MEDICINES IN HEALTH CARE DELIVERY

SRI LANKA

Situational Analysis:

16-27 March 2015

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

January 2016

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1. ABBREVIATIONS

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
CME	Continuing Medical Education
CPD	Continuing Professional Development
DDG	Deputy Director General
DGHS	Director General Health Services
DHO	District Health Office
DIC	Drug Information Centre
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutics Committee
GDP	Good Dispensing Practice
EM	Essential Medicines
EML	Essential Medicines List
GPP	Good Prescribing Practice
HOD	Head of Department
IPD	In-patient Department
M&E	Monitoring & Evaluation
MIC	Medicines Information Centre
MO	Medical Officer
MOH	Ministry of Health
MSD	Medical Supply Division
NAC	National Advisory Committee
NMRA	National Medicines Regulatory Authority
NDP	National Drug Policy
NDQAL	National Drug Quality Assurance Laboratory
NGO	Non-Governmental Organisation

NMP	National Medicines Policy
OPD	Outpatient Department
OTC	Over-the-Counter
PDHS	Provincial Director of Health Services
PHC	Primary Health Care
PV	Pharmacovigilance
QA	Quality Assurance
RDHS	Regional Director of Health Services
RMSD	Regional Medical Supplies Division
RUM	Rational Use of Medicines
SLMA	Sri Lanka Medical Association
SLMC	Sri Lanka Medical Council
SOP	Standard Operating Procedures
SPC	State Pharmaceutical Corporation
STG	Standard Treatment Guidelines
TOR	Terms of Reference
VEN	Vital, Essential, Non-essential – method for classifying drug importance
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Sri Lanka during 16-27 March 2015. The Terms of Reference were to examine medicines in health care delivery with respect to medicines supply, selection, use, regulation and policy. It was agreed that the WHO/SEARO workbook tool would be used and that a team of government officials, led by the Medical Supplies Division and the Drug Regulatory Authority, facilitated by WHO/SEARO, would conduct the situational analysis.

The team members consisted of:

Dr Kathleen Holloway, Regional Advisor Essential Drugs & Other Medicines, WHO/SEARO

Dr Devika Mendis, Medical Supplies Division (MSD), MOH

Ms Lathika Chandanie Wanniarachchi, Medical Supplies Division (MSD), MOH

Ms Amara Pinnawala, National Drug Quality Assurance Laboratory (NDQAL), MOH

Mr Vajira Asela Agampodi, National Drug Quality Assurance Laboratory (NDQAL), MOH

Mr K.P.H. Sandaruwan, National Drug Regulatory Authority (DRA), MOH

Mr Chaminda Dissanayake, National Drug Regulatory Authority (DRA), MOH

Prof Gitanjali Batmanabane, WHO Consultant and Prof. Pharmacology

Jawarhalal Nehru Institute of Postgraduate Medical Education and Research, India

Ms Indunil Priyangika Athukoralage, WHO, Sri Lanka

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 over a period of two weeks. 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 33 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 27 March 2015where 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

In the public sector, drugs are procured by the State Pharmaceutical Corporation (SPC), a government-owned corporation, and supplied to health facilities through the Medical Supplies Division (MSD) in the Department of Health Services, as was the case in 2010. Availability of key essential drugs was over 90% in teaching hospitals but 72-79% in lower level facilities, where some staff complained of stock-outs and where medicines normally reserved for higher level facilities were sometimes used.

Government has seriously followed the recommendation of the last situational analysis to extend the new electronic Medicines Supply Management Information System (e-MSMIS) (initiated in 2009 at the centre) to the regional medical supplies Divisions (RMSDs) and the teaching hospitals, though not yet to the smaller hospitals where drug management is still done manually. As the MSD and RMSD realize the potential of this tool it will be used to generate data which can guide policy makers. Nevertheless, training of more staff in using the e-MSMIS is required. Methods of quantification and forecasting remain sub-optimal in some health facilities because these facility staff are still using manual methods, based on past drug consumption during which there were frequent stock-outs. However, the e-MSMIS started functioning in April 2014 in several RMSD stores and was fully functional in all stores from January 2015 so more accurate estimation for 2016 will be done through the past consumption data extracted from the e-MSMIS.

There is still limited harmonization between SPC and MSD, leading to delays. The process of drug procurement remains similar to what was done in 2010 and is not well coordinated with distribution and demand. Only a one-envelope international tendering system is used, technical and price criteria being submitted and judged simultaneously. The only quality criteria used in procurement is registration with the drug regulatory authority of Sri Lanka. Unfortunately, a number of stock-outs were caused by 12 product withdrawals and 99 batch withdrawals in 2014 due to quality testing failure and most of these product samples were referred by end-users in health facilities.

Recommendations were to:

- Build on progress made since 2010 to extend the e-MSMIS already established at the centre and regional warehouses to all hospitals and train staff in using the system in order to improve stock management and forecasting.

- Employ at least one pharmacist to manage all hospital and regional warehouse drug stores and sub-stores in order to improve stock management.

- Review the State Pharmaceutical Corporation (SPC) procurement system with special attention to:
    - the tendering system with regard to technical criteria and whether to establish a 2-envelope system, where only the bids of suppliers passing the technical criteria are considered with regard to price;
    - changing the criteria for referral to cabinet for approval (from cost of individual products to the cost of the total tender) so that fewer tenders are referred to cabinet for approval (which would reduce procurement lead time);
    - employing a specialized agency within the foreign exporting country to undertake inspection and random quality check of products within procurement consignments, prior to export (so as to avoid poor quality products being “dumped” in Sri Lanka).

- Review drug management practices, particularly with regard to:
    - Storage conditions and use of vertical as well as horizontal space in warehouses and facility stores through the use of adequate shelving in health facility stores and warehouses;
    - Stock management and quantification procedures to ensure timely orders and reduced lead time for new supplies;
    - Transport facilities in terms of lorries and human resources;
    - Regular supervision of drug stores and warehouses by senior officials;
    - Hospital inpatient ward management of drugs including the use of stock registers, and individual patient dispensing sheets;
    - Regional Directors of Health Services and Heads of institutions may do this and submit a comprehensive report to the Medical Supplies Division and the Director General of Health Services.

- Continue to promote local manufacturers because procurement from them is easier than importing medicines manufactured abroad, their drug quality is equally good, delivery is shorter, shelf-life is longer, and they may buy back supplies if nearing expiry.
    - May be done by giving tax incentives to the local manufacturers and continuing to implement a purchase preference policy and exempting such purchases from normal tender procedures by arranging for drug prices to be decided by a Pricing Committee appointed by Ministry of Finance

2.3. Medicines Selection

As was recommended in 2010, the National Essential Medicines List (EML) was updated in 2013, using a sound and transparent process, after a gap of four years. However, the updated national EML was not widely disseminated and appears not to be used for pre-service and in-service training. The utility of following the EML though taught in the medical student curricula is not followed because of the lack of role models, national STGs and strict implementation of policies related to rational use of medicines.

At present, nearly all non-EML drug requests by consultants are procured without any real processing through the hospital Drug and Therapeutic Committees (DTCs). While the recommendation of the 2010 situational analysis to establish DTCs in all hospitals has been followed the spirit of the recommendation to have all non-EML purchase requests justified and reviewed by these DTCs has not been followed. Similarly, the 2010 recommendation that colleges and specialists boards provide guidance on “reasonable” specialist drugs for non-EML purchase and that a permanent national sub-committee be established to decide on such requests has not been followed.

The national EML and MSD procurement list are not completely harmonized and are actually prepared by two different agencies – the drug regulatory authority and the MSD, respectively. Unless there is harmonization of the national EML and the MSD procurement list, with close alignment to recommended treatment protocols for different levels of healthcare, plus strict monitoring of non-EML drug procurement, compliance with, and utility of, the national EML will remain limited. If the national EML were prepared by the MSD rather than the Drug Regulatory Authority (DRA), harmonization of the MSD list and national EML would be easier. The new e-MSMIS, currently being extended, , will make monitoring of EML compliance easier.

Recommendations were to:

- Continue to update regularly the national EML in a transparent manner with wide representation, which would include:
    - Establishing a Standing Committee on Essential Medicines with representation from all the specialties (including general practice, pharmacology and pharmacy) and a mandate to regularly revise the EML list;
    - Using the e-MSMIS portal to disseminate information in the updating process (already planned);
    - Coordination of activities by the MSD.

- Harmonize the national EML and the procurement list of the MSD:
    - will require harmonization of activities between the Hospital Formulary Committee and the proposed national Standing Committee in updating EML list.

- Monitor compliance to the national EML list (taking into account facility and prescriber type) through regular surveys and collection of data on prescribing patterns and drug utilization:
    - to be done by DTCs in major hospitals, and by a regional committee comprising the Medical Officers of Health, Divisional Pharmacists, and the Food and Drugs Inspectors under supervision of Regional Director of Health Services (RDHS) for other health facilities and the private sector .
    - All surveys to be reported to the Standing Committee of the EML and to MOH

- Ensure stricter adherence to the EML by:
    - Programme of educating prescribers and dispensing officers on the use of the national EML to be coordinated by the Standing Committee on Essential Medicines;
    - Referral hospital DTCs judging all requests for non-EML drugs;
    - Colleges and specialists boards providing guidance on “reasonable” specialist drugs for non-EML purchase;
    - permanent sub-committee judging all out-of-list requests at the national level.

2.4. Medicines use

Medicines prescribing and use remains similar to what was found in 2010 although the average number of medicines prescribed per patient and the percentage of patients prescribed antibiotics both seem to have risen slightly. Similarly, dispensing practices remain similar to what was previously seen. Monitoring of prescribing and dispensing is not generally done.

The major change since 2010 is that Drug and Therapeutic Committees (DTCs) have been established in all teaching and provincial hospitals and in the regional health departments, as recommended in the previous situational analysis. In hospitals, this has been done by upgrading the previous hospital Drug Review Committees although their terms of reference appear to remain the same. Though started with the aim of monitoring drug use, the DTCs are not doing this.

Apart from establishing DTCs, implementation of policies to improve medicines use remains weak, much as was found in 2010. Continuing medical education (CME) is adhoc and minimal for most prescribers, though the Sri Lanka Medical Association (SLMA) and other professional bodies do organize lectures on specific conditions, normally concerning secondary rather than primary care. Though the CME lectures discuss

common problems like hypertension, diabetes mellitus, the focus is always on newer treatment modalities and new drugs, but not on the management of common conditions at primary and secondary health care facilities using available resources.

Previous recommendations to develop National Standard Treatment Guidelines (STGs) and to run public education campaigns on prudent use of medicines run have not been undertaken. Plans of the Sri Lanka Medical Council and the Sri Lanka Medical Association to develop an accreditation system based CME have not further advanced because many peripheral doctors would not be able to come to Colombo or the other major cities for the CME.

Recommendations were to:

- Monitor drug use by undertaking prescription audit, which will require revision of prescription forms to include diagnosis.

- Improve awareness of the current patterns of drug use in the country by dissemination of situational analysis findings at the next Health Development Committee meeting and to prescribers through the Regional Directors and Hospital Directors.

- Develop STGs including OPD treatment of simple primary care conditions with emphasis on using fewer medicines and disseminate to every doctor and student and incorporate into CME.

- Improve continuing medical education by:
    - requiring consultant physicians to take the lead in providing CME and disseminating STGs to prescribers in in their own hospitals and also to private general practitioners who work locally;
    - organizing regular CME sessions that have credit points assigned to practitioners for attendance which is linked to promotion and increments.
    - Incorporating prescription audit and feedback and ethics into CME;
    - Ensuring that the Sri Lanka medical council (SLMC) and professional associations continue to be involved in delivering CME.

- Educate patients and care givers on common illnesses and on drug/non-drug management, using:
    - social media (TV, videos at clinics);
    - all the health education channels used by the MOH.

- Promote DTCs to undertake monitoring of use and policy implementation, which will require:
    - Standardised DTC terms of reference;
    - The pharmacist of the drugs and therapeutic committee being given the responsibility for conducting quarterly audits on drugs in common use and those which are irrationally used (e.g. antibiotics, NSAIDS, Proton Pump Inhibitors, antihistamines etc.);
    - The findings from the audits being sent to the Standing EML Committee (and the National DTC coordinated by the MSD) and also the executive unit in the MOH, which should meet regularly and provide feedback to the hospitals.

- Improve the consulting environment in order to improve prescribing by:
    - Exploring the possibility of establishing a referral system to decrease overcrowding in hospital outpatients;
    - Analysing prescriber workload to ensure more equal distribution of staff and workload to ensure sufficient consultation time.

2.5. Medicines Regulation

Since 2010 the national drug regulatory authority (DRA) has remained weak and very similar in function, despite a small increase in staff numbers and some training on dossier evaluation and GMP inspection. Drug registration remains particularly problematic. Although some staff have been trained on dossier evaluation and GMP inspection (with WHO support) they have not always been assigned to work in these areas after their training. The computerized system for drug registration (developed with WHO support) is still not used. By contrast, the National Drug Quality Assurance Laboratory (NDQAL) has become much stronger, testing more samples and participating in international quality assurance assessment schemes. Even so, many of its pharmacists and other staff are transferred every 2-3 years so that the skills developed during their time there are lost to the NDQAL after their transfer.

Most focus since 2010 has been on developing a new Drug Regulatory Authority Bill and this was passed as a new National Medicines Regulatory Authority Act on 19 March 2015. Currently new accompanying regulations are being drafted. The new National Medicines Regulatory Authority (NMRA) will be independent of the MOH. It remains to be seen how the new Act will be implemented.

Recommendations were to:

- Establish the new NMRA, as per the new National Medicines Regulatory Authority Act 2015 which has been approved in the Parliament, and implement an effective monitoring and evaluation system (see medicines policy and coordination).
- Strengthen the NMRA by:
    - recruiting more technical staff, including pharmacists and inspectors:-
        - at least 25 more pharmacists should be recruited immediately , as follows: New Chemical Entity -3; Existing molecules- 10; BTP – 3; Domestic sector – 03; Recall and pharmacovigilance – 03; Approvals for manufacturing facilities – 03.
        - The Director of the NMRA (DRA) and DGHS should try to facilitate this process.
    - Training both existing staff and newly recruited staff of the DRA;
    - Developing SOPs for all procedures and training new employees on their use;
    - Ensuring trained personnel are posted in positions where they are given the responsibility of carrying out work related to the area in which they received training.

- Make the registration process more stringent in order to improve quality and reduce the number of products in the market by:
    - Implementing the computerized database system software (which has already been procured)within three months and training staff to use it;
    - Assigning staff who have been trained in dossier evaluation to do this work and training more staff to do dossier evaluation;
    - including stronger criteria in the evaluation of products for registration (e.g. bioequivalence studies, dissolution profiles, stability studies) and revising the SOPs to include these criteria;
    - more stringent compliance with the SOPs and the recommendations of the Drug Evaluation Sub-committee.
- Strengthen compliance with Good Manufacturing Practices for products and APIs by:
    - Developing SOPs for GMP inspection;
    - Assigning staff who have been trained in GMP inspection to do this work and training more staff to do GMP inspection.

2.6. Medicines Policy and Coordination

The national medicines policy (NMP), coordination and structure remain similar to the situation in 2010. Implementation of many parts of the NMP remains weak. No unit dedicated to monitoring prescribing was established in the MOH but a national DTC to oversee hospital DTC activities has been established and is coordinated by the MSD. Most focus has been on developing a new National Medicines Regulatory Authority Act, which was finally passed by parliament in March 2015. It remains to be seen how the new National Medicines Regulatory Authority (NMRA) will be established. At the time of writing new regulations to accompany the Act were being drafted.

Recommendations were to:

- Establish the new NMRA, as per the new National Medicines Regulatory Authority Act 2015 which has been approved in the Parliament, and implement an effective monitoring and evaluation system (see regulatory section).
- Strengthen the National Advisory Committee (NAC) to oversee implementation of the national drug policy and the new NMRA.
- Appoint a subcommittee in the NMRA to:
    - define key performance indicators (KPIs) and targets for all areas of medicines management including medicines use and implementation of regulations and the national drug policy;
    - coordinate among stakeholders regarding implementation of medicines policies and carrying out the recommendations of the National Advisory Committee (NAC).

- Establish a Division in MOH to ensure that data is collected regularly on key performance indicators for monitoring purposes.

- MOH to organize an annual meeting with participation of all stakeholders to discuss, inform and present data on KPIs, targets achieved, and forecast and plan for future medicines situation analysis in the country.

- Allocate budget to the MOH, National Medicines Regulatory Authority (NMRA) and National Advisory Committee (NAC) for all the above activities.

3. PROGRAMME AGENDA

Day	Date	Time	Places visited
1	Mon 16/3/15	Am	Visits to WHO country office
		Pm	Visits to Ragama Teaching Hospital
2	Tues 17/3/15	Am	Visits to Director General Health Services,
		Pm	Visits to Drug Regulatory Authority, National Drug Quality Assurance Laboratory
3	Wed 18/3/15	Am	Visits to Medicines Supply Division
		Pm	Visits to Pharmacology Dept. Colombo University, Sri Lanka Medical Association
4	Thurs 19/3/15	Am	Visits to Sri Lanka Medical Council in Colombo and travel to Galle in Southern Province
		Pm	Visits to Regional Director Health Services and Regional Medical Supplies Depot in Galle, private pharmacies & Osu Sala pharmacy in Galle
5	Fri 20/3/15	Am	Visits to Karapitiya Teaching Hospital in Galle
		Pm	Visits to Ahangama Division C hospital and Ahangama Central Dispensary, Southern Province
6	Sat 21/3/15	Am	Visits to Base Hospital Balapitiya, Southern Province
		Pm	Return to Colombo
7	Sun 22/2/15	Am	Travel to Anuradhapura in North Central Province
		Pm	Travel to Anuradhapura in North Central Province
8	Mon 23/3/15	Am	Visits to Anuradhapura Teaching Hospital and Regional Director Health Services
		Pm	Visits to Thalawa Div Hospital B, Thambuththegama Base Hospital, private pharmacies & Osu Sala pharmacy in North Central Province
9	Tues 24/3/15	Am	Visits to Regional Medical Supplies Depot in Anuradhapura and Central dispensary Galadivulwewa in North Central Province
		Pm	Telephone interviews with Director Health Education Bureau and Province Director Health Services in North Central Province and return to Colombo
10	Wed 25/3/15	Am	Visits to State Pharmaceutical Corporation
		Pm	Visits to Family Health Bureau, Pharmaceutical Society of Sri Lanka, EML chair
11	Thurs 26/3/15	Am	Visits to Central Dispensary Battaramulla, Colombo
		Pm	Preparation for the workshop
12	Fri 27/3/15	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	√		Medical Supplies Division (MSD)
Quantification	√		MSD
Procurement		√	State Pharmaceutical Corporation (SPC)
Pricing		√	SPC
Storage	√		MSD
Distribution	√		MSD
Monitoring & evaluation	√		MOH, Hospitals

4.2. Drug availability

No reports were found that describe recent data on drug availability, apart from the report of the last situational analysis done in 2010. At that time it was reported that demand outstripped supply by about 25-30% with frequent complaints of stock-out and patient having to buy medicines from outside pharmacies, but no survey of key essential drug availability was done. This time, a survey was done of availability of key essential medicines in both public health facilities and private pharmacies. Table 4.2.1 show some data on stock availability and stock-out.

The % of key EML drugs available was based on a list of 33 drugs chosen by the team from the national EML, consisting of: paracetamol tablets & liquid, chlorpheniramine tablets & liquid, prednisolone tablets, atropine injection, carbamazepine tablets & liquid, mebendazole tablets, amoxicillin tablets or capsules & liquid, metronidazole tablets, erythromycin tablets or capsules, griseofulvin tablets or capsules, ferrous sulphate tablets, enalapril tablets, atenolol tablets, furosemide tablets& injection, atorvastatin tablets, benzyl benzoate lotion, miconazole cream, oral rehydration solution sachets, domperidone tablets, metformin tablets, ciprofloxacin eye drops, ergometrine injection, amitriptyline tablets, salbutamol tablets& inhaled formulations, omeprazole capsules, cefuroxime injection and meropenem injection.

The availability of medicines at government teaching hospitals was good; the availability of essential medicines being nearly 90% with only 2-3% of commonly used items being out of stock. However, availability of key essential medicines in base and divisional hospitals and central dispensaries was only 72-79% (for those medicines that should have been there) and one divisional hospital only had 50% of the key medicines from the EML. The fact that the number of currently used items out of stock was less than 5% in all facilities as compared to 20-30% of key items not being available indicates that a number of essential medicines were not being used by many lower level facilities. Even with 20-30% of key essential drugs not being available, there were usually alternatives and over 90% of all prescribed medicines were dispensed.

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

Public Referral Hospitals	Referral Hospital 1	Referral Hospital 2	Referral Hospital 3		Average
% currently used items out of stock*	3.7%	3.3%	0.4%		2.5%
% key EML drugs available	84.5%	87.5%	96.9%		89.6%
% prescribed drugs dispensed**	81.3%	99.0%	94.7%		91.7%
Public Divisional and Base Hospitals	Base Hospital 1	Divisional Hospital 1	Base Hospital 2	Divisional Hospital 2	
% currently used items out of stock*	7.2% (14.1%)	?	1.6%	?	
% key EML drugs available**	66.7%	42.4% (58%)	100%	75.0% (93%)	71% (79%)
% prescribed drugs dispensed***	85.1%	86.6%	95.0%	98.5%	91.3%
Public primary health care centres / dispensaries	Dispensary 1	Dispensary 2	Dispensary 3		Average
% EML/currently used items out of stock*	5.8%	6.2%	2.5%		4.8%
% key EML drugs available**	64.5% (86%)	45.2% (50%)	67.8% (81%)		59% (72%)
% prescribed drugs dispensed***	100%	100%	98%		99.3%
Public Regional Warehouse	Warehouse 1	Warehouse 2			Average
% currently used items out of stock*	3.5%	5.0%			4.3%
% key EML drugs available	75.0%	81.5%			78.3%
Public *Osu Sala* pharmacies	Osu Sala 1	Osu Sala 2			Average
% key EML drugs available	100%	85.2%			92.6%
% prescribed drugs dispensed**	89.1%	88.8%			89.0%
Private pharmacies in Galle	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
% key EML drugs available	81.0%	71.4%	84.8%	81.8%	79.8%
% prescribed drugs dispensed***	76.2%	100%	80.6%	77.5%	83.4%
Private pharmacies in Anuradhapura	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
% key EML drugs available	83.3%	92.6%	?	81.8%	85.9%
% prescribed drugs dispensed***	100%	82.1%	97.5%	97.5%	93.5%

? = data not available

*The list of ordered items varied enormously between health facilities of the same level. Thus the number of items ordered was 240-959 in teaching hospitals (including non-EML drugs), around 400 items in regional warehouses,385-411 items in base hospitals (including non-EML drugs), and 80-102 items in dispensaries. In most hospitals, the stock-out in the main store only was measured but in one hospital the stock-out in both the main store and the OPD dispensary was measured and the number in brackets refers to the total number of items out of stock in both main store and OPD dispensary excluding duplicates.

** The numbers in brackets refer to availability if the drugs that they do not use from the key list of essential drugs are excluded (i.e. omeprazole cap, cefuroxime inj, meropenem inj. in dispensaries and divisional hospitals)

***From prescription audit done during the health facility survey

Most of the doctors were appreciative of the government effort to make sure medicines were available. There were some concerns over the shortage of chlorpheniramine tablets which is widely prescribed and anti-snake venom which is necessary in a country like Sri Lanka where snake bites are common. Every month some drugs would not be available due to problems of poor quality, often noted at the facility and later confirmed by the national drug quality assurance laboratory. Quality failures led to the withdrawal of several batches each month and about 12 products in 2014. In the teaching hospitals, the consultants were happy with availability since any out-of-stock medicines were being supplied by local purchase. The smaller facilities were not happy with the supply and wanted more "expensive" medicines and high-end antibiotics. In one primary health centre the team found antibiotics, which were not to be prescribed at that level, easily available. The doctor-in-charge said that she would personally visit MSD in her car and bring whatever medicines were needed for the clinic. This shows that the medical personnel were determined to ensure availability and would take all steps to have the drugs patients needed and that the MSD was quite flexible in issuing medicines and was not sticking to the approved level of entitlement for facilities.

Availability of key essential medicines in government *Osu Sala* pharmacies was over 90% and in private pharmacies in Galle and Arunadhapura was over 80%.

4.3. Annual aggregate data of medicines distribution / consumption

Table 4.3.1 shows national aggregate data on drug distribution from the MSD for the year 2014. It is a consequence of the new electronic medicines supply management information system (MSMIS) that such data could easily be extracted and analysed. It can be seen that the top 24 (3%) drugs cost nearly one-third of the budget. About 18% of the budget was spent on antibiotics and 72% on drugs belonging to the national EML (as opposed to 74% which belonged MSD's VEN list). Four of the top 24 medicines were not on the national EML but were high value items with a critical life-extending function in a small minority of the population.

Table 4.3.2 shows aggregate data on drug distribution from the MSD for the year 2014 in two districts. Most drugs belonged to the national EML, but there were a few high-priced items in the top 20 items by value. In Anuradhapura district the top 20 drugs by value included three that did not belong to the national EML as compared to Galle district where only one of the top 20 drugs did not belong to the national EML. Per capita expenditure on medicines in Galle was only 60% of that in Anuradhapura. Otherwise drug consumption patterns were similar, 25-25% of the budget being spent on antibiotics and 95% of all drugs belonging to the national EML.

Table 4.3.3 show the top 24 items consumed by value in three teaching hospitals. It can be seen that compared to the national and district levels, as might be expected, many more non-EML drugs were being consumed, and only 64-82% of consumed drugs belong to the national EML. It may be questioned why nearly 40% of drugs in one teaching hospital were non-EML when only 20% in another teaching hospital were non-EML. The proportion of the budget spent on antibiotics was 14-17%.

Vitamin consumed 1-3% of the budget at all levels.

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

Source of data: MSD/MOH. Year: 2014

Rank	Item Name (including strength& formulation)	Unit costs SRL Rupees	Monetary Value SRL Rupees	EML** Yes/No
1	Normal saline 500ml inj	49.02	398,826,748	Yes
2	Trastuzumab 440mg inj	201424.12	362,160,560	No
3	Factor VIII 250 IU inj	9170.78	334,018,149	Yes
4	Sol/Isophane Insulin inj	303.29	276,207,525	Yes
5	Metformin 500mg tab	0.75	254,419,012	Yes
6	Paracetamol 500mg tab	0.75	231,325,056	Yes
7	Anti-Rabies vaccine	734.03	228,469,594	Yes
8	Hum.immunoglob 5-6g	22418.79	224,748,378	Yes
9	Hum.immunoglob 2-3g	16234.92	219,431,142	Yes
10	Amoxicillin 250mg cap	1.65	217,535,769	Yes
11	Amoxyclav 1g/0.2g inj	102.95	213,328,880	Yes
12	Hum.albumin 20% inj	3147.02	187,181,603	Yes
13	Rituximab 500mg inj	105252.87	186,718,600	No
14	Cephalexin 250mg cap	3.37	174,218,540	Yes
15	Meropenem 1g inj	447.58	164,797,948	Yes
16	Atorvastatin 10mg tab	0.86	156,419,484	Yes
17	Beclomethazoneinhal/cap	2.21	140,675,098	Yes
18	Clopidogrel 75mg tab	1.83	140,466,485	Yes
19	Losartan 50mg tab	0.89	139,056,136	No
20	Sod.valproate 200mg tab	3.39	137,678,862	Yes
21	Valganciclovir 450mg tab	2457.13	135,486,148	No
22	Anti-D immunoglobinj	4973.03	135,291,357	Yes
23	MMR vacc. 10 dose vial	1343.07	134,307,000	Yes
24	Desferioxamine 500mg inj	447.58	130,598,776	Yes
	% budget on top 24 medicines (3% items)*:	32%		
	% (total) budget spent on antibiotics:	18%		
	% (total)budget spent on vitamins:	3%		
	% (total)budget spent on EML medicines**:	74%		
	Per capita annual expenditure on medicines	79.81 SRL Rupees (2.43 USD***)		

*Budget covers about 40 equipment items e.g. dressings, bandages, antiseptics, electrocardiogram. paper, x-ray plates, contrast media and IV giving sets (but not syringes and needles).
**National EML which is different from MSD's "vital, essential & non-essential" list.
***From country pharmaceutical profile 2010.

Table 4.3.2: ABC analysis of top 20 items – regional level

Source of data: MSD/MOH Year: 2014

Rank	RMSD Galle Region			RMSD Anuradhapura Region		
	Item Name/Strength	Monetary Value	EML	Item Name/Strength	Monetary Value	EML **
1	Amoxicillin cap 250mg	9,813,480.00	Yes	Paracetamol tab 500mg	11,310,679.00	Yes
2	Paracetamol tab 500mg	9,621,318.00	Yes	Amoxicillin cap 250mg	8,181,011.00	Yes
3	Anti-Rabies inactivated tissue culture vaccine	5,998,792.80	Yes	Cephalexin cap 250mg	7,274,760.00	Yes
4	Cephalexin cap 250mg	5,021,720.00	Yes	Metformin tab 500mg	6,779,766.00	Yes
5	Anti D (Rho) inj 300mcg	4,968,870.00	Yes	Anti-Rabies inactivated tissue culture vaccine	5,738,865.60	Yes
6	0.9% saline inj 500ml	4,693,760.00	Yes	Prednisolone tab 5mg	5,448,925.00	Yes
7	Metformin tab 500mg	3,946,693.00	Yes	Cloxacillin cap 250mg	5,054,870.00	Yes
8	Co-amoxyclavinj 1.0/0.2g	3,486,376.00	Yes	Alfacalcidol cap 250ng	4,792,500.00	No
9	Prednisolone tab 5mg	3,369,108.00	Yes	Calcium carbonate tablet 1.25g	4,591,510.00	No
10	Cloxacillin caps 250mg	3,363,290.00	Yes	0.9% Saline inj 500ml	4,578,256.00	Yes
11	Amoxycillin cap 500mg	2,978,690.00	Yes	Losartan tab 50mg	4,259,683.20	No
12	Atorvastatin tab 10mg	2,591,602.00	Yes	Biphasic Human Insulin 30% Sol/70% Isophane	3,984,739.30	Yes
13	Losartan tablet 50mg	2,304,316.80	No	Amoxicillin &clavulanic acid tab 375mg	3,717,900.00	Yes
14	Biphasic Human Insulin 30% Sol/70% Isophane	2,300,708.10	Yes	Anti D. (Rho) inj 300mcg	3,474,769.40	Yes
15	Anti-rabiesseruminj 1000 I.U.	2,120,078.50	Yes	Cap Beclomethazonedipropionate 400mcg	3,305,613.00	Yes
16	Cefuroxime Inj 750mg	2,014,908.00	Yes	Atorvastatin tab 10mg	3,188,440.00	Yes
17	Cloxacillin cap 500mg	1,925,000.00	Yes	Clopidogrel tab 75mg	2,973,320.00	Yes
18	Ciprofloxacin tab 250mg	1,766,478.00	Yes	Co-amoxiclav tab 625mg	2,613,888.00	Yes
19	Clopidogrel tab 75mg	1,754,200.00	Yes	Cephalexin syrup 125 mg in 5ml,100ml bottle	2,270,733.00	Yes
20	Sod.valproate tab 200mg	1,674,072.00	Yes	Enalapril tab 5mg	2,249,437.00	Yes
	% budget on top 20(5%) drugs*	52%		% budget on top 20(5%) drugs**	49%	
	% budget on Antibiotics	35%		% budget on Antibiotics	25%	
	% budget on vitamins	1%		% budget on vitamins	3%	
	% budget on EML drugs**	95%		% budget on EML drugs*	94%	
	Per capita annual expenditure on medicines supplied (SRL Rupees)	14.19		Per capita annual expenditure on medicines supplied (SRL Rupees)	23.55	

*Budget covers about 40 equipment items e.g. dressings, bandages, antiseptics, electrocardiogram. paper, x-ray plates, contrast media and IV giving sets (but not syringes and needles).

**National EML which is different from from MSD's "vital, essential & non-essential" list.

Table 4.3.3:ABC analysis of top 24 items – 3 referral teaching hospitals

Source of data: MSD/MOH Year: 2014

Rank	Ragama Hospital, Colombo			Karapitya Teaching Hospital			Anuradhapura Teaching Hospital		
	Item Name/Strength	Monetary Value	EML **	Item Name/Strength	Monetary Value	EML **	Item Name/Strength	Monetary Value	EML **
1	Deferasirox tab 400mg	15,295,203.00	No	Trastuzumabinj 440mg with solvent 20ml ϕ	31,736,560.00	Yes	Desferrioxamine injection 500 mg	29,504,648.60	Yes
2	Human immunoglobulin IV inj 5g - 6g vial	14,746,586.40	Yes	Nimotuzumab injection 50mg in 10ml vial	20,828,000.00	No	Dried factor VIII Fraction,250 IU vial	26,613,603.56	Yes
3	Infliximab reconstituting inj powder 100mg	13,386,470.00	No	Bevacizumab Injection 100mg/4mi	20,820,526.24	Yes	0.9% Saline 500ml	16,587,456.00	Yes
4	Biphasic Human Insulin 30% Sol/70% Isophane	12,642,285.00	Yes	Infliximab reconstituting inj powder 100mg	18,878,158.00	No	Meropeneminj 1g vial	13,620,761.50	Yes
5	Human Immunoglobulin IV Inj 2.5g - 3.0g vial	12,042,413.37	Yes	Human Immunoglobulin IV Inj 2.5g - 3.0g vial	17,291,670.48	Yes	Trastuzumabinj 440mg with solvent 20ml ϕ	9,274,000.00	Yes
6	0.9% Saline inj 500ml	11,147,584.00	Yes	ImipenemCilastatin Sodium Infusion 500mg	15,708,656.00	No	Human immunoglobulin IV inj 5g - 6g vial	8,482,286.40	Yes
7	Desferrioxamine injection 500 mg	10,028,129.10	Yes	0.9% Saline inj 500ml	15,496,604.00	Yes	Deferasirox tab 400mg	7,137,761.40	No
8	Co-amoxyclav Injection 1000/200mg vial	7,603,947.81	Yes	Rituximab Inj 500mg	14,668,000.00	No	Rituximab Inj 500mg	7,122,500.00	No
9	Peginterferonealfa 2a 180mcg in 0.5ml	7,412,000.00	No	Dried factor VIII Fraction,250 IU vial	14,031,293.40	Yes	Enoxaparin Inj 60mg / 0.6ml, prefilled Syringe	6,931,946.16	Yes
10	Human Albumin Solution 20%,50ml	6,914,002.94	Yes	Human Albumin Solution 20%,50ml	11,077,510.40	Yes	Anti Rabies inactivated tissue culture vaccine	6,870,236.10	Yes
11	Atorvastatin tab 10mg	6,698,545.00	Yes	Meropeneminj 1g	10,964,876.18	Yes	Human Albumin Solution 20%, 50ml	6,860,503.60	Yes
12	Dried factor VIII Fraction,250 IU vial	5,961,007.00	Yes	Ticarcillin disodium 3g &Clavulanate 200mg inj	10,656,360.00	No	Anti D Immunoglobulin inj 300mcg in 2ml vial	5,945,446.00	Yes
13	Meropeneminj 1g vial	5,863,276.96	Yes	Human immunoglobulin IV inj 5g - 6g vial	9,218,070.92	Yes	Atorvastatin tab 10mg	5,391,555.00	Yes
14	Metformin tab 500mg	5,838,917.00	Yes	Co-amoxyclavInj 1/0.2 g	8,953,992.55	Yes	Meropeneminj 500mg	5,306,095.90	Yes

Rank	Ragama Hospital, Colombo			Karapitya Teaching Hospital			Anuradhapura Teaching Hospital		
	Item Name/Strength	Monetary Value	EML **	Item Name/Strength	Monetary Value	EML **	Item Name/Strength	Monetary Value	EML **
15	Human immunoglobulin I.V. Inj 5g Vial	5,064,583.60	Yes	Erlotinib Hydrochloride tablet 150mg	8,879,940.00	No	Valganciclovir tab 450mg	5,159,973.00	No
16	Nicorandil tablet 10mg	4,745,716.00	No	Meropeneminj 500mg	6,716,881.10	Yes	Basiliximab IV inj 20mg	5,007,848.40	No
17	Amoxicillin cap 250mg	4,694,590.00	Yes	Clindamycin Inj 300mg	6,645,936.00	No	Imatinibmesilate cap 100mg	4,953,566.40	No
18	Deferasirox tab 100mg	4,607,555.40	No	Biphasic Human Insulin 30% Sol/70% Isophane	6,371,732.00	Yes	Epoetininj 4,000IU-5,000IU prefilled syringe	4,835,461.20	Yes
19	Dried factor VII fraction 2mg (100 KIU) vial	4,236,446.69	No	Methoxy polyethylene glycol-epoetininj 0.1mg	6,350,400.00	No	Alfacalcidol cap 250ng	4,504,950.00	No
20	Isoflurane 250ml Bottle	3,915,468.72	Yes	Gliclazide Tablet 80mg	6,028,425.00	Yes	Metformin tab 500mg	4,391,341.00	Yes
21	Anti Rabies inactivated tissue culture vaccine	3,705,644.10	Yes	Noradrenaline inj 4mg	5,947,359.40	Yes	Paracetamol tab 500mg	4,311,506.00	Yes
22	Sodium valproate tab 200mg	3,607,176.48	Yes	Somatropin injection 24 IU(8mg) powder	5,009,015.00	No	Human Immunoglobulin IV Inj 2.5g - 3.0g in Vial	4,290,414.48	Yes
23	Meropenem injection for IV use, 500mg vial	3,496,233.40	Yes	Ticarcillin sodium 1.5g + Clavulanic acid inj 0.1g	4,779,388.80	No	Deferasirox tab 100mg	4,184,460.00	No
24	Cephalexin cap 250mg	3,337,680.00	Yes	Paracetamol tab 500mg	4,703,730.00	Yes	Epoetinalfa injection for SC or IV use 4000 IU	4,161,963.20	No
	%budget on top 24(5%) drug items*	50%		%budget on top 24(4%) drug items*	46%		%budget on top 24(4%) drug items*	40%	
	% budget on ABs	14%		% budget on ABs	17%		% budget on ABs	15%	
	% budget on vits	2%		% budget on vits	2%		% budget on vits	< 1%	
	% budget on EML drugs**	82%		% budget on EML drugs	64%		% budget on EML drugs	77%	

* Budget covers about 50 equipment items (excluding those in the top 24 items) e.g. dressings, bandages, antiseptics, electrocardiogram paper, x-ray plates, contrast media and IV giving sets (but not syringes and needles).

**National EML which is different from MSD's "vital, essential & non-essential" list. ϕTrastuzumab injection is on the EML but is not classified as essential on MSD's list.

The top 10 causes of hospitalization are: traumatic injuries, diseases of lower respiratory system, viral diseases, diseases of gastro-intestinal tract, obstetric conditions, urinary diseases, skin and subcutaneous conditions, diseases of musculoskeletal system and connective tissues, eye disease, intestinal infectious disease and disease of the upper respiratory tract (MOH 2012).

The top 10 causes of hospital deaths are: ischaemic heart disease, neoplasms, pulmonary heart disease, cerebrovascular disease, diseases of lower respiratory system, zoonotic and bacterial diseases, urinary diseases, pneumonia, diseases of gastro-intestinal tract, and traumatic injuries (MOH 2012).

Review of drug consumption, particularly in teaching hospitals, shows that the top drugs by value include a number of non-EML innovator drugs, including drugs used in viral infections, various types of cancer, organ transplants, angina, calcium and vitamin D supplementation, and in the anaemia of renal failure. It is surprising that these very expensive non-EML drugs are used since there are alternative less costly EML drugs available for these diseases, which are not all featuring in the top causes of morbidity and mortality.

Table 4.3.4 shows a comparison of unit procurement prices in USD between Sri Lanka, a government hospital in India and international prices. The unit prices of the top 24 drug items were compared with unit prices in Jawaharlal Institute of Postgraduate Medical Education and research (JIPMER) in Puducherry India, and with the 2014 Edition of the MSH International Drug Price Indicator Guide. It was found that Sri Lankan unit prices were approximately 53% more than those in JIMPER and 96% less than those in the MSH International Drug Price Indicator Guide.

Table 4.3.4: Comparative procurement unit prices of the top 24 items by value at the national level in USD

Rank	Item Name (including strength & formulation)	Sri Lanka unit costs	India unit costs (JIPMER Hos (Puducherry)	International (MSH) unit costs	% difference SLR/India	% difference SLR/MSH
1	Normal saline 500ml inj	0.37	0.23	0.5	38	-35
2	Trastuzumab 440mg inj	1508.69	624.77	1877.355	59	-24
3	Factor VIII 250 IU inj	68.69	52.82	75.8056 (300 IU inj)	23	
4	Sol/Isophane Insulin inj (?40 IU/10ml)	2.27	1.49	2.6	34	-15
5	Metformin 500mg tab	0.01	0.003	0.0262	70	-162
6	Paracetamol 500mg tab	0.01	0.003	0.0051	70	+49
7	Anti-Rabies vaccine	5.5	2.45	15.6334	55	-184
8	Hum.immunoglob 5-6g	167.92	125.44	NA	25	
9	Hum.immunoglob 2-3g	121.6	NA	NA		
10	Amoxicillin 250mg cap	0.12	0.01	0.0207	92	+83
11	Amoxyclav 1g/0.2g inj	0.77	0.46	1.37	40	-78
12	Human Albumin 20% inj 50ml	23.57	NA	28.16		-19
13	Rituximab 500mg inj	788.35	272.58	796.465	65	-1
14	Cephalexin 250mg cap	0.03	NA	0.047		-57
15	Meropenem 1g inj	3.35	2.67	9.255	20	-176
16	Atorvastatin 10mg tab	0.011	0.002	0.0533	81	-385
17	Beclomethazone inhaler/cap 400mcg	0.02 (400mcg)	0.02 (200mcg)	0.017 (250mcg)		
18	Clopidogrel 75mg tab	0.014	0.01	0.0775	29	-454
19	Losartan 50mg tab	0.012	0.002 (25mg)	0.0202	83	-68
20	Sod.valproate 200mg tab	0.03	0.01	0.1704 (500mg)	67	
21	Valganciclovir 450mg tab	18.4	2.55	20.5755	86	-12
22	Anti-D immunoglob inj	37.25	30.58	NA	18	
23	MMR vaccine 10 dose vial	Volume unknown	NA	0.2370/dose		
24	Desferioxamine 500mg inj	3.35	NA	6.7579		-102

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

Drug Procurement is done by the State Pharmaceutical Corporation (SPC) which is a semi -governmental organization (corporation owned by the government) which is trusted with the import, distribution and retail sales of pharmaceutical throughout the country. SPC procures medicines for the MOH as well as for the open market (where it operates on a for-profit basis) and is the largest distributor in the country. It employs 841 people and has an annual turnover of 22 billion Sri Lankan rupees. SPC supplies drugs for the open market through 31 *Rajya Osu Salas* which are the marketing outlets; 54 private distributors to retail pharmacies; 105 franchises and 11 authorized retailers. More than 9000 items were procured last year and a lot of time is taken up with small orders.

