MEDICINES IN HEALTH CARE DELIVERY

THAILAND

Situational Analysis:

23 November – 4 December 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

February 2016

CONTENTS

1. ABBREVIATIONS

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AMR	Antimicrobial Resistance
ASEAN	Association of Southeast Asian Nations
ASU	Antibