MEDICINES IN HEALTH CARE DELIVERY

NEPAL

Situational Analysis:

17-28 November 2014

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

January 2015

CONTENTS

1. ABBREVIATIONS

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AHW	Auxiliary Health Worker
AMR	Antimicrobial Resistance
ANM	Auxiliary Nurse Midwife
APUA	Alliance for the Prudent Use of Antibiotics
CME	Continuing Medical Education
CPD	Continuing Professional Development
CTEVT	Council for Technical Education and Vocational Training
DDA	Department of Drug Administration
DDC	District Development Committee
DG	Director General
DH	District Hospital
DIC	Drug Information Centre
DOHS	Department of Health Services
DPHO	District Public Health Office
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutics Committee
GDP	Good Dispensing Practice
EDL	Essential Drug List
EML	Essential Medicines List
FCHV	Female Community Health Volunteer
GPP	Good Prescribing Practice
HA	Health Assistant
HOD	Head of Department
HP	Health Post
INRUD	International Network for the Rational Use of Drugs

IPD	In-patient Department
IOM	Institute of Medicine, Kathmandu
LMD	Logistics Management Division under the Department of Health Services
M&E	Monitoring & Evaluation
MO	Medical Offcer
MOHP	Ministry of Health and Population
NDP	National Drug Policy
NGO	Non-Governmental Organisation
NML	National Medicines Laboratory
NMP	National Medicines Policy
NPGJ	Nepalgung
OPD	Outpatient Department
OTC	Over-the-Counter
PHC	Primary Health Care Centre
PHCRD	Primary Health Care Revitalisation Division
POM	Prescription-only medicine
PV	Pharmacovigilance
QA	Quality Assurance
RUM	Rational Use of Medicines
SAHW	Senior Auxiliary Health Worker
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
TUTH	Tribhuvan University Teaching Hospital
VEN	Vital, Essential, Non-essential – method for classifying drug importance
VHW	Village Health Worker
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Nepal during 17-28 November 2014. The Terms of Reference were to examine medicines in health care delivery with respect to medicines supply, selection, use, regulation and policy. It was agreed that the WHO/SEARO workbook tool would be used and that a team of government officials, led by the Department of Drug Administration, facilitated by WHO/SEARO, would conduct the situational analysis.

The team members consisted of:

Dr Kathleen A Holloway, Regional Advisor Essential Drugs & Other Medicines, WHO/SEARO
Prof Dr Kumud Kafle, Clinical Pharmacology
Gajendra Bhuju, INRUD Nepal and formerly DG, Department of Drug Administration (DDA)
Buddhi Raj Kafle, Primary Health Care Revitalisation Division, Department of Health Services (DOHS)
Bade BabuThapa, Logistics Management Division, DOHS
Pan Bahadur Kshetry, DDA Kathmandu
Ninu Shrestha, DDA Nepalgunj
Sushma Shakya DDA and WHO Nepal
Dr Ravi Kafle, WHO Nepal

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 22 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 28 November 2014 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

Drugs are supplied to the public sector districts from the Logistic Management Division (LMD) in the same way as they were supplied in 2011 and government expenditure on drugs remains low, being 1.52 USD / person / year in 2011 covering all medicines, but much less than this in the districts visited where it was USD 0.31 – 0.53 USD. As before 35-40 drugs for free distribution to patients are supplied. However, local purchase has now increased. The Primary Health Care Revitalisation Division (PHCRD) is supplying some budget to all district public health offices (DPHOs) for local purchase and the Ministry of Local Development is supplying some budget to some districts for local purchase through the district development committees.

Unfortunately the infrastructure for good supply chain management is lacking, there being no functional electronic drug management information system, many unfilled posts in the LMD and drug warehouses and a lack of pharmacists at district level (hospital and DPHO). Now that medicines are being procured locally, using different government funding sources (PHCRD and DDC), as well as centrally through the LMD, there is a real need for some overall monitoring of medicines procurement and an electronic drug management information system that extended down to the level of the district is much needed. Former proposals to revise procurement, including electronic tendering, international and national competitive bidding, and 3 year procurement planning, could not be implemented due to lack of infrastructure and control mechanisms. Quantification and ordering is still adhoc and health workers still complained of stock-outs of needed drugs and dumping of unneeded ones.

Recommendations were to:

- Increase central government expenditure on medicines.
- Establish harmonised, functional, electronic, web-based, drug management information system, to monitor consumption, stock-out, expiry, which is necessary to improve quantification:
    - start centrally and then extend to DPHO and all public hospitals;
    - employ a data-entry staff for this purpose at hospital and DPHO level.
- Strengthen drug stock management by:
    - Employing at least one pharmacist to manage stock at all public hospitals (including district hospitals)and District Public Health Offices;
    - Training staff in monitoring medicine consumption and quantification;
    - Improving district and regional stores.
- Develop policies to better manage drugs, ensure quality and contain costs in the new local procurement system:
    - Consider central pooled procurement with regard to price negotiation, and prequalification of suppliers and products with local purchase based on a “pull” system and staggered delivery;
    - Clarify the roles of LMD, Regional Health Directorate, Regional Medical Store, and the PHCRD in central procurement, supply, selection, quantification and budgeting.

2.3. Medicines Selection

The national EML 2011 contains 321 drugs divided into core and complementary, but not by level of prescriber or facility. The government is currently supplying 40 of these medicines for free distribution at government health facilities at district level, but have recently increased this list to 70 drugs, a few of which are not on the current EML. The development process for the national EML involves a core team in the DDA and input from various specialists, but the development process for the list of medicines for free distribution is unclear. Implementation of the national EML is good at district level, in part because they have no other choice but to use what government provides. However, at the referral hospitals, where they do their own purchase, implementation of the national EML is low and shows that specialist doctors are not currently following the EML. This may be partly due to lack of awareness but also because they do not believe it is relevant for them, not having been involved in developing the list.

Recommendations were to:

- Revise the EML:
    - include drugs for all levels of care;
    - classify each drug according to level of care, therapeutic class;
    - have wide representation of specialists, generalists and pharmacists, and a transparent process to improve acceptance.
- Ensure list consistency:
    - between national EML and PHCRD lists and LMD procurement list.
- Implement the revised EML (in both the public and private sectors):
    - Consider policy to ensure that most local procurement (e.g. 80% at tertiary level and 90% at district level) consists of EML drugs;
    - Ensure all providers are sensitized/trained on the EML;
    - Monitor compliance.
- Establish a transparent system to review all requests for non-EML drugs:
    - Drug & Therapeutic Committees in all referral hospitals could consider such requests.

2.4. Medicines use

Irrational use of medicines remains a serious problem as in 2011. The average number of drugs prescribed per patient was 2.8 in hospitals, 2.5 in HPs and sub-HPs and 2.5 in private pharmacies. In public sector facilities, 40-50% of patients received antibiotics, 0-10% injections, 16-30% vitamins. Private sector prescribing was similar except that only 4-5% patients purchased vitamins and in one very large pharmacy serving mainly chronic specialist cases, particularly diabetics, the average every patient purchased 4 drugs at more than NRs 2000 and 47% patients purchased an injection. The % of drugs prescribed by generic name was 2% in referral hospitals, 66-80% % in district level facilities and 11% in the private sector (as seen in pharmacies). The % of prescribed drugs belong to the EML was 32% in referral hospitals, 71-94% in district level facilities and 36% in private sector (as seen in pharmacies). The % of upper respiratory tract infection cases treated with antibiotics was 63-71% which is high and shows inappropriate use.

There is little monitoring of medicines use even though outpatient registers at district level facilities are often well maintained and could be used, as opposed to the poorly maintained registers in referral hospitals. The exception to this has been the effective work by INRUD Nepal on prescription audit and feedback for HP staff in some districts. As in 2011, general policies to promote rational use of medicines, though nominally present, are often sub-optimally implemented. Thus, while there are recently updated standard treatment guidelines for paramedical prescribers in HPs and sub-HPs, they have not been distributed. There are no STGs for doctors. Though many hospital drug and therapeutic committees (DTCs) exist, few function well. Continuing medical education (CME) remains adhoc for many prescribers. Although public education is undertaken by village and community health workers, on various topics such as maternal and child health, no messages on the safe and prudent use of medicines have been given.

Recommendations were to:

- Monitor prescribing and drug use:
    - Improve OPD registers to include diagnosis and treatment and improve their maintenance by getting nurses to assist doctors in their completion, in order to monitor prescribing;
    - Monitor drug consumption through the LMD and DPHO procurement and distribution records;
    - Monitor impact of peer-review program in 21 districts (as planned with INRUD Nepal);
    - Monitoring may be done by staff from DDA, DPHO, hospital DTCs, pharmacologists, pharmacists and should be reported to MOHP.
- Develop/update Standard Treatment Guidelines:
    - Develop/update STGs for 1º and 2º levels, targeting doctors as well as HP staff
    - Disseminate to every prescriber and incorporate into undergraduate education and CME.
- Establish Drug and Therapeutic Committees (DTC):
    - In every referral hospital to monitor drug use, maintain hospital formulary, monitor ADRs, encourage CME, and report annually on activities to MOHP
    - should be an accreditation requirement for all teaching hospitals.
- Medical education:
    - Nepal Medical Association, Nepal Medical Council should develop a credit system for CME and incorporate prescription audit and feedback and ethics into it;
    - Nepal Pharmacists Association, Nepal Pharmacy Council should develop CME on Good Pharmaceutical Practice;
    - Request CTEVT to include Good Pharmaceutical Care in the curricula of paramedical workers.
- Undertake nationwide public education campaign
    - Core pharmaceutical messages e.g. *simple coughs & colds do not need antibiotics?*
    - Give the messages through established channels including Village Health Workers, Community Health Volunteers and the media.

2.5. Medicines Regulation

Since 2011 the Department of Drug Administration has been upgraded to Directorate General level (although it is still called the Department of Drug Administration) – and is now directly under the Ministry of Health rather than under the Department of Health Services. Unfortunately, this has not resulted in an increase in human resources, which are actually at lower levels than in 2011 due to unfilled posts. The inability to fill posts has been due in part to the constitutional crisis which is disabled the national planning commission from recruiting new staff and giving official promotion to existing staff. Despite this, the pharmaceutical sector continues to grow, with now over 15,000 products registered, over 300 manufacturing units and over 16,000 drug retail pharmacies, all to be managed by 22 staff in post. With such under-staffing the DDA has great difficulty to fulfil all its obligations. The national medicines control laboratory is similarly understaffed and was only able to process 687 samples in the last fiscal year.

Recommendations were to:

- Strengthen the DDA:
    - Urgently fill all posts and create more posts – particularly for more inspectors and pharmacists;
    - Develop Standard Operating Procedures and guidelines for all processes;
    - Amend current Drug Act to allow more punitive actions;
    - Consider introducing web-based and risk-based regulatory procedures.
- Strengthen the Medicines Control Laboratory:
    - Urgently fill all vacant lab posts;
    - work for ISO 17025 accreditation;
    - establish regional minilabs;
    - train staff.
- Strengthen the drug registration process:
    - Higher fee for imported drugs & stronger criteria e.g. bioequivalence and bio-availability studies, with stricter application of criteria;
    - Ensure all products are reviewed by the technical advisory committee and make the process more transparent (website update);
    - Will help to reduce the number of products registered.
- Update and enforce the drug schedules:
    - update and enforce the OTC & POM lists, which will require a reclassification of many drugs;
    - consider establishing new schedule for drugs used only in tertiary referral hospitals (special pharmacies) e.g. oncology drugs, new antibiotics.
- Start unit to monitor drug promotional activities:
    - Develop monitoring of promotional activities, ethical guidelines.

- Drug pricing:

  Consider methods to improve transparency of drug price setting, including the regular monitoring of drug prices.

2.6. Medicines Policy and Coordination

The national drug policy, coordination and structure remain similar to the situation in 2011. Some important objectives of the 1995 national drug policy remain unfulfilled and some policies to promote rational use of medicines and to monitor medicines use are not implemented by any MOHP department or unit. During the previous situational analysis in 2011, it had been proposed to update the national medicines policy document and to consider establishing a Division of Pharmaceutical Services directly under the Minister of Health, with the Chief Pharmacist as the chief of this unit, in order to coordinate action between ministries. However, neither of these recommendations have been implemented.

Recommendations were to:

- Establish a permanent statutory committee or body to advise the Minister of Health/Secretary on Pharmaceuticals, able to manage inter-ministerial coordination and with wide membership including laypersons, professional bodies …
- Establish an Executive Division in MOHP to carry out the statutory committee recommendations – Division of *Pharmaceutical Affairs/Services*?
    - To coordinate action between DDA, DOHS (LMD, PHCRD) etc.;
    - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, public education;
    - Could liaise with universities to provide students to collect information needed by the MOHP, as part of their research studies;
    - To update the National Medicines Policy to be more specific and to include an implementation plan and time line.

3. PROGRAMME AGENDA

Day	Date	Time	Places visited
1	Mon 17/11/14	Am	Visits to WHO country office; Dept. Drug Administration(DDA) MOHP; Nepal Pharmacy Council;
		Pm	Visits to Kist Medical College and private pharmacy in Kathmandu
2	Tues 18/11/14	Am	Visit to Kathmandu District Public Health Office (DPHO)
		Pm	Visits to Tribhuvan University/Institute of Medicine Pharmacology department and Tribhuvan University Teaching Hospital outpatient pharmacy in Kathmandu
3	Wed 19/11/14	Am	Visits to Logistics Management Division (LMD) and to Primary Health Care Revitalisation Division (PHCRD), MOHP
		Pm	Visits to Nepal Medical Council, International Network of Rational Use of Drugs - Nepal Group
4	Thurs 20/11/14	Am	Travel to Nepalgunj and visit to Bheri Zonal Hospital
		Pm	Visit to Banke DPHO in Nepalgunj
5	Fri 21/11/14	Am	Visits to Nepalgunj Medical College Hospital in Kohalpur and nearby private pharmacies;
		Pm	Visits to DDA Banke branch and Bankatuwa Primary Health Care Centre (PHC) in Banke district
6	Sat 22/11/14	Am	Visits to private pharmacies in Kohalpur, Nepalgunj
		Pm	Free
7	Sun 23/11/14	Am	Visits to Bardia DPHO and Bardia District hospital
		Pm	Visits to Kalika HP and Mainapokhari HP in Bardia district
8	Mon 24/11/14	Am	Travel to Kathmanudu
		Pm	Visits to Madhyapur private hospital and nearby private pharmacy in Bhaktapur
9	Tues 25/11/14	Am	Visits to Tokha PHC and Dhapasi sub-HP in Kathmandu valley
		Pm	Visit to Thankot HP in Kathmandu valley
10	Wed 26/11/14	Am	Preparation for the workshop
		Pm	Preparation for the workshop
11	Thurs 27/11/14	Am	Preparation for the workshop
		Pm	Situational analysis team meeting to finalize the presentation to be made at the workshop
12	Fri 28/11/14	Am	National workshop
		Pm	National workshop

4. MEDICINE SUPPLY

4.1. Responsible Agents/Departments

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Selection	√		Department of Drug Administration, MOHP
Quantification	√		Logistics Management Division (LMD) for centrally supplied drugs and DPHOs and hospital directors for locally purchased drugs
Procurement	√		LMD for centrally supplied drugs and DPHOs and hospital directors for locally purchased drugs
Pricing	√	√	While MOHP has provision in the Drug Act to control prices, in practice prices are set by manufacturers with the 6-10% mark-up by wholesalers and 16% mark-up by retailers allowed officially
Storage	√		Health facilities and LMD/MOHP
Distribution	√		LMD/MOHP and DPHOs
Monitoring & evaluation	√		DPHOs are supposed to monitor medicines management in district health facilities

4.2. Drug availability

Very few reports have published recent data on the availability of essential medicines. One survey was done by WHO in 2004 (WHO 2006) and found that availability of key essential medicines was 93% in public facilities and 87% in private facilities. However, since then, the government has reduced the number of medicines it supplies to district facilities from over 100 medicines to 35-40 medicines. The pharmaceutical country profile conducted by WHO through a questionnaire to MOHP in 2011 found that per capita pharmaceutical expenditure was 1.52 USD per capita per year(WHO 2011) which is very low.

Central government procurement has not changed much since the situational analysis in 2011, the same 35-40 drugs being supplied to district-level facilities. However, local budget provided by the Primary Health Care Revitalisation Division and also by the Ministry of Local Development to District Health Committees has increased in 2014 so that overall public sector purchase has increased. It was only possible to collect information on local purchase manually through review of the DPHO purchase records. In Banke district central purchase by LMD constituted over 82% of the total budget and more than this in Bardia and Kathmandu districts. In 2014, plans have been developed to increase the 40 drugs supplied to districts to 70 drugs, but the budget and process for quantification of the new items has not yet been agreed.

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 22 drugs chosen by the team from the national EML, consisting of: caps/tabs of amoxicillin, ciprofloxacin (tab or eye/ear drops), cotrimoxazole, metronidazole, albendazole, ferrous/folic acid, atenolol, metformin, paracetamol, ibuprofen, chlorpheniramine, antacid, ranitidine, frusemide (tab or inj.), salbutamol; oral rehydration solution; gamma benzene hexachloride lotion; benzoic/salicylic acid ointment, atropine injection; diazepam injection, dexamethasone injection and ringer lactate intravenous fluid. In

addition, a sensitivity analysis was done examining the availability of 30 essential medicines (based upon the availability of all essential formulations of above 22 drugs) and these results are shown in brackets. The 22 essential drugs consisted of 18 from the current PHCRD of 40 drugs and 4 from the new PHCRD list of 70 drugs (diazepam, metformin, ranitidine, ibuprofen).

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

Referral Hospitals	TUTH (pub)	NPGJ (priv)	Banke (pub)	KTM (priv)	Average
% items out of stock	108/795=14%	-	108/164=66%	-	
% key EML drugs available*	86 (90) %	82 (86) % Priv 87 (93) % Sajha	75 (67) %IPD 96 (97) % Priv	68 (80) %	82 (86) %
% prescribed drugs dispensed**	52%	96% Priv 57% Sajha	100% Priv 79% Sajha	95%	80%
Public district hospitals/PHCs	PHC 1	District Hosp	PHC 2		Average
% items out of stock	7/61=11%	3/40=8%	20/45=44%		21%
% key EML drugs available*	82 (70) %	91 (93) %	73 (63) %		82 (76) %
% prescribed drugs dispensed**	80%	51%	96%		76%
Public HPs and sub-HPs	HP 1	HP 2	HP 3	sub-HP	Average
No. items out of stock	14/45=31%	27/46=59%	6/36=17%	19/44=43%	38%
% key EML drugs available*	68 (60) %	77 (67) %	73 (63) %	55 (50) %	68 (60) %
% prescribed drugs dispensed**	94%	97%	92%	88%	93%
Private pharmacies in Banke	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
% key EML drugs available*	67 (62) %	68 (67) %	75 (78) %	55 (47) %	71 (69) %
Large private pharmacy in KTM	1				-
% key EML drugs available*	90 (93) %				

* The first figure presented is based on 22 essential drugs of specific formulation and the figure in brackets is based upon 30 drugs (all the formulations for the above 22 drugs)
** From prescription audit done during the health facility survey

The table shows that availability of essential drugs was 68-95% in tertiary hospitals (private pharmacies in the hospital compound), 63-91% in public district hospitals & PHCs, 50-77% in public HPs & sub-HPs, 47-78% in small private pharmacies, and 80-97% in large private pharmacies (Pharmacia and the private pharmacies in hospital compounds). Interestingly, the availability of key essential medicines was not as good in small/medium-sized private pharmacies as in the public sector, which is in contrast to many studies in other countries which show better availability in the private sector.

The non-availability of some items was due to the non-supply and non-use of medicines for non-communicable diseases, particularly in lower level facilities (PHCs, HPs and sub-HP) at district level. It can also be seen that with local procurement, every facility is operating upon slightly different formulary lists, varying between 40-61 drugs at district hospital and PHC level and 36-46 drugs at HP and sub-HP level. The

number of items out-of-stock refers to those drugs out of stock that are in active use as reported by the health staff.
Availability of essential drugs at both public and private referral hospitals was based upon private pharmacies within the hospital compounds. For public referral hospitals, there was generally both a Sajha pharmacy (government operated but not under the MOHP or the facility) and a private pharmacy. The % of prescribed drugs dispensed was collected by observing patient prescriptions at the outpatient pharmacies. Most facility staff complained of stock-outs. On the day of the survey visit, prescribing at public facilities below district hospital was done by paramedical staff, who did not generally prescribe medicines for non-communicable diseases or those that were not in stock – hence the % of prescribed medicines dispensed in such facilities was high. Many paramedical staff said that they adjusted their prescribing to what was in stock.

4.3. Annual aggregate data of medicines distribution / consumption

Tables 4.3.1 shows aggregate purchase data for the year 2013 in 3 districts – Kathmandu, Bardia and Banke. The aggregate data was extracted from manual records and typed into an excel spreadsheet for analysis. During the process a large amount of manual recording was done and as a result there may be some inaccuracies. Unfortunately, due to the lack of functional drug management information systems at both the central and peripheral levels, all analysis had to be done manually and may therefore contain error. Furthermore, accurate data on local procurement and procurement using the PHCRD budget was only available from one district – Banke (where it was collected manually in the DPHO office) - and not available from the other two DPHOs visited (where details about local purchase were asked by phone). This may be one of the reasons why it appears that the percentage of medicines supplied from the LMD, as compared to local purchase using the PHCRD or District Development Committee budgets, is smaller in Banke(82%) as compared to Bardia (90%) and Kathmandu (98%).

Since the LMD is supplying the majority of medicines according to pre-determined formulae of past consumption and patient attendance, it is not surprising that the top 20 drugs in all 3 districts are similar. It is interesting to note that the top 20 items consuming the drug budget include items that are not strictly on the EML, e.g. Bal Bhita (MNP) in Kathmandu and Lambda-Cyhalothrin 10 WP in Bardia and Banke districts.

The per capita expenditure on medicines supplied by the LMD varies substantially between districts. It is least in Kathmandu district, but this is not strictly comparable because there are many government national referral centres that may be accessed by the Kathmandu population. However, the per capita expenditures in Banke and Bardia districts are quite different, being NRs 38.36 and NRs 52.87 respectively, and it is not clear why expenditure is so different for two similar districts. Furthermore, some of the medicines for free distribution for use at the primary care level were supplied to Banke and Bardia districts but not to Kathmandu district e.g. calamine lotion, gamma benzene hexachloride cream, chlorpheniramine tab, and metoclopramide injection. Some drugs not on the free drug list were also supplied to Banke and Bardia districts but not to Kathmandu e.g. tetracycline eye ointment, tetracycline tabs, gentamycin injection.

Table 4.3.1: ABC analysis of top 20 items in 3 districts

Rank	Banke		Bardia		Kathmandu	
	Item Name/Strength	Rupees	Item Name/Strength	Rupees	Item Name/Strength	Rupees
1	Condoms	3378240	Condoms	8394520	Bal Bhita (MNP)	18709950
2	Amoxycillin 500mg	2436000	Amoxycillin 500mg	2332920	Depo (DMPA-Injectable) +Syringe	12550104
3	Zinc Sulphate 20 mg	1492860	Amoxycillin 250mg, Dispersible tablet	1687000	Condoms	8633200
4	Ciprofloxacin Eye Ointment 0.3% w/v	1485800	Zinc Sulphate 20 mg	1362100	Albendazole 400 mg, Chewable	4184280
5	Amoxycillin 250mg, Dispersible tablet	1420200	Lambda-Cyhalothrin 10 WP	1118000	D E C Tablets	2602800
6	Vitamin B Complex	1063125	Contraceptive Pills	991980	Amoxycillin 500mg	1122000
7	Lambda-Cyhalothrin 10 WP	946000	Ciprofloxacine Eye Ointment 0.3% w/v	786600	Amoxycillin 250mg, Dispersible tablet	810300
8	D E C Tablets	715000	Ciprofloxacin 500 mg	686625	Contraceptive Pills	768785
9	Contraceptive Pills	669587	Paracetamol 500mg	661800	Ciprofloxacin Eye Ointment 0.3% w/v	699200
10	Hyoscinebutylebromide 10 mg	642688	D E C Tablets	605000	Ferrous Salt 60mg + Folic Acid 0.4 mg	697500
11	Ferrous Salt 60mg + Folic Acid 0.4 mg	639000	Ferrous Salt 60mg + Folic Acid 0.4 mg	516790	Oral Rehydration Salts Powder	671040
12	Oral Rehydration Salts Powder	554616	Cotrimoxazole 480mg Tab.	481430	Vitamin B Complex	590625
13	Paracetamol 500mg	539150	Vitamin B Complex	478125	Paracetamol 500mg	378000
14	Benzoic Acid+Salicylic Acid Ointment 30gm	496818	Metronidazole 200mg	298550	Ciprofloxacin 500 mg	350175
15	Ciprofloxacin 500 mg	482600	Oral Rehydration Salts Powder	285228	Salbutamol 4mg	316000
16	Cotrimoxazole 480mg	477800	Ciprofloxacin 250 mg	274680	Ciprofloxacin 250 mg	254016
17	Tetracycline 1% Eye Ointment, 5 mg	437000	Cotrimoxazole 120mg	263160	Chlorpheniramine Maleate 4 mg	237000
18	RingerLactate IV Solution 500ml	431460	Tetracycline 1% Eye Ointment, 5 mg	262200	Diclofenac 50mg	199000
19	Albendazole 400 mg, Chewable	372330	Ringer Lactate IV Solution 500ml	258358.4	Chloramphenicol Eye Applicab 1%	187200
20	Metronidazole 200mg	346800	Cotrimoxazole 960mg Tab.	235413	Metronidazole 400mg	170100
	% budget on top 20 drugs	83%	% budget on top 20 drugs	88%	% budget on top 20 drugs	98%
	% budget (excl. Lam. Cyhalothrin)on ABs	38%	% budget (excl. Lam. Cyhalothrin)on ABs	32%	% budget (excl. Bal Bhita) on antibiotics	10%
	% budget (excl. Lam. Cyhalothrin) on vits	5%	% budget (excl. Lam. Cyhalothrin) on vits	2%	% budget (excl. Bal Bhita) on vitamins	2%
	% budget on EML drugs	96%	% budget on EML drugs	96%	% budget on EML drugs	66%
	% value of drugs supplied by LMD	82%	% value of drugs supplied by LMD	90%	% value of drugs supplied by LMD	98%
	Per capita expenditure on drugs supplied by LMD	38.36	Per capita expenditure on drugs supplied by LMD	52.87	Per capita expenditure on drugs supplied by LMD	31.13

Antibiotics consumed about one-third of the drugs in Banke and Bardia but only 10% in Kathmandu and vitamins consumed 2% of the drug budget in Banke and Bardia but 5% in Kathmandu. This does not mean that antibiotic consumption is less in Kathmandu district but rather that patients are getting their antibiotics elsewhere. Also, the district drug supply from LMD mainly covers acute primary care disease and not non-communicable diseases, hence the large proportion of the budget spent on antibiotics.

The same drug may be supplied by both the LMD and through local procurement, and thus a small investigation into amount of amoxycillin and some other drugs was undertaken. It was found that in Banke district (the only district with full data), per capita consumption of amoxicillin in 2013 in the public sector was equivalent of eight 250mg tablets – which is a large amount considering that the majority of health care is still received in the private sector. Annual per capita paracetamol consumption was equivalent to four 500 mg tablets, metronidazole to four 200mg tablets and antacid to 1.5 tablets. Therefore, there is a need for much closer monitoring of procurement and distribution of medicines at the district level by quantity and value.

Tables 4.3.2 shows aggregate purchase data for the year 2013 in 3 tertiary referral hospitals, the Institute of Medicine in Kathmandu which is the main national public tertiary referral and teaching hospital, the Bheri Zonal Hospital which is a public peripheral referral hospital in Nepalgunj and a private hospital in Kathmandu.

The data from the hospitals show that the top drugs mainly consist of intravenous fluids and injectable antibiotics. Over half the top 20 drugs were non-EML ones in both the national public referral centre (Institute of Medicine), and a relatively small private hospital in Kathmandu. This is not surprising since large national referral centres and private facilities often use non-EML drugs although whether this degree of non-EML drug use is justified should be investigated. Surprisingly, in the public zonal hospital, which is only able to supply inpatient drugs, 6 of the top 20 drugs were non-EML ones.

Table 4.3.2: ABC analysis of top 20 items in 3 tertiary referral hospitals

Rank	Tribhuvan Univ Hosp, Kathmandu 500 beds; 795 drugs		Bheri Zonal Hosp, Nepalgunj 200 beds; 164 drugs (IPD only)		Thimi Hosp., Kathmandu 51 beds; approx. 1000 drugs	
	Item	NRs	Item	NRs	Item	NRs
1	Ceftriaxone inj	5,220,000	Ringer lactate IV 500ml	240,000	Ceftriaxone inj	925,180
2	Iodinated contrast media	3,036,000	Ceftriaxone 1gm inj	240,000	Pantoprazole inj*	754,521
3	Piperacillin+tazebactaminj*	2,010,000	Dextrose Saline IV 500ml	210,000	Esomeprazole tab*	577,967
4	Tramadol inj*	1,720,000	Metronidazoleinj	210,000	Protein supplements*	408,805
5	Dobutamine 250mg inj	870,000	Normal saline IV 500ml	205,000	Piperacillin+ tazebactam*	325,406
6	Normal saline IV 500ml	645,000	5% Dextrose IV 500ml	205,000	Cefixime tab	306,463
7	Noradrenaline inj*	640,000	Oxytocin inj	174,000	Serratio-peptidase tab*	282,236
8	Human albumin IV	624,000	Ceftriaxone 500mg inj	130,000	Dextrose saline IV 500ml	261,115
9	Dextrose Saline IV 500ml	516,000	Rectified spirit	130,000	Diclofenac gel*	236,960
10	Ringer Lactate IV 500ml	510,000	Ciprofloxacin inj*	110,000	Methylcobalamin tab*	232,956
11	Vancomycininj*	504,000	Amikacin 500mg inj*	75,000	Edaravoneinj*	210,000
12	Methylpred-nisolone 1gm inj*	360,900	Amikacin 250mg inj*	60,000	Flucloxacillin cap	199,534
13	Cefepime 1gm inj*	316,000	Betadine 5% soln.	60,000	Cefixime 400mg	188,977
14	Dextrose IV 500ml	301,000	Xylocaine(lidocaine) 2% + adrenaline inj	58,000	Pantoprazole tab*	187,507
15	Clindamycininj*	253,000	Xylocaine 2% inj	54,000	Calcium supplements	168,373
16	Imipenem+ cilastatin inj*	219,600	Dextrose 10% inj	50,000	Optiray (ioversol) 350mg/100mlinj*	151,631
17	Ceftazidineinj*	153,000	Pantoprazole 40mg inj*	47,500	Aceclofenac*	146,850
18	Azithromycin Inj*	69,750	Ampicillin + Cloxacillin 500mginj*	46,000	Betadine solution 100ml	145,127
19	Cefepime+ sulbactam inj*	61,350	Distilled water	45,000	Amoxycillin + Clav. Acid 625mg tab	144,362
20	Amoxycillin + clavulanic acid inj*	14,000	Mephentramine inj*	45,000	Metronidazole inj	141,277
	% budget on top 20 drugs	42%	% budget on top 20 drugs	65%	% budget on top 20 drugs	31%

*non-EML drugs

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

The logistics management division (LMD) is responsible for central government procurement. Pooled donor funds are used for the 40 free drugs supplied to districts for use at district hospitals and lower level health facilities. World Bank standard bidding documents must be used and World Bank guidelines followed and international competitive bidding undertaken when procuring these free drugs using pooled donor funds. However, it was mentioned that 80% of LMD's procurement budget comes from the government, not pooled donor funds, and covers drugs outside of the free drug list including drugs and equipment for hospital use. With regard to drugs procured with government funds, LMD staff mentioned that all line items are procured annually and that there is currently no international or national competitive bidding, no electronic tendering and no prequalification of suppliers. Thus, the plans mentioned in the 2011 situational analysis to start international competitive bidding, using a 3-year procurement plan and electronic tendering have not been implemented. LMD staff said that competitive bidding and an electronic tendering system could not be initiated due to lack of electricity and internet connection, lack of trained manpower, weak bidders, and a lack of controlling mechanisms at the central management level.

All LMD procurement using government funds must follow government procurement rules and technical criteria include: national registration of the product and supplier; 18 months shelf-life; agreed delivery time; replacement of poor/damaged goods; provision of package inserts; GMP certificate; "government free drugs" box labels (though not on the strip packaging so individual strips could still be "leaked"). All procurement must be approved by the DG Health Services and the Ministry of Finance but there appears to be no wider outside membership of procurement decisions, so leaving the system potentially open to undue influence from various sources. Indeed there had recently been some scandals resulting in a change of senior staff in LMD.

4.4.2. Provincial/District/Health facility Drug Procurement

Local procurement at district level is generally decided upon by the District Public Health officer and the District Medical Officer, generally in response to requests from health facilities for drugs that are out of stock or in short supply. Estimates for the amounts to procure are based upon past consumption. Local procurement generally occurs about twice year. Local purchase must follow government rules, but most district purchases are small and so do not require a tendering process. Thus, it was seen that unit prices for the same product varied between districts and even within the same district at different times within the same financial year. Table 4.4.1 compares the LMD (central) unit price for medicines that were supplied centrally with the unit price for medicines that were procured locally in Banke district (the only district that could supply accurate local purchase data). As can be seen local unit prices were about 30% higher than central ones. Such small purchases without sufficient technical input into the procurement process are likely to result in higher prices for poorer quality medicines.

Table 4.4.1: Unit price comparisons between central and local purchases

Name	LMD unit price	Local unit price	% greater price of local unit price compared to central LMD unit price
Amoxycillin 125mg/5ml syrup	0.8	1.09	36.25
Amoxycillin 250mg tablet	1.11	1.44	29.72973
Amoxycillin 500mg tablet	2.04	2.52	23.52941
Benzoic /salycylic acid ointment	15.73	19.7	25.2384
Calamine lotion	10.25	20.9	103.9024
Chlorpheniramine 4mg tablet	0.12	0.19	58.33333
Ciprofloxacin 500mg tablet	1.27	2.35	85.03937
Ciprofloxacin eye/ear drops	6.77	10.83	59.97046
Cotrimoxazole 240 mg tablet	0.52	0.83	59.61538
Cotrimoxazole 480 mg tablet	0.78	0.79	1.282051
Ferrous Folic acid tablet (0.33-0.49)*	0.41*	0.43	4.878049
Gamma benzene hexachloride cream	14.47	16.8	16.10228
Hyoscine tablet	1.84	2.88	56.52174
Metronidazole 200mg tablet	0.36	0.41	13.88889
Oral rehydration salts (4.68-4.74)*	4.71*	5.4	14.64968
Oxytocin injection	4.64	9.7	109.0517
Paracetamol 125mg/5ml syrup (6-12)*	9.0*	12.5	38.88889
Paracetamol 500mg tablet	0.35	0.38	8.571429
Ringer Lactate 500ml	39	30.45	-21.9231
Zinc sulphate tablet (0.61-2.4)*	1.51*	0.78	-48.3444
Average % difference			33.75879

*Price range for unit prices in which case the average was taken.

Most districts procure from multiple suppliers. There is no prequalification of suppliers and also there appeared to be no criteria for judging the quality or reliability of suppliers. Also there are no “government free drugs” box labels on locally purchased drugs. In referral hospitals, procurement is generally decided by the medical superintendent after consultation with medical staff. Large public tertiary hospitals and private referral hospitals employ pharmacists, who can oversee the process and provide technical input. This may ensure, to some extent, the quality of products purchased, although in the hospitals visited samples were sent for quality testing very rarely and none mentioned any problems of quality. However, in the zonal hospital and the districts (hospitals and district public health office) visited there were no pharmacists to provide technical input into the procurement process. This lack of pharmacists was observed in 2011 and will be felt more acutely by all smaller hospitals and districts as local purchase increases.

4.5. Allocation of budget for medicines in the public sector

The situational analysis of 2011 found that the central budget allocation had been calculated according to population and past usage and that the drug budget allocation in 2010 varied between NRs 7-76/- per illness episode (Chhetri and Deva 2010). The pharmaceutical country profile conducted by WHO in 2011 found that per capita pharmaceutical expenditure was 1.52 USD per capita per year which is very low. Data from 3 districts in 2013 (table 4.3.1) shows central government annual per capita drug expenditure (excluding the vertical disease control programs) as being less than 1USD, which is extremely low. It was

mentioned that central budget allocation was based, as previously, on patient attendance at health facilities (Holloway 2011). However, attendance will depend on drug availability and thus past data showing low usage will result in low allocation which is likely to be well below actual need.

4.6. Drug quantification in the public sector

The process of quantification has not changed since 2011 and is based on last year's consumption. Districts and hospitals send consumption data every 3 months to the LMD, where the information is entered into an electronic database kept centrally. This information is consolidated annually and forms the basis of amounts to be ordered in the coming year. The amounts are adjusted according to the central budget allocation discussion between the LMD, the PHCRD, the DG Health Services, the various disease control programs and the Ministry of Finance. There is also a forecasting meeting attended by the DPHOs to discuss the quantities needed, taking into account past consumption, the amount already in the procurement pipeline, the current balance, stock-outs and expiry. However it is unclear how much this meeting influences the final decision and quantities procured and also the degree to which stock information is used since this information was not easily available in the LMD.

A decision has recently been made to increase the free drug list from 40 to 70 drugs. The PHCRD mentioned that a method to quantify the amounts needed had not yet been agreed. Currently, the same drugs as are supplied by the LMD may also be procured locally and it is thus difficult to estimate the total quantities consumed. It was mentioned that there are plans to allow local purchase of only those medicines not supplied by the LMD.

At district facility level, staff ordered drugs when they had run out or were close to running out. No specific formula for estimating needs appeared to be followed. No training on estimating drug need and ordering appeared to have been given to the staff in the health facilities visited and DPHOs have no pharmacist to give such training and do supervisory follow-up.

4.7. Drug Storage and Distribution in the public sector

4.7.1. Drug Storage and Distribution at the central national level

The system of distribution remains similar in 2014 to the system reported in 2011. The LMD operates a centrally controlled "push" system in which pre-determined quantities of medicines are sent once a year from the central LMD warehouses to the five regional warehouses, and from there to the district warehouses every 3-4 months. District drug store staff mentioned that the quantities sent from the regional store did not always meet their needs and that some unwanted items were sent and needed items not sent and that every month they had to make emergency orders. The regional stores also supply emergency drugs (about 10% of the LMD budget). There was no electronic management information system operating in any district warehouse or health facility visited. The LMD was unable to say what the value of expired medicines was in the last fiscal year. However, several sources in Kathmandu mentioned that that lakhs of medicines had expired. Re-distribution of short-dated medicines between districts is only possible after permission is given from the central level and appears to be done rarely. It was mentioned

that monitoring and evaluation is weak and that 60% of the posts within the LMD and the drug warehouses at various levels were unfilled. Public referral hospitals received no medicines from the LMD and did all their own purchase. All staff working in the LMD complained of insufficient storage space and the LMD warehouse in Kathmandu was very crowded with boxes stacked up to high levels, one on the other.

4.7.2. Drug Storage and Distribution at district level in the public sector

Drugs are distributed from the public district health office stores to the health facilities once every 3-4 months, although the dates are not fixed. Currently this also includes the district hospital although there are plans to have district hospital drugs delivered separately from the DPHO supplies. All DPHO staff and many health facility staff complained of lack of storage space and poor storage conditions.

Health facility staff mentioned that the quantities sent from the district store did not always meet their needs and that some unwanted items and were sent and needed items not sent. Some facilities also mentioned having to make emergency orders every month. There were no pharmacists at district level and so there was limited technical capacity to manage drugs. Redistribution of short-dated medicines between health facilities within a district needs only permission from the DPHO and appears to be done quite often in some health facilities, some mentioning that they returned short-dated medicines 2-3 times per year to the DPHO. However, other health facilities mentioned that the Village Development Committees were unhappy for them to return drugs, in which case there is an incentive to report drugs as dispensed rather than expired. All these reasons may account for the relatively low amounts of expired items reported in the health facilities visited.

4.7.3. Pharmaceutical Human Resources

The lack of pharmacists in District Public Health Offices, District Hospitals and even some Zonal hospitals seriously hampers drug management. One district public health officer stated “Drug supply chain management is a jungle. We do not know what basic stock we have, what to order and what has expired”. A pharmacist could provide technical support and monitoring in all aspects of drug management, including procurement, quantification, distribution, storage and the monitoring of drug consumption and prescribing. This will become increasingly important with local procurement. The MOHP’s Hospital Pharmacy Operational Guidelines (MOHP 2013) state that all hospitals must have at least one pharmacist. While the private sector is now employing more pharmacists in hospitals, the public sector has yet to do so.

4.8. Patient Flow in the Health Facilities

Health services are distributed over 75 districts, each district having: one district hospital with 25-50 beds and several doctors; 2-3 primary health care centres with 3-4 observation beds and at least one doctor; about 10 health posts with no beds and staffed by a health assistant (3 years training) and auxiliary health workers (1 year training); and about 40—50 sub-health posts staffed by auxiliary nurse midwives (3 months training). It was mentioned that all the sub-HPs are in the process of being upgraded to health posts. Bardia district hospital is in the process of being upgraded from 25 to 50 beds although the medical officer said that the number of inpatient admissions did warrant this expansion.

At district level, OPD registers are kept by prescribing staff where diagnosis and treatment are recorded but in referral hospitals, treatment was often not recorded. Hospital IPD records included individual patient sheets for clinical notes, clinical observations, and drugs dispensed.

At each health facility, outpatients must pay a small registration fee NRs 5/- (in hospitals with less than 25 beds) or NRs 10/- (in hospitals with more than 25 beds) after which all services are free. Inpatients must pay NRs 10/- registration fee, fees for laboratory investigations, NRs 50/- at discharge irrespective of the length of stay and also a small daily fee for public hospital beds. Very poor patients are exempt the registration fee. However, in referral hospitals all patients had to buy their medicines from private pharmacies and even in district hospitals a significant proportion of patients must purchase their medicines from outside private pharmacies. In the private sector, fees varied enormously. In Nepalgung medical college hospital, which is private, the outpatient registration fee was NRs 50/- for first visits and NRs 10/- for follow-up visits and inpatients had to pay NRs 150-200 per day or up to NRs 1000 per day for a private cabin.

Traditional Medicine

There are separate hospitals for traditional medicine, one referral hospital in Kathmandu with inpatient beds and some zonal hospitals without inpatients. There is a separate Director General for traditional medicine (Ayurveda) in the MOHP but the DDA regulates all medicinal products used in traditional medicine. Although there has been some discussion of placing traditional medicine practitioners in district hospitals, so far this has not happened.

4.9. Insurance

Although there have been various small scale experiments with community insurance, the vast majority of the population is not insured. There were no insurance schemes operating in any of the health facilities observed.

4.10. Drug Manufacturing

The government has one manufacturer, the Nepal Drug Company Limited. However, there are about 347 manufacturers operating in Nepal and of these 300 are Indian or International and 47 are Nepali. The majority of manufacturers produce allopathic medicines but 64 manufacture ayurvedic medicines and about 30 manufacture veterinary medicines. There is no policy to buy most medicines from the government manufacturer, which appears not be used much in government or local purchase. However, it was mentioned that currently about 20% of government purchase is from Nepali-owned/government-owned manufacturers and that government plans to increase this to 80%.

4.11. Drug management in the private sector

Six private pharmacies were visited in two areas – Kathmandu and Banke. In Kathmandu, one very large central pharmacy, serving many private practitioner patients, and one small pharmacy nearby a private hospital were visited. In Banke four small to medium-sized pharmacies in a central town area were visited.

In addition, private pharmacies exclusively serving referral hospital patients were visited. In the case of Nepalgung Medical School hospital and Bheri Zonal hospital, one private pharmacy and one Sajha (government-owned) pharmacy were inside the hospital compound but not inside the hospital building. In the case of the Institute of Medicine hospital and Madyapur hospital (Thimi) in Kathmandu, the pharmacies were actually inside the hospital building and more accountable to the hospital management and thus not included in the qualitative analysis below of private pharmacy practices from interviewing pharmacy staff.

In Kathmandu a visit was made to one of the largest and most sophisticated pharmacies, which served about 700 patients per day (mostly private patients with specialist prescriptions), stocked about 10,000 products, purchased from about 100 wholesalers/suppliers, employed 23 staff (including a chief pharmacist), ran an on-site clinic with about 4-5 doctors, and had a daily turnover of many lakhs rupees.

The private pharmacies visited within the hospital compounds of Nepalgunj Medical School hospital and Bheri Zonal hospital served about 100-200 patients per day, stocked about 1300 – 2500 products, were open 24 hours and staffed by 6-11 people, and had daily sales of about NRs 50,000 – 80,000. The Sajha pharmacies purchased medicines from their warehouse but the other pharmacies tended to purchase from about 20 wholesalers. The Sajha pharmacies all had staff with a pharmaceutical qualification on site at the time of the visit, but not all the other private pharmacies had someone with a pharmacy qualification on-site.

Private pharmacies operating outside hospital compounds were of small to moderate size, seeing 10 – 90 patients per day, generally staffed by paramedical workers (mostly Auxiliary Health Workers) and stocking about 200-800 products purchased from 2-10 wholesalers. Those with larger patient attendance had small clinics operated by a health Assistant and in these pharmacies half the patients self-medicated and the other half got prescriptions from the paramedic. In the smaller pharmacies, nearly all the patients observed self-medicated. Most purchase occurred once very few days and daily sales ranged from NRs 800 – 25,000. Very few of the pharmacies had a staff member with a pharmaceutical qualification and some staff were working alone for long hours. All the pharmacies were practicing generic substitution.

The private pharmacies seen in the compounds of the referral hospitals in Nepalgunj and those seen in the town centre some distance from hospitals are probably more typical of what is found in most towns in Nepal. Very few of these pharmacies were issuing bills and labelling was poor or non-existent. Competition between pharmacies is intense and many have to work long hours. Many pharmacies are run by auxiliary health workers and nurses who cannot find other employment in the public sector. While pharmaceutical practices may be poor in such circumstances, many of the staff running these pharmacies/shops would be capable and open to respond to interventions to promote Good Pharmaceutical Practice.

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

Drugs are supplied to the public sector districts from the Logistic Management Division (LMD) in the same way as they were supplied in 2011 and government expenditure on drugs remains low, being 1.52 USD/person/year in 2011 covering all medicines, but much less than this in the districts visited where it was USD 0.31 – 0.53 USD. As before 35-40 drugs for free distribution to patients are supplied. However, local purchase has now increased. The Primary Health Care Revitalisation Division (PHCRD) is supplying some

budget to all district public health offices (DPHOs) for local purchase and the Ministry of Local Development is supplying some budget to some districts for local purchase through the district development committees.

Unfortunately the infrastructure for good supply chain management is lacking, there being no functional electronic drug management information system, many unfilled posts in the LMD and drug warehouses and a lack of pharmacists at district level (hospital and DPHO). Now that medicines are being procured locally, using different government funding sources (PHCRD and DDC), as well as centrally through the LMD, there is a real need for some overall monitoring of medicines procurement and an electronic drug management information system that extends down to the level of the district. Former proposals to revise procurement, including electronic tendering, international and national competitive bidding, and 3-year procurement planning, could not be implemented due to lack of infrastructure and control mechanisms. Quantification and ordering is still adhoc and health workers still complain of stock-outs of needed drugs and dumping of unneeded ones.

4.13. Medicines Supply: Recommendations

- Increase central government expenditure on medicines.
- Establish harmonised, functional, electronic, web-based, drug management information system, to monitor consumption, stock-out, expiry, which is necessary to improve quantification:
    - start centrally and then extend to DPHO and all public hospitals;
    - employ a data-entry staff for this purpose at hospital and DPHO level.
- Strengthen drug stock management by:
    - Employing at least one pharmacist to manage stock at all public hospitals (including district hospitals)and District Public Health Offices;
    - Training staff in monitoring medicine consumption and quantification;
    - Improving district and regional stores.
- Develop policies to better manage drugs, ensure quality and contain costs in the new local procurement system:
    - Consider central pooled procurement with regard to price negotiation, and prequalification of suppliers and products with local purchase based on a “pull” system and staggered delivery;
    - Clarify the roles of LMD, Regional Health Directorate, Regional Medical Store, and the PHCRD in central procurement, supply, selection, quantification and budgeting.

5.MEDICINE SELECTION

5.1. National Essential Medicines List (EML)

From review of the national EML:

- Responsible government department or agency: Department of Drug Administration, MOH
- Date of publication of latest EML: 2011
- Previous publication dates: 1986; 1992; 1997; 2002
- Number of active pharmaceutical ingredients (APIs):321
- Number of formulations for all APIs:
- Number of products (incl. all brand names & formulations) registered on the market:15,247
- Categories by level of use:
    - Essential and complementary
- Number of persons involved in drafting the latest EML 2011:
    - Core team: 5 staff from the DDA managed the process with input from a further 21 officials and experts from various other government departments, academia and professional bodies, all coordinated by the Chief Pharmacist within the MOHP;
    - Experts: 14 sub-committees of experts considered what additions and deletions to make the 2002 EML;
    - Drug Advisory Committee approved the final revised EML.
- Specialties represented (including general practice):
    - General medicine, surgery, obstetrics & gynaecology, paediatrics, ENT, psychiatry, anaesthesia, tuberculosis, ophthalmology, oncology, orthopaedics, dentistry, dermatology, and immunization.
- Geographic representation of experts:
    - Input received from 10 districts.
- Consistency with national STGs?
    - The national EML is consistent with the national vertical disease control programs and all medicines recommended in the 2012 STGs for HPs and sub-HPs.
    - The National Antibiotic Treatment Guidelines 2014, for all levels of health care, mention 73 antibiotics out of which 34 antibiotics (46%) are not on the national EML. Of these 34 non-EML antibiotics, eighteen may be prescribed by any non-specialist doctor and a further eight (tables of ampicillin,cefadroxil, cephalexin, cefpodoxime, cefpodoxime+clavulanic acid, norfloxacin, rifaximin and neomycin ointment) may be prescribed paramedical staff as well as doctors. One antibiotic combination is also not on the EML although it is as individual antibiotics (cloxacillin + amoxicillin).

5.2. Other Medicine Lists

Central procurement

- The PHCRD has selected 40 essential drugs for free distribution by the LMD. Within this, 40 drugs can be used at district hospitals, 35 in PHCs and HPs and only 25 at sub-HPs. This list of 40 drugs has recently been expanded by the PHCRD to 70 drugs, which are categorized by level of facility – all at district hospital, 68 at PHCs and 39 at HPs (and sub-HPs all of which are being upgraded to HPs). It is not clear how this list has been decided upon. All the 40 free drugs are on the national EML with the exception of aminophylline tablets, a surprising finding. A number of the drugs on the proposed free list of 70 drugs are not on the national EML, including amlodipine tablets, indomethacin tablets, and neomycin ointment.

Districts

- District Public Health Offices and District Hospitals receive some allocation of budget to do local purchase. There appear to be no guidelines as to what drugs they are allowed to purchase. Nearly all the drugs purchased locally belonged to the national EML, although one district was observed to purchase pentazocine injection which is not on the EML. However, many of the purchased items were outside the list of 40 free drugs. Purchase is decided by the district public health officer on the basis of what the HP in-charges and the doctors request.

Referral Hospitals

- Referral hospitals undertake all their own purchase. Public sector hospital purchase is often limited to drugs for inpatients only, outpatients having to purchase their medicines from outside private pharmacies. Many non-EML drugs are used even in public zonal hospitals (see table 4.3.3) e.g. injections of amikacin, mephentramine, ciprofloxacin and pantoprazole.

5.3. Development / updating of national EML

The current list is the 4th revision. A core team consisting of 5 DDA staff and the Chief Drug Administrator in MOHP sent out the 2002 EML (3rd edition) to 14 expert sub-committees, convened for the purpose and requested that they update their sections, adding and deleting medicines. The 14 specialist expert committees met several times and sent back a revised list to the core team. In addition, there was a district-level meeting involving 5 district offices and written comments received from 8 districts. Thirteen specialist organisations also reviewed the EML. All comments were then considered by 24 experts who incorporated the comments and finalised the revision for consideration by a final meeting of 26 senior government staff and experts. After this, the revised EML was considered by the Drug Advisory Committee which approved it and then sent it to the MOHP for final approval. Thus the process of revision was quite inclusive. However, categorization of medicines by level of facility was not done as in the previous edition as it was anticipated that this would be done by the DOHS in consultation with the DDA.

5.4. Implementation of EML

Virtually all medicines consumed in public facilities at district level belong to the national EML (see table 4.3.1), although local purchase lists often included a few products not on the national EML or PHCRD lists e.g. cloxacillin + amoxicillin and etophylline + theophylline. The high use of EML drugs is because 80-90% of the drugs come from the LMD, who follow the national EML. By contrast a significant proportion of the drugs procured by the public referral hospitals are non-EML drugs (see table 4.3.2). Table 5.4.1 shows findings of EML implementation as observed at the facilities.

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

Referral Hospitals	TUTH (pub)	NPGJ (priv)	Banke (pub)	KTM (priv)	Average
% key EML drugs available*	86 (90) %	82 (86) % Priv 87 (93) % Sajha	75 (67) % IPD 96 (97) % Priv	68 (80) %	82 (86) %
% prescribed drugs belonging to the EML**	39.2%	29.2% Priv 15.7% Sajha	33.3% Priv 36.5% Sajha	34.8%	32.9%
EML available in pharmacy? Yes/No	No	No	No	No	No
Public district hospitals/PHCs	PHC 1	District Hosp.	PHC 2		Average
% key EML drugs available*	82 (70) %	91 (93) %	73 (63) %		82 (76) %
% prescribed drugs belonging to the EML**	92.7%	79.7%	98.7%		90.4%
EML available in pharmacy? Yes/No	No	No	No	No	No
Public HPs and sub-HPs	HP 1	HP 2	HP 3	sub-HP	Average
% key EML drugs available*	68 (60) %	77 (67) %	73 (63) %	55 (50) %	68 (60) %
% prescribed drugs belonging to the EML**	92.9%	95.2%	87.3%	100%	93.9%
EML available in pharmacy? Yes/No	No	No	No	No	No
Private pharmacies in Banke	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
% key EML drugs available*	67 (62) %	68 (67) %	75 (78) %	55 (47) %	71 (69) %
% prescribed drugs belonging to the EML**	43.5%	33.3%	29.6%	41.7%	37.0%
EML available? Yes/No	No	No	No	No	No

* The first figure presented is based on 22 essential drugs of specific formulation and the figure in brackets is based upon 30 drugs (all the formulations for the above 22 drugs) – see also table
** From prescription audit done during the health facility surveys

The 2011 situational analysis found that the % of prescribed medicines belonging to the national EML was 55% in referral hospitals, 72% in district hospitals and PHCs and 92% in HPs and sub-HPs (Holloway 2011). In 2014, it seems that the % of prescribed drugs belonging to the EML is lower in the public referral hospitals, but similar in other facility types. The seemingly higher use of EML drugs in the PHCs and district

hospitals in 2014 as compared to 2014 is likely to reflect the absence of doctors at the PHCs on the day of the visit. The national EML booklet was not seen in any public hospital or public health office.

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

The national EML 2011 contains 321 drugs divided into core and complementary, but not by level of prescriber or facility. The government is currently supplying 40 of these medicines for free distribution at government health facilities at district level, but have recently increased this list to 70 drugs, a few of which are not on the current EML. The development process for the national EML involves a core team in the DDA and input from various specialists, but the development process for the list of medicines for free distribution is unclear. Implementation of the national EML is good at district level, in part because they have no other choice but to use what government provides. However, at the referral hospitals, where they do their own purchase, implementation of the national EML is low and shows that specialist doctors are not currently following the EML. This may be partly due to lack of awareness but also because they do not believe it is relevant for them, not having been involved in developing the list.

5.6. Drug Selection: Recommendations

- Revise the EML:
    - include drugs for all levels of care;
    - classify each drug according to level of care, therapeutic class;
    - have wide representation of specialists, generalists and pharmacists, and a transparent process to improve acceptance.
- Ensure list consistency:
    - Between the national EML and the PHCRD lists and the LMD procurement list.
- Implement the revised EML (in both the public and private sectors):
    - Consider making a policy to ensure that most local procurement (e.g. 80% at tertiary level and 90% at district level) consists of EML drugs;
    - Ensure all providers are sensitized/trained on the EML;
    - Monitor compliance.
- Establish a transparent system to review all requests for non-EML drugs:
    - Drug & Therapeutic Committees in all referral hospitals could consider such requests.

6.MEDICINE USE

6.1. Responsible Agents/Departments

From discussion with senior MOH officials

Function/ Organisation	MOHP	Other Agency	Name of Agency/MOH Department
Monitoring medicines use in hospitals	?		Heads of clinical faculty are responsible for monitoring medicines prescribing, but monitoring is mostly not done.
Monitoring medicines use in Primary care	?		The District Public Health Office is responsible for monitoring medicines prescribing, but monitoring is mostly not done.
Development of national STGs	√	√	Department of Health Services (DOHS) and the PHCRD were responsible for the STGs for HPs and sub-HPs and APUA-Nepal with the DDA for the Antibiotic Treatment Guidelines.
Development of national formulary	√		DDA, MOHP
Drug Information Centre	√	√	No National Drug Information Centre. DDA and some teaching hospitals run some services.
Provision of independent drug information	√	√	DDA and some teaching hospitals.
Monitoring Hospital DTCs	√		Department of Health Services (DOHS), MOHP, but there are few functional hospital DTCs and no monitoring.
Monitoring Hospital quality of care	√		DOHS, MOHP
Monitoring DTCs in provinces/districts	√		DOHS, MOHP, but there are no functional district DTCs and no monitoring
Undergraduate education for health professionals	√	√	Ministry of Education with Nepal Medical Council for doctors, Ministry of Health with Council for Technical Education and Vocational Training (CTEVT) for paramedical workers.
Continuing medical education for health professionals	√	√	DOHS, MOHP is responsible for refresher training for district level health workers, and teaching hospitals for resident staff.
Public education on medicines use	√		DOHS responsible but little public education on drugs done.
Implementing generic policies	√		DDA and DOHS

6.2. Past prescription surveys

Since the situational analysis done in 2011, no new surveys have been found, although two new publications since 2011 were identified. The table from the 2011situational analysis report on baseline prescribing in public primary care, updated with results from publications in the last ten years is given below for reference.

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

Reference	Karkee et al 2004	WHO 2006	Shrestha et al 2006	Holloway et al 2008	Kafle et al 2009	Holloway 2011	Khanal et al 2013	Kafle et al 2014
Year of survey	2002	2004	2002	1995-2000	2003-04	2011	2009	2012
Av. no. drug/Px	1.9-2.2	2.0	2.5-2.6	1.8-2.4	-	1.9-2.3	-	-
% Px with ABs	54-57	53	42-43	52-63	-	21-54	-	-
% Px with INJs	5-6	7	-	5-7	-	2-7	-	-
% generic drugs	-	70	51-56	-	-	42-77	-	-
% EML drugs	-	89	64-71	-	-	55-92	-	-
% diarrhoea given ABs	-	30	-	-	81	-	5-12	9
% diarrhoea given ORS	-	80	-	-	12	-	58-60	89
% pneumonia given correct AB	-	100	-	-	58	-	-	85
% viral URTI given ABs	-	70	-	-	22	72-74	-	14
% Px with VITs	-	-	-	9-22	-	5-12	19	-
% Px per STGs	-	-	15-21	40-48	-	-	-	-

Px=prescription; AB=antibiotic; INJ=injection; EML=Essential Medicines List; ORS=oral rehydration solution; VIT=vitamin; URTI=upper respiratory infection; STG=Standard Treatment Guideline.

These studies show similar prescribing patterns over the last decade. Diarrhoea treatment appears to have improved over time with less use of antibiotics and more use of ORS. However, some of the latter surveys showing these improvements have taken place in districts that have received some interventions aimed at improving prescribing, including Banke district in 2 studies (Khanal 2013, Kafle 2014), and it may not be the case elsewhere. Similarly, the use of antibiotics in upper respiratory tract infection appears to be very low in some areas where they have been interventions to improve use (Kafle 2009, 2014) but other studies, including this situational analysis and the one in 2011 show much higher levels.

6.3. Current prescribing practices

A prescription survey in public facilities was done reviewing 30 prescriptions from prescribers on the day of the visit to each facility. Care was taken to select only primary care type cases in the hospitals. Data for general prescribing indicators was collected prospectively from prescriptions as patients came to the OPD pharmacy for the medicines to be dispensed. Data could not be collected retrospectively from the records kept in the pharmacy because medicines to be purchased outside are not recorded, pharmacy records being kept only for the purposes of counting dispensed stock. In the case of referral hospitals without their own OPD pharmacy data was collected from 60 outpatient prescriptions, 30 presented at the private pharmacy and 30 presented at the Sajha pharmacy in the hospital compound and an average of the 60 prescriptions calculated to reflect prescribing. In these hospitals, it was not easy to ensure that specialist cases were excluded.

In district health facilities, 30 case records for upper respiratory tract infection were reviewed in the OPD register since prescribers were keeping a record of diagnosis and treatment. However, this could not be done in referral hospitals as the OPD registers were not well kept, often without any record of treatment or diagnosis. Mostly the OPD registers were maintained by the prescribers, who said that they were too busy to fill it in, but in Nepalgunj medical college hospital, the nurses assisting the doctors actually maintained the OPD registers and so it may be easier in these circumstances to record diagnosis and treatment. In district facilities where treatment for children under the age of 5 years and other patients were recorded separately (in the IMCI and main OPD register respectively), then a sample of children under 5 years and other patients was taken from both registers, ensuring that the sample reflected the same proportions of children under 5 years and other patients as normally attend the facility.

In private pharmacies, data was collected from 30 patients as they came to the pharmacy to purchase medicines. There were no records kept in the pharmacy so the only means of collecting data was from patients. Since patient flow was slow in the pharmacies, different members of the team collected data from different pharmacy shops. The cost per prescription was based on what the patients paid, not on what was prescribed, which may have been more than what was bought.

The results of the prescription survey done during this situational analysis are shown below in table 6.3.1.Overall, prescribing in public district health facilities remains similar in 2014 to that seen in 2011 for most indicators of prescribing, although comparison of results in tables 6.3.1 and 6.2.1 appears to show an increase in vitamin use and a slight decrease in antibiotic use decreased slightly at district level. However, prescribing in referral hospitals appears to have worsened, with lower generic prescribing and lower use of EML drugs. Compared to other countries, injection use in the public sector was admirably low. However, use of antibiotics for upper respiratory tract infection was still high in all health facilities where it could be measured as was the case in 2011 and certainly much higher than in recent published intervention studies (Kafle et al 2009, 2014). This demonstrates the effectiveness of the interventions to improve use in targeted facilities but also the lack of longer-term or more widespread effect.

Prescribing in the referral hospitals and in the district hospital visited was done by doctors but all prescribing done in the PHCs, HPs, and sub-HPs was done by paramedical staff, health assistants in the PHCs and auxiliary health workers (AHWs), sometimes senior AHWs, in the HPs. The only sub-HP visited had already been upgraded to a HP, as per the current government policy. Most prescribers in public district level facilities and in the private hospitals seen were seeing 15-30 patients per day, so the workload was not so heavy so as to preclude good prescribing. The OPD workload in public referral hospitals was not seen.

Table 6.3.1: Results of prescription audit from health facility survey

Referral Hospitals	TUTH (public)	NPGJ (private)	Banke Zonal (public)	KTM (private)	Average
Average number of drugs per patient	2.89	2.26	3.09	3.07	2.83
% patients prescribed antibiotics	37.8	22.6	61.7	33.3	38.9
% patients prescribed injections	5.4	2.8	0	0	2.1
% patients prescribed vitamins	8.1	20.0	13.3	23.3	16.2
% drugs prescribed by generic name	0	0	0	6.5	1.6
% prescribed drugs belonging to the EML	39.2	22.8	34.9	34.8	32.9
Average cost per prescription	193.70	408.75	344.02	584.87	382.84
Public district hospitals/PHCs	PHC 1	District Hosp	PHC 2		Average
Average number of drugs per patient	3.05	2.63	2.63		2.77
% patients prescribed antibiotics	64.5	30.0	26.7		40.4
% patients prescribed injections	0	0	0		0
% patients prescribed vitamins	32.2	16.7	40.0		29.6
% drugs prescribed by generic name	81.5	50.6	65.8		66.0
% prescribed drugs belonging to the EML	92.7	79.7	98.7		90.4
% URTI patients prescribed antibiotics	81.1	73.3	59.4		71.3
Public HPs and sub-HPs	HP 1	HP 2	HP 3	sub-HP	Average
Average number of drugs per patient	2.33	2.07	2.1	1.4	2.0
% patients prescribed antibiotics	70.0	60.0	36.7	16.7	45.9
% patients prescribed injections	0	0	0	0	0
% patients prescribed vitamins	26.7	36.7	30.0	0	23.4
% drugs prescribed by generic name	77.1	93.5	81.0	66.7	79.6
% prescribed drugs belonging to the EML	92.9	95.2	87.3	100	93.9
% URTI patients prescribed antibiotics	83.2	77.3	57.5	33.3	62.8
Private pharmacies in Banke	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
Average number of drugs per patient	2.88	2.8	2.7	1.6	2.5
% patients prescribed antibiotics	43.8	53.8	60.0	40.0	49.4
% patients prescribed injections	0	15.4	3.3	0	4.7
% patients prescribed vitamins	0	7.7	10.0	0	4.4
% drugs prescribed by generic name	0	0	42.0	0	10.5
% prescribed drugs belonging to the EML	43.5	33.3	29.6	41.7	37.0
Average cost per prescription	234.44	308.85	240.27	73.93	214.37

Table 6.3.1: Prescribing audit, from health facility survey, continued

Private pharmacies in Kathmandu	Pharmacy 1 (very large)	Pharmacy 2 (very small)			
Average number of drugs per patient	4.17	1.77			
% patients prescribed antibiotics	0	46.2			
% patients prescribed injections	46.7	0			
% patients prescribed vitamins	16.7	0			
% drugs prescribed by generic name	0	0			
% prescribed drugs belonging to the EML	40.0	30.4			
Average cost per prescription	2072.88	240.23			

In the private sector, prescribing was very different depending on whether the pharmacy was serving hospital inpatients or outpatients or private specialist cases with chronic disease or private general practitioner cases or self-medicating customers. Many small pharmacy shops were being run by paramedical workers who were in fact undertaking consulting and prescribing work as well as selling medicines. Effort was made to exclude inpatient prescriptions, which tend to have many injections present. The very large Kathmandu pharmacy was almost exclusively selling medicines for patients with specialist prescriptions for chronic disease, particularly diabetes and so the injection rate was high, the antibiotic rate zero and the average drug cost per patient very high. However, all the other private pharmacies visited were quite small and selling medicines most for acute primary care cases, with a mix of patients receiving paramedical prescriptions and self-medicating customers. As might be expected, those pharmacies with the greatest proportion of self-medicating customers tended to sell less number of drugs per patient and have lower drug costs per patient. The use of EML drugs and generic prescribing was low in all private pharmacies compared to the public sector.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

Dispensing in the OPD pharmacies of public district facilities was generally done by a paramedical worker or nurse. In the Institute of Medicine(IOM) private OPD pharmacy and the Madhyapur private hospital OPD pharmacy, a pharmacist was supervising all the dispensing. Nepalgunj Medical School Hospital and Bheri Zonal hospital did not have their own OPD pharmacies. The dispensing workload in IOM pharmacy is unknown but in all the other facilities visited, mostly at district level, outpatient attendance tended to be 15-40 patients a day with one staff prescribing and another staff dispensing to all these patients. Thus there should be sufficient time for adequate dispensing procedures. Nevertheless, it was observed that dispensing time was often less than 1 minute, with little instruction given to patients and with no labelling apart from writing the number of tablets per dose and the frequency of doses per day on the strip packaging. In some facilities, dosing was not written on the strip but rather the side of the strip was cut slightly to indicate dosing frequency.

6.4.2. Health Facility Inpatients (wards)

The record keeping for dispensing of medicine to inpatients in the two private (Nepalgunj and Madhyapur) and one public (Bardia) hospital visited was adequate with individual dispensing sheets for each patient, that allowed for the doctor to write down the drug prescription and for the nurse to sign after dispensing each dose. Record keeping was adequate but some storage facilities were sub-optimal. Unfortunately, no inpatient wards of any public referral hospital were observed.

6.4.3. Private pharmacies

Dispensing in private pharmacies was sometimes done by pharmacy shop-owners who had a paramedical qualification or a DDA retailer qualification and sometimes by unqualified staff. Even though many of the pharmacy shops visited had someone with a paramedical or DDA retailer qualification that did not mean that all dispensing was supervised by that person all the time. Only in the large Kathmandu pharmacy was there a qualified pharmacist present. The Sajha pharmacies all had staff with the DDA retailer qualification. As in public OPD dispensaries, the dispensing observed in private pharmacies was found to be often less than 1 minute, with little instruction given to patients and with no labelling apart from writing the number of tablets per dose and the frequency of doses per day on the strip packaging. Very few pharmacies issued receipts. All pharmacies were undertaking generic substitution and many antibiotics were being sold without a doctor's prescription (although sometimes there was a paramedical worker's prescription). Storage of the medicines was sometimes inadequate, with small quantities of many products, placed in a haphazard manner with no protection from heat, sunlight, etc.

6.5. Policies to promote rational use of medicines

6.5.1. Monitoring and supervision of prescribing/dispensing by supervisors

No monitoring, prescription audit or drug utilization review has been or is being done on a regular basis for prescribers, particularly with regard to doctor prescribing. The pharmacology departments in various medical colleges have undertaken adhoc research studies involving prescription audit. However, these appear few and have not been used to instigate change. By contrast, an NGO, INRUD Nepal, has been working with government to conduct prescription audit and feedback in various districts, mainly aimed at paramedical workers in HPs and sub-HPs and focused on the treatment of acute respiratory tract infection, diarrhoea, anaemia, and the use of iron/folic acid in pregnancy (Kafle 2009, 2014). In the districts where this intervention has been conducted, there has been much improvement in prescribing. However, so far the treatments for only a few diseases have been covered and the full cycle of prescription audit and feedback has only been completed in some districts. Also frequent transfer of staff also undermines the impact. There are plans to extend this initiative to 21 districts and include other disease treatments.

6.5.2. Standard Treatment Guidelines (STGs)

There is a national Standard Treatment Guideline, aimed at primary care in HPs and sub-HPs, first published in 1988, and revised 1999 and 2012. The last revision was done by the PHCRD and DOHS and involved a

steering committee, a technical working group and a resource persons group constituted to update the STGs. A workshop was held prior to finalization. The STGs have been printed but they are not yet distributed. The degree to which these guidelines are included in pre-service and in-service training is unclear. However, few prescribers were using it and not a single copy was seen in any district health facility visited and it did not appear to be on the government website. There are no standard treatment guidelines for hospital care.

In 2014, National Antibiotic Treatment Guidelines were published. These guidelines cover the treatment of all infectious diseases requiring antibiotics, by specialty, and for all levels of care. Antibiotics are divided into 4 categories as follows:

- Group 1: non-restricted prescriptive antibiotics;
- Group 1A: non-restricted prescriptive antibiotics to be prescribed as per national protocol for TB and leprosy;
- Group 2: Restricted to be prescribed by a medical officer, i.e. a doctor and not a paramedical worker;
- Group 3: Very restricted to be prescribed by faculty, specialist and consultant.

The antibiotic guidelines were drafted by APUA Nepal with input from about 50 experts covering all the major specialties. A workshop was held before finalisation and submission to government through the DDA. On review of the list of the guidelines 34 (46%) out of 73 of the recommended antibiotics are not on the national EML, 26 (36%) may be prescribed by non-specialist doctors, and 8 (11%) may be prescribed by paramedical workers. The antibiotic guidelines are available on the government website: http://www.mohp.gov.np but no printed copies were seen and implementation appears not to have started yet. APUA Nepal, who produced the guidelines, mentioned that they would be undertaking training, but the extent of this and whether medical schools and hospitals will take it up is unclear.

6.5.3. National Formulary

The second edition of the Nepal National Formulary was published in 2010 by the MOHP. The formulary contains details of: drug indications; contra-indications; dosing; side-effects; drug interactions; preparations available; guidelines on rational prescribing; prescribing for vulnerable groups including children, the elderly, pregnant women, breast feeding mothers, the terminally ill and those with hepatic or renal impairment. The degree to which these guidelines are included in pre-service (including medical and pharmacy undergraduate) training is unclear and distribution appears sub-optimal. Few doctors appeared to be using it, no printed copies were seen in any health facility and it was not on the government website www.dda.gov.np though it was stated that there are plans to include it on the website.

6.5.4. Drug information Centre

There is no national drug information centre operating a phone service to all prescribers and dispensers who have questions concerning drugs. The DDA has one staff member operating a drug information unit which produces a drug bulletin 3 times per year and which is published on its website. It is not clear who is using the bulletin as hard copies are few and many health workers are unable to access the website. The Drug Information Network of Nepal (DINON) used to actively distribute drug information but this network

has stopped operating with the cessation of donor funds. In addition to producing the Bulletin, the drug information unit also handles the pharmacovigilance program, communication with the international narcotics board and monitoring of advertisements.

Some teaching hospitals, such as the Institute of Medicine Teaching Hospital, operate their own drug information centre and may produce newsletters, for use by their own staff.

6.5.5.Independent drug information

Independent drug information produced by the MOHP relates mainly to a few clinical guidelines from the vertical disease control programs, the Standard Treatment Guidelines for HPs and sub-HPs, the national antibiotic treatment guidelines, the national formulary and the Nepal Drug Bulletin, but the distribution of these guidelines is sub-optimal. Apart from the vertical disease control programs the DDA produces these guidelines and last year 3 issues of the Nepal Drug Bulletin were produced and 15,000 copies distributed (DOHS 2070/2071). However, few prescribers appeared to be using any of these publications.

The Drug and Therapeutics Letter is issued quarterly from Drug Information Unit in the Department of Clinical Pharmacology, Tribhuvan University Teaching Hospitals, Institute of Medicine, Kathmandu. The APUA-Nepal Newsletter, which publishes sensitivity patterns, is issued annually from the Alliance for the Prudent Use of Antibiotics, Nepal Chapter. The Pharmaceutical Products Directory of Nepal 2012 was produced by an NGO, the Pharmaceutical Horizon of Nepal (PHON).

Medical colleges have libraries, internet access and pharmacology departments who can provide independent drug information but it is unclear to what extent these resources are used by practicing clinicians, who have little spare time outside of their clinical duties. Medical representatives are not allowed to visit clinicians in some hospitals, but in others they do so. It was mentioned that most doctors, particularly in the private sector, get most of their drug information from the pharmaceutical industry.

6.5.6.Drug and Therapeutics Committees

There is no national DTC. There are Health Institution Operation Guidelines that require hospitals to have a DTC but in reality only a minority of hospitals, mainly teaching hospitals, have a DTC. All the teaching hospitals visited (TUTH, KIST, Nepalgunj) mentioned that they had a DTC which was mainly responsible for managing the hospital formulary and deciding upon what drugs to purchase. KIST mentioned that their DTC had not met for 2-3 years following a change in Hospital Director. In the TUTH, the DTC is chaired by the Hospital Director and the Head of the Pharmacology Department in the Institute of Medicine is a member. The OPD pharmacists mentioned that the hospital formulary had not been update since 2002 and that they procured drugs according to the request of the DTC, but they were not involved in the DTC meetings. In Nepalgung, the Head of Pharmacology is a chief member of the DTC, which is concerned mainly with what inpatient drugs to purchase since there is no OPD dispensary although there are plans to start one. None of these DTCs was undertaking any drug utilization review or monitoring of medicines use.

6.5.7. Undergraduate education on medicines use

Medicine

Prescribing principles are taught to undergraduate medical students during pharmacology teaching in the 1st and 2nd years of the course and all receive about 180 hours of teaching, which includes both theory and practical. The curricula must be approved by the Nepal Medical Council and includes the essential medicines concept, the national EML, the Guide to Good Prescribing and *"P" Personal drugs*, the problems of drug promotion, and social pharmaceutical issues. In the Institute of Medicine and some of its affiliated colleges, a prescribing practical has been included at the end of every teaching module on each bodily system. However, the degree to which all these aspects of medicines management and prescribing are taught in the various medical colleges is unclear. No specific clinical guidelines are used, although students are introduced to the vertical disease control program guidelines and in the future may be introduced to the newly publish antibiotic guidelines. It was mentioned that the undergraduate medical program is overloaded and that pharmacology is not prioritized. Many pharmacologists appear to have a very limited input into the clinical practices of the hospitals attached to their medical schools. While some pharmacology departments were undertaking pharmacovigilance, reporting 40-100 ADRs per year, very few studies on drug utilization or prescription audit were being done. Thus, the prescribing principles taught in pharmacology may be undermined by the lack of emphasis given to good prescribing in later clinical studies and practice.

Pharmacy

Four universities, under the Ministry of Education, are teaching 4-year Bachelor of Pharmacy courses, in which manufacturing, quality control, marketing, and hospital management are included. The Pharmacy Council does not have input into the curriculum although they are now collecting information on the various curricula with a view to harmonize them. Most of the graduates from these courses go into the private sector or manufacturing and 40% work abroad.

Other training Institutions, under the Council for Technical Education and Vocational Training (CTEVT) are responsible for teaching a 3-year Diploma course, where there is more emphasis on hospital management, community pharmacy and practical teaching. Most of these graduates go into managing hospital pharmacies or community pharmacies, mostly privately-owned. According to MOHP hospital pharmacy operational guidelines 2013, every hospital should have a diploma pharmacist, but this has not yet been implemented in the public sector by the planning commission.

The DDA used to run a 3-week drug retailer training course, aimed particularly at pharmacy shop owners working in the villages and remote areas of Nepal where there are few graduate pharmacists. This course was stopped and it is not clear how the needs for qualified pharmacy staff will be filled in remote areas. From time to time the DDA runs refresher courses for such persons in liaison with the Nepal Drug and Chemists Association.

Paramedical workers and nurses

Paramedical workers include Health Assistants (3 years), Auxiliary Health Workers (1-1.5 years), and Assistant Nurse Midwives (3 months) who are trained by various institutions under the supervision of the CTEVT. Many of the institutions are privately-owned and there has been some concern over the quality of training in past years. Some of these workers undertake prescribing and basic prescribing skills are taught. Community Health Volunteers are trained for a few weeks locally by MOHP staff and some of these have

been involved in community case management programs where they are taught to prescribe for childhood cases of ARI and diarrhoea in the community. Nurses are taught in various hospitals in both the public and private sector, but their training does not cover prescribing. Staff nurses follow a 3-year course and Bachelor Nursing follow a 4-year course and the curricula must be approved by the Nursing Council. It was mentioned that since so many public sector paramedical workers are responsible for dispensing that they should be trained on goof pharmaceutical care.

Traditional Medicine

There is one training institution for Ayurveda practitioners under the Department of Traditional Medicine within the MOHP. The DDA is responsible for regulating all traditional medicine products but the Department of Traditional Medicine is responsible for regulating the Ayurveda practitioners. The Bachelor of Ayurvedic and Medicines Surgery (BAMS) course is 5 and half years in length. There is no specialization and there are no post-graduate courses. However, an MD Course for BAMS graduates has been started in the Tribhuvan University, Institute of Medicine, Ayurveda campus, Kirtipur, for Internal Medicine.

6.5.8. Continuing Medical Education on medicines use

Continuing medical education (CME) is adhoc for most practitioners just as it was in 2011. Heads of individual units in teaching hospitals organize seminars and teaching ward rounds for in-service staff. Outside teaching hospitals and districts, CME is not mandatory for doctors and often not followed. Some private general practitioners attend seminars organized by the Medical Association and funded by the pharmaceutical Industry. Some specialists attend lectures organized by the specialist societies and often funded by the pharmaceutical industry. The MOHP vertical disease control programs run refresher training for district level staff from time to time and most health workers mentioned having attended some such training in the last year, although one health worker complained that he had not received any refresher training for 16 years! The Nepal Pharmacy Association has run some workshops on Good Pharmacy Practice.

The Nepal Medical Council is currently working towards the development of a points system for CME but there are no plans to make it mandatory for relicensing and currently Nepali doctors get licenses for life (unlike foreign doctors who need annual renewal). Prescribing seems to receive very little focus in any CME and none of the prescribers met reporting having learned about prescribing in any CME. The Nepal Pharmacy Council does not have plans for any obligatory CME.

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

Some small studies have been undertaken by NGOs, particularly INRUD Nepal, on public education with regard to use of medicines. Such studies have focused on groups such as school children, mothers, journalists (Kafle et al 2010) and drug sellers (Kafle et al 2013, Bista et al 2002, Khan et al 2006). District-level facilities, such as HPs and sub-HPs have Village Health Workers and Community Health Volunteers attached to them and these health workers have undertaken a lot of public education with regard to maternal child health, treatment of childhood illness, particularly diarrhoea and ARI, and vaccination. The topics taught by Village Health Workers and Community Health Volunteers to communities are decided by MOHP and so far these workers have not included the prudent and proper use of medicines, although many people felt this would be good to do as patient demand for drugs is high and many people self-

medicate buying medicines directly from pharmacy shops without consulting health workers. Relevant messages could include “don’t take antibiotics without seeing a health worker first” or “medicines are not needed for simple coughs and colds” or “ask your doctor whether your child really needs more than two medicines”.

6.5.10. Generic Policies

There are no policies on generic prescribing. Generic substitution was practiced in all private pharmacies observed, including those serving hospital outpatients. In the public sector district facilities, generic substitution was not much observed because prescribers only prescribed what they knew was in stock. Generic prescribing is not mandatory and was extremely low in teaching hospitals and by private doctors (as reflected in the prescriptions seen in private pharmacies) but was 66% in district hospitals and PHCs and 80% in HPs and sub-HPs.

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

Irrational use of medicines remains a serious problemI2014, as it was in 2011. The average number of drugs prescribed per patient was 2.8 in hospitals, 2.5 in HPs and sub-HPs and 2.5 in private pharmacies. In public sector facilities, 40-50% of patients received antibiotics, 0-10% injections, 16-30% vitamins. Private sector prescribing was similar except that only 4-5% patients purchased vitamins and in one very large pharmacy serving mainly chronic specialist cases, particularly diabetics, on average every patient purchased 4 drugs at more than NRs 2000 and 47% patients purchased an injection. The % of drugs prescribed by generic name was 2% in referral hospitals, 66-80% % in district level facilities and 11% in the private sector (as seen in pharmacies). The % of prescribed drugs belong to the EML was 32% in referral hospitals, 71-94% in district level facilities and 36% in private sector (as seen in pharmacies). The % of upper respiratory tract infection cases treated with antibiotics was 63-71% which is high and shows inappropriate use.

There is little monitoring of medicines use even though outpatient registers at district level facilities are often well maintained and could be used, as opposed to the poorly maintained registers in referral hospitals. The exception to this has been the effective work by INRUD Nepal on prescription audit and feedback for HP staff in some districts. As in 2011, general policies to promote rational use of medicines, though nominally present, are often sub-optimally implemented. Thus, while there are recently updated standard treatment guidelines (STGs) for paramedical prescribers in HPs and sub-HPs, they have not been distributed. There are no STGs for doctors. Though many hospital drug and therapeutic committees (DTCs) exist, few function well. Continuing medical education (CME) remains adhoc for many prescribers. Although public education is undertaken by village and community health workers, on various topics such as maternal and child health, no messages on the safe and prudent use of medicines have been given.

6.7. Medicines use: Recommendations

- Monitor prescribing and drug use:
    - Improve OPD registers to include diagnosis and treatment and improve their maintenance by getting nurses to assist doctors in their completion, in order to monitor prescribing;
    - Monitor drug consumption through the LMD and DPHO procurement and distribution records;
    - Monitor impact of peer-review program in 21 districts (as planned with INRUD Nepal);
    - Monitoring may be done by staff from DDA, DPHO, hospital DTCs, pharmacologists, pharmacists and should be reported to MOHP.
- Develop/update Standard Treatment Guidelines:
    - Develop/update STGs for 1º and 2º levels, targeting doctors as well as HP staff
    - Disseminate to every prescriber and incorporate into undergraduate education and CME.
- Establish Drug and Therapeutic Committees (DTC):
    - In every referral hospital to monitor drug use, maintain hospital formulary, monitor ADRs, encourage CME, and report annually on activities to MOHP
    - should be an accreditation requirement for all teaching hospitals.
- Medical education:
    - Nepal Medical Association, Nepal Medical Council should develop a credit system for CME and incorporate prescription audit and feedback and ethics into it;
    - Nepal Pharmacists Association, Nepal Pharmacy Council should develop CME on Good Pharmaceutical Practice;
    - Request CTEVT to include Good Pharmaceutical Care in the curricula of paramedical workers.
- Undertake nationwide public education campaign
    - Core pharmaceutical messages e.g. *simple coughs & colds do not need antibiotics?*
    - Give the messages through established channels including Village Health Workers, Community Health Volunteers and the media.

7. MEDICINE REGULATION

7.1. Responsible Agents/Departments

From discussion with senior MOHP officials

Regulatory function	DRA	Other Agency	DRA/MOH department/Name of Agency
Drug Schedules	√		Department of Drug Administration (DDA), MOHP
Licensing &Inspection of drug outlets	√		DDA
Drug registration	√		DDA
Pharmacovigilance	√	√	DDA coordinates ADR monitoring in 7 regional sites. Many teaching hospitals also monitor ADRs.
Drug quality testing	√		National Medicines Laboratory under the DDA
Drug promotion	√		DDA
Drug pricing	√	√	DDA and manufacturers
Health professional licensing/accreditation		√	Professional councils (Medical Council, Pharmacy Council, Nursing Council, ??Ayurveda council); DDA licenses drug retailers who have passed the DDA exam (now discontinued)
Health facility/hospital licensing/accreditation	√	√	DDA licenses pharmacies, Department Health Services, MOHP, licenses hospitals and health facilities

7.2. Pharmaceutical sector

From discussion with national drug regulatory authority

- Number of products on the market: 15,247
    - Foreign: 8831; Domestic: 6416
    - From the current software operating in DDA it's not possible to separate the different types of product into herbal or allopathic. The DDA is currently revising the software.
- Number of manufacturers: 339
    - 331 allopathic (280 foreign-owned and 51 domestically owned)
    - 35 veterinary (27 foreign and 8 domestic)
    - 93 Ayurvedic (32 foreign and 61 domestic)
- Number of wholesaler outlets: 2698
- Number of retailer outlets: 16,640
- Number of blood outlets: managed by Nepal Red Cross Society

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

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
Drug Act 1978 revised in 2001	1978, 2001
Drug registration regulation	1981
Regulations on Drug Standards (1986), Drug Inspection and Investigation (1983)	1986, 1983
Regulation on Code of Drug Manufacturing	1984
Regulation on the formation of the Drug Advisory Committee and the Drug Advisory Council	1980

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

Area / Activity Covered?	Y/N	Document Name
Establishment & functioning of National MRA	Y	Drug Act
Medicines marketing authorisation	Y	Drug Registration Regulation
Medicines scheduling	Y	Drug Standard Regulation
Licensing of medicines handling premises, personnel & practices	Y	Drug Registration Regulation
Licensing of prescribers	N	
Mandatory CME for prescriber licence renewal	N	
Licensing of pharmaceutical personnel	N	
Mandatory CME for pharmacy licence renewal	N	
Regulatory inspections/ enforcement activities	Y	Drug Inspection and Investigation Regulation
Medicines quality	Y	Drug Standard Regulation
Medicines packaging & labelling	Y	Drug Registration Regulation
Medicines promotion	Y	Drug Act
Post-market surveillance/ pharmacovigilance	N	
Collection of fees	Y	Drug Registration Regulation
Clinical trials	Y	Drug Act
Generic substitution	N	
TRIPS-related issues	N	
Transparency & accountability[2]	N	
Banning of unsafe medicines	Y	Drug Act

[1]Medicines regulation issues may be covered in more than one law and may have multiple associated regulations, so ensure that all relevant documentation is identified & obtained for review.

[2] Includes provisions for the MRA to define and publish its policies and procedures, publicly account for its decisions, conduct and actions, and follow a regulatory code of conduct.

7.4. National Regulatory Authority for medical products

- Name of National Drug Regulatory Authority: Department of Drug Administration (DDA), MOHP

- Total number of staff:
    - technical staff: 49 posts but only 22 currently filled (excluding the national medicines lab under the DDA and branch office staff). Staff includes pharmacists, ayurvedic doctor, computer officer, veterinary doctor)
    - non-technical staff: 18 posts, all filled
    - Number of temporary contract employees: 2 non-technical staff
    - Organisation and Management Survey by government recommended 100 posts
    - Recruitment is always by the Public Service Commission and pharmacists may be transferred between the NRA and other units such as hospital pharmacies and the LMD.

- Website address: http://www.dda.gov.np

- Annual report of activities:
    - Section on the DDA in chapter 8 of the Dept. of Health Services (DOHS) Annual Report 2070/2071 (in English) http://dohs.gov.np/wp-content/uploads/2014/04/Annual_Report_2070_71.pdf

- Annual Budget last year: NRs 28,515,000 (DOHS Annual report 2014)

- Written SOPs for the following key regulatory procedures?

Key procedure	Written SOP? (Yes/No)	SOP Seen? (Yes/No)
Product dossier evaluation	No	
Registration of medicines	No	Guideline exists
Inspection of manufacturing premises	Yes	
Inspection of retail premises	Yes	On DDA website in English
Sampling for Quality Control testing	No	Regulation exists
Medical product recall or withdrawal	Yes	On DDA website in English

    - Other SOPs include SOPs for SOPs, equipment in each section, quality of documents including coding and control, raw data and record management, complaint handling, change control procedure, and non-conforming works.

- Position in hierarchy of government structure:
    - Directorate General under the MOHP

- Committees advising the DDA:
    - Drug Advisory Committee advises the DDA overall and is also responsible for final approval of registration of new molecules
    - Various other committees oversee DDA functions including the drug registration committee (that evaluates new molecules prior to registration) and the drug price monitoring committee (that oversees monitoring of drug prices in the market).

- Structure of the DDA

  The DDA is divided into the following sections:
    - important and export;
    - industry (which covers marketing authorization as well as regulation of manufacturing plants);
    - pharmacy registration;
    - training and drug information (which covers drug seller refresher training; disseminating information about medicines; publishing quarterly the Drug Bulletin of Nepal; revising the national EML, national formulary and standard treatment guidelines; making recommendations for import of narcotic and psychotropic substances and liaising with the International Narcotics Control Board; undertaking pharmacovigilance and ADR monitoring and reporting).
    - Inspection (which covers inspection of manufacturers as well as wholesalers and retailers).

- Decentralised capacity?
    - Number of branch offices: 3
    - Number of staff in each office: 9 posts in 2 branches and 8 posts in one branch, with 4 staff per branch currently in post
    - Functions of branch offices: registration and inspection of pharmacies
    - Functions outsourced to public health authorities: local administration helps in inspection but does not do anything alone.

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

  The national medicines laboratory has various sections including:
    - Chemical analysis
    - Microbiology
    - Pharmacology
    - Instrumental analysis.

7.5. Drug Schedules

There are three drug schedules:

- Ka – for psychotropic and narcotic drugs, only available with an authorized doctor's prescription
- Kha – for antibiotic and hormones, which should be only available with an authorized doctor's prescription, but are available without prescription in practice
- Ga – for over-the-counter (OTC) medicines which are legally available without prescription

All trained pharmacy personnel can sell all types of medicine from a registered pharmacy. In practice, all medicines apart from psychotropic and narcotic drugs are freely available without prescription. Also traditional practitioners and other lay practitioners are also prescribing prescription-only medicines. Each product is allocated to a drug schedule as per Drug Standard Regulation. However, the DDA mentioned that the drug schedules have not been revised for over 20 years and that it was not possible to take punitive action for selling prescription-only medicines OTC. The 1978 Drug Act was revised in 2001 to allow para-medical workers to prescribe some medicines, despite strong objections from the Nepal Medical Council.

7.6. Regulation and inspection of drug outlets

Retail outlet licenses should be renewed annually but the DDA has insufficient inspectors to visit all retail and wholesale outlets annually. An SOP for inspections is followed and in the last fiscal year 2451 inspections were done (Regulatory News 2013-2014). Problems found were that trained staff were absent from 50% of the shops, documentation for controlled drugs was poor, storage areas were not clean, management of expired medicines was poor, there were some unregistered drugs in border areas and 10-15% of pharmacy outlets were unregistered, mainly being operated by paramedical health workers. Very few cases come to court, there only being one last year in Kathmandu.

Actions taken again retail outlets include:

- Closure of unregistered pharmacies, with return of all registered medicines to the wholesaler from where they were purchased and documented proof of such return;
- Destruction of all unregistered medicines;
- Suspension of the outlet license for a period of time such as one week or one month;
- Warning letters.

The Nepalgung DDA branch mentioned that they had about 4000 retail outlets and one manufacturing unit in their area and that they had done about 400 inspections in the last fiscal year. Five unregistered outlets had been closed and several licenses temporarily suspended.

Manufacturing plants are generally inspected when they have applied to manufacture a new product. In addition, domestic manufacturers are required to renew their licence annually and therefore effort is made to inspect them annually. By contrast, foreign companies do not need a licence from the DDA. In the last fiscal year, 117 inspections to domestic manufacturing companies and 10 inspections to foreign manufacturing companies were made (Regulatory News 2013-2014). Criticism has been made that Indian manufacturers are never inspected despite supplying medicines for many years and the Nepal Pharmacy Association have stated that they would like to carry out joint inspections of these companies with the DDA in order to add " an independent" element to inspections.

7.7. Drug Registration

The system of registration has not changed since 2011 and is managed by a unit of 6 staff within the DDA. The system is currently in the process of being computerized.

Product registration for old molecules already on the market only requires review of all specifications within a dossier, including information on the active pharmaceutical ingredient and excipients, pharmacopoeial specifications, stability studies, Good Manufacturing Practice, certification of the pharmaceutical product and a satisfactory laboratory quality testing report. Old molecules do not need to be reviewed by the Drug Advisory Committee and approval is given from the registration division within the DDA.

Product registration for new molecules requires review and approval by the Drug Advisory Committee once information about the product is gathered by the Drug Registration Committee within the DDA. New molecules are only considered if they are already registered in a country with a stringent national regulatory authority and the review process involves evaluation of the product pharmacopoeial specifications and characteristics, efficacy, safety profile including ADRs, clinical data and price. A checklist is used for the summary product characteristics. In addition the manufacturing plant is inspected.

The registration fee is USD37 (NRs 2700/-) for old and new molecules and all revenue is sent to the National Treasury. A criticism was made by a Member of the Drug Advisory Committee in 2011 that products should only be registered for use after thorough review and approval by the Drug Advisory Committee but that this was not happening for some products. It was not clear if the process had improved in 2014.

The number of products on the market is now over 15,000, an increase of about 5,000 in the past 3 years. There are multiple brands of some drugs e.g. 30 or more brands of some analgesics and antibiotics, so it is increasingly difficult to monitor and control the market. The DDA Chief admitted to the need for some restriction on the number of products registered due to their limited capacity to monitor and control such a large market. However, there is a conflict of interest because the government wants to encourage manufacturers to Nepal and they only start up if they are allowed to manufacture products for which there is already a market. One possible way to limit the number of products registered would be to increase the stringency of the registration process and another may be to increase the registration fee, which is quite low. A large increase in registration fee may help to cut down the number of registrations and could raise income which could be used to strengthen the DDA, rather than just going to the treasury as at present.

7.8. Pharmacovigilance

The national pharmacovigilance program is under the Department of Drug Administration and was started in 2004. Nepal became a full member of the WHO Programme for International Drug Monitoring in 2006. Hospitals report ADRs to the regional centres which send the reports to the national centre through a web-based system called “Vigi-flow”. These reports are then sent to the Uppsala Monitoring Centre in Sweden. At present there are seven regional pharmacovigilance centres located in the following teaching medical college hospitals - Manipal Teaching Hospital in Pokhara, Tribhuvan University Teaching Hospital in Kathmandu, Nepal Medical College Hospital in Kathmandu, KIST Medical College in Lalitpur, BP Koirala Institute of Health Science Teaching Hospital in Dharan, Civil Service Hospital in Kathmandu Patan Hospital in Lalitpur. The DDA mentioned that one person handles the both the drug information section and the ADR program and that during the last 10 years, 547 ADRs had been reported and sent to Upsalla. The

number of ADRs in the last 3 years has been about 100 but one medical college mentioned that they had reported over 100 ADRs the previous year. The exact number of ADRs reported by the DDA is as below:

Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
No. ADRs	8	23	9	69	206	50	52	30	23	53	24

It was reported that the ADRs are not investigated, merely reported. If this is so, then it is not clear how sure one can be that all these adverse drug events are true ADRs. In the last 8 years, only nimesulide syrup has been withdrawn after ADRs.

7.9. Drug Promotion

The drug information unit in the DDA, operated by one person and also covering drug information and pharmacovigilance, also monitors drugs adverts. According to the 1978 Drug Act, advertisement for OTC medicines only is permitted with pre-approval of the adverts. However, in practice such pre-approval is not done. The DDA has developed *Ethical Criteria for Drug Promotion* based on WHO Guidelines but by "understanding" permission is neither requested nor given to advertise modern medicines. By contrast, there is pre-approval of adverts for some traditional medicines. Package inserts are not pre-approved. Adverts for prescription-only medicines in medical journals and other for a directed to medical doctors are not monitored or pre-approved.

7.10. Drug Price controls

Responsibility for controlling drug prices rests with the DDA and the Drug Pricing Monitoring Committee, which is chaired by the Director General of the DDA and co-chaired by the Chief Drug Administrator in the MOHP. The secretary of this committee is a senior pharmacist in the DDA and membership includes representatives from the Association of the Pharmaceutical Producers of Nepal, Nepal Drug and Chemists Association, Nepal Pharma Association, Consumers Forum of Nepal.

There is no standard method to calculate maximum retail price (MRP). Medicines prices are decided in several steps. Firstly, the manufacturer sets the price based on prevailing prices. Secondly, wholesalers add a further 8-10% mark-up and thirdly, retailers add a further 16% mark-up. Although the Drug Act has the provision to control prices, this clause is rarely implemented. In practice, the MOHP has constituted the Drug Price Monitoring Committee to fix the ceiling for the prices of some medicines and more products are in the process. The ceiling of a drug price is decided by taking the average of the MRP of products already in the market and these prices are collected during routine inspection. A new method being considered is to take the median of MRP of the top 10 selling brands in the market and compare it with the international Reference Price. In practice the Committee decides the MRP based upon the price surveys and sometimes revises the MRP after request from the pharmaceutical industry.

According to the 1978 Drug Act, prices should be printed on the label of all medicines. For medicines manufactured in Nepal, the price is printed in Nepalese rupees. For medicines manufactured in India, the price should not be higher than in India and the price is mentioned in Indian rupees. For medicines manufactured elsewhere the price is mentioned in Nepali rupees where possible. Medicines should not be

sold at a higher price than what is printed on the label. If they are sold at higher price, this is defined as "black marketing" which is covered by a separate Act. In about 8 remote districts, where the retailer has to pay transport charges, such transport costs will also be added into the price with the prior agreement of the Chief District Officer. It is not clear how much supervision of prices charged is done and it may be sub-optimal in many rural and remote areas.

7.11. National Medicines Laboratory (NML)

The DDA has its own National Medicines Control Laboratory. The main functions of the NML (DOHS 2020/2071) are to:

- Test and analyse the quality of medicines as empowered according to the Drug Act 1978;
- Issue Lot Release Certificates for vaccines;
- Develop Secondary Reference Standards and make them available for use by the pharmaceutical industries and laboratories ;
- Audit laboratories of Nepalese pharmaceutical industries.

The laboratory has 40 sanctioned posts, 33 technical and 7 non-technical but currently only 22 staff are in post. There are SOPs for some procedures (SOP for quality documents, SOP for instruments, calibration and maintenance) but the laboratory has not reached any ISO standards. In last fiscal year, 687 samples were tested and 588 (14%) failed. The types of samples tested were as below:

Sample source	Number of samples tested	Pass	Fail
Branch offices, inspection division and import division of DDA	136	69 (allopathic) 10 (Ayurvedic)	35 (allopathic) 22 (Ayruvedic)
Other sources	534	492	42
Market surveillance	17	17	0
Total	687	588	99

Source: MOHP/DDA Regulatory News 2013-2014

Most failed samples were pre-marketing samples and a high proportion of Ayurvedic products failed. It was mentioned that the failure rate from market sources was only about 3%. Clearly the number of samples tested is very small for the size of the market. The DDA is aware that it is not able to test sufficient number of samples and tends to concentrate on one therapeutic class per year. Many doctors are suspicious of the quality of drugs on the market, particularly generic products and cite this as a reason for brand prescribing. It was mentioned that the DDA will be working with WHO to strengthen the National Medicines control Laboratory in the coming year.

7.12. Licensing and accreditation of health professionals

The Nepal Medical Council licenses doctors, the Nepal Pharmacy Council licenses pharmacists of diploma level or above, and the Nepal Nursing Council licenses nurses.

The Medical Council regulates doctors and runs a licensing exam, with a section on pharmacology, which must be taken by both foreign graduates (many of whom are Nepali) and home-grown graduates, even if they have already passed the university-run degree. Most home grown graduates pass but 30% of foreign graduates fail. On passing, Nepalis may get a licence for life having once successfully completed 2 years of temporary registration, whereas foreigners must renew their licences annually. The licence fee is NRs 1200/- for Nepalis and NRs 5000/- for foreigners. The Medical Council also runs postgraduate exams. There are 15,000 doctors registered (as opposed to only 4000 registered with the Medical Association) but not all are currently practicing in Nepal. The Council has developed codes of conduct for doctors and examines about 8-10 ethical complaints per month, most of which concern unlicensed practitioners, generalists doing specialist work and poor treatment resulting in death. However, no licenses have ever been revoked. The Medical Council must approve the medical curricula of all medical colleges and also provide accreditation (for a fee) to all medical colleges whom they deem suitable to train doctors. Accrediting medical colleges requires undertaking an inspection annually to check on the infrastructure, faculty, the attached hospital facilities, etc. If any shortfalls are found action may be taken, generally in the form of reducing the permitted medical student intake. In addition the Medical Council is currently working on developing a points system for CME and re-accreditation.

The Nepal Pharmacy Council regulates pharmacists and both Diploma-level and Bachelor-level pharmacists must register with the council for a fee of NRs 1000/- and NRs 2000/-, respectively. Nepalis get a licence for life but foreigners must renew their licence every 2 years. The Council has started a licensing exam this year for NR 1500/- and 30% of diploma candidates failed although all bachelor candidates passed. All pharmacists have to pass this exam before practicing in hospital and community pharmacies. The Council does not currently have to approve pharmacy curricula, although it is currently collecting details of different university curricula with a view to harmonization and greater influence on the content. The Council does provide accreditation of universities to train pharmacies and undertakes annual inspections to review infrastructure, faculty, etc. They mentioned that they had suspended the accreditation of the TUTH to teach pharmacists for nine months due to poor faculty attendance and lack of practical sessions for students. The Council does also investigate a few complaints and last year suspended the licence of a diploma pharmacist who got 2 licenses to run 2 pharmacies using the same certificate. The DDA and not the Pharmacy Council regulates the certificate drug retailers who have passed the DDA exam following 3-week course (which is now discontinued). The Drug Controller of the DDA is automatically a member of the Pharmacy Council, which has 8 councilors and 5 staff.

7.13. Licensing and accreditation of health facilities and pharmacies

Drug retail outlets are regulated by the DDA, and granted annual licenses. Unfortunately the DDA is not able to inspect all outlets so some annual licences must be renewed on presentation of the documentations only. Private hospitals and clinics are regulated by the Curative division under MOHP, and granted annual licenses dependent upon a successful inspection by an inspection team, which uses a checklist. Licenses for medical colleges are granted by the Ministry of Education after consultation with the Nepal Medical Council and licenses for Universities to train pharmacists by the Ministry of Education after

consultation with the Nepal Pharmacy Council. The CTEVT grants licenses to training institutions to train paramedical workers.

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

Since 2011 the Department of Drug Administration has been upgraded to Directorate General Level (although it is still called the Department of Drug Administration) – and is now directly under the Ministry of Health rather than under the Department of Health Services. Unfortunately, this has not resulted in an increase in human resources, which are actually at lower levels than in 2011 due to unfilled posts. The inability to fill posts has been due in part to the constitutional crisis which has disabled the national planning commission from recruiting new staff and giving official promotion to existing staff. Despite this, the pharmaceutical sector continues to grow, with now over 15,000 products registered, over 300 manufacturing units and over 16,000 drug retail pharmacies, all to be managed by 22 staff in post. With such under-staffing the DDA has great difficulty to fulfil all its obligations. The national medicines control laboratory is similarly understaffed and was only able to process 687 samples in the last fiscal year.

7.15. Medicines regulation: Recommendations

- Strengthen the DDA:
    - Urgently fill all posts and create more posts – particularly for more inspectors and pharmacists;
    - Develop Standard Operating Procedures and guidelines for all processes;
    - Amend current Drug Act to allow more punitive actions;
    - Consider introducing web-based and risk-based regulatory procedures.

- Strengthen the Medicines Control Laboratory:
    - Urgently fill all vacant lab posts;
    - work for ISO 17025 accreditation;
    - establish regional minilabs;
    - train staff.

- Strengthen the drug registration process:
    - Higher fee for imported drugs and stronger criteria e.g. bioequivalence and bio-availability studies, with stricter application of criteria;
    - Ensure all products are reviewed by the technical advisory committee and make the process more transparent (website update);
    - Will help to reduce the number of products registered.

- Update and enforce the drug schedules:
    - update and enforce the OTC and POM lists, which will require a reclassification of many drugs;
    - consider establishing new schedule for drugs used only in tertiary referral hospitals (special pharmacies) e.g. oncology drugs, new antibiotics.

- Start a unit to monitor drug promotional activities:
    - Develop monitoring of promotional activities, ethical guidelines.

- Drug pricing:
    - Consider methods to improve transparency of drug price setting, including the regular monitoring of drug prices.

8. MEDICINE POLICY AND COORDINATION

8.1. National Medicines Policy

There is a national drug (medicines) policy (NMP) document 1995 (DDA/MOHP 1995), which was developed in accordance with the National Health Policy 1991 to fulfil the government's commitment to provide health for all.

The national drug policy aims:

"*to maintain, safeguard and promote the health of people by making the country self-reliant in drug production, ensuring the availability of safe effective, standard quality drugs at an affordable price in quantities sufficient to cover the need of every corner of the country and to manage effectively all the drug related activities* " (DDA/MOHP website 2015).

The NMP document has 11 objectives and 10 strategies covering drug production, import, export, storage, supply, sale distribution, quality assessment, regulatory control, rational use and information flow.

Unfortunately, the NMP does not have a section on monitoring and evaluation and also lacks details with regard to many of the components. This lack of detail and the fact that there is no implementation plan with budget may account partly for the fact that many aspects of the policy are not implemented. Many people complained that the NMP was only on paper and nothing was implemented. The current government is currently updating the NMP, but this process was also on-going in 2011.

More recently a new National health Policy (NHP) 2071 (2014) has been adopted. An unofficial English translation of 8th August 2014 (available at URL: https://drive.google.com/file/d/0BxYPsAJu5Bn_dm5FZHh6ZThzSlU/view?pli=1) mentions that the NHP 2014 has the goal "*to provide health services through an equitable and accountable health system while increasing the access of every citizen to quality health services to ensure health as a fundamental human right to every citizen*". The objectives of the NHP are to:

1. *Provide free of cost the basic health services that remain a fundamental right of a citizen;*
2. *Establish effective and accountable health services that are easily accessible and are equipped with essential drugs, diagnostics and skilled human resource;*
3. *Promote participation of people in health service provision. Including the promotion of ownership while increasing involvement/partnership of private sectors and NGOs in health service delivery and effectively managing partnership to build ownership with government and the private sector*.

There are 14 policies to achieve these objectives and numerous strategies to achieve each policy. The NHP 2071 is complementary to the NMP of 1995 and effective management of medicines is particularly relevant to the second objective. Thus, recommendations from the situational analysis will help to achieve the second objective.