The SPC follows the Standard Procurement Guidelines prepared by the Government and approved by parliament in 2007.

The tender process is through a world-wide tender floated in newspapers. There is no electronic tendering process as yet. It is a single bid system. There are more than 1000 suppliers out of which 250 are regular suppliers. Eighty percent of the suppliers are from India and 55 drugs which are manufactured in Sri Lanka are also procured. Officials preferred drugs manufactured in Sri Lanka as the drug quality was good, there was flexibility in ordering, good storage, and satisfaction in promoting local manufacturers.

All products that are procured must be registered with the Drug Regulatory Authority. Manufacturers should have the capacity to produce three times the annual requirement of that particular drug. A technical evaluation committee evaluates the tender (costing 50-100 million SL rupees) and recommends procurement. This technical evaluation committee consists of the Deputy Director General (as chairperson), two medical consultants, one person from Finance department and one person from SPC. High volume and high cost tenders (more than 200 million rupees) will be sent to the cabinet for approval. Those which are less than 50 million rupees will be evaluated by an in-house evaluation team consisting of pharmacists. Approximately 900 items are procured for MSD and about 650-700 for *Rajya Osu Salas*. Value-wise about 80% of the procurement is for MSD and 20% for the local market.

Most of the medicines that are procured are essential medicines but non-essential medicines are also procured as they supply the retail market also. Quality assurance is done by sending samples from some batches for testing to the National Quality Control Drug Testing Laboratory. If a batch fails quality testing the supplier should replace all the supply of the particular batch or pay the value of the batch quantity plus pay 25% of the total value of the batch quantity as administrative charges. However, replacement of quality-failed stock is very problematic if it has been imported and very few items. Replacement has not been done in the recent past but SPC has surcharged according to the Government requirement. have been replaced by foreign companies. Many drug quality problems are detected after drugs arrive at the health facilities and samples are then sent to the NDQAL. Sometimes, all stock has been used up by the time notice of a quality failure arrives. Employing an agency to inspect and undertake random quality checks and tests of drugs within procurement consignments in the foreign exporting country could result in the prevention of poor quality products being exported and then “dumped” in Sri Lanka.

The common reasons for stock-outs are that (a) the MSD quantification process is delayed, (b) the lead time is one year, (c) high value tenders go to cabinet for clearance, and that (d) the tender process is

lengthy. Some orders placed in 2008 were getting processed in 2015. When drugs are out of stock, emergency tendering is done. There were 196 emergency tenders in 2014 and 77 so far in 2015. Drugs such as anti-snake venom, enoxaparin, human immunoglobulin, human albumin, and streptokinase were some of the drugs for which emergency tenders were floated. About 7 billion SLR were spent on emergency orders. Thus many of the procurement problems found in 2010 were similar in 2015 although it was mentioned that there had been harmonization between MSD and SPC with regard the electronic drug inventory systems. About 1.6% of GDP is spent on health. Previously one third of health budget was for drugs but now it is one quarter. About 35 billion Sri Lankan rupees are to be spent on medicines for this financial year.

4.4.2. Provincial/District/Health facility Drug Procurement

While health facilities are able to order drugs as per need from the MSD, according to their allocated budgets, in practice nearly all funds are controlled centrally. Only 10% of allocated budgets is available for teaching hospitals to undertake direct purchase, usually from the local *Rajya Osu Sala* pharmacy. Some base hospitals are also allowed to undertake local purchase if both they and the MSD have a stock-out and after getting permission from the MSD to do a purchase. It appears that health facilities are not refused medicines because of over-spending or lack of budget although they may not always be sent the full amounts that they order. All local purchases have to follow government rules and this means getting a minimum of three quotations from DRA-registered pharmacies including *Rajya Osu Sala* for all tenders and choosing the lowest priced products. If the medicine is available at *Rajya Osu Sala* it will be purchased from there at the offered price. However, one hospital mentioned not being able to do local purchase even when there was a stock-out because of lack of an accountant.

Previously, the MSD operated a quarterly push system but now a pull system operates with health facilities ordering monthly or even weekly. Teaching hospitals are now connected to the electronic management information system operated by MSD, so they can order through the internet and send their orders on-line to MSD. If drugs are out of stock, local procurement is done. Sometimes drugs which are urgently needed are given from another facility which is geographically closely located, if that facility has a large stock. However, some base and divisional hospitals mentioned that since the teaching hospitals had become linked up to the new electronic medicines supply management information system (MSMIS) they had no longer been able to send drug supplies from their stocks.

4.5. Allocation of budget for medicines in the public sector

Budget allocation for each province, district and health facility is decided centrally but how it is done is unclear. Teaching hospitals get 10% of their drug budget for local purchase. Some other larger base hospitals and RMSDs may do local purchase in the case of stock-out with the permission of the MSD but it is unclear whether the funds used for this are part of their own drugs budget or general hospital budget. Nevertheless it would seem that, depending on the type of facility, the number and types of medicines that can be ordered have been decided. Even if a facility underestimates their requirement stock is sent on request. At times, consultants order very expensive medicines which are not indicated. For example, Factor VIII is given to patients with Dengue, even though it is not required. This costs 70,000/= SLR per vial. MSD rarely refuses to supply medicines.

4.6. Drug quantification in the public sector

Drug quantities are estimated based on past annual consumption with a 10-15% increase. One hospital mentioned calculating annual requirements based on the average monthly consumption multiplied by 14 months (i.e. calculating for 2 months buffer stock). The estimation is done by the doctor or pharmacy assistant in the periphery and then sent to the regional store from where it is sent to MSD, where all information is collated and an extra 10% included for buffer stock. As space for storage is short, large stocks are difficult to manage. Since quantification is based on past consumption when there were stock-outs, it is likely that quantification methods will under-estimate stock needed. This problem may become less acute as the new MSMIS system is rolled out to lower level facilities, provided real-time monitoring of stock-levels is done.

4.7. Drug Management and Distribution in the public sector

4.7.1. Drug Storage and Distribution at the central national level

Drug storage and distribution at the central level is by the Medical Supplies Division (MSD). The MSD supplies the entire country through 26 regional medical supply divisions (RMSDs) and 53 Line ministry hospitals and institutions. The MSD places orders to SPC including dates of delivery and the SPC procures the medicines. The MSD produces a list which is used for procurement. The drugs on this list are selected by a team led by the Director General Health Services (DGHS) and including others such as pharmacists, pharmacologists and clinicians. This is called the hospital formulary list which is revised every three years and which is not the same as the national EML.

The central MSD is situated in Colombo and has 18 warehouses scattered in different parts of Colombo city. The main storage depot is situated where the offices of the MSD are housed. The MSD has a total cadre strength of 472 staff out of which there are 30 pharmacists. There are 71 vacant positions at present. Recruitment to these central positions is by the administrative division of MOH and by the Public Service Commission.

The RMSDs are under the control of the provincial councils and there is no uniformity in RMSD staff patterns which are not based on the population. Not all RMSD stores are managed or supervised by Pharmacists. Hence in some provinces which are thickly populated such as the Western Province, the RMSD has a difficult time with storage and distribution. All drugs reach the MSD in Colombo and are sent to the RMSDs from there. The central MSD has vehicles used for transportation. This also included refrigerated trucks for carrying drugs that have to be kept under refrigeration. RMSDs also have vehicles which are used to deliver the drugs to the peripheral units but they don't have sufficient number of vehicles and refrigerated trucks.

An electronic medicines supply management information system (MSMIS) is in place at the centre and in all the RMSDs and teaching hospitals. This e-MSMIS, though initiated in 2009, was extended to RMSDs and hospitals quite recently and has made ordering and supply tracking much more easy, quick and transparent. The re-structuring of the stock control unit to align with the new e-MSMIS is ongoing. Some officials felt

that the internal control could be better in order to prevent stock-outs. The MSMIS also allowed collection of consumption data as shown in tables 4.3.1, 4.3.2, and 4.3.3.

Distribution is mostly a pull system with stocks being sent out on a monthly basis. However, at times stock is sent at much shorter intervals and at times even weekly. The bottle-necks as described by the officials at the centre are:

- lengthy tender processes and a lead time of one year
- lack of storage space in many hospitals (particularly line ministry hospitals and teaching hospitals)so prohibiting storage of large volumes of drugs and thus resulting in frequent supplies.
- quality failures leading to stock-outs. When a product is withdrawn it is difficult to find alternate suppliers in a hurry. Hospitals are given permission to call for restricted quotations and procure locally. 196 emergency tenders were called last year, and during the first three months of this year 72 emergency tenders have been called. There were 12 product withdrawals and 99 batch withdrawals in 2014. If 5 batches of a drug product fail quality tests, the product is withdrawn.

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

The RMSDs have storage facilities to store stocks prior to distribution to peripheral hospitals and healthcare facilities. All regional stores had the new e-MSMIS and could connect with MSD in Colombo. The storage facilities at the RMSDs were reasonably good but could be easily improved without much financial outlay. The stores that were supervised by a pharmacist were managed well with proper arrangement of the drugs, First-in-First-out policy for distribution, segregation of expired items, and so on.

The stores that were managed by non-technical staff were not well maintained, nor adequately supervised. The limited floor space in the stores could have been overcome by vertical stacking. In some stores, nearly one third of floor space was taken up by drugs awaiting disposal as they were quality failed/expired. Storage of such quality-failed or expired drugs goes back to as far as five to twelve years. Timely removal and destruction of these stocks by SPC would permit better store management. One of the RMSDs visited had not been cleaned for some time and the discarded cardboard boxes were also lying inside the store. One drug (same molecule, strength and dosage form) was found in more than one location inside the store and some drugs were in direct sunlight. Broken window panes, a leaking roof and a general neglect of the store were found. There seemed to be an apparent lack of security for the stores.

In the line ministry hospitals, the store space was limited leading to drugs being stored in corridors, under stair cases and in any area where there was some space. Alternate arrangements for storage need to be made in these hospitals. The staff complained that the temperature was too high for storing drugs, that there was no air-conditioning of the store area and that large walk-in coolers to store drugs were needed but had not been procured. In one of the teaching hospitals peritoneal dialysis fluid was being stored in large plastic cans under the stair case and the medical officer commented that when patients needed to collect water, some of them would empty the can of its contents and take the can for personal use.

Drugs are distributed from RMSDs according to orders made by the health facilities, often weekly by larger hospitals but monthly by smaller hospitals and dispensaries. Some drug stock was redistributed between facilities within the same district. Some hospital pharmacists regularly watched slow moving stock and actively sought to redistribute the stock that was close to expiry to another hospital which had short

supplies and could use the stock. Likewise when they were short of stock they would actively seek out large stocks in another hospital and ask for some of it to be sent to them. This redistribution had become easier with the new MSMIS. However, smaller hospitals complained that since they were not yet included in the MSMIS system they were now excluded from getting stocks from larger hospitals redistributed to them in times of stock-out.

Medicines storage in OPD dispensaries was reasonably well done given the limitations of space, shelves, coolers, and so on. They were mostly arranged by therapeutic class. Stock registers were kept and mostly found updated. The smaller centres stocked the expired drugs along with the other drugs. The quality of medicines was uniformly good with good packaging.

Medicines in hospital wards were generally well stored in cupboards and resupplied weekly from the central hospital drug store. Documentation of ward stock-management involved quite heavy paperwork and varied across hospitals. There were often multiple stock-registers – different ones for tablets, syrups, injections, topical, etc. –which were usually well maintained. There was a separate register for highly priced medicines in one hospital and a separate drug purchase register in another hospital. In one ward, some drugs were very near expiry with many vials of different expiry dates all stored together. In one hospital, the nurses did not have sufficient dispensing and treatment sheets.

4.7.3. Pharmaceutical Human Resources

At MSD there were 472 staff for 605 positions, including 30 pharmacists. Vacant positions at the senior most level leave a gap in managerial activities. Some staff who had been managing the functions of the senior positions for a long time may not be appointed to the regular post due to recruitment policy changes.

In the periphery, there were few technical persons. Many drug stores were managed by store-keepers who have no training or knowledge in storage of pharmaceutical products and the principles involved. While, most positions were filled in the periphery, the strength was not adequate as many healthcare facilities relied on one person to do the duties of ordering, collection, storage, book-keeping, and dispensing. When that person was on leave there was nobody to do the job. In one health facility the cleaner was asked to dispense medicines. Positions were almost full in the RMSDs and district hospitals because the provincial councils make sure the posts are filled. Nevertheless, this was still not adequate for optimal functioning of the store as the store-in-charges go to Colombo often to collect the stock and then there is no one to manage the store in the RMSD.

4.7.4. Traditional Medicine

Traditional medical practitioners do not work alongside the other healthcare workers in health facilities. Hence in public healthcare facilities no traditional medicines are stocked or prescribed. Traditional medicine is practiced in separate clinics which dispense traditional medicine products. In the public sector there are 62 Ayurvedic hospitals, 208 Central Ayurvedic dispensaries, and 230 local government dispensaries which provide treatment free of charge (Ministry of Indigenous Medicine 2015).

It is not known to what degree patients must buy traditional products from private traditional practitioners or from private pharmacy shops.

4.8. Patient Flow in the Health Facilities

Most of the health facilities are overcrowded with large numbers of patients attending the outpatient clinics. Patients are registered at a counter in larger hospitals, only if they are admitted. In smaller healthcare centres, patients are given a slip of paper with a number and their name written on it, which is also entered into a register. No admission fee is charged. The patients stand outside the doctors' clinic and await their turn to be seen. Patients needing urgent treatment are treated in a separate ward and may be admitted if needed. Almost all medicines required for the management of these patients including syringes, dressings etc., are given free and were available.

Once the doctor prescribes medicines, patients go to the pharmacy counter and give their prescription which is then dispensed. The time taken by the doctor to elicit history, examine and prescribe is around 1-2 minutes per patient. The time taken for dispensing 3-4 drugs is also 1-2 minutes per patient including the time taken for locating the drugs, putting them into envelopes, and giving the patient instructions. The pharmacist notes down the name of the medicines to be dispensed but not the diagnosis. Patient registers recording diagnosis and treatment were not kept by doctors or other health staff in the OPD. Patients do not have to pay any fees for registration, inpatient or outpatient services of any sort, in public facilities.

4.9. Insurance

There is no health insurance for the majority of the population.

4.10. Drug Manufacturing

There is one government-owned manufacturer called the Sri Lanka State Pharmaceuticals Manufacturing Corporation which supplies 35 pharmaceuticals to the MSD. This manufacturer has been in existence since 1987 and has been a steady supplier to the government. Eleven private sector local manufacturers, more recently established, are registered at DRA, and they supply 56 pharmaceuticals to MSD on 5-year 'Buy Back' Agreement from 2015. Purchase preference has been given for locally manufactured pharmaceuticals since 2014 and procurement procedures have been exempted from tendering by having a Pricing Committee, appointed by Ministry of Finance, decide the prices.

4.11. Drug Management in the private sector

Eight private pharmacies and two *Rajya Osu Sala* pharmacies (government-owned) were visited in two districts. All of them were open for 12 or more hours per day. The pharmacies were mostly situated near both public and private health facilities, which serve those patients coming to the facilities or who are admitted in those facilities. Other private pharmacies were situated in the main shopping area of the cities and served patients coming to private doctors in their clinics, and also those who self-medicate. Pharmacies were owned by private owners who were not necessarily pharmacists, or by a chain. Though by law, it is necessary to employ a pharmacist, some did not have pharmacists serving customers. Untrained staff have learnt to read prescriptions and dispense drugs over a period of time.

In the shops visited during the situational analysis, the drugs on the shelves were arranged by therapeutic class. Pharmacies stocked from about 300 to over 3000 drug products. The number of suppliers engaged in supplying these pharmacies depended on the size of the pharmacy and the number of items on the shelves, and varied from 10 to over 200 suppliers. Most pharmacies received medical representatives frequently, sometimes daily, and in some shops the representatives brought re-supplies with them. The frequency of ordering supplies varied from daily to monthly. Daily sales varied from SRL Rs. 5000 in the smallest pharmacy to SRL Rs. 20,000 in the largest one. However, the *Rajya Osu Sala* pharmacies had much greater daily sales than this.

About half of the private pharmacies and the two *Rajya Osu Sala* pharmacies visited served only customers with prescriptions during the period of observation. One pharmacy served only self-medicating customers and the other pharmacies served a mix of customers. Interaction time between the dispenser and the patient was often less than a minute with about another two minutes to locate the drugs and put them into an envelope. Some pharmacies had envelopes made out of old newspapers and wrote on the envelope the name of the drug and the dosage frequency, but in one pharmacy no labelling was done. In the majority of private pharmacies a receipt was not given to the customer unless he/she specifically asked for one. By contrast all receipts were given for all purchases in the *Rajya Osu Sala* pharmacies.

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

In the public sector, drugs are procured by the State Pharmaceutical Corporation (SPC), a government-owned corporation, and supplied to health facilities through the Medicines Supplies Division (MSD) in the Department of Health Services, as was the case in 2010. Availability of key essential drugs was over 90% in teaching hospitals but 72-79% in lower level facilities, where some staff complained of stock-outs and where medicines normally reserved for higher level facilities were sometimes used.

Government has seriously followed the recommendation of the last situational analysis to extend the new electronic Medicines Supply Management Information System (e-MSMIS) (initiated in 2009 at the centre) to the regional medical supplies divisions (RMSDs) and the teaching hospitals, though not yet in the smaller hospitals where drug management is still done manually. As the MSD and RMSD realize the potential of this tool it will be used to generate data which can guide policy makers. Nevertheless, training of more staff in using the e-MSMIS is required. Methods of quantification and forecasting remain sub-optimal in some health facilities because these facility staff are still using manual methods, based on past drug consumption during which there were frequent stock-outs. However, the e-MSMIS started functioning in April 2014 in several RMSD stores and was fully functional in all stores from January 2015 so more accurate estimation for 2016 will be done through the past consumption data extracted from the e-MSMIS.

There is still limited harmonization between SPC and MSD, leading to delays. The process of drug procurement remains similar to what was done in 2010 and is not well coordinated with distribution and demand. Only a one-envelope international tendering system is used, technical and price criteria being submitted and judged simultaneously. The only quality criteria used in procurement is registration with the drug regulatory authority of Sri Lanka. Unfortunately, a number of stock-outs were caused by 12 product withdrawals and 99 batch withdrawals in 2014 due to quality testing failure and most of these product samples were referred by end-users in health facilities.

4.13. Medicines Supply: Recommendations

- Build on progress made since 2010 to extend the e-MSMIS already established at the centre and regional warehouses to all hospitals and train staff in using the system in order to improve stock management and forecasting.

- Employ at least one pharmacist to manage all hospital and regional warehouse drug stores and sub-stores in order to improve stock management.

- Review the State Pharmaceutical Corporation(SPC) procurement system with special attention to:
    - the tendering system with regard to technical criteria and whether to establish a 2-envelope system, where only the bids of suppliers passing the technical criteria are considered with regard to price;
    - changing the criteria for referral to cabinet for approval (from cost of individual products to the cost of the total tender) so that fewer tenders are referred to cabinet for approval (which would reduce procurement lead time);
    - employing a specialized agency within the foreign exporting country to undertake inspection and random quality check of products within procurement consignments, prior to export (so as to avoid poor quality products being “dumped” in Sri Lanka).

- Review drug management practices, particularly with regard to:
    - Storage conditions and use of vertical as well as horizontal space in warehouses and facility stores through the use of adequate shelving in health facility stores and warehouses;
    - Stock management and quantification procedures so to ensure timely orders and reduced lead time for new supplies;
    - Transport facilities in terms of lorries and human resources;
    - Regular supervision of drug stores and warehouses by senior officials;
    - Hospital inpatient ward management of drugs including the use of stock registers, and individual patient dispensing sheets;
    - Regional Directors of Health Services and Heads of institutions may do this and submit a comprehensive report to the Medicines Supply Division and the Director General of Health Services.

- Continue to promote local manufacturers because procurement from them is easier than importing medicines manufactured abroad, their drug quality is equally good, delivery is shorter, shelf-life is longer, and they may buy back supplies if nearing expiry.
    - May be done by giving tax incentives to the local manufacturers .and continuing to implement a purchase preference policy and exempting such purchases from normal tender procedures by arranging for drug prices to be decided by a Pricing Committee appointed by Ministry of Finance .

