DMSHI (MSPD & MSDD) and DMS (EMTD & HCDD) still too weak to implement NDP
- Many parts of the NDP implemented e.g. EML, BNF, STGs, formation of DRA, but ….
  - Human resources not adequately improved in DMSHI & DMS and with regard to hospital pharmacists
  - EDP (under EMTD) has been reduced in capacity
  - Functional DTCs not established in hospitals and monitoring of drug use not done adequately
  - NDP indicators are not adequately incorporated into the HMIS
  - Drug Information Centre not established

Group work

- Each group to draft 3-5 recommendations with practical steps including
  - What will you do?
  - Who will do it?
  - In what time line?
- Groups
  - Drug supply
  - Drug selection
  - Promoting rational drug use
  - Drug regulation
  - National coordination and drug policy