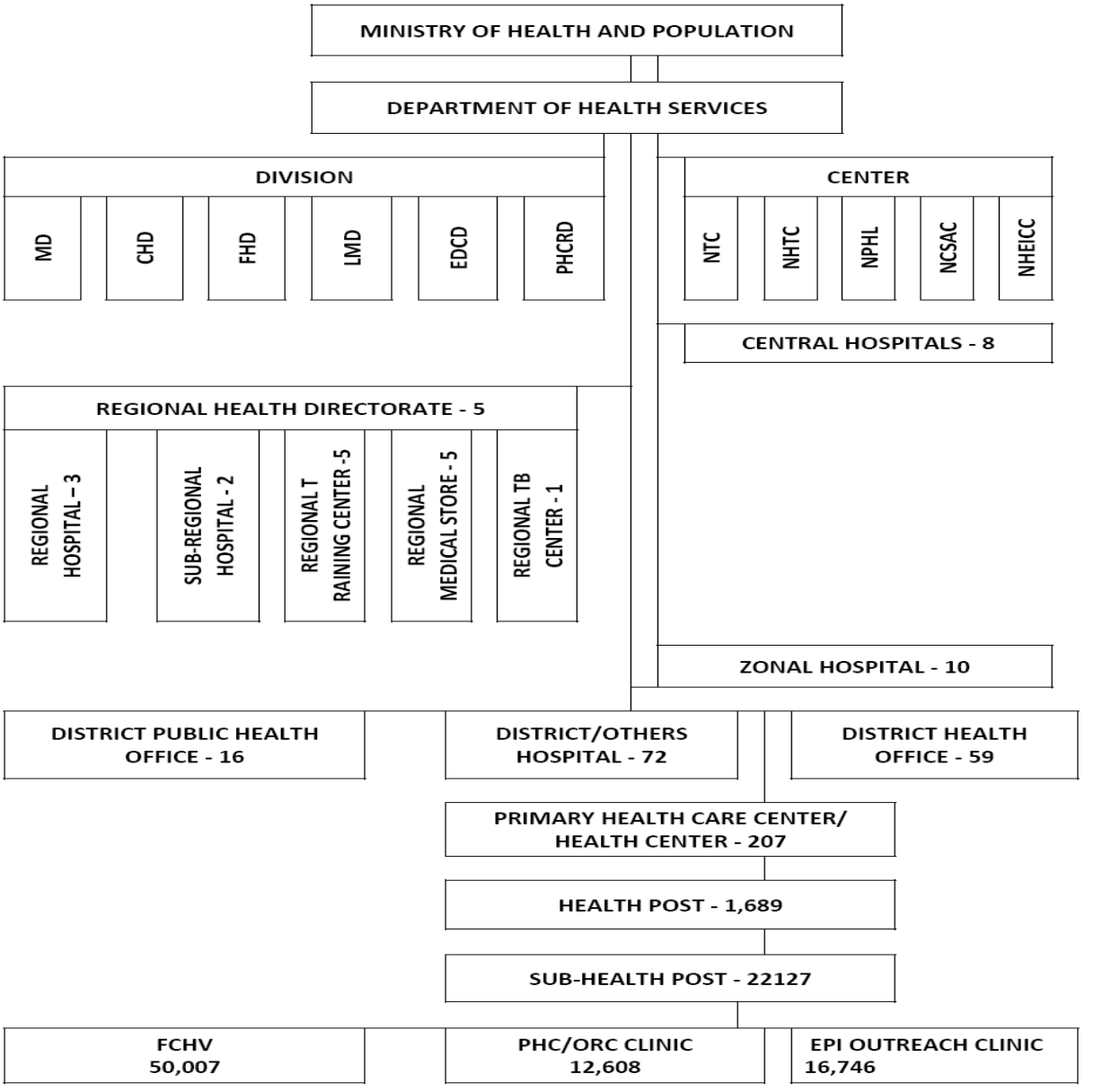
8.2. Summary of medicines policies in place to promote rational use of medicines

Policy	Implementation status
National Medicines Policy (NMP)	Official NMP document 1995, with some aspects implemented but many not implemented, currently being updated.
National Essential Medicines List (EML)	National EML 2011
National Standard Treatment Guidelines (STGs)	STGs for HPs and sub-HPs 2012 and National Antibiotic Treatment Guidelines 2014, but no STGs covering common conditions aimed at doctors.
National Formulary manual	National Formulary 2010
National government unit dedicated to promoting rational use of medicines	No government unit dedicated to promoting rational use of medicines
Monitoring medicines use	Very little monitoring done and then only by INRUD Nepal.
Drug and Therapeutic Committees (DTCs)	DTCs in most teaching hospitals but few are functional.
National Drug Information Centre (DIC)	No national DIC, although the DDA and some teaching hospitals operate their own drug information units.
Generic Policies	Generic substitution allowed and extensively practiced in the private sector.
Health insurance	None for most of the population.
Payment for medicines by patients	All drugs dispensed free of charge in the public sector at district level, although many drugs are not available. Above district level, patients must purchase drugs in outside private pharmacies. Some cost-sharing fees for diagnostic tests in public hospitals.
Provider revenue from medicines	No provider revenue from medicines in the public sector. Some private doctors dispense.
Undergraduate training on pharmacology & prescribing	Training on the essential medicines concept, EDL and prescribing is done.
CME training on pharmacology & prescribing	Adhoc continuing medical education (CME), mostly through the vertical disease control programs for public sector prescribers and no CME for most private prescribers
Public education on medicines use	No public education campaigns on the safe and prudent use of medicines, apart from a few small studies by NGOs in discrete areas.
Pharmacovigilance	ADR monitoring done by with 7 regional centres which report to the national centre for Pharmacovigilance (1 person unit) within the DDA
Regulation of drug promotion	Government regulation only but no capacity to undertake any pre-approval for drug adverts in practice
National strategy to contain Antimicrobial Resistance	National strategy on antimicrobial resistance document developed in 2001, but official status of the document is unclear.
Over-the-counter availability of prescription-only medicines including antibiotics	Antibiotics frequently available over-the-counter without prescription.

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

8.3.1. Department of Health Services Organogram

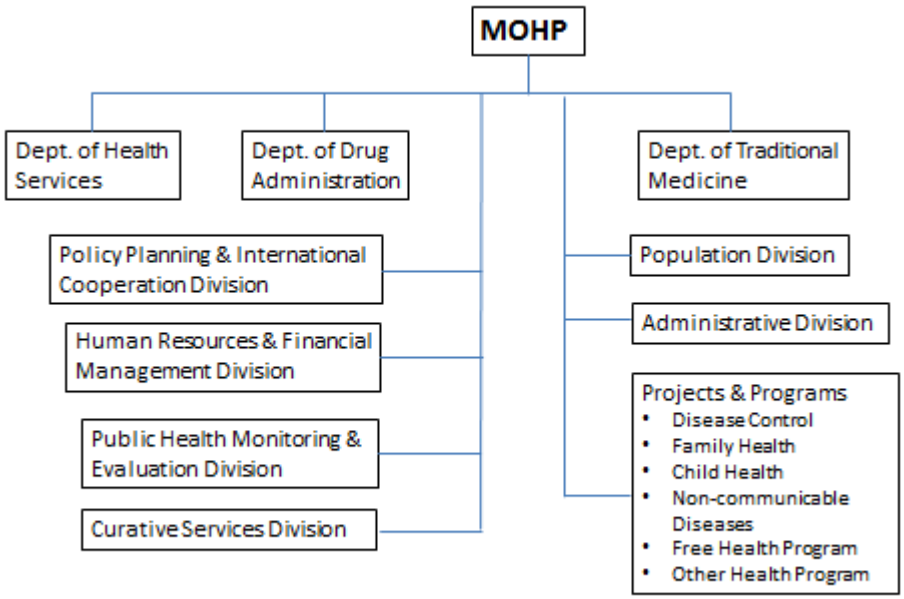
Fig. 1.1: Organogram of Department of Health Services (DoHS)



4 DoHS, Annual Report 2069/70 (2012/2013)

MD: Management Division; **CHD:** Child Health Division; **FHD:** Family Health Division; **LMD:** Logistics Management Division; **EDCD:** Epidemiology and Disease Control Division; **PHCRD:** Primary Health Care Revitalization Division; **NTC:** National Tuberculosis Centre; **NHTC:** National Health Training Centre **NPHL:** National Public Health Laboratory; **NCASC:** National Centre for AIDS and STD Control **NHEICC:** National Health Education, Information and Communication Centre; **FCHVs:** Female Community Health Volunteers; **PHC/ORC:** Primary Health Care/outreach Clinics; **EPI:** Expanded Programme of Immunization.

8.3.2. Ministry of Health Organogram



Source: URL: http://www.mohp.gov.np/index.php/2014-03-21-09-41-44/dept-of-health-services/chd

8.3.3. Coordination within the Ministry of Health and Population (MOHP)

Under the Ministry of Health, there are three main Directorate-General Departments, the Department of Health Services (DOHS), the Department of Drug Administration (DDA) and the Department of Traditional Medicine. In addition, a number of Divisions and a number of projects and programs also report directly to the Minister of Health, as indicated in the schematic organogram above. There is a statutory drug consultative council to advise the MOHP on medicines regulatory issues although its terms of reference are unclear and its function within the regulatory framework currently under recommendation.

Under the Department of Health Services, there are also a number of Divisions, including: Logistics Management Division (LMD), Primary Health Care Revitalisation Division (PHCRD), Finance, Administration, Management, Family Health, Child Health, National Public Health, Leprosy, and Epidemiology and Disease Control.

The main MOH departments concerned with management of medicines are the DDA and the DOHS, particularly the LMD and PHCRD. The Chief Pharmacist, one of the most senior pharmacy officials in government, sits in the Planning Division directly under the Minister of Health. Since s/he is not the chief of this Division, s/he has no authority over the DDA or DOHS or the units therein. The post-holder is responsible for developing policy but does not actually have executive power. Currently this position is vacant. In addition, the curative care division under the MOHP has responsible for quality of care (including appropriate use of medicines) in hospitals, the Human Resource Development Division under MOHP has responsibility concerning what cadres of health worker (including pharmacists) are needed, and various divisions under the DOHS, such as child health, family health, PHCRD, National Health Education, Information and Communication Centre, have responsibility for public education (which could include messages on appropriate medicines use).

Policies that fall between different departments within the MOHP are as follows:

- The EML is developed by the DDA but must be implemented by the LMD and PHCRD and also followed in local procurement by DPHOs and hospitals;
- The drug budget allocation and quantification requires coordination between the LMD, PHCRD, and Finance Division;
- Human resource planning particularly with regard to pharmacists and medicines management in the public sector requires coordination between different divisions under the MOHP such as the Human Resource Development Division and the Planning Division;
- Public education requires coordination between different divisions within the DOHS, such as PHCRD, child health, family health and the National Health Education and Information Centre;
- Quality of care with regard to prescribing requires coordination between the Curative Division and the DOHS, but it would appear that no department or division is monitoring drug use, encouraging DTCs, developing general national STGs for hospitals, running a Drug Information Centre, or managing continuing medical education (outside the vertical disease control programs).

It is not clear how coordination is managed or which department would take up the functions currently not done. Furthermore, the same experts sit on many different committees, such as selection of medicines for the national EML, drug registration, drug procurement, etc. This may be very time consuming for some experts who may also have conflict of interest.

8.4. Other Ministries with medicines-related functions

Other Ministries involved in medicines-related policies include:

- Ministry of Finance and Treasury – provides budget (which may not be enough) for:
    - human resources employed in all sectors of the MOHP;
    - public sector medicines supplied through the LMD,PHCRD and local drug purchase.

- Ministry of Trade and Industry – sets rules (which may not always serve the public health interest) for:
    - Medicines prices and mark-ups;
    - Duties and taxes on the importation of medicines;
    - The fees for licensing of importer and drug outlets and the ruling that disallows any kind of limitation on the number of drug outlets, particularly retail pharmacy shops;
    - The ruling that disallows any limitation on the registration of medicines.

- Ministry of Education – sets training programs and curricula for health professionals:
    - May not give the same importance to some topics as would the MOHP in determining health service delivery needs.

- Public Services Commission (human resources) - decides on the number of posts in MOHP:
    - May not assign posts as MOHP needs e.g. there are very few posts for pharmacists in the public sector outside the DDA

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

- Excessive number of drug products on the market, especially me-too products, resulting in extra regulatory burden, because limits cannot be placed on new products of molecules already existing on the market due to trade rules concerning competition.
- Excessive number of pharmacies in Nepal, resulting in extra regulatory burden, because limits cannot be placed on new pharmacies due to trade rules concerning competition.
- Very large number of manufacturers, resulting in extra regulatory burden, including for traditional medicines, because limits cannot be placed on new manufacturing plants due to trade rules concerning competition.
- Lack of pharmacists in the human resource plan, but without them, quantification and efficient procurement sufficiently in advance cannot be done.
- Lack of clinical pharmacology and clinical pharmacy departments and activities in the clinical setting, without which good pharmaceutical care cannot be introduced and which will require coordination between different directorates/departments within the MOHP and the Ministry of Education.
- Lack of economies of scale and capacity to ensure quality products are procured in the current system of partial local procurement by districts and hospitals – which could be rectified by negotiating prices and pre-qualified suppliers centrally for use in local procurement in the public sector.

It is not clear how coordination between the different ministries is managed. It had previously been suggested that policy coordination could be managed by creating a new Division of Pharmaceutical Services directly under the Minister of Health, with the Chief Pharmacist as the chief of this unit (Holloway 2011). However, no changes have been made in the organogram to address this issue.

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

The national drug policy, coordination and structure remain similar to the situation in 2011. Some important objectives of the 1995 national drug policy remain unfulfilled and some policies to promote rational use of medicines and to monitor medicines use are not implemented by any MOHP department or unit. During the previous situational analysis in 2011, it had been proposed to update the national medicines policy document and to consider establishing a Division of Pharmaceutical Services directly under the Minister of Health, with the Chief Pharmacist as the chief of this unit, in order to coordinate action between ministries. However, neither of these recommendations have been implemented.

8.6. Medicines policy and coordination: Recommendations

- Establish a permanent statutory committee or body to advise the Minister of Health/Secretary on Pharmaceuticals, able to manage inter-ministerial coordination and with wide membership including laypersons, professional bodies …
- Establish an Executive Division in MOHP to carry out the statutory committee recommendations – Division of *Pharmaceutical Affairs/Services*?
    - To coordinate action between DDA, DOHS (LMD, PHCRD) etc.;
    - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, public education;
    - Could liaise with universities to provide students to collect information needed by the MOHP, as part of their research studies;
    - To update the National Medicines Policy to be more specific and to include an implementation plan and time line.

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10. PERSONS MET DURING THE SITUATIONAL ANALYSIS

	Name	Designation and Affiliation
1	Balkrishna Khakurel	Director-General, DDA
2	Dr Ramesh Kumar Khanal (Kharel)	Director, PHCRD, DOHS
3	Dr B. S Tuikavi	Director, LMD
4	Krishna Pd. Gautam	Under Secretary, DOHS/LMD
5	Mr Achyut Lamichhane	Senior Public Health Administrator, PHCRD, DOHS
6	Dr J Mahaseth	Director, Nepalganj Medical College
7	Dr Arjun Bhatta	MO, Bardia District Hospital
8	Nagendra Chawthai	DPHO, Banke
9	Shree Krishna Bhatta	DPHO, Kathmandu
10	Mr Birkha Bahadur Shahi	DPHO, Bardia
11	Dr Sangha Ratna Bajracharya	Associate Professor, IOM, Maharajgung Medical College Campus
12	Dr Anish Mudvari	Associate Professor, IOM, Maharajgung Medical College campus
13	Vabha Rajbhandari	Acting Director, NML
14	Dr Kumud K. Kafle	Co-ordinator, INRUD
15	Gajendra B Bhuju	Member, INRUD& former DG DDA
16	Yagya Pd. Neupane	Chairman, Nepal Pharmacy Council
17	Dr. Jageshwor Gautam	Chairman, Nepal Medical Council
18	Dr Jamardan Lamichane	Chief of party, HUL Logistic
19	Sujit Banskota	National Consultant, NHSSP, LMD
20	Chandra Mani Dhungana	RHCS Program Analyst, UNFPA
21	Nirupama Rai	AID Department, Program Assistant, USAID
22	Anjana Hengaju	Consultant, Lifeline Nepal
23	Prakash Man Pradhan	CEO, Prakash Pharmacia
24	Sunita Ranjit	Senior Pharmacist, TUTH IOM, Maharajgung Campus
25	Sangita Mathama	Pharmacist, TUTH IOM, Maharajgung Campus
26	Bharat Bhattarai	Drug Administrator, DDA
27	Ram Bdr. Basnet	Account Officer, DDA
28	Ishor B. Maharten	DDA
29	Narayan Pd. Dhakal	Drug Administration, DDA
30	Sushma Shakya	Pharmacist, WHO/DDA
31	Dr Ravi Kafle	National Program Officer, WHO Nepal
32	Buddhi Raj Kafle	Senior Pharmacist, PHCRD

	Name	Designation and Affiliation
33	Pen Bahadur Kchetry	DDA, Drug Administrator
34	NinuShrestha	Pharmacist Officer, Nepalgung DDA
35	Mr. Gyan Krishna Shrestha	Chairman, Mahyapur Hospital, Timi, Kathmandu
36	Dr. Ram Krishna Shrestha	Managing Director, Mahyapur Hosp, Timi, KTM
37	Ms Jasmine Karanjit	Pharmacist, Mahyapur Hospital, Timi, KTM
38		2nd staff from Bardia district hospital
39	Sunil Pandey	2nd staff from Bardia DPHO
40		2nd staff from Kathmandu DPHO
41	Dr Subash Sharma	MO, Bankatuwa PHC
42	Pratichhya Rawal	Pharmacist Supervisor, Bheri Zonal hospital
43	Madhav Gyawali	Store keeper, Bheri Zonal hospital
44	Ganesh Thapa	HA, Bankatuwa PHC
45	Shibha Chaudhari	Kalika HP in-charge, (HA)
46	Kamal Bhatarai	2nd staff from Kalika, (SAHW)
47	Mohan Khadka	Mainapokhari HP in-charge (SAHW)
48	Tol Prashad Lamichhane	2nd staff from Kalika, (SAHW)
49	Ujwal Kumar Sharma	SAHW, Dhapasi HP in-charge
50	Bindu Sharma	SAHW, Dhapasi HP
51	Tika Das Shrestha	AHW, Dhapasi HP
52	Narayan Acharya	SAHW, Thankot HP in-charge
53	Mr. Laxman Shrestha	AHW, Thankot HP
54	Mr. Surendra Shrestha	AHW, Thankot HP
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58	Ganesh Thapa	Drug Retailer, Thapa Medical Hall, Kohalpur
59	Hari Paudel	Drug Retailer, Ujjwol Medical Hall, Kohalpur
60	Bishnu Prasad Poudel	Drug Retailer, BhishnuSwasthya Clinic, Kohalpur
61	Mr. Tek Nahadur Bika	Drug retailer, priv. pharmacy, Nepalgung Medical College compound
62	Santosh Ghartimagar	Drug retailer, private pharmacy, Bheri Zonal hospital compound
63	Bharat Prashad Dhakal	Sajha drug retailer, Nepalgung Medical College compound
64	Paspati Sapkota	Sajha drug retailer, Bheri Zonal hospital compound

11. PARTICIPANTS OF THE STAKEHOLDER WORKSHOP

	Name	Designation and Affiliation
1	Dr J Mahaseth	Director, Nepalganj Medical College
2	Dr Arjun Bhatta	MO, Bardia District Hospital
3	Nagendra Chawthai	DPHO, Banke
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6	G B Bhuju	Member, INRUD
7	Dr K. K. Kafle	Co-ordinator, INRUD
8	Dr B. S Tuikavi	Director, LMD
9	Pen Bahadur Kchetry	DDA, Drug Administrator
10	Prakash Man Pradhan	CEO, Prakash Pharmacia
11	Dr Jamardan Lamichane	Chief of party, HUL Logistic
12	Sujit Banskota	National Consultant, NHSSP, LMD
13	Chandra Mani Dhungana	RHCS Program Analyst, UNFPA
14	Nirupama Rai	AID Department, Program Assistant, USAID
15	Anjana Hengaju	Consultant, Lifeline Nepal
16	Vabha Rajbhandari	Acting Director, NML
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20	Ninu Shrestha	Pharmacist Officer, DDA
21	Ishor B. Maharten	DDA
22	Sushma Shakya	Pharmacist, WHO/DDA
23	Narayan Pd. Dhakal	Drug Administration, DDA
24	Krishna Pd. Gautam	Under Secretary, DOHS/LMD
25	Sunita Ranjit	Senior Pharmacist, TUTH IOM, Maharajgung Campus
26	Sangita Mathama	Pharmacist, TUTH IOM, Maharajgung Campus
27	Dr Ramesh Kumar Khanal	Director, PHCRD, DOHS
28	Dr Ravi Kafle	NPO, WHO Nepal
29	Balkrishna Khakurel	Director-General, DDA
30	Bharat Bhattarai	Drug Administrator, DDA

12. WORKSHOP SLIDE PRESENTATION

Medicines in Health Care Delivery in Nepal

Situational Analysis: 17-28 November 2014

Dr Kathleen Holloway, WHO/SEARO
Prof Kumud Kafle, Clinical Pharmacology
Gajendra Bhuju, INRUD & formerly DG/Dept. Drug Admin.
Buddhi Raj Kafle, PHC Revitalisation Div., DHS
Bade Babu Thapa, Logistics Mgt. Div., DHS
Pan Bahadur Kshetry, DDA Kathmandu
Ninu Shrestha, DDA Nepal Ganj
Sushma Shakya DDA & WHO Nepal
Dr Ravi Kafle, WHO Nepal

Program of the workshop

- 09:00 – 10:00 Registration
- 10:00 – 10.30am: Opening
- 10:30 – 10.45: Tea/coffee
- 10.45 – 11:45am: Presentation by K.A.Holloway on behalf of the situational analysis team of the findings, main problems and possible solutions
- 11:45 – 13:00pm: Group work to discuss possible solutions and develop recommendations for action
  - include main activities, who will do them, and in what time frame
- 13:00 – 14:00: Lunch
- 14:00 – 15:45pm: Presentation of group work with plenary discussion and finalization of recommendations
  - Road map for MOH, stakeholders and WHO to follow
- 15.45 – 16:00: Closing

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 MOHP;
  - 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 17-28 November, 2014

- **17 Nov:** visit to WHO country office; Dept. Drug Administration; Nepal Pharmacy Council; Kist Medical College; private pharmacy
- **18 Nov:** visit to Kathmandu DPHO; PHC Revitalisation; TU/IOM Pharmacology dept; TU Teaching Hospital OPD pharmacy;
- **19 Nov:** visit to Logistics Mgt. Div., Nepal Medical Council, INRUD
- **20 Nov:** travel to Nepalgunj and visits to Bheri Zonal Hospital and Banke DPHO in Nepalgunj
- **21 Nov:** visits to Nepalgunj Medical College Hospital in Kohalpur; DDA Banke branch; and PHC in Banke district
- **22 Nov:** visits to private pharmacies in Nepalgunj
- **23 Nov:** visits to DPHO, District hospital, HP, Sub-HP in Bardia
- **24 Nov:** travel to Kathmanudu and visits to Madhyapur private hospital & nearby private pharmacy in Bhaktapur
- **25 Nov:** visits to PHC, HP, Sub-HP in Kathmandu valley
- **26-27 Nov:** Preparation for the workshop
- **28 Nov:** 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
- Develop an action plan to implement recommendations
  - What activity?
  - Who will do it?
  - Timeline?