5. MEDICINE SELECTION

5.1. National Essential Medicines List (EML)

- Responsible government department or agency: National Drug Regulatory Authority
- Date of publication of latest EML: 2013-2014
- Previous publication dates: 2009
- Number of active pharmaceutical ingredients (APIs):361
- Number of formulations for all APIs:>400
- Number of traditional medicine products: None
- Number of products (incl. all brand names & formulations) registered on the market:8,095
- Categories by level of use:
    - Essential and complementary and also into 4 levels by facility type (dispensaries, divisional hospitals, district/ base hospitals and provincial/teaching hospitals).
- Number of persons involved in drafting the latest EML:
    - Core team: 8 experts, including the Director of Medical Technology and Supplies, MOH
    - Experts: 70 specialists, representing most of the major specialties including community medicine, though not general practice or general surgery. It is not clear how many experts came from the provinces.
- Consistency with national STGs?
    - There are no national STGs, covering all the major diseases in one book, developed by government. There are a few treatment guidelines for specific individual conditions developed by MOH e.g. Factor VII, VIII, IX usage guidelines; Haemophilia treatment guideline; Antibiotic guidelines for intra-abdominal infections, oral cavity and related structures, pregnancy related infections, severe sepsis and septic shock, antibiotics in special conditions, infections of the eye, medical prophylaxis, sexually transmitted infections, specific infections like tetanus, brucellosis, enteric fever, typhus etc.; Dengue treatment guidelines; General manual for Tuberculosis control; Leptospirosis treatment guideline; Malaria treatment guideline; Human influenza treatment guidelines; etc.. All the drugs mentioned in these guidelines are in the national EML.

5.2. Other Medicine Lists

5.2.1. Central level

The MSD has a list (the Hospital Formulary List) which it uses to order drugs from the SPC. This had all the national EML drugs as well as some non-EML drugs listed. All drugs on the MSD list were classified into Vital, Essential and Non-essential. While there was high consistency between the national EML and the MSD list, a few drugs on the national EML were classified as non-essential in the MSD list. In the past, the MSD list has been compiled taking into account various specialist requests and also after receiving quotes of non-EML drugs from foreign suppliers sometimes as alternatives to EML ones.

5.2.2. Province/Region

Regional Medical Supply Divisions (RMSD) used only the MSD list for ordering purposes. Thus they commonly ordered a few drugs that are on the MSD list but not on the national EML, such as losartan, alfacalcidol and calcium carbonate. It was explained that the MSD list includes some non-EML drugs to treat special rarer ailments such as alfacalcidol and calcium carbonate which are requested to treat Chronic Kidney Disease prevalent in several districts.

5.2.3. Hospital

District hospitals use only the MSD list, getting their medicines through the RMSDs. However, teaching hospitals (which have 10% of their budgets available for discretionary local purchase)also procure non-EML drugs either from the MSD or from other sources if the MSD is unable to supply these drugs. Thus, teaching hospitals were commonly using some drugs that were neither on the national EML and classified as non-essential on the MSD list e.g. Rituximab Injection, Basiliximab IV injection, Infliximab injection, , Erlotinib Hydrochloride tablet, Peginterferone alfa injection, Nimotuzumab injection, , Valganciclovir tablet, Nicorandil tablet, and Imatinib mesilate capsules (see table 4.3.3)

5.2.4. Insurance

There is no insurance in the public sector apart from the insurance scheme for all government workers from the state owned insurance company, Sri Lanka Insurance Corporation which reimburses hospital bills for inpatient care in private hospitals and pays Rs.500 per day for inpatients treated in Government hospitals). Private insurance schemes will reimburse the cost of any medicine (whether EML or non-EML) from private hospitals provided the prescription is written by the consultant.

5.3. Development / updating of national EML

Currently, the national DRA is responsible for the updating of the national EML, although in past years the MSD had been responsible. Responsibility for updating the EML had moved from the MSD to the DRA when the Director of MSD was transferred to be the Director of the DRA. The latest national EML was published in 2013-2014. The previous EML was published in 2009. It does not contain any traditional medicines. All APIs listed are registered in Sri Lanka. The list has core essential and complementary drugs (minimum needed medicines for basic healthcare) and complementary drugs (requiring specialized diagnosis/ monitoring/ healthcare) in the same manner as the WHO Model EML. The EML also sets out the facility type for each of the drugs listed thereby clearly indicating the level of use. The present list has 361 drugs divided by 4 levels of care (Level 1 – Primary Medical Care Unit, Central dispensaries, Maternity Homes; Level 2 - Divisional Hospitals, , rural hospitals, peripheral unit; Level 3 – District Base Hospital, District General Hospital; Level 4 – Provincial General Hospital, Teaching Hospital).

Sri Lanka follows the methodology adopted by WHO to a large extent in preparing/updating their national EML. The core committee for the fifth edition was a group of eight carefully chosen experts, some of whom have served in the WHO expert committee. There is also transparency in the process of preparation and a large number of healthcare professionals from around the country contributed to this edition. The committee membership included government officials and consisted of all persons involved in the prescribing, dispensing, procurement, regulation, transportation and financial aspects of medicines. The committee had regional representation and support from government and WHO.

The EML booklet acknowledges 70 experts who contributed to the process but the list does not include any general surgeon or general practitioner and it is not clear how much geographical representation there was. The chairperson and the secretary of the EML committee were those with experience in updating the WHO model EML and who have first-hand knowledge and experience in the process. Hence they brought in the transparency and procedural formalities that were required for this activity. There were no external experts or consultants from WHO in this committee as Sri Lanka has the necessary technical expertise to update the list.

The selection criteria were evidence-based and depended on efficacy, safety and price. Sources of evidence included published reviews, meta-analyses, and clinical trials published in peer reviewed journals, various clinical guidelines and the WHO model list.

The process for addition and deletion was not as structured as it is for the WHO Model list. Consultants who wanted to add new drugs gave a write-up with the reasons. This was checked against the evidence. Three main criteria which were considered in addition to efficacy, safety and cost-effectiveness were (a) whether the drugs were registered in Sri Lanka, (b) whether they were in the list of medicines used for procurement, and (c) whether they could be used in the facilities available in the country. The process was fairly transparent and minutes recorded. All members declared their conflicts of interest.

5.4. Implementation of EML

Implementation the national EML has not been proactive and implementation is sub-optimal, particularly at the level of teaching hospitals. After the latest revision of the EML, a small booklet was printed and distributed to a few of the people involved in the updating process. Large nationwide distribution has not been done, although it could easily be sent out to health facilities along with the drug supply. The EML is available on the website of the Drug Regulatory Authority for download, although downloading is not easy. No other website has the current EML at the time of writing this report. No EML booklet was found in any health facility and the new EML does not appear to have been distributed to medical schools for inclusion in the medical student curricula. Review of health facility ordering lists showed some non-EML drugs in the lists of MSD and teaching hospitals.

The National EML appears to be viewed by many central policy makers and clinicians as an academic exercise which the country needs so that it is seen to be keeping in line with the WHO policy rather than being useful at the ground level in the health facilities. Some consultants in the major cities insist on prescribing very expensive medicines which are not on the national EML. Hence procurement, and thus use, are based on the MSD list rather than the national EML. This MSD list is more extensive than the national EML and, while drugs are classified into Vital, Essential and Non-Essential, the criteria used are unclear. Furthermore, it was mentioned that some expensive non-EML drugs were not used after purchase by the MSD and subsequently expired – usually because the concerned consultant had transferred to a different hospital by the time the concerned drug arrived at the hospital.

Public sector compliance with the national EML was quite high, mainly due to the central supply of drugs by the MSD and fairly good consistency between the MSD list and the national EML, particularly with regard to drugs for use at district base hospital and lower level facilities. In the previous situation analysis in 2010 the percentage of prescribed drugs that were from the EML was 99% while this time round in 2015 it was 90-93% in public facilities. By contrast, the percentage of prescribed drugs that were from the EML in the private sector was much lower, being 57% in 2010 and 49-53% this time round in 2015.

Thus, there appears to be a very slight fall in EML compliance and this may point to the fact that there is little continuing medical education (CME) on rational use of medicines or on the Essential Medicines concept. Furthermore, there was evidence of availability of higher facility drugs at lower levels e.g. omeprazole, norfloxacin, clarithromycin, and co-amoxyclav in some dispensaries. As mentioned previously, availability of 33 key essential drugs was 90% in teaching hospitals, 79% in base & divisional hospitals, and 72% in dispensaries (taking into account levels of use). Non-availability of some EML medicines may lead to use of other medicines. Few of the prescribers met in health facilities knew that the national EML was different from the MSD list or could say much about the national EML. Thus, it seems that while those involved in policy development at the central level may all be convinced of the usefulness of the essential medicines concept there seems to be very little awareness and confidence at the peripheral level.

Table 5.4.1 show some data on EML implementation.

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

Public Referral Hospitals	Referral Hospital 1	Referral Hospital 2	Referral Hospital 3		Average
% key EML items available*	84.5%	87.5%	96.9%		89.6%
% prescribed drugs belonging to the EML**	86.9%	94.0%	88.8%		89.9%
EML booklet available in pharmacy?Yes/No	No	No	No		No
Public Divisional and Base Hospitals	Base Hospital 1	Divisional Hospital 1	Base Hospital 2	Divisional Hospital 2	Average
% key EML items available*	66.7%	42.4% (58%)	100%	75.0% (93%)	71% (79%)
% prescribed drugs belonging to the EML**	94.0%	86.6-98.6%	90.5%	95.5%	93.2%
EML booklet available in pharmacy? Yes/No	No	No	No	No	No
Public primary health care centres / dispensaries	Dispensary 1	Dispensary 2	Dispensary 3		Average
% key EML items available*	64.5% (86%)	45.2% (50%)	67.8% (81%)		59% (72%)
% prescribed drugs belonging to the EML**	85.0%	98.0%	93.0%		92.0%
EML booklet available in pharmacy? Yes/No	No	No	No		No
Private pharmacies in Galle	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
% key EML items available*	81.0%	71.4%	84.8%	81.8%	79.8%
% prescribed drugs belonging to the EML**	71.4%	63.6%	25.8%	35.5%	49.1%
EML booklet available in pharmacy? Yes/No	No	No	No	No	No
Private pharmacies in Anuradhapura	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
% key EML items available*	83.3%	92.6%	?	81.8%	85.9%
% prescribed drugs belonging to the EML**	72.7%	53.8%	30.6%	54.7%	53.0%
EML available in pharmacy? Yes/No	No	No	No	No	No
Public Osu Sala pharmacies	Osu Sala 1	Osu Sala 2			Average
% key EML items available*	100%	85.2%			92.6%
% prescribed drugs belonging to the EML**	55.4%	59.8%			57.6%
EML available in pharmacy? Yes/No	No	No			No

* Belonging to the national EML - please see the same indicator recorded in table 4.2.1.

** From prescription audit done during the health facility surveys – please see the same indicator recorded in table 6.3.1. In one divisional hospital, where a range is shown, some drugs prescribed for outside purchase could not be reviewed and so estimates were made for EML compliance based upon all or none of the drugs for outside purchase belonging to the EML.

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

As was recommended in 2010, the national Essential Medicines List (EML) was updated in 2013, using a sound and transparent process, after a gap of four years. However, the updated national EML was not widely disseminated and appears not to be used for pre-service and in-service training. The utility of following the EML though taught in the medical student curricula is not followed because of the lack of role models, national STGs and strict implementation of policies related to rational use of medicines.

At present, nearly all non-EML drug requests by consultants are procured without any real processing through the hospital Drug and Therapeutic Committees (DTCs). While the recommendation of the 2010 situational analysis to establish DTCs in all hospitals has been followed the spirit of the recommendation to have all non-EML purchase requests justified and reviewed by these DTCs has not been followed. Similarly, the 2010 recommendation that colleges and specialists boards provide guidance on "reasonable" specialist drugs for non-EML purchase and that a permanent national sub-committee be established to decide on such requests has not been followed.

The national EML and MSD procurement list are not completely harmonized and are actually prepared by two different agencies – the drug regulatory authority and the MSD, respectively. Unless there is harmonization of the national EML and the MSD procurement list, with close alignment to recommended treatment protocols for different levels of healthcare, plus strict monitoring of non-EML drug procurement, compliance with, and utility of, the national EML will remain limited. If the national EML were prepared by the MSD rather than the Drug Regulatory Authority (DRA), harmonization of the MSD list and national EML would be easier. The new e-MSMIS being set up, as recommended in 2010, will make monitoring of EML compliance easier.

5.6. Drug Selection: Recommendations

- Continue to update regularly the national EML in a transparent manner with wide representation, which would include:
    - Establishing a Standing Committee on Essential Medicines with representation from all the specialties (including general practice, pharmacology and pharmacy) and a mandate to regularly revise the EML list;
    - Using the e-MSMIS portal to disseminate information in the updating process;
    - Coordination of activities by the MSD.

- Harmonize the national EML and the procurement list of the MSD:
    - will require harmonization of activities between the Hospital Formulary Committee and the proposed national Standing Committee in updating EML list.

- Monitor compliance to the national EML list (taking into account facility and prescriber type) through regular surveys and collection of data on prescribing patterns and drug utilization:
    - to be done by DTCs in major hospitals, and by a regional committee comprising MOH, Divisional pharmacists and Food and Drugs Inspectors[) under supervision of the Regional Director of Health Services (RDHS) for other health facilities and the private sector .
    - All surveys to be reported to the Standing Committee of the EML and to MOH

- Ensure stricter adherence to the EML by:
    - Programme of educating prescribers and dispensing officers on the use of the national EML to be coordinated by the Standing Committee on Essential Medicines;
    - Referral hospital DTCs judging all requests for non-EML drugs;
    - Colleges and specialists boards providing guidance on “reasonable” specialist drugs for non-EML purchase;
    - Permanent sub-committee judging all out-of-list requests at the national level.

6. MEDICINE USE

6.1. Responsible Agents/Departments

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Monitoring medicines use in hospitals	√		Hospital DTCs are responsible though little monitoring is done
Monitoring medicines use in Primary care	√		Not done
Development of national STGs		√	Sri Lanka Medical Association though the individual colleges.
Development of national formulary	√		Medical Supplies Division (MSD)
Drug Information Centre		√	Department of Pharmacology, University of Colombo
Provision of independent drug information		√	Department of Pharmacology, University of Colombo
Monitoring Hospital DTCs	√		National DTC coordinated by the MSD
Monitoring Hospital quality of care			Health Care Quality & Safety Division headed by a Director under DDG/Medical Services
Monitoring DTCs in provinces/districts	√		Regional Director Health Services (RDHS)
Undergraduate education for health professionals		√	University of Colombo and other universities with medical schools
Continuing medical education for health professionals		√	Sri Lanka Medical Association
Public education on medicines use			No national public education campaign done
Implementing generic policies			Not done

6.2. Past prescription surveys

Only one previous prescription survey done in the last 10 years was identified – the one done during the situational analysis of 2010, results shown below.

Table 6.2.1: Results of situational analysis prescription survey done in 2010

Indicators	Holloway KA. Pharmaceuticals in Health Care Delivery: Situational analysis. WHO/SEARO, 2010.
Year of survey	2010
Facility type	2 teaching hospitals, 1 district hospital, 2 PHC facilities and 5 pharmacies
Public / private	5 public facilities, 2 public and 3 private pharmacies
Average number of drugs per patient	Public 3.0; Private 3.5
% patients prescribed antibiotics	Public 49%; Private 23%
% patients prescribed vitamins	Public 23%; Private 22%
% drugs prescribed by generic name	Public 63%; Private 37%
% prescribed drugs belonging to the EML	Public 99%; Private 57%
Average cost per prescription	SRL Rupees 685

6.3. Current prescribing practices

A prescription survey in public facilities was done reviewing 30 consecutive 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 addition to this, 15-30 patients coming to the OPD dispensary were asked by the pharmacist whether they had come to the facility for a cough, cold, sore-throat, runny nose or earache – all symptoms of upper respiratory tract infection – and a record made for those with such symptoms on whether an antibiotic had been prescribed. This was done because prescriptions did not have any diagnosis written nor were prescribers keeping any patient registers with diagnosis and treatment recorded.

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 pharmacies 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.

Table 6.3.2: Results of prescription audit from health facility survey

Public referral hospitals	Referral Hospital 1	Referral Hospital 2	Referral Hospital 3		Average
Average number of drugs per patient	3.5	2.8	4.1		3.5
% patients prescribed antibiotics	48.4%	33.0%	54.2%		45.2%
% patients prescribed injections*	-	-	1.7%		< 5%
% patients prescribed vitamins	20.0%	17.0%	28.9%		22.0%
% drugs prescribed by generic name	64.6%	67.0%	72.2%		67.9%
% prescribed drugs belonging to the EML	86.9%	94.0%	88.8%		89.9%
% URTI patients prescribed antibiotics	-	33.0%	61.0%		47.0%
Public Divisional and Base Hospitals	Base Hospital 1	Divisional Hospital 1**	Base Hospital 2	Divisional Hospital 2	Average
Average number of drugs per patient	3.4	2.7	3.7	4.8	3.7
% patients prescribed antibiotics	71.7%	70.0%	58.3%	69.0%	67.3%
% patients prescribed injections	-	-	1.7%	-	< 5%
% patients prescribed vitamins	6.7%	3.3%	13.4%	14.3%	9.4%
% drugs prescribed by generic name	81.6%	90.3%	75.7%	81.6%	82.3%
% prescribed drugs belonging to the EML	94.0%	86.6-98.6%	90.5%	95.5%	93.2%
% URTI patients prescribed antibiotics	89.6%	-	78.4%	93.1%	85.4%
Public primary health care centres / dispensaries	Dispensary 1	Dispensary 2	Dispensary 3		Average
Average number of drugs per patient	3.0	2.3	3.3		2.9
% patients prescribed antibiotics	38.7%	74.0%	40.0%		50.9%
% patients prescribed injections	-	-	3.3%		< 5%
% patients prescribed vitamins	15.9%	6.5%	16.7%		13.3%
% drugs prescribed by generic name	74.6%	77.0%	76.0%		75.9%
% prescribed drugs belonging to the EML	85.0%	98.0%	93.0%		92.0%
% URTI patients prescribed antibiotics	37.5%	100.0%	66.7%		68.1%

*Patients prescribed injections went straight to an injection room or inpatient ward for administration and the injection was not recorded on the same prescription presented to the OPD dispensary so that injection usage could not be estimated except by reviewing the injection register in the OPD and the injection register in the ward for all patients discharged the same day and comparing the number of patients receiving an injection with the total OPD attendance.

** In one divisional hospital, where a range is shown, some drugs prescribed for outside purchase could not be reviewed and so estimates were made for EML compliance based upon all or none of the drugs for outside purchase belonging to the EML.

Table 6.3.2 prescribing consolidation sheet continued

Private pharmacies in Galle	Pharmacy 1	Pharmacy 2	Pharmacy 3	Pharmacy 4	Average
Average number of drugs per patient	2.6	2.2	3.1	4.1	3.0
% patients prescribed antibiotics	12.5%	20.0%	20.0%	34.6%	21.8%
% patients prescribed injections	0%	0%	0%	0%	0%
% patients prescribed vitamins	0%	10.0%	0%	26.9%	9.2%
% drugs prescribed by generic name	33.3%	68.2%	30.0%	14.9%	36.6%
% prescribed drugs belonging to the EML	71.4%	63.6%	25.8%	35.5%	49.1%
Average cost per prescription SRLRs	-	557.86	-	714.38	636.37
Private pharmacies in Anuradhapura	Pharmacy 1*	Pharmacy 2*	Pharmacy 3	Pharmacy 4*	Average
Average number of drugs per patient	1.4	1.4	2.2	1.8	1.7
% patients prescribed antibiotics	25.0%	21.4%	5.4%	56.7%	27.1%
% patients prescribed injections	0%	0%	0%	0%	0%
% patients prescribed vitamins	0%	14.3%	11.4%	6.7%	8.1%
% drugs prescribed by generic name	?	25.6%	29.1%	30.2%	28.3%
% prescribed drugs belonging to the EML	72.7%	53.8%	30.6%	54.7%	53.0%
Average cost per prescription SRLRs	149.88	202.00	537.94	178.19	267.00
Public Osu Sala pharmacies	Osu Sala 1	Osu Sala 2			Average
Average number of drugs per patient	3.2	3.7			3.5
% patients prescribed antibiotics	21.9%	24.1%			23.0%
% patients prescribed injections	3.1%	0%			1.6%
% patients prescribed vitamins	6.3%	13.8%			10.1%
% drugs prescribed by generic name	19.8%	25.2%			22.5%
% prescribed drugs belonging to the EML	55.4%	59.8%			57.6%
Average cost per prescription SRLRs	550.90	678.53			614.72

*Many OTC self-medicating patients

The prescribing survey shows similar prescribing patterns to that seen in 2010, though the number of medicines prescribed per patient appears to have increased slightly from 3.0 to 3.0 - 3.5 and the % patients prescribed antibiotics from 45% to 45-67% in the public sector. Antibiotic prescribing for upper respiratory tract infection (URTI) was very high in all facility types but appeared to be worse in district hospitals where 82% of patients with URTI were prescribed antibiotics as compared to 47% in teaching hospitals and 68% in dispensaries.

Vitamin use remains similar to 2010 in teaching hospitals where 22% patients received vitamins but appears to have decreased (improved) in district hospitals and dispensaries where 9-13% of patients received vitamins. Injection use remains admirably low. Likewise prescribing by generic name remains similar to 2010 in teaching hospitals where 65% of drugs were prescribed by generic name but appears to have increased (improved) in district hospitals and dispensaries where 75-82% of drugs were prescribed by generic name.

As found in 2010, and as expected, prescribing by generic name and according to the national EML was much lower in the private as compared to the public sector. The % of patients receiving antibiotics was lower in the private pharmacies compared to the public facilities due to the greater proportion of chronic patients included in the prescription sample.

The drug cost per prescription in the *Rajya Osu Sala* and some private pharmacies was similar to what was seen in 2010 which is perhaps surprising when considering general inflation and increased prices. However, the drug cost per patient was observed to be much lower in the pharmacies in Anuradhapura district and this was due to these pharmacies being smaller and more rural and serving more self-medicating patients.

The quality of prescriptions was rather unsatisfactory. In both the public and private sectors, many prescriptions were illegible. Many acronyms (PCM for paracetamol, AMO for amoxicillin) were used but generally, particularly in the public sector, the dispensers could easily decipher the prescriptions. The quality of prescribing depended on individual doctors who clearly were not following any STGs. In one public facility, almost every patient with a respiratory infection was prescribed an inhaler (steroid or beta agonist), the same beta agonist as an oral formulation, one antibiotic and one anti histamine. In another public facility almost all patients received an anthelminthic. For some cases of cough and cold, two antibiotics (cephalexin and nitrofurantoin) plus prednisolone or dexamethasone was prescribed. Although most doctors were satisfied with the drug supplied, some doctors had the idea that drugs purchased outside the hospital were better than the government ones. One doctor stated "*I like to prescribe better drugs so I give prescriptions for outside purchase which the patients can pay for even if they cannot afford to see a private doctor*."

In outpatients, it appeared that many general doctors were seeing more than 100 patients a day, with consultation times often of 1-2 minutes, and thus lack of consultation time may contribute to poor prescribing practices, polypharmacy and unnecessary hospital admission.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

The dispenser-patient interaction time in all outpatient clinics was less than two minutes from the time the patient came up to the dispensing counter till he/she left the counter which included the physical act of finding and dispensing the medicines as well as talking to the patient. Dispenser-patient interaction times were generally less than one minute. Most public facilities labelled medicines with the names of the medicines, strength and frequency of intake. A few of the facilities did not do any labelling. The dispenser explained the dosage to the patient once only and there was hardly any time for the patients to clarify their doubts. Tablets were counted by hand and patients were asked to split tablets when necessary. In one centre a tube of ointment was observed to be cut in half with scissors and the top half dispensed to one patient and the bottom half to another patient. In one facility, all medicines were put into one envelope with dosing instructions written on the envelope for the white pill and the red capsule.

Prescriptions were given back to the patients. All pharmacies recorded the name of the patient, age and drugs dispensed in a dispensing register. Though doctors prescribed by brand most of the time, except for drugs like paracetamol which was written in an acronym, generic medicines were substituted. Therapeutic substitution was not recorded.

The dispensing was usually done by pharmacists in the larger hospitals and by trained dispensers in the central dispensaries and rural hospitals. The workload was rather high with each pharmacist or dispenser attending to at least 100 to 150 patients in a day. The problem was acute in places where there was only a single pharmacist or dispenser posted. When this person took leave someone else had to double up. In one place an untrained person was called to dispense for a long period of time.

6.4.2. Health Facility Inpatients (wards)

In the wards, the medicines were dispensed by the nurses at the patients' bedside from a drug trolley in which the patients' medicines were kept. The bottles in this drug trolley were filled from a stock cupboard in the ward. The drug stock was re-filled from time to time usually on a weekly basis. Individual drug dispensing sheets were kept for each patient and the medicines given were entered by hand. Narcotic agents were kept under lock and key.

The quality of prescription was inadequate as it was found that in many cases the orders were written once and then repeated by number. Thus, transcription errors may arise with the system that is being followed. At times antibiotics were being given for long duration without any review. Some hospitals did not have facility for culture sensitivity testing.

In one hospital the doctor in charge complained that though insulin was available for diabetic patients the hospital did not have a glucometer. The strips which are required for testing were quite expensive and the hospital often ran out of stock. Hence monitoring became a problem.

6.4.3. Private retail pharmacies

In the private retail pharmacies also the dispensing time was under 3 minutes from the time the patient steps up to the counter until he/she left the pharmacy. The dispenser-patient interaction time was often less than one minute. Labelling was not done. In most private pharmacies, the medicines were put into an envelope, sometimes made of old newspaper. At times the dispenser wrote the number of tablets to be taken on the envelope. The prescription was always handed back to the patient.

6.5. Policies to promote rational use of medicines

6.5.1. Monitoring and supervision of prescribing/dispensing by supervisors

Prescription audits, drug utilization reviews and indicator studies were not done routinely. None of the officers interviewed could recall anything that was done. Thus prescribing and dispensing are not monitored. Though hospital DTCs are supposed to monitor, they are not doing so since all their focus is on availability of drugs only. Prescribing and dispensing comes under responsibility of the MOH, as the MOH

recruits health staff, transfers them and posts them to different healthcare facilities. However, no government unit appears to be monitoring the treatments given. The consultants can prescribe any medicine they want and it will be procured. This fact is well known and the ABC analysis shown in table 4.3.3 is evidence of this fact. As can be seen many monoclonal antibodies are within the top 20 drugs. When this issue was discussed, the hospital directors agreed that prescription monitoring could be done under their supervision, though with the actual work being done by the pharmacists. However, monitoring consultant prescribing would not be easy as they have been given a carte blanche by everyone in past years. Unfortunately the poor prescribing practices of senior doctors are imbibed by the junior doctors.

6.5.2. Standard Treatment Guidelines (STGs)

National STGs, covering all common disease in one book, have not been developed. There are a few treatment guidelines for specific individual conditions (as mentioned in chapter 5) developed by MOH and which the DGHS has instructed be published on the web in order that doctors be encouraged to follow them and the posted documents do not seem to reach them. However, there seems to be little active dissemination of these guidelines and no monitoring to see whether they are adhered to.

Some STGs were developed by the Sri Lanka Medical Association (SLMA) using their own funds. The different professional colleges prepared their own STGs with funding from World Bank in 2007. Although it was reported that the various STG booklets had been sent to all hospitals, no STGs of any sort were seen at any clinic or hospital. Furthermore, none of the doctors interviewed had seen any of the aforementioned STGs. It was mentioned that there was inconsistency between the various STGs developed by the professional colleges and the SLMA and the national EML, that an evidence-based process had not always been followed in developing the STGs and that not all interested parties had been involved. This is probably the reason for there being no consensus on the use of STGs by consultants. In addition, some doctors may not believe in the utility of STGs. One general doctor stated that "*according to STGs, one must treat coughs, colds and fever with paracetamol and/or chlorpheniramine and only give antibiotics later if there is no response but I like to give the complete treatment from the start*" (the complete treatment including antibiotics).

6.5.3. National Formulary

No national formulary has been published since 1994, so in practice no national formulary was in use. No copy was available to be seen and it is not used in training. By contrast, the British National Formulary is used in both the public and private sectors and is taught to medical students.

6.5.4. Drug information Centre

There is no government-run national Drug Information Centre, but the Pharmacology department in the University of Colombo runs a local unit, supported by the university. It is only open during office hours and supplies information regarding drug dosage, strength, availability, drug interactions, indications, contraindications, and so on, to whosoever asks for it. However, it is not clear whether any prescribers outside of Colombo university attached hospitals use it. The frequency of use is quite low as most people

are able to navigate the internet and get information. Some other teaching hospitals also have their own drug information units. None of the health workers met had used any drug information centre.

6.5.5. Independent drug information

Sources of independent drug information are few. Very few doctors had seen any of the STGs developed. Some doctors were receiving the Sri Lanka Prescriber (produced by the SLMA and sponsored by the SPC) and some teaching hospitals were receiving the Australian Prescriber and 1-2 other journals.

6.5.6. Drug and Therapeutics Committees (DTCs)

As recommended in the 2010 situational analysis, DTCs have now been established in all secondary and tertiary hospitals. In general, the DTCs have been established by upgrading the previous hospital Drug Review Committees that used to review drug shortages. A national DTC, chaired by the DGHS, has also been established under the coordination of the MSD, and is required to review information from the peripheral DTCs. Hospital DTCs consist of the head of the hospital/medical superintendent, the pharmacist, the nursing supervisor or matron, and one or two consultants. In regional level DTCs, the Regional Director of General Health Services (RDGHS), the medical officers in charge of the hospitals under the region, and the person in charge of the RMSD, are members. The meetings are usually held once a month.

The stipulated functions are to: review drug availability, distribution and storage of medicines; discuss issues in provision of health care; review prescription audits and monitoring of medicines use; to discuss budget issues; and to review drug policies. In practice, however, almost all the time is spent on discussing drug non-availability only. None of the DTCs in the hospitals and regions visited had been involved in a prescription audit and none discussed rational use of medicines.

Forming DTCs was one of the recommendations of the situational analysis done in 2010 which was implemented. However, many of the doctors in the periphery were not clear of the objectives and usefulness of DTCs. Some mentioned that only senior people are given the opportunity to state their problems and discuss them so most junior and mid-level doctors keep quiet. In the regional DTCs, it was stated that the peripheral hospitals do not get to state their problems as the senior people in the committee only discuss non-availability at the larger hospitals. Thus, it would appear that there needs to be a change in the manner of functioning of the DTCs and that the chairpersons should start focusing on the rational use of medicines, as well as drug availability.

6.5.7. Undergraduate education on medicines use

Curricula for medical students include the Essential Medicines Concept but the national EML is not formally taught. Since the national formulary is 20 years old and not available and since there are no national STGs, these cannot be taught. However, the British National Formulary is taught. There is modular teaching, problem –based pharmacotherapy and teaching of rational prescribing practices. However, it was mentioned that while prescribing principles are taught at undergraduate pre-clinical level in sufficient detail, this is not followed up during clinical studies so that rational prescribing principles may be undermined by later clinical studies and work with senior consultants. Nevertheless, all medical students are provided an

internship in the government sector and most go on to serve in government hospitals so they are exposed to use of medicines on the national EML. The curricula for pharmacy students do cover drug supply chain management, clinical pharmacy and good pharmaceutical care.

The curricula for the various courses are set by the university and the MOH has no role in them. Although teaching hospitals have departments of pharmacology, the faculties are not generally engaged in clinical patient care or in providing continuing medical education or in-service training to clinical undergraduate students and postgraduate training doctors. Students of modern medicine are not taught anything of traditional medicine.

There are various types of pharmacy education, including bachelor (4 years study) and diploma (2 years study) levels. Most working pharmacists are diploma level. There are also certificate-level "pharmacists" who work in retail pharmacy shops and who obtain their qualification by doing several months apprenticeship with another "pharmacist" who may also have a certificate-level qualification and who may be totally unsuitable to teach novices. At the end of the apprenticeship the student must sit the certificate exam which is run by the Ceylon Medical College Council. According to the law, a retail pharmacy need only be managed by a certificate-level "pharmacist" but many pharmacologists and graduate pharmacists complained about the level of competency of these certificate level "pharmacists" and felt they should not be called "pharmacists" and that their education should be changed.

6.5.8. Continuing Medical Education on medicines use

Continuing medical education (CME) does not include much on prescribing or rational use of medicines and for most part consists only of lectures sponsored by the pharmaceutical industry. While the SLMA and SLMC do hold monthly meetings, these are not mandatory. For most prescribers, CME is adhoc or minimal and visits by pharmaceutical representatives are frequent or sometimes daily. All doctors graduating from medical schools in Sri Lanka are provided an internship in the government health sector and the majority continue in government service so there is an opportunity, perhaps not sufficiently utilised at present, for further teaching on the utility of following the national EML and other rational prescribing principles.

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

There have been no public education campaigns on prudent use of medicines in the last ten years. However, there was one very successful campaign on the use of ORS for diarrhea many years ago. All MOH health facilities have a public education unit that is used to spread various public health messages in the community. The MOH, mainly the Family Health Bureau, decides the topics to be taught. So far these units have not been used to spread any messages for the public on the prudent use of medicines. Many people felt this would be good to do undertake public education campaigns as patient demand for drugs is high and there is much overuse of antibiotics. 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 2 medicines".

6.5.10. Generic Policies

There are no generic prescribing policies. Most doctors write many drugs by brand name, particularly in teaching hospitals and the private sector. Generic substitution is legal and is undertaken in the public sector and sometimes in the private sector. Doctors use the well-known brand names to prescribe medicines even if they know that it is the generic drug that is given in public hospitals. In private sector, most doctors insist on the same brand as they prescribe being dispensed and use a prescription stamp to prohibit generic substitution for branded products. Since the income of private pharmacies comes from percentage mark-ups, the retailer also has an incentive to sell the branded product rather than a generic one, although retailers will substitute a cheaper generic product if requested rather than lose the customer, particularly in *Rajya Osu Sala* pharmacies, where there are salaried pharmacists who do not get income from the sale of medicines.

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

Medicines prescribing and use remains similar to what was found in 2010 although the average number of medicines prescribed per patient and the percentage of patients prescribed antibiotics both seem to have risen slightly. Similarly, dispensing practices remain similar to what was previously seen. Monitoring of prescribing and dispensing is not generally done. Without monitoring, enforcement of all strategies to promote rational use of medicines will be difficult, since there is little transparency and accountability concerning how medicines are used.

The major change since 2010 is that Drug and Therapeutic Committees (DTCs) have been established in all teaching and provincial hospitals and in the regional health departments, as recommended in the previous situational analysis. In hospitals, this has been done by upgrading the previous hospital Drug Review Committees although their terms of reference appear to remain the same. Though started with the aim of monitoring drug use, the DTCs are not doing this.

Apart from establishing DTCs, implementation of policies to improve medicines use remains weak, much as was found in 2010. Continuing medical education (CME) is adhoc and minimal for most prescribers, though the Sri Lanka Medical Association (SLMA) and other professional bodies do organize lectures on specific conditions, normally concerning secondary rather than primary care. Though the CME lectures discuss common problems like hypertension, diabetes mellitus, the focus is always on newer treatment modalities and new drugs, but not on the management of common conditions at primary and secondary health care facilities using available resources.

Previous recommendations to develop National Standard Treatment Guidelines (STGs) and to run public education campaigns on prudent use of medicines run have not been undertaken. Plans of the Sri Lanka Medical Council and the Sri Lanka Medical Association to develop an accreditation system based CME have not further advanced because many peripheral doctors would not be able to come to Colombo or the other major cities for the CME.

6.7. Medicines use: Recommendations

- Monitor drug use by undertaking prescription audit, which will require revision of prescription forms to include diagnosis.

- Improve awareness of the current patterns of drug use in the country by dissemination of situational analysis findings at the next Health Development Committee meeting and to prescribers through the Regional Directors and Hospital Directors.

- Develop STGs including OPD treatment of simple primary care conditions with emphasis on using fewer medicines and disseminate to every doctor and student and incorporate into CME.

- Improve continuing medical education by:
    - requiring consultant physicians to take the lead in providing CME and disseminating STGs to prescribers in their own hospitals and also to private general practitioners who work locally;
    - organising regular CME sessions that have credit points assigned to practitioners for attendance which is linked to promotion and increments.
    - Incorporating prescription audit and feedback and ethics into CME;
    - Ensuring that the Sri Lanka medical council (SLMC) and professional associations continue to be involved in delivering CME.

- Educate patients and care givers on common illnesses and on drug/non-drug management, using:
    - social media (TV, videos at clinics);
    - all the health education channels used by the MOH.

- Promote DTCs to undertake monitoring of use and policy implementation, which will require:
    - Standardised DTC terms of reference;
    - The pharmacist of the drugs and therapeutic committee being given the responsibility for conducting quarterly audits on drugs in common use and those which are irrationally used (e.g. antibiotics, NSAIDS, Proton Pump Inhibitors, antihistamines etc.);
    - The findings from the audits being sent to the Standing EML Committee and the National DTC coordinated by the MSD and also the executive unit in the MOH, which should meet regularly and provide feedback to the hospitals.

- Improve the consulting environment in order to improve prescribing by:
    - Exploring the possibility of establishing a referral system to decrease overcrowding in hospital outpatients;
    - Analysing prescriber workload to ensure more equal distribution of staff and workload to ensure sufficient consultation time.

7. MEDICINE REGULATION

7.1.Responsible Agents/Departments

Regulatory function	DRA	Other Agency	DRA/MOH department/Name of Agency
Drug Schedules	√		
Licensing &Inspection of drug outlets	√		
Drug registration	√		
Pharmacovigilance		√	Pharmacology Department, Colombo University
Drug quality testing		√	National Drug Quality testing Laboratory
Drug promotion	√		
Drug pricing		√	Ministry of Trade & Industry and the Sri Lanka Manufacturer's Association
Health professional licensing/accreditation		√	Sri Lanka Medical Council
Health facility/hospital licensing/accreditation		√	Patient Care Services under the Department of Health Services

7.2. Pharmaceutical sector

From discussion with national drug regulatory authority

- Number of products on the market:
  - Allopathic: 8095 registered (though not all are currently on the market)
  - Traditional: approximately 960 herbal medicines

- Number of manufacturers:
  - Allopathic: 12 locally-owned, 884 foreign-owned manufacturers export to Sri Lanka

- Number of wholesaler outlets: 790

- Number of retailer outlets:
  - Allopathic: 3297 (though not all may function and some unregistered ones may operate)

- Enforcement of regulations in last fiscal year:
  - Prosecutions: 312 for drugs, 54 for cosmetics and 40 cases for devices last year
  - Value of fines: SLRs 2 million for drugs, 442,000 for cosmetics and 328,000 for devices
  - Number of people imprisoned: none

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

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
Cosmetics, Devices and Drugs Act (CDDA) No 27 of 1980 with several amendments from 1985	1980
National Medicines Regulatory Authority Act	2015

b) Coverage:

Area / Activity Covered?	Y/N	Document Name
Establishment & functioning of National Drug Regulatory Authority	Y	1980, 2015
Medicines marketing authorisation	Y	
Medicines scheduling	Y	
Licensing of medicines handling premises, personnel & practices	Y	
Licensing of prescribers	Y	Medical Council
Mandatory CME for prescriber licence renewal	N	Does not exist
Licensing of pharmaceutical personnel	Y	Medical Council
Mandatory CME for pharmacy licence renewal	N	Does not exist
Regulatory inspections/enforcement activities	Y	
Medicines quality	Y	
Medicines packaging & labelling	Y	
Medicines promotion	Y	
Post-market surveillance/ pharmacovigilance	Y	
Collection of fees	Y	
Clinical trials	Y	
Generic substitution	?	
TRIPS-related issues	?	
Transparency & accountability[2]	?	
Banning of unsafe medicines	Y	

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

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

7.4. National Regulatory Authority for medical products

- Name of National Drug Regulatory Authority: Central Department for Drug Administration (CDDA)
- Total number of staff posts:57, number of unfilled posts: 25
    - Number of technical posts: ? number of posts filled:?
    - Number of non-technical posts: ? number of posts filled:?
- Website address: www.cdda.gov.lk
- Number of quality-control (drug testing) laboratories:1 national drug quality control laboratory under the MOH but not under the drug regulatory authority
- Annual report of activities? No annual report provided:
- Annual Budget last fiscal year: ?

- Written SOPs for the following key regulatory procedures?

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

- Other SOPs are as follows: Manufacturer license, import licence, personal user licence, on-the-job training, duty waiver for purchasing material, wholesaler licence, formulation approval letter, registration of company profiles, sample import licence and retail licence.
- Position in hierarchy of government structure: under the Directorate General of Health Services, MOH, until March 2015, but now independent of the Directorate General of Health Services and directly accountable to the Minister of Health.
- Decentralised capacity: No branch offices
    - Functions outsourced to public health authorities: 35 Food and Drug Inspectors in the regions under the Regional Directors of Health, trained by 6 DRA inspectors (3 in post) at the centre.

7.4.1. Technical committees to advise the drug regulatory authority

The Technical Advisory Committee (TAC) is the most senior committee which advises the Minister of Health on all pharmaceutical issues and regulatory matters, and which has both technical expertise and representation from trade associations. It has 22 members, including the Director General of Health Services, the Director of the Medical Supplies Division, the Director of the Drug Regulatory Authority, the Director of the National Drug Quality Assurance Laboratory, and other representatives who are members by virtue of the positions they hold as follows: DDG/Laboratory services; Government Analyst; Chairman/ SPC; Pharmacologist/ Medical Research Institute; Professors of Pharmacology); Member each from the Colleges of - Physicians, Surgeons, General Practitioners, and Gynaecology & Obstetrics; Representative each from the SLMA, Sri Lanka Pharmaceutical Manufacturers Association, Pharmaceutical Society of Sri Lanka, Sri Lanka Pharmaceutical Traders Association, Dental Association, Independent Medical Practitioners Association and Bureau of Sri Lanka Standards.

Under the TAC there are a number of sub–committees as follows:

- Drug Evaluation sub-committee that decides upon drug registration;
- Clinical Trials sub-committee that oversees clinical trials;
- Safety and risk evaluation sub-committee that reviews adverse drug reactions and decides upon what actions to take;
- Advertising sub-committee that reviews unethical and misleading adverts and decides upon what action to take;
- Cosmetics evaluation sub-committee that decides upon the registration of cosmetic products;
- Devices evaluation sub-committee that decides upon the registration of devices; and
- Recall sub-committee that decides upon when to recall products.