Mission findings

- Extensive health care system, with substantial infrastructure, trained hardworking health care personnel, and…
- Some areas of progress since last situational analysis in 2011, but some serious problems remain in all areas of drug management
- Some problems can be addressed by existing resources and capacity and others need substantial coordinated effort by all partners.

Drug supply

- Govt. drug expenditure 2013-2014 from central (LMD/RMS) & local (DDC, PHCRD) budgets in KTM, Banke & Bardia
  - NRs 25/-; 61/-; 99/- per person per year expenditure, respectively
- Drugs supply to health facilities:
  - 35-40 "free essential drugs" supplied by LMD/RMS, "central push system", according to an allocated budget decided by DHS/MOHP
  - Free and other essential drugs (and some non-EDL drugs) locally purchased using PHCRD and DDC budgets with mix of "push & pull" systems at district level
- Inventory management poor – no electronic LMIS
  - Many complaints from health workers that unneeded drugs are sent and needed ones not sent leading to stock-outs of needed drugs and expiry of unneeded ones

Drug availability

- Situation in 2014 compared to 2011
  - Central system same, but increased local purchase
- Many health worker complaints of stock-outs of needed drugs and dumping of unneeded ones
- Many referral hospital patients must purchase their drugs from private pharmacies (often in hospital compounds)
- Availability of 22 key EDL drugs, 18 from current PHCRD list and 4 from new PHCRD list (diaz, metformin, ranit, ibuprof)
  - 68-95% in tertiary hospitals (private pharmacies in hosp. compound)
  - 63-91% in public district hospitals & PHCs
  - 50-77% in public HPs & sub-HPs
  - 47-68% in small private pharmacies
  - 75-93% in large private pharmacies
- Some non-availability due to non-use of NCD drugs at S/HP

Drug procurement

- Central procurement of 35-40 free essential drugs done annually
  - WB standard bidding document used,
- National/international competitive bidding for 3-year cycles planned since 2011, & started, but stopped because:
  - Lack of electricity, internet connection & trained manpower, weak central mgt. with inadequate control mechanisms & weak bidders
- Technical criteria include
  - national registration of the product and supplier, 18 months shelf-life, delivery time, replacement of poor/damaged goods, provision of package inserts, GMP certificate, "govt. free drugs" box labels
- Local purchase by referral hospitals & DPHO
  - No economies of scale
  - All purchases from wholesalers, importers & none from manufacturers
  - Most purchases in Rupees and 1-2 times per year
  - No pharmacist at district level to manage tendering process

Stock management

- All drug supply manual, no functional electronic LMIS system
  - Difficult to assess stock condition re stock-outs and expiry
  - 3-monthly district LMIS reports entered manually into LMD computer
- Central push system & mixed push/pull system at district level
  - Redistribution of drugs between health facilities within district
    - Biannual distribution from LMD to district and 3-4 monthly ordering from health facilities to DPHO with frequent emergency orders
    - with some stock-outs and dumping of short-dated drugs
    - Quantification adhoc based on limited past consumption data at all levels
- Pharmacists in 3º hospitals but not in district hospitals or at DPHO level & below, where non-tech staff (e.g.storekeeper) manage stock
- Many DPHOs & health facility stores have inadequate space, shelving, temperature & humidity control
- New electronic LMIS pilot project in 3 districts planned

Drug Supply: recommendations

- Increase central government expenditure on medicines
- Establish harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry, which is necessary to improve quantification
  - start centrally & then extend to DPHO & all public hospitals
  - employ a data-entry staff for this purpose at hospital & DPHO level
- Employ at least one pharmacist to manage stock at all public hospitals & DPHOs
- Train staff in monitoring medicine consumption and quantification
- Develop policies to better manage drugs, ensure quality and contain costs in the new local procurement system
  - Consider central pooled procurement with regard to price negotiation, and prequalification of suppliers and products with local purchase
  - Clarify the roles of LMD, RHD, RMS & PHCRD in central procurement, supply, selection, quantification and budgeting

Drug selection

- **National Essential Medicines List (EML) 2011 produced by DDA**
  - 460 formulations (approx. 321 API) divided into Essential and Complementary drugs, but not by prescriber type or facility level
- **Free Essential Medicines List produced by PHCRD**
  - 35-40 drugs for last 3 years but due to increase to 70 drugs categorised by facility level but some drugs not on EML e.g. cetirizine, indomethacin, neomycin ointment, amlodipine
- **Implementation of National EML in 2014**
  - Some purchase lists include drugs not on EML or PHCRD lists e.g. e.g. amoxycillin+cloxacillin, etophyliine+theophylline, nimuselide
  - Local purchase drug selection based on recommendations of hospital clinical dept. heads, not on updated hospital formularies
  - OPD prescribing survey: % EML prescribed drugs 30-39% (3º hospitals); 80-100% (district facilities); 30-43% (private pharmacies)

Top 11 drugs by value in referral hospitals in 2013-14

BHERI Zonal (pub) 164	TUTH, KTM (pub) 795	BKT,THIMI (priv) 1000+
Ceftriaxone inj	Human albumen IV	Ceftriaxone inj
Normal saline IV	Ceftriaxone inj	Pantoprazole inj*
Ringer Lactate IV	Ceftazidine inj*	Esomeprazole tab*
Dextrose saline IV	Vancomycin inj*	Protein supplements*
Dextrose IV	Piperacillin+tazebact*	Piperacillin+tazebact*
Metronidazole inj	Normal saline	Cefixime tab
Ciprofloxacin inj*	Methyl prednisol. inj*	Serratiopeptidase tab*
Oxytocin inj	Ringer lactate	Dextrose saline IV
Amikacin inj*	Imipenem+cilastatin*	Diclofenac gel*
Xylocaine inj	Clindamycin inj*	Methylcobalamin tab*
Amoxy+Clox. Inj*	Amoxy+clav. acid inj	Edraravone inj*
Top12%items:58% budg	Top3%items:42%budg	Top3%items:31%budg

* non-EML drugs

Drug Selection: recommendations

- **Revise the EML:**
  - include drugs for all levels of care
  - classify each drug according to level of care, therapeutic class
  - have wide representation of specialists, generalists & pharmacists, and transparent process to improve acceptance
- **Ensure list consistency**
  - between national EML & PHCRD lists and LMD procurement list
- **Implement the revised EML**
  - Consider policy to ensure that most local procurement (e.g. 80% at tertiary level and 90% at district level) consists of EML drugs
  - Ensure all providers are sensitized/trained on the EML
  - Monitor compliance
- **Establish a transparent system to review all requests for non-EML drugs**
  - Drug & Therapeutic Committees in all referral hospitals could consider such requests

Drug use (1)

- No routine monitoring of drug use or prescription audit
  - OPD registers generally well kept by paramedical staff and sometimes at district hospitals, but not by doctors at higher level facilities, where brand prescribing is usual
  - OPD registers could be better kept and hospital pharmacists could monitor prescribing and report to DTCs
  - IPD individual patient dispensing sheets are well kept and HODs could monitor inpatient prescribing and report to DTCs
- No hospital Drug & Therapeutic Committees (DTCs)
  - Only procurement committees
  - Should be a requirement for accreditation for teaching hosp status
  - Set drug policy, monitor ADRs, monitor use, encourage CME, etc
- National Standard Treatment Guidelines (STGs)
  - STGs for S/HP 2012 but not for higher levels (public & private)
  - few prescribers (doctors & paramedics) using STGs

Health worker statements

- **DPHO staff:**
  - *Drug supply chain management is a jungle. We do not know what basic stock we have, what to order and what has expired.*
- **HP in Charge (HA)**
  - *I have not had any refresher training for 16 years. There is no refresher training program in hill districts, only in the Tarai.*
- **SAHW**
  - *We are sent short-dated medicines we do not need even when we ask them not to send these medicines. On the other hand we are not sent the medicines we need and have asked for, so we have stock-outs.*

Drug use (2)

- Independent drug information
  - no functional national Drug Information Centre, although some teaching hospitals and the DDA have drug information units
  - frequent pharma rep visits to private facilities & referral hospitals
- Pharmacology & prescribing taught at medical undergrad pre-clinical level in the 1st & 2nd years but not in 3rd, 4th and 5th years
  - Pharmacology/prescribing knowledge undermined by clinical studies and later work
- CME regular in medical colleges but rare outside, especially for private GPs, and not much on prescribing
  - MOHP vertical disease control programs for government staff
  - Adhoc CME seminars for specialists through societies
  - Peer review of prescribing in 21 districts starting soon, after successful pilot in 23 districts

Public sector drug consumption in Banke 2013-14

- Paracetamol 500mg
  - 4 tabs per person per year
- Amoxycillin 250mg
  - 4 tabs per person per year
- Amoxycillin 500mg
  - 2 tabs per person per year
- Metronidazole 200mg
  - 2 tabs per person per year
- Metronidazole 400mg
  - 1 tab per person per year
- Antacid
  - 1.5 tabs per person per year

Calculated from review of LMD & RMS supplies plus review of local purchase using DDC and PHCRD budgets.

What about consumption in the private sector?

Drug use (3)

- No nationwide public education campaign on medicines use
  - Successful pilot research projects by INRUD & other NGOs have been done, including training of school teachers, journalists and mothers, community education and school programs
  - Female CHVs have successfully taught MCH issues to communities
- Workload
  - Doctors/paramedics generally see about 20-30 patients / day in district facilities (though more than this in some facilities in summer) so there is sufficient time to do good consultation & prescribing
- Dispensing
  - Dispenser-patient interaction time often <1 minute
  - labelling is inadequate – snipping the strip pack to indicate dosing frequency

Drug use: recommendations

- **Monitor prescribing and drug use**
  - Improve OPD registers to include diagnosis & treatment
  - Monitor impact of peer-review program in 21 districts
- **Develop/update Standard Treatment Guidelines**
  - Develop/update STGs for 1º and 2º levels, disseminate to every prescriber and incorporate into UG education and CME
- **Establish Drug and Therapeutic Committees (DTC)**
  - In every referral hospital to monitor drug use, maintain hospital formulary, monitor ADRs, encourage CME, and report annually on activities to MOHP – should be a requirement for all teaching hosp
- **Continuing medical education (CME)**
  - NMA, NMC should develop a credit system for CME & incorporate prescription audit and feedback and ethics into it
  - NPA, NPC should develop CME on Good Pharmaceutical Practice
- **Undertake nationwide public education campaign**
  - Core pharmaceutical messages e.g. *simple coughs & colds do not need antibiotics?* through Community Health Volunteers & media

Drug use indicator survey

Drug use indicator	Ref hosp n=4	DH/PHC n=3	HP/ SHP n=4	Retailer n=6
Av.no.drugs/patient	2.8	2.8	2.0	2.7
% patients with ABs	39%	40%	46%	41%
% patients with INJs	2%	0%	0%	11%
% patients with VITs	16%	30%	23%	6%
% generic drugs	2%	66%	80%	7%
% EML drugs	33%	90%	94%	36%
% URTI given ABs	-	71%	63%	-
% drugs dispensed	78%	76%	93%	98%
Av.cost/Px (NRs)	382	-	-	528

Drug regulation (1)

- **Dept. Drug Administration (DDA) executes:**
  - Drug Act 1978 and regulations for drug registration, drug standards, inspection and investigation, code of drug manufacturing, and formulation of drug advisory committee & drug advisory council
- **DDA manages a sector consisting of:**
  - 15,247 Products 459 manufacturing units
  - 2,698 wholesalers 16,640 retail shops
- **DDA extremely under-resourced**
  - Has 49 posts (22 filled) in KTM, but needs 100 posts (O&M survey)
  - Has 3 branches (Nepalgunj, Birgunj, Biratnagar) each with 8-9 posts (4-5 filled) to manage a sector of about 4,000 outlets each
- **SOPs/Checklists**
  - SOPs for outlet inspection & medical product recall
  - Checklist for drug registration & regulation for QC test sampling

Drug regulation (2)

- **National Medicine Control Laboratories**
  - 1 lab with 40 posts (22 filled),
  - 687 samples tested per year – 14% failed in 2013
- **Outlet inspections**
  - 2,451 inspections of retail & wholesale pharmacy yearly, 117 inspections of manufacturing units, 10 inspections of foreign comps.
- **Drug Schedules**
  - OTC (Ga), POM (Kha) and controlled drugs (Ka)
  - All drugs apart from controlled drugs available OTC sometimes dispensed by unqualified persons
  - All qualified pharmacy personnel can sell all drug types
- **Drug Registration**
  - New molecule (non-pharmac) approval by Drug Advisory Committee
  - Old molecule (pharmac.) approved by DDA without referral to DAC
  - Some feel the criteria are too easy so allowing too many products

National drug policy & coordination

- **National Drug Policy 1995 comprehensive but old, no implementation plan & inadequately implemented**
  - Redrafting in process?
  - implementation by DDA, LMD & PHCRD, all under-resourced
- **NDP implementation requires coordination of policy**
- **Which unit in MOHP can coordinate between**
  - **different departments & divisions in MOHP?** DDA (EML, STGs) Curative Division (quality of care); Human Resources; Health Education & Info (public education); Family Health (Pub ed);
  - **other ministries and other stakeholders?** Min Educ (training of health professionals, school curricula); Min Finance (drug budget); Min of Local Development (local drug budgets); civil service commission (pharmacy posts); Min Commerce (prices of drug imports); Min Industry (Manufacturers)

Drug Regulation (3)

- **1836 warnings, 2 prosecutions in 2013**
  - 5 unregistered shop closures & some suspensions in M.W. Region
- **Monitoring of drug promotion**
  - No drug adverts allowed legally, but social marketing for ORS, OC, Zn
  - Pre-approval of adverts only for some traditional medicines and no approval of package inserts done
- **Adverse Drug Reaction Monitoring**
  - 50 ADRs reported in 2013 reported from 7 regional centres
- **Drug Price Controls**
  - Prices set by Drug Pricing Monitoring Committee chaired by DG DDA & representatives from MOHP, industry, retailers, consumers
  - Max Retail Price set as the average price found in the market, by collection of prices during inspection, and from Drug & Chemists Association & Association of Pharmaceutical Producers of Nepal
  - Mark-up 8-9% for wholesalers and 16% for retailers

Possible solutions for coordinating structure and national policy

- **Permanent statutory committee to advise the Minister of Health/Secretary on Pharmaceuticals with wide membership incl. laypersons, professional bodies …**
- **Executive Division in MOHP to carry out the statutory committee recommendations – Division of Pharmaceutical Services?**
  - To coordinate action between DDA, DHS (LMD, PHCRD etc
  - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, public education
  - Could liaise with universities to provide students to collect information needed by the MOH as part of their research studies
  - To update the National Medicines Policy to be more specific and to include an implementation plan and time line

Drug regulation: recommendations

- **Strengthen the DDA and the Drug Testing Lab**
  - More inspectors & pharmacists - fill posts & create more posts
  - Standard operating procedures and guidelines for all procedures
  - Amend current Drug Act to allow more punitive actions
  - Fill lab posts, work for ISO 17025 accreditation, establish reg. minilabs
- **Strengthen the drug registration process**
  - Higher fee for imported drugs & stronger criteria e.g. bioequivalence and bio-availability studies, with stricter application of criteria
  - Ensure all products are reviewed by the technical advisory committee and make the process more transparent (website update)
  - Will help to reduce the number of products registered
- **Update and enforce the drug schedules**
  - update and enforce the OTC & POM lists
  - consider establishing new schedule for drugs used only in tertiary referral hospitals (special pharmacies) e.g. oncology drugs, new ABs
- **Start unit to monitor drug promotional activities**
  - Develop monitoring of promotional activities, ethical guidelines

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 structure and drug policy

Coordination and management

- **MOHP Structure:**
  - 3 departments: DHS, DDA, Ayurveda,
  - 5 divisions: Planning, Admin, Curative, Human Resources Development, Monitoring & Evaluation
  - 5 centres: TB, HIV/AIDS, Nat Pub Health Lab, Health Education & Info, National Health Training Centre
- **Department Health Services (DHS):**
  - 6 divisions: LMD, PHCRD, Management, Family Health, Child Health, Epidemiology & Disease Control (incl. leprosy)
- **Different units look after different functions:**
  - DDA updates EML, PHCRD maintains Free List and allocates drug budgets for local purchase, LMD procures & supplies 35-40 drugs for free distribution. No unit does public health education on drug use or monitors drug use, performance of hospital DTCs, CME.
- **Same experts sit on many different committees**
  - e.g. NEML selection, drug registration, drug procurement
  - Lack of time, conflict of interest?