The degree to which these sub-committees are active varies and some sub-committees are not very active, as discussed in the following sections.

7.4.2. Regulation of Traditional Medicine

All indigenous medicine practice is controlled by the Ayurveda Act No.31 1961. This Act makes it illegal for medical doctors to practice Ayurveda unless also registered as an Ayurvedic practitioner. Regulation of traditional medicine, including registration of traditional medicine products, post-market surveillance and outlet inspection, is done by the Department of Ayurveda under the Ministry of Indigenous Medicine.

While it appears that allopathic doctors do not practice Ayurveda, it would seem that Ayurvedic practitioners commonly prescribe pharmaceuticals (Canaway 2015, Forsberg 2013). Apparently all traditional medicine products may be freely sold in pharmacies over-the-counter or by Ayurvedic practitioners. However, in the pharmacies observed during the situational analysis few traditional medicine products were sold. It is not clear what post-market surveillance for traditional medicine products is done

or whether any inspection of pharmacy shops for sales of Ayurvedic or other herbal medicines is done by the Department of Ayurveda under the Ministry of Indigenous Medicine.

7.5. Drug Schedules

There are four drug schedules as follows.

- Schedule 1 covers medicines that can be sold over-the-counter (OTC) without prescription from any shop;
- Schedule 2a covers medicines that can be sold over-the-counter (OTC) without prescription but only from licensed pharmacies;
- Schedule 2b covers medicines that can only be sold with a prescription (prescription-only).
- Schedule 3 covers narcotics and controlled drugs that are available in hospitals and in *Rajya Osu Sala* pharmacies which may sell them only with a prescription.

Schedules 1, 2a and 2b medicines are freely available without prescription. In addition, Ayurvedic practitioners, homeopaths and other traditional medicine practitioners are also prescribing antibiotics and other prescription-only medicines. Unfortunately, the OTC list has not been updated for many years and is not available so that many pharmacists may not know what is on the OTC list. The DRA mentioned that it was not possible to take punitive action for the selling of schedule 2 drugs without prescription.

Opium is issued to Ayurvedic practitioners and a Board in each district decides how much may be issued to each practitioner.

7.6. Regulation and inspection of drug outlets

There are over 4000 registered drug outlets and these are recorded in a database maintained the DRA. However, it was reported that the database is not adequately maintained and contained outlets no longer in operation and also duplicate entries. Regular updating of the database would help in planning for inspection and inspectors.

By law, all pharmacies, wholesalers and distributors are supposed to receive a visit from the DRA annually in order to renew their licenses. However, in practice, due to the large number of outlets and a shortage of inspectors and funding for transport, some pharmacies and distributers are not visited. Where they are visited it is often not possible to do more than give a cursory look at the premises. A pharmacist should always be present on the pharmacy premises to supervise dispensing, but it is not possible to enforce this due to the shortage of human resources, particularly inspectors.

in 2013, despite staff shortages, 12,793 routine inspections were undertaken, including 1,444 surprise inspections and 312 cases were prosecuted and 2 million fines issued for contravention of regulations. Contraventions included not having a valid license, absence of a pharmacist on the premises, selling

prescription-only medicines without a prescription, and the presence of unqualified persons, including traditional medicine “doctors”, practising in clinics.

Currently there are 35 Food and Drug inspectors in the regions under the Regional Director of Health Services and 3 inspectors currently in post centrally (3 further posts being unfilled) to inspect more than 4000 outlets (pharmacies and distributers). The DRA stated that 20 more inspector posts had recently been approved. It was mentioned that there were too many pharmacies causing not only difficulties in inspection but also excessive competition resulting in behaviours, some unethical, that do not always benefit the patient (e.g. selling of prescription-only drugs OTC). However, the DRA staff felt there was no means for the DRA to refuse licensing more pharmacies if the applicants fulfilled all criteria. There is no regulation to limit the density of pharmacists in relation to the population.

Drug manufacturing plants located in Sri Lanka are also inspected annually for Good Manufacturing Practice (GMP), but it was mentioned that the DRA lacked sufficient staff with expertise to inspect manufacturers for GMP. Even though some staff have been trained overseas (WHO fellowships) and nationally (national training conducted by the Malaysian WHOCC in 2013), they are not necessarily been assigned to conducting GMP inspections by the DRA after the training.

7.7. Drug Registration

There are 8095 products registered although not all are currently available in the market. Some products have been registered as a result of SPC tenders. Thus there are over 100 products of sildenafil, 40 products of omeprazole and 40 products of esomeprazole registered; all of which are clearly not available in the market. Nevertheless there are a large number of products available in the market for some commonly used drugs (e.g. paracetamol). There is a database of all registered products but, it was reported that the database is not adequately maintained and products no longer in the market and also duplicate entries. Regular maintenance of this database would be extremely useful for the DRA, MSD and the pharmaceutical sector as a whole.

Drug registration remains unchanged from 2010 and is under the control of the Drug Evaluation sub-committee, which is chaired by the Director of the DRA and has a secretary who is a professor of pharmacology. Other members include the Director of the Medical Supplies Division, Director of the National Drug Quality Assurance Laboratory and representatives from all the medical colleges. It meets 2-3 times per year. The Drug evaluation sub-committee only decides upon new molecules that are not already on the market. For new products of molecules that are already on the market (i.e. a me-too product for a molecule already approved by the DRA), whether the manufacture is local or the product is to be imported, the DRA can issue a license for marketing authorisation without referral to the drug evaluation sub-committee, provided the manufacturer can provide proof of satisfactory quality as determined by examination of dossier of documents and inspection of the premises.

For new molecules, not on the market, the Drug evaluation sub-committee will only consider them for registration if they are already registered in UK, USA, Australia, France, Germany, Switzerland or Japan. The Drug Evaluation sub-committee will consider the dossier of documents and the evidence concerning

efficacy, safety, usefulness and quality (which involves checking the adequacy of manufacture) and make a recommendation to the DRA Director who will then grant or not grant registration.

Provisional registration is for one year with a fee of SLR Rs. 11,200 and full registration is granted for a period of 5 years for a fee of SLR Rs. 28,500. In addition there are processing fees of SLR Rs. 12,000 for processing the company plus SRL Rs. 11,100 for old molecules, SRL Rs. 26,000 for new dosage forms of old molecules and SRL Rs. 56,000 for new molecules. The fees charged are not commensurate with the level of effort involved in evaluating the product dossiers for registration.

Many people complained about the registration process. The following problems were reported.

(1) Evaluation of dossiers is often inadequate and it was mentioned that following a serious adverse drug reaction, wherein a local anaesthetic for use prior to bladder catheterization had resulted in urethral stricture, re-review of the concerned product dossier revealed that the product had been misclassified as a steroid! Many people felt the registration criteria were too easy.

(2) The DRA lacks sufficient staff with expertise to evaluate dossiers for drug registration. Even though some staff had been trained overseas (WHO fellowships) and nationally (national training conducted by the Malaysian WHOCC in 2013), they had not necessarily been assigned to evaluating dossiers by the DRA after the training. Due to lack of internal expertise, the DRA outsources dossier evaluation for new molecules and products with a history of “problems” to the pharmacology department in Colombo University for minimal or no remuneration. Due to non-payment of clinicians to evaluate dossiers the process is often delayed.

(3) Although there are standard forms for applicants to fill and checklists for staff to follow in evaluating new products, there are no formal SOPs and even the informal SOPs are not always followed. A recent review of dossiers by the pharmacology department in Colombo university found that only about half the criteria used internationally to evaluate products were used by the DRA and that a significant proportion of the products granted registration did not actually pass all the criteria supposedly applied in the DRA.

(4) Although the Drug Evaluation sub-Committee regularly meets there have been frequent disagreements between the sub-committee and the Director of the DRA who had sometimes overruled the recommendation of the Drug-evaluation sub-committee and granted registration to a product against their recommendation.

(5) Many “No-objection letters” are issued for emergency orders often when there have been quality failures and withdrawal of batches or products. However, there are no clear criteria for issuing such letters.

(6) Non-use of a computerised system already developed for managing/tracking the registration process. Currently, dossiers are stacked to the ceiling in the DRA and finding the dossier of a particular drug product in the case of an emergency following a serious adverse drug reaction, may be difficult. Furthermore, the computerised system was untested, with no clear algorithms for mapping and tracking the registration process, and was little supported by the Director DRA. Thus, there is still a lot of work to be done to make the computerised system work.

It was further mentioned that when a sample fails quality testing at the National Drug Quality Assurance Laboratory (NDQAL), the NDQAL informs the DRA, who then informs the MSD – all by letter which takes time. It is only the MSD which takes action to withdraw the product from the public sector. In the case of a product or batch withdrawal, the DRA issues a letter to the supplier to withdraw all stocks of the relevant batch or product from the market with copies to RDHS, PDHS, Director /Private sector health development. In addition the registration certificate is also withdrawn after recall committee has issued decision for product withdrawal). However, it was mentioned that sometimes, there is failure to withdraw a batch from the private sector and this has become apparent when the same failed product has been submitted in a new tender called by the MSD to replace the failed product.

The number of products on the market was felt to be excessive in 2010 and the number of products has not decreased in the last 5 years but has slightly increased to 8,095. There seems to be no way of restricting registration of new products if a manufacturer can prove his product is equal to others already on the market in terms of quality. Having such a large number of products on the market creates a large regulatory burden, which cannot be fulfilled with current resources and could compromise patient safety (from the perspective of drug quality and overdosing on the same molecule by patients who are unaware that different brands and combinations may contain the same molecule). Some people felt that the registration process would be greatly improved by using the computerized system already developed for the purpose (supported by WHO), increasing the quality criteria for registration, increasing the registration fees and ensuring that there was no conflict of interest of members who sit not only on the drug evaluation sub-committee but also on other sub-committees such as the recall sub-committee.

7.8. Pharmacovigilance

Pharmacovigilance was outsourced to the Clinical Pharmacology Department in Colombo University. However, responsibility for national collection of ADR reports and reporting to the WHO monitoring system in Upsala was shifted to the national drug regulatory authority in 2011. The Pharmacology department stated that last year about 100 adverse drug reactions (ADRs) were reported, of which 23 were serious and two results in patient death. In the case of severe ADRs confirmed by investigation reports, product withdrawal is undertaken. Two products were recalled after causing the deaths of two patients and after quality testing was done by the national regulatory authority in Australia (TGA) and GMP inspection to manufacturer with expert support. Altogether there are over 1000 ADRs, reported by doctors, nurses and pharmaceutical companies, in the central database and the national centre has reported to the WHO monitoring centre in Uppsala. However, since the national DRA took responsibility for national collection of ADRs in 2011, the pharmacology department has stopped reporting ADRs to Upsala and it is unknown if the DRA has continued to report to Upsala or not.

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

Year	2015	2014	2013	2012	2011	2010
No. ADRs	40	64	56	14	?	125

7.9. Drug Promotion

Drug promotional activities are not systematically monitored. There is an Advertising sub-committee to examine and approve (pre-use) adverts for OTC drugs aimed at consumers, but it does not review adverts aimed at prescribers, nor is there any other system to review such adverts. Once an advert aimed at consumers has been approved there is no adequate mechanism for monitoring whether the concerned company sticks to the letter of the agreed text for the advert. Last year there was only one prosecution for inappropriate advertising of a schedule 1 (OTC) drug to consumers. There is a prohibition of medical representatives entering government hospitals during working hours but it is not clear how well this is enforced. However, pharmaceutical representatives visit all doctors in private practice, including those who also work in the public sector. Other promotional activities of drug companies are not monitored.

7.10. Drug Price controls

There is no pricing policy and the DRA is not responsible for monitoring prices or setting drug pricing policy. Drugs are sold at the retail price set by the pharmaceutical companies. The Ministry of Trade and industry together with the Sri Lanka Manufacturers Association and the Sri Lankan Standards Institute has agreed to local manufacturers setting drug prices based on a mark-up of 20% on manufacturing costs. There is a regulation that all drug prices, as agreed with manufacturers, must be marked on the packaging, and the Consumer Affairs Authority is responsible for enforcing this regulation. Since prices are based on a "cost plus" system, which may work against affordable drugs. Some respondents argued that a pricing policy is needed to encourage use of essential drugs and discourage use of non-essential ones. In particular, any pricing policy would need to address both essential and non-essential ones as if the margin on essential drugs is small importers would switch to non-EML ones with a higher margin. The SPC presence in the private sector with its *Rajya Osu Sala* pharmacies has had a check on prices since the SPC has a focus on providing affordable medicines. The SPC has a standard mark-up and, though government-owned, does and not having a responsibility to provide a "return on investment" to the government.

7.11. Drug Testing Laboratories

There is one government laboratory – the national drug quality assurance laboratory (NDQAL) under the Director General Health Services within the MOH and there is also an additional approved analyst. There is also one private drug testing laboratory in Sri Lanka.

The NDQAL has three divisions (chemical, microbiological, biological as well as an administration office) and its main function is analysis of locally manufactured and imported pharmaceuticals, at the pre-marketing and post-marketing stages, in order to ascertain the quality of products and to issue recommendations on quality. The laboratory also tests the quality of some devices such as syringes, needles, cannula, sutures, gauze and gloves. They are planning to test the quality of condoms and inhalers in the future. The NDQAL has SOPs for some (but not all) procedures, including sampling, using reference materials and some testing

procedures. The NDQAL participates in the external quality assurance assessment (proficiency testing) schemes conducted by WHO/EDQM and FIP-LMCS Netherlands.

There are 40 technical staff in post and 19 unfilled positions. In addition, there are 37 non-technical staff in post. Technical staff includes graduates in chemistry, botany, zoology, pharmacy with postgraduate qualifications in pharmaceutical analysis, pharmaceutical technology, pharmaceutical services, analytical chemistry, experimental biotechnology, biochemistry, molecular biology, polymer chemistry and food technology. Most scientific officers have had training on pharmaceutical analysis, Good Laboratory Practice and Good Manufacturing Practice from national regulatory authorities of Australia, Malaysia, Singapore, and Thailand, or from the National Institute of Pharmaceutical Educational Research in India. The pharmacists are transferable every 2-3 years and only 13 staff are permanent so limiting the capacity of the lab.

About 800-900 samples of drug products are tested per year, many referred from end-users in the public sector, and of these about one-third failed. In addition about 10% of all devices failed quality testing. The failed samples last year led to 99 batches and 12 products being recalled by the MSD in 2014.

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

Year	Samples received		Samples tested		Samples found to be substandard	
	Pre-market authorisation	Post-market authorisation	Pre-market authorisation	Post-market authorisation	Pre-market authorisation	Post-market authorisation
2010	102	662	78	521	31	190
2011	139	567	124	493	38	141
2012	225	602	186	479	48	174
2013	267	654	218	546	60	261
2014	151	719	178	505	34	132

7.12. Licensing and accreditation of health professionals

The core function of the Sri Lanka Medical Council (SLMC) is to license the health professionals, regulate professional conduct and maintain standards of medical education. Registration is for 5 years and doctors must pay SRL Rs. 6,000 initially and then SLR Rs. 2,500 every 5 years. The SLMC licenses not only doctors, but also all other categories of health worker including dentists, graduate and diploma pharmacists, and other categories of health worker, with the exception of nurses who have their own Nursing Council. Currently there are about 23,000 active members, of whom 14,000-15,000 work in the government service. The SLMC run a licensing exam for foreign doctors.

With regard to pharmacists there are about 6,500 pharmacists registered of whom 1,500 are in government service. Pharmacists are also licensed by the SLMC. Most pharmacists are diploma-level which requires two years study but there are also certificate-level "pharmacists" who have training of less than one year often as an apprentice to a licensed pharmacist. Many people, including the Sri Lanka Pharmaceutical Association, were critical of the quality of the certificate-level "pharmacists" of whom there are about 3000 operating retail pharmacy shops.

The SLMC evaluates complaints against health professionals received from the MOH or by public affidavit. There is a formal complaints committee operated by five council members. However, very few complaints are investigated or disciplinary actions taken. Last year the SLMC investigated two cases of doctors giving a prescription without seeing the patients and also some cases of prescriptions on behalf of an insurance company.

Eight Medical School Deans and faculty representatives are statutory members of the council. Medical education is set by the eight government medical schools and the SLMC gives approval. The SLMC contributes to medical school curricula and inspects the medical schools for fitness to train medical students. The Ceylon Medical College Council set the pharmacy curricula and exam and also contributes to medical school curricula as well as the SLMC. Although the SLMC and SLMA encourage CME by holding monthly meetings, these are not mandatory. The SLMA and SLMC would like to develop an accreditation points system for re-licensing but this cannot be started in any mandatory way because doctors working in the periphery would not be able to attend the meetings.

7.13. Licensing and accreditation of health facilities and pharmacies

Private retail pharmacies are granted annual licenses by the DRA, according to a checklist of criteria and an inspection by the regional food and drug inspectors. However, due to lack of inspectors, many outlets cannot be inspected and some people stated that there may be up to 10,000 unregistered outlets.

Private hospitals and clinics are regulated by the Medical Care Services under the Department of Health Services through the Private Health Services Regulatory Council, and granted annual licenses dependent upon a successful inspection by an inspection team, which includes the Regional Director of Health Services. The team is appointed by the Provincial Director of Health Services (PDHS) from the region, headed by RDHS, and includes the Director/ Private Health Sector Development from the central DGHS/MOH. The team uses a checklist which requires collection of information on the physical facility, equipment and staffing, but does not require any information on drug use.

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

Since 2010 the national drug regulatory authority (DRA) has remained weak and very similar in function, despite a small increase in staff numbers and some training on dossier evaluation and GMP inspection.

Drug registration remains particularly problematic. Although some staff have been trained on dossier evaluation and GMP inspection (with WHO support) they have not always been assigned to work in these areas after their training. The computerized system for drug registration (developed with WHO support) is still not used. By contrast, the National Drug Quality Assurance Laboratory (NDQAL) has become much stronger, testing more samples and participating in international quality assurance assessment schemes. Even so, many of its pharmacists and other staff are transferred every 2-3 years so that the skills developed during their time there are lost to the NDQAL after their transfer.

Most focus in the last two years has been on developing a new Drug Regulatory Authority Bill and this was passed as a new National Medicines Regulatory Authority Act on 19 March 2015. Currently new accompanying regulations are being drafted. The new National Medicines Regulatory Authority (NMRA) will be independent of the Directorate General of Health Services but still under the MOH. It remains to be seen how the new Act will be implemented.

7.15. Medicines regulation: Recommendations

- Establish the new NMRA, as per the new National Medicines Regulatory Authority Act 2015 which has been approved in the Parliament, and implement an effective monitoring and evaluation system (see medicines policy and coordination).
- Strengthen the NMRA by:
    - recruiting more technical staff, including pharmacists and inspectors:-
        - At least 25 more pharmacists should be recruited immediately , as follows: New Chemical Entity -3; Existing molecules- 10; BTP – 3; Domestic sector – 03; Recall and pharmacovigilance – 03; Approvals for manufacturing facilities – 03.
        - The Director of the NMRA (DRA) and DGHS should try to facilitate this process.
    - Training both existing staff and newly recruited staff of the DRA;
    - Developing SOPs for all procedures and training new employees on their use;
    - Ensuring trained personnel are posted in positions where they are given the responsibility of carrying out work related to the area in which they received training.
- Make the registration process more stringent in order to improve quality and reduce the number of products in the market by:
    - Implementing the computerized database system software (which has already been procured) within three months and training staff to use it;
    - Assigning staff who have been trained in dossier evaluation to do this work and training more staff to do dossier evaluation;
    - including stronger criteria in the evaluation of products for registration (e.g. bioequivalence studies, dissolution profiles, stability studies) and revising the SOPs to include these criteria;

- more stringent compliance with the SOPs and the recommendations of the Drug Evaluation Sub-committee.

- Strengthen compliance with Good Manufacturing Practices for products and APIs by:
  - Developing SOPs for GMP inspection;
- Assigning staff who have been trained in GMP inspection to do this work and training more staff to do GMP inspection.

8. MEDICINE POLICY AND COORDINATION

8.1. National Medicines Policy

There is a national medicines policy (NMP) document published in 2005 which has the following objectives:

1. To ensure the availability and affordability of efficacious, safe and good quality medicines relevant to the health care needs of the people in a sustainable and equitable manner;
2. To promote the rational use of medicines by health care professionals and consumers;
3. To promote local manufacture of Essential Medicines.

To achieve these objectives the national medicines policy has the following elements:

- Selection of essential medicines;
- Affordability and equitable access;
- Financing options;
- Supply systems and donations;
- Regulation and quality assurance;
- Quality use of medicines;
- Research;
- Human Resources;
- Viable Local pharmaceutical Industry;
- Monitoring and evaluation.

However, the NMP document mentions that the NMP a “policy of principles” and so each element is described in the policy document very briefly, lacking detail. Unfortunately, no further implementation of the NMP has been undertaken since the last situational analysis in 2010, despite various meetings of the Standing Committee and a court case brought by the People’s movement against the government. All focus has been on getting a new National Medicines Regulatory Authority Act passed in parliament and this eventually occurred in March 2015. It is intended that the new NMRA will revise the NMP.

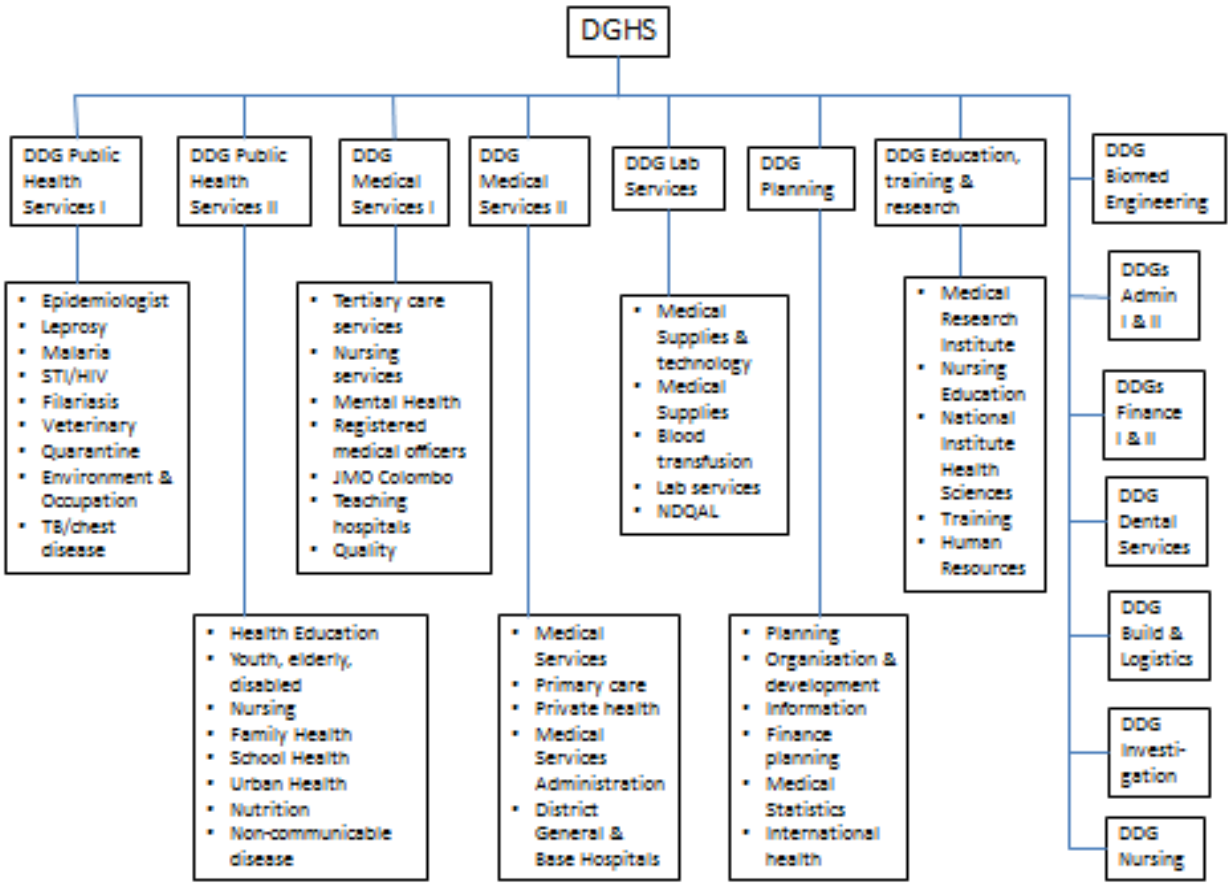
The various medicine policies that may impact on drug use and are in place, as found during the situational analysis, and as reported to WHO in the country pharmaceutical survey of 2010, are shown in table 8.2.

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

Policy	Implementation status
National Medicines Policy (NMP)	Official document 2005 & implementation plan, but implementation not yet started
National Essential Medicines List (EML)	National List 2013-2014 used in public sector procurement
National Standard Treatment Guidelines (STGs)	No national STGs (although standard treatment guidelines have been produced by the Specialist Colleges and the SLMA)
National Formulary manual	National formulary published in 1994 but no longer available
National government unit dedicated to promoting rational use of medicines	No government unit dedicated to promoting rational use of medicines
Monitoring medicines use	Monitoring of drug consumption done centrally in terms of quantity &cost, but very little information available on actual prescribing
Drug and Therapeutic Committees (DTCs)	A national DTC coordinated by the MSD is established to oversee hospitals all of whom should have DTCs and submit reports on their activities to the national DTC, but few DTCs do more than discuss stock-outs.
National Drug Information Centre (DIC)	No national DIC but University of Colombo has a local unit
Generic Policies	No specific policies but generic substitution is practiced in the public sector, though not much in the private sector where doctors use stamps to prohibit generic substitution
Health insurance	No public health insurance for most of the population
Payment for medicines by patients	All medicines received by patients free of cost in the public sector.
Provider revenue from medicines	Revenue from medicines sales is never used to pay salaries in the public sector
Undergraduate training on pharmacology & prescribing	National EML and STGs are not part of the curricula, but training on prescribing and problem-based pharmacotherapy are included
CME training on pharmacology & prescribing	No non-commercially funded CME, but SMLA does run CME lectures
Public education on medicines use	No public education campaigns on medicines use done in the past 2 years
Pharmacovigilance	Done by the national centre for Pharmacovigilance contracted out to Colombo University
Regulation of drug promotion	Pre-approval for OTC drug adverts only but monitoring is very adhoc
National strategy to contain Antimicrobial Resistance	No national strategy on antimicrobial resistance
Over-the-counter availability of prescription-only medicines including antibiotics	Antibiotics and other prescription-only drugs frequently available over-the-counter without prescription

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

8.3.1. Organogram of Director General of Health Services



Legend: DGHS = Director General Health Services; DDG = Deputy Director General

Above the DGHS is the Secretary of Health who reports to the Honorable Minister of Health. The Chief Accountant and Chief Internal Auditor act under the Secretary of Health.

Formerly the National Drug Regulatory Authority was under the DDG Lab Services and thus under the DGHS. However, a new independent National Medicines Regulatory Authority (NMRA) is now being formed in accordance with the new National Medicines Regulatory Authority Act passed by Parliament in March 2015. The new NMRA will report directly to the Minister of Health and thereby to Parliament.

8.3.2. Coordination within the Ministry of Health

In the Ministry of Health, the Secretary of Health is in charge of five additional secretaries (covering medical services, public health services, development, procurement, and administration), the chief accountant, chief internal auditor, the Director of the Medical Statistics Unit and the Director General of Health Services.

Under the Director General of Health Services are a number of departments headed by Deputy Director Generals covering the following areas (Annual Health Bulletin 2012):

- Public Health Services, covering community health services including the family health bureau, environmental & occupational health, epidemiology, dengue, nutrition & quarantine, and specialized public health programmes;
- Patient Care Services, covering hospital services, nursing, mental health services, regional medical care, teaching hospitals, quality;
- Laboratory Services, covering medical technology and supplies, Medical Supplies division, national drug quality assurance laboratory, logistic division, laboratory services, biomedical engineering services, and the Drug Regulatory Authority;
- Education, Training & Research Services, covering the Education Training & Research Unit, the Medical Research Institute, National Institute of Health Sciences, the Health Education Bureau and the National Blood Transfusion Service;
- Other units covering planning, administration, finance, building and logistics.

Problem policies that fall between different departments within the MOH:

- National EML is currently updated by the DRA only because the Director of the MSD transferred some years ago to being the Director of the DRA and many felt that the function of updating the national EML should be an MSD function and thus revert to the MSD, since it is the MSD which supplies all medicines in the public sector;
- Drug budget allocation and quantification requires coordination between the DGHS, MSD and SPC;
- Public education requires coordination between different bureaus within the DGHS, particularly Family Health Bureau and the Health Education Bureau for the distribution of specific messages related to medicines use.
- There is a national DTC established under the coordination of the MSD to oversee hospital DTCs but coordination is needed with the Patient Care Services (under the Department of Health Services)which manages hospital quality of care
- No MOH department or division is monitoring prescribing, developing general national STGs for common conditions or managing continuing medical education (outside the vertical disease control programs), running a Drug Information Centre, or developing public education messages on the prudent and safe use of medicines.

It is not clear how coordination is managed or which department will take up the functions currently not done and this is one reason for poor implementation of the NMP. The current MOH structure may not lend itself to better coordination of drug policy because divisions and departments responsible for pharmaceuticals, such as the medical research institute (responsible for vaccine regulatory activities), the Drug Quality Assurance laboratory, the Medicines Supply Division (and until recently the DRA), are relatively low in the hierarchy of MOH and this, in turn, limits their ability to coordinate with other units, recruit staff and get resources. While, the DRA may get higher status with the new National Medicines Regulatory Authority Act, it is not clear that the situation of the other divisions, e.g. MSD, looking after pharmaceuticals will change.

There has been much disagreement within the national stakeholders concerning where the DRA should be in the organogram and which body should be responsible for the NMP for many years and it is hoped that with the new National Medicines Regulatory Authority Act of March 2015 that these disagreements will be resolved and better drug policy coordination within the MOH achieved. Nevertheless, all stakeholders felt that there should be a dedicated properly resourced unit somewhere within the MOH to monitor medicines use and coordinate policies to improve medicines use.

8.4. Other Ministries with medicines-related functions

Other Ministries, apart from the Ministry of Health, 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 MOH and public sector medicines supplied by the MSD;
    - negotiates drug prices for public sector purchase from Sri-Lankan based manufacturers together with the Ministry of Trade and Industry, Sri Lanka Manufacturers Association and the Sri Lankan Standards Institute, with inputs from the MSD and SPC.

- Ministry of Trade and Industry – sets rules (which may not always serve the public health interest) for:
    - Medicines prices together with Sri Lanka Manufacturers Association and the Sri Lankan Standards Institute basing mark-up of 20% on manufacturing costs;
    - 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 number of medical products registered.

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

- Public Services Commission (human resources) - decides on the number of posts in MOH:
    - May not assign posts as MOH needs e.g. there are very few posts for bachelor or diploma pharmacists in the regional warehouse and hospital drug stores and too few posts in the DRA;
    - The chief of specialist departments may not be filled by a specialist from that field e.g. the DRA chief need not be a pharmacist though some DRA staff feel the position should be reserved for a pharmacist.

Coordination between the MOH 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 numbers of drug products, especially me-too products, are on the market, 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 Sri Lanka, resulting in extra regulatory burden (such that the DRA and the regional FDA inspectors cannot inspect all pharmacies regularly and such that many pharmacy outlets are not staff by pharmacists), because limits cannot be placed on new pharmacies due to trade rules concerning competition.
- Lack of sufficient bachelor pharmacists in the human resource plan, but without them, efficient quantification and procurement cannot be done sufficiently in advance and many regulatory processes cannot be managed adequately.
- 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 MOH and the Ministry of Education.
- Lack of sufficient drug budget to meet demand although coordination between MOH and MOF is good since MOF does pay promptly for the procurement of medicines and the drug budget has increased since 2010.

In order to coordinate between the different ministries on functions, which lie outside the normal remit of the DRA, some people feel there is a need for a new independent mandated committee or body directly under the MOH with wide responsibility for many functions in addition to the traditional regulatory ones. Such less traditional functions, include control of drug pricing, drug information, drug monitoring etc. Others disagreed and felt that the current Technical Advisory Committee, which has previously overseen

the DRA, could be strengthened and its oversight widened to undertake such a coordinating function. Nevertheless, all stakeholders felt that there should be some high-level body or committee to oversee coordination between Ministries with an executive unit somewhere in the MOH to carry out their recommendations.

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

The national medicines policy (NMP), coordination and structure remain similar to the situation in 2010. Implementation of many parts of the NMP remains weak. No unit dedicated to monitoring prescribing was established in the MOH but a national DTC to oversee hospital DTC activities has been established and is coordinated by the MSD. Most focus has been on developing a new National Medicines Regulatory Authority Act, which was finally passed by parliament in March 2015. It remains to be seen how the new National Medicines Regulatory Authority (NMRA) will be established. At the time of writing new regulations to accompany the Act were being drafted.

8.6. Medicines policy and coordination: Recommendations

- Establish the new NMRA, as per the new National Medicines Regulatory Authority Act 2015 which has been approved in the Parliament , and implement an effective monitoring and evaluation system (see regulatory section).

- Strengthen the National Advisory Committee (NAC) to oversee implementation of the national drug policy and the new NMRA.

- Appoint a subcommittee in the NMRA to:
    - define key performance indicators (KPIs) and targets for all areas of medicines management including medicines use and implementation of regulations and the national drug policy;
    - coordinate among stakeholders regarding implementation of medicines policies and carrying out the recommendations of the National Advisory Committee (NAC).

- Establish a Division in MOH to ensure that data is collected regularly on key performance indicators for monitoring purposes.

- MOH to organize an annual meeting with participation of all stakeholders to discuss, inform and present data on KPIs, targets achieved, and forecast and plan for future medicines situation analysis in the country.

- Allocate budget to the MOH, National Medicines Regulatory Authority (NMRA) and National Advisory Committee (NAC) for all the above activities.

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10. PERSONS MET DURING THE SITUATIONAL ANALYSIS

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1	Mr. Trifee Athukoralle	Chief Pharmacist, Ragama Teaching Hospital
2	Ms. Nirmala Senanyake	Pharmacist, Ragama Teaching Hospital
3	Dr. U.H.M. Samaranayake	Director, Ragama Teaching Hospital
4	Dr. A.R.M. Thowfeek	Deputy Director, Ragama Teaching Hospital
5	Dr. Palitha Mahipala	Director General of Health Services, Ministry of Health, Colombo
6	Dr. Ananda Gunasekara	Deputy Director General (Laboratory Services), Ministry of Health
7	Mr. Ajith Priyadrashana	Director, Laboratory Services (NDQAL), Ministry of Health
8	Mr. WPWD Pathiratna	Assistant Director, ICT, MSD
9	Dr. Kamal Jayasinghe	Director, Medical Supplies Division, Ministry of Health
10	Prof. Jennifer Perera	President, Sri Lanka Medical Association
11	Prof. Geetha Fernando	Professor, Sri Jayawardenepura Medical College
12	Prof. Carlo Fonseka	President, Sri Lanka Medical Council
13	Dr. Herath	Registrar, Sri Lanka Medical Council
14	Dr. P.K. Wijewickrrama	Regional Director of Health Services, Galle
15	Dr. W.A.M. Shelton Perera	Director, Teaching Hospital Karapitiya, Galle
16	Dr. D.N.P. Jayasinghe	Medical Officer in-charge, Divisional Hospital, Ahangama, Galle
17	Ms. Bodhika Galapati	Dispenser, Divisional Hospital, Ahangama, Galle
18	Dr. Pushpa Liyanage	Medical Officer in-charge, Base Hospital, Balapitiya, Galle
19	Ms. Nimanthika Liyanage	Chief clerk, Base Hospital, Balapitiya, Galle
20	Ms. K.T.M. Indrani	Matron, Base Hospital, Balapitiya, Galle
21	Dr. Iresha Pathirage	Medical Superintendent, Base Hospital, Balapitiya, Galle (interviewed over phone)
22	Ms. G.T. Kumudu Visuddhika	Chief Pharmacist, Base Hospital, Balapitiya, Galle
23	Mr. H.G.S. Pushpakumar	Pharmacist, HG Pharmacy (retail pharmacy), Galle
24	Ms. Udayangani	Dispenser, HG Pharmacy (retail pharmacy), Galle
25	Mr. G.T.M.K.S. Hewawasam	Pharmacist, Methrula Pharmacy (retail pharmacy), Galle
26	Mr. Chandana Weeraratne	Pharmacist, Lanka Hospital Pharmacy (retail pharmacy), Galle
27	Ms. Sarojani	Assistant Pharmacist, Lanka Hospital Pharmacy (retail pharmacy), Galle
28	Mr. Kapila	Pharmacist, Union Pharmacy (retail pharmacy), Galle
29	Mr. Jagat Kumar	Chief Pharmacist, Osusala, Galle
30	Mr. K.A.D.R. Kumarasinghe	Pharmacist, Osusala, Galle
31	Mr. Priyankara Perera	Chief Pharmacist, Anuradhapura Teaching Hospital
32	Dr. W. Attapattu	Director, Anuradhapura Teaching Hospital

	Name	Designation and Affiliation
33	Mr. D.M.A.K. Dissanayake	Ward Master, Ward 17, Anuradhapura Teaching Hospital
34	Dr. Dilkushi	Registrar, Ward 17, Anuradhapura Teaching Hospital
35	Dr. Nimal Senanayaka	Consultant Physician, Anuradhapura Teaching Hospital
36	Mr. D.M. Gunatilake	Ward Master, Ward 18, Anuradhapura Teaching Hospital
37	Dr. N.C.D. Ariyarathne	Deputy Regional Director of Health Services, Anuradhapura
38	Mr. K.A.G.K. Ratnayake	Pharmacist, RMSD, Anuradhapura
39	Mr. Chamila Priyadharshan	Pharmacist,RMSD, Anuradhapura
40	Mr. S. Ananda	Dispenser,RMSD, Anuradhapura
41	Dr. Senapathi	Medical Superintendent, Thambuththegama Base Hospital, Anuradhapura
42	Dr. Buddika Abeyratne	Medical Officer
43	Dr. D.M.A.C. Dissanayake	Medical Officer in-charge, Primary Care Unit, Galadivulwewa, Anuradhapura
44	Mr. K.B. Jayalath	Pharmacist, Chamee Pharmacy (retail pharmacy) Anuradhapura
45	Mr. R.A.G. Priyadharshan	Trainee pharmacist, Chamee Pharmacy (retail pharmacy) Anuradhapura
46	Mr. N. Thennakoon	Trainee pharmacist, Admas Pharmacy, (retail pharmacy) Anuradhapura
47	Mr. A.M.A.K. Abeykoon	Pharmacist, MN Pharmacy, (retail pharmacy) Thalawa, Anuradhapura
48	Mrs. Sriyani Mallika	Owner, Dinusha Pharmacy, (retail pharmacy) Anuradhapura
49	Mr. K.A.L. Ranwan	Pharmacist, Osusala, Anuradhapura
50	Ms. Chinta Abeywardene	President, Sri Lanka Pharmacist Association
51	Dr. Rohini Fernandopulle	Professor
52	Dr. Hemantha Beneragama	Director, Maternal & Child Health, Family Health Bureau, Colombo
53	Dr. Priyadharshani Galappatthy	Professor of Pharmacology, Faculty of Medicine, University of Colombo
54	Dr. D.M.H. Dissanayake	Medical Officer, Central dispensary, Folk Art centre, Battaramulla
55	Dr. R.M.N. Kumari	Medical Officer, Central dispensary, Folk Art centre, Battaramulla
56	Ms. S.A.W. Priyadharshani	Dispenser, Central dispensary, Folk Art centre, Battaramulla
57	Dr. Palitha Abeykoon	Immediate Past President, Sri Lanka Medical Association
58	Mr. Sarath Liyanage	Chairman, State Pharmaceuticals Corporation of Sri Lanka, Colombo
59	Prof. R. L. Jayakody	Professor of Pharmacology, University of Colombo
60	Dr Amal Harsha De Silva	Additional Secretary, Ministry of Health (Director/DRA)
61	Mrs Sugi Sivayogarajan	Director Operations, Gamma Pharmaceuticals (Pvt) Ltd, Colombo
62	Prof Kusumde Abrew	Professor of Pharmacology, University of Colombo
63	Dinusha Dassanayake	General Manager, State Pharmaceuticals Corporation of Sri Lanka, Colombo
64	Ayanthi Alwis	Manager Post Delivery Operations (Imports), State Pharmaceuticals Corporation of Sri Lanka, Colombo

	Name	Designation and Affiliation
65	Dr S. Sridharan	Director, Healthcare Quality and Safety, Ministry of Health
66	Mario Alphael	Country Manager, Sanofi Lanka Limited, Colombo
67	Gopi Krishantha de Silva	Senior Regulatory Pharmacist, Drug Regulatory Authority
68	Dr Krisantha Weerasuriya	Former Medical Officer, WHO Geneva; now CEO NMRA

11. PARTICIPANTS OF THE STAKEHOLDER WORKSHOP

	Name	Designation and Affiliation
1	H.W.K. Nanayakkara	Pharmacist, Teaching Hospital (TH) Karapitiya
2	Dr. M.S.G. De Silva	Representative, SLMA
3	Mahanma Dodampege	Past President, SLCPI
4	Dr. Kamal Jayasinghe	Director, MSD
5	Kamal Rathnayake	Pharmacist, RMSD
6		Secretary, SLCPI
7	Sugi Sivayogaraja	President, SLPMA
8	Dr.C.L.K. Atapattu	Council member/SLMC
9	Dr. S. Perera	Director, Karapitiya TH
10	Dr. A.L.M. Wazeem	Medical Superintendent, District Medical Hospital, Kalmunai
11	Ms. L.C. Wanniarachci	Pharmacist, MSD
12	Dr. S. Sridhar	Director
13	Dr. Amal Harsha de Silva	Director, DRA
14	Dr. Sriyani Dissanayake	Deputy Director, DRA
15	Mr. Asela Agampodi	Pharmaceutical Analyst, NDQAL
16	Ms. Thilaka Dharmadasa	Chief Pharmacist, NDQAL
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20	Prof. Jennifer Perera	President, SLMA
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22	Mr. P. Liyanagama	Pharmacist, TH Karapitya
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24	Prof. R. Fernandopulle	Pharmacologist, Kothalawala Defence University
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27	Mr. Sarath Ananda	Dispenser
28	Prof. Galappaththi	Pharmacologist, University of Colombo
29	Prof. K.de Abrew	Pharmacologist, University of Colombo
30	Ms. Chinta Abayawardena	President, Pharmaceutical Society of Sri Lanka

	Name	Designation and Affiliation
31	Ms. Ganga Senaratne	Representative, Pharmaceutical Society of Sri Lanka
32	Dr. D. Mendis	Deputy Director, MSD
33	Dr. A.H. Alwis	Manager, State Pharmaceutical Corporation
34	Mrs. Amara Pinnawala	Deputy Director, NDQAL
35	Mr. K.P.H. Sadaruwan	Pharmacist, DRA
36	Mrs. R.M. Monika	Pharmacist, DRA
37	Mr. S.A. Kuruppu	Pharmaceutical Analyst, NDQAL
38	Mr. M.S.P. Perera	Pharmacist, TH Anuradhapura
39	Dr. Neelamani	Director, Health Education Bureau
40	Mr Chaminda Dissanayake	Pharmacist/DRA
41	Indunil Priyangika Anchorage	WHO Sri Lanka
42	Dr Krisantha Weerasuriya	CEO NMRA, Formerly WHO
43	Dr Gitanjali Batmanabane	Prof Pharmacology, WHO Consultant;
44	Dr Kathleen Holloway	Regional Adviser Essential Drugs and Other Medicines, WHO/SEARO

12. WORKSHOP SLIDE PRESENTATION

Medicines in Health Care Delivery in Sri Lanka

Situational Analysis: 16-27 March 2015

Dr Kathleen Holloway, WHO/SEARO
Dr Devika Mendis, MSD/MOH
Ms Lathika Chandanie Wanniarachchi, MSD/MOH
Ms Amara Pinnawala, NDQAL/MOH
Mr Vajira Asela Agampodi, NDQAL/MOH
Mr K.P.H. Sandaruwan, DRA/MOH
Mr Chaminda Dissanayake, DRA/MOH
Prof Gitanjali Batmanabane, WHO Consultant
Ms Indunil Priyangika Athukoralage, WHO, Sri Lanka

Agenda of the workshop

AM

- Presentation by situational analysis team with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
  - include main activities, who will do them, and in what time frame

PM

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

Terms of Reference

- To conduct a rapid assessment of medicines in health care delivery covering drug supply, selection, use, regulation and policy,
  - In liaison with national counterparts nominated by the MOH;
  - Taking into account progress made since the last situational analysis done in 2010
- To report on the findings and develop an action plan in a workshop of government officials and other stakeholders.

Mission 16-27 March, 2015

- 16 Mar: visits to WHO country office, Ragama Hospital
- 17 Mar: visits to DG Health Services, DRA, NDQAL
- 18 Mar: visits to MSD, Pharmacology Dept. Colombo University, SLMA
- 19 Mar: visits to SLMC, RDHS & RMSD Galle, private pharmacies & Osusala pharmacy in Galle
- 20 Mar: visits to Karapitiya Teaching Hospital, Ahangama Division C hospital, Ahangama Central Dispensary
- 21 Mar: visit to Base Hospital Balapitiya;
- 23 Mar: visit to Anuradhapura Teaching Hosp, Thalawa Div Hospital B, Thambuththegama Base Hospital, private pharmacies & Osusala pharmacy in Anuradhapura district, RDHS Anuradhapura
- 24 Mar: visit to RMSD Anuradhapura & Central dispensary Galadivulwewa, telephone interviews with Director Health Education Bureau & PDHS North Central Province
- 25 Mar: visit to SPC, Family Health Bureau, PSSL, EML chair
- 26 Mar: visit to Central Dispensary Battaramulla Colombo
- 27 Mar: workshop

Objectives of the workshop

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

Methods

- 2-week data collection using WHO/SEARO situational analysis tool
- Interviews with concerned government officials & stakeholders
- Visits to public health facilities & private pharmacies
  - Stock-check for availability of 33 selected essential drugs, stock-out, expired drugs, storage conditions, quality-failed stock, etc.
  - OPD prescription survey for WHO indicators
  - In-patient drug management
  - Drug consumption
  - Health system & health care factors

Mission findings

- Extensive health care system, with substantial infrastructure, trained hardworking health care personnel and good health indicators, and…
- Some areas of progress since last situational analysis in 2010, 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 Procurement (1)

- All government drugs from foreign manufacturers procured by SPC (MSD purchases 55 drugs from local manufacturers including SPMC)
  - SPC purchases drugs worth 22 billion SLR per year, 80% for MSD, 20% for Osusalas
  - >9000 products procured & lot of time taken up with small orders
- 11 month lead time to procure drugs in order to get max amount of drugs for least budget
  - Cannot have shorter lead time & respond quickly to emergency orders due to admin & financial regulations
- In 2014, SPC and MSD drug management information systems harmonized through MSMIS to enhance coordination

Drug Supply

- Drugs supplied to RMSD & hospitals by MSD through "pull" system according to an allocated budget decided by DGHS and MOH
- "Push" system quarterly from RMSD to district health facilities according to annual estimation plus emergency order from facilities
- "Pull" system weekly or more where hospitals "order" drugs according to past consumption, stock balance and within the agreed allocation
- In 2014, MSMIS implemented at MSD, regional medical stores and at the teaching hospitals, but not at smaller facilities. Harmonised with SPC system.
- Still complaints of stock-out from most health facilities, due to central stock-outs or due to delayed transport
- Drug quality failures in 132 batches, including withdrawal of 12 products last year, leading to stock-outs while waiting for re-supply
- Local purchase allowed if stock-out at MSD – usually from Osusala pharmacy (local purchase generally <5% of annual budget)

Drug Procurement (2)

- One-bid tendering system reviewing technical criteria and price simultaneously
- Technical criteria lax
  - Quality criteria reliant on DRA registration only
  - Regular random quality testing upon delivery not built into the tenders/contracts
  - In-house quality standards considered for some products not found in standard pharmacopoeias e.g. BP, USP, IP, etc.
  - Supplier criteria should include:
    - 3-year market standing not just 3-year manufacturing experience
    - Substantial annual turnover, e.g. USD 100,000, not just ability to manufacture 3 times the quantity needed.

Selected key essential medicines

- Paracetamol tab/liquid; chlorpheniramine tab/liquid; prednisolone tab; atropine inj; carbamazepine tab/liquid; mebendazole tab; amoxycillin tab/liquid; metronidazole tab; erythromycin tab; griseofulvin tab; miconazole cream; benzyl benzoate lotion; ferrous sulphate tab; enalapril tab; atenolol tab; metformin tab; furosemide tab/inj; ORS; atorvastatin tab, domperidone tab; ciprofloxacin eye drop; ergometrine inj; amitriptyline tab; salbutamol inhaler/tab; omeprazole cap; meropenam inj; cefuroxime inj

Stock Management

- Poor inventory control in some public sector facilities
  - no electronic systems in all district-level health facilities
  - under-estimation of need in all facilities due to forecasting on last year's consumption (when there were stock-outs), fear of expiry
  - frequent emergency orders
- Poor stock management in some stores
  - Stock not stored according to FIFO
  - Some stores dirty, lack shelving, humidity control
  - Expired items stored with in-date items
- In-patient ward drug mgt. very heavy on paper-work
- Store keeper only managing some stores, with no supervision from a pharmacist
- Lack of storage space, especially in large hospitals, who can no longer use space in the RMSD stores

Drug Availability

- **Situational analysis 2015**
  - Availability of 33 key EML drugs: 90% in teaching hospitals, 79% in base & divisional hospitals, 59% (72% excl.inj) in dispensaries, 75-88% RMSD, 80-90% in private pharmacies
  - Some non-availability due to non-use / non-ordering
  - Alternative drugs available for many non-available items
  - over 90% of prescribed drugs dispensed in public facilities
  - Complaints of stock-out for some drugs (sometimes non-EML ones) in many facilities
- **Situational analysis 2010**
  - No info on availability or % prescribed drugs dispensed
  - Many complaints of stock-out for some drugs

Drug supply: possible solutions

- Extend electronic inventory management system for all hospitals for better stock mgt. & forecasting
  - Great improvement since 2010
  - Train staff in using the electronic MSMIS to monitor medicine consumption and use in quantification
- Employ at least one pharmacist to manage all hospital & RMSD drug stores/sub-stores
- Review ward management of drugs
  - Stock registers, individual patient dispensing sheets
- Improve stores - use space, shelving, humidity etc.
- Ensure adequate lorries/drivers for drug transport
- Regular store supervision/visits by senior officials
- Review the STC tendering system with regard to technical criteria and consider establishing a 2-bid system

Drug selection

- **National EML 2013-2014**
  - 361 drugs divided by 4 levels of care (dispensary, divisional hospitals, district hospitals and provincial/teaching hospitals)
  - Drug also divided into core essential (minimum needed medicines for basic healthcare) and complementary drugs (requiring specialized diagnosis/monitoring/healthcare)
- **Implementation of EML**
  - Review of health facility ordering lists: some non-EML drugs in the lists of MSD and teaching hospitals
  - OPD prescribing survey: ≥90% drugs prescribed are EML in all public facilities
  - Availability of higher facility drugs at lower levels e.g. omeprazole, norfloxacin, clarithromycin, co-amoxyclav in some dispensaries
  - Consultants are able to request non-EML drugs, or EML drugs not previously estimated, and the drugs may be purchased, but then the drugs are not used, so leading to expiry

Drug use (1)

- No routine monitoring of drug use or prescription audit
  - OPD patient records or OPD registers recording diagnosis or drug treatment are not kept in any health facilities, and
  - IPD patient records often disorderly without folders and individual patient dispensing sheets are drafted by hand by nurses, so
  - Drug use monitoring is not done
- Hospital Drug & Therapeutic Committees (DTCs) exist
  - Discuss mainly out-of-stock & local procurement, but generally do not set drug policy, monitor ADRs, monitor use, encourage CME, etc
  - Should be a requirement for accreditation for teaching hosp status
- National Standard Treatment Guidelines (STGs)
  - No national STGs for most common conditions only for a few vertical disease control programs
  - few docs use STGs and none seen in any OPD consulting room

Top drugs by value supplied by MSD in 2014

	Drug name	SLR		Drug name	SLR
1	Normal saline 500ml inj	398,826,748	13	Rituximab 500mg inj	186,718,600
2	Trastuzumab 440mg inj	362,160,560	14	Cephalexin 250mg cap	174,218,540
3	Factor VIII 250 IU inj	334,018,149	15	Meropenem 1g inj	164,797,948
4	Sol/Isophane Insulin inj	276,207,525	16	Atorvastatin 10mg tab	156,419,484
5	Metformin 500mg tab	254,419,012	17	Beclomethazone inhal/cap	140,675,098
6	Paracetamol 500mg tab	231,325,056	18	Clopidogrel 75mg tab	140,466,485
7	Anti-Rabies vaccine	228,469,594	19	Losartan 50mg tab	139,056,136
8	Hum.immunoglob 5-6g	224,748,378	20	Sod.valproate 200mg tab	137,678,862
9	Hum.immunoglob 2-3g	219,431,142	21	Valganciclovir 450mg tab	135,486,148
10	Amoxicillin 250mg cap	217,535,769	22	Anti-D immunoglob inj	135,291,357
11	Amoxyclav 1g/0.2g inj	213,328,880	23	MMR vacc. 10 dose vial	134,307,000
12	Hum.albumin 20% inj	187,181,603	24	Desferioxamine 500mg inj	130,598,776

Top 24 (3%) items cost 32% budget and antibiotics cost 18%.

Drug use (2)

- Independent drug information
  - no functional national Drug Information Centre, although some teaching hospitals have drug information units
  - frequent pharmaceutical rep visits to public sector facilities and doctors working in private practice in the evenings
- Pharmacology & prescribing taught at medical undergrad pre-clinical level in 2nd – 5th years in some colleges
  - Pharmacology/prescribing knowledge may be undermined by clinical studies and later work
- CME regular in medical colleges but rare outside, especially for private GPs, and not much on prescribing
  - MOH vertical disease control programs for government staff
  - Adhoc CME seminars for specialists through societies
  - Few of the OPD MOs had attended any CME in the last one year

Drug consumption in districts and hospitals

Area	% Total expenditure on			Annual per capita expenditure in SLR
	top 20 drugs	antibiotics	vitamins	
National level	29.4	17. 6	3.0	79.81
RMSD Anuradhapura	49.1	24.2	3.0	23.55
Teaching Hospital Anuradhapura	38.7	14.9	-	-
RMSD Galle	51.5	32.5	1.0	14.19
Teaching Hospital Karapitiya	42.7	16.7	2.0	-
Teaching Hospital Ragama	46.7	13.7	-	-

Drug use (3)

- Most doctors do private practice in the evenings and see pharmaceutical representatives regularly
- No gate-keeper referral system from primary level to secondary to tertiary levels
- Huge overcrowding in clinics
  - Some doctors see 150 patients/day & have 1 minute consultations
  - leads to polypharmacy and maybe to unnecessary IP admissions
- Some small divisional hospitals have many empty beds even though they may report high bed occupancy
  - Patients are admitted for an injection and then go home the same day but they are recorded as occupying a bed

Drug selection: possible solutions

- Continue to update regularly the national EML in a transparent manner with wide representation
- Harmonize MSD and national EML lists
  - Some essential MSD drugs are not on EML e.g. losartan
- Monitor compliance with national EML taking into account level of use
  - Whether lower levels are using higher level drugs
- Stricter adherence to EML
  - Drug & Therapeutic Committee in each referral hospital to judge all requests for non-EML drugs
  - colleges and specialists boards to provide guidance on "reasonable" specialist drugs for non-EML purchase
  - permanent sub-committee to judge all out-of-list requests at the national level

Drug use OPD indicator survey

Medicines (drug) use indicator	Teaching hospital n=3	Base & divisional hospital n=4	Central Dispensary n=3	Retail pharmacy n=10
Av.no.drugs/patient	3.5	3.7	2.9	2.6
% patients given ABs	45.2	67.3	50.9	24.2
% URTIs given ABs	47.0	85.4	68.1	-
% patients given INJs	< 5	< 5	<2	0 – 3
% patients given VITs	22.0	9.4	13.3	8.9
% generic drugs	67.9	82.3	75.9	30.7
% EML drugs	89.9	94.7	92.0	52.3
% drugs dispensed	91.7	91.3	99.0	88.6
Av.cost/Px (IRs)	-	-	-	446.27

Examples of inappropriate prescribing & dispensing

- All caps & tabs put into the same paper envelope with dosing instructions written on the envelope for the white pill and the red capsule
- Half a capsule of amoxycillin prescribed and issued to a 3-year old child
- Half a tube of miconazole cream prescribed & dispensed
- 2 antihistamines - chlorpeniramine & promethazine prescribed together
- 2 antibiotics cephalexin & nitrofurantoin prescribed together
- Dexamethasone or prednisolone often prescribed for coughs & colds
- >4 medicines often prescribed for simple conditions

Health worker views (1)

- **Sub-store pharmacist**
  - *The store keeper in the other sub-store does not accept my authority so I cannot prevent poor stock management*
- **High antibiotic prescribing doctor**
  - *According to STGs, for fever, coughs and colds, we should give paracetamol and or chlorpheniramine for a few days and only give antibiotics if there is no response, but I like to give the complete treatment from the start.*
- **Doctor**
  - *I like to prescribe better drugs so I give prescriptions for outside purchase, which patients can pay for even though they cannot afford to see private doctors*

Health worker views (2)

- **Senior consultant physician**
  - *I am surprised how this country manages to supply all medicines free of cost and I am very satisfied with the medicines supplied.*
- **MSD staff**
  - *We are blamed for all stock-outs & accused of corruption even though we have no control over the situation because we do not receive drugs on time*

Drug use: possible solutions (1)

- **Monitor drug use**
  - Do prescription audit using diagnosis
  - Revise prescriptions to have diagnosis as well as drugs treatment
  - Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices
  - Should be done by all teaching hospitals & Regional Health Depts.
- **Analyse prescriber workload**
  - To ensure equal workload for all prescribers, which could lead to…
  - More prudent prescribing, better dispensing, less return of old patients so reducing OPD crowding (and possibly IPD admission/crowding)
  - Lobby central level for more staff and redistribution of staff according to workload & to match expertise with equipment
- **Establish a referral system to decrease overcrowding**

Drug use: possible solutions (2)

- **Standard Treatment Guidelines (STG)**
  - Develop STGs including OPD treatment of simple primary care conditions with emphasis on using fewer medicines
  - Disseminate to every doctor & student & incorporate into CME
- **Drug and Therapeutic Committees (DTC)**
  - Require the hospital DTCs to monitor drug use, encourage CME, and report annually on these activities to MOH
- **Continuing medical education (CME)**
  - Incorporate prescription audit & feedback and ethics into CME
  - Involve Sri Lanka medical council & professional associations
- **Public Education**
  - Core pharmaceutical messages e.g. does my child need more than one medicine? Antibiotics not needed for simple coughs and colds through health education channels and the media
  - Through all channels used by different MOH units

Drug regulation (1)

- **National Drug Regulatory Authority (DRA) executes:**
  - Cosmetics, Devices & Drug Act 1980 & some amendments (quite comprehensive)
  - National Medicines Regulatory Authority Bill, passed by parliament in March 2015 will make the DRA directly accountable to the Minister of Health (not DGHS) & give it an external board
- **DRA manages a sector consisting of:**
  - 8,095 Products — 896 manufacturing units (12 locally owned)
  - 790 wholesalers — 3,297 retail shops
- **DRA extremely under-resourced**
  - Has 57 staff (25 technical staff) and no branch offices
  - Food & drug inspectors under the provinces inspect pharmacies
- **SOPs/Checklists**
  - SOPs for some procedures e.g. outlet licensing, product recall, registration
  - Checklists for other procedures e.g. drug evaluation report

Drug regulation (2)

- **National Drug Quality Assurance Laboratory**
  - 1 lab with 77 posts (19 unfilled),
  - About 800 samples tested per year with about 30% failure rate
- **Outlet inspections**
  - 14,237 inspections of retail & wholesale pharmacies in 2013
- **Drug Schedules**
  - OTCs that can be sold by anyone (1), OTCs that can only be sold by a pharmacist (2a), POM (2b) and Controlled drugs (3)
  - All drugs, except controlled drugs, are sometimes available OTC and sometimes dispensed by unqualified persons
- **Drug Registration**
  - New & old molecule approval by Drug Evaluation Sub-Committee
  - Separate guidelines for old and new molecules
  - Some say: SOPs not followed, Drug Evaluation Sub-Committee may be overruled, trained staff not used, computer system not used

Drug Regulation (3)

- **312 prosecutions (287 concluded) in 2013**
  - 2 million SLR fines
  - Reasons: no valid licences, absence of pharmacist, issuing POM drugs OTC, unqualified people storing drugs, issuing wrong medicines
- **Adhoc monitoring of drug promotion**
  - Pre-approval of drug labels, package inserts and adverts
  - 1 label for an OTC drug failed last year
- **Adverse Drug Reaction Monitoring**
  - 200-300 ADRs reported to DRA last year, 23 serious with 2 deaths, but no reporting to Upsalla
  - Colombo University pharmacology dept. used to be national centre, reporting to Upsalla, but now they report to DRA (44 ADRs last year)
- **Drug Price Controls**
  - Prices not controlled by DRA (or anybody else)

Drug regulation: possible solutions

- Strengthen the DRA
  - More inspectors, pharmacists
  - Standard operating procedures & guidelines for all procedures
  - Strengthen monitoring of drug promotion & pharmacovigilance
- Make the registration process more stringent in order to improve quality & reduce number of products
  - Stronger criteria e.g. bioequivalence studies, dissolution profiles, stability studies
  - Stricter application of criteria, follow the SOPs & recommendations of Drug Evaluation Sub-Committee
  - Use the computerized system already developed
  - Ensure all staff trained on dossier evaluation & GMP inspection are assigned these tasks
- Implement the new National Medicines Regulatory Authority Bill 2015
  - Establish effective monitoring & evaluation systems

Coordination and management

- MOH Structure: DDG Laboratory services in charge of: Health Labs, Medical Research Inst., NDQA lab, MSD, DRA, but…
  - What unit is actively looking after:
    - Updating and implementing EML & STGs?
    - Monitoring of DTC function and prescribing?
    - Continuing medical education and public education?
- Same experts are serving on various committees e.g. EML selection, drug registration, technical advisory committee, drug procurement
  - Lack of time and conflict of interest
  - Need for permanent MOH staff to gather the evidence for the experts to consider in the various sub-committees
- Drug policy 2005 not implemented
  - Non-specific content and past court action by patients
- New Drug Act 2015 to make DRA more independent passed by parliament but not yet implemented
- How is coordination between ministries managed?

Coordinating structure and national policy: possible solutions

- Expand the role of the Technical Advisory Committee to cover all drug policy issues (not just drug regulation) and expand the membership to include laypersons, more professional bodies ….
- Identify an executive unit in the MOH to be responsible for rational use of drugs:
  - EML, STGs, Drug & Therapeutic Committees, monitor use, Continuing Medical Education, Drug Information Centre, public education
  - Liaison with universities to provide students to collect information needed by MOH as part of their research studies
- Consider revising the National Medicines Policy 2005 to be more specific once the new Drug Act is implemented

Group work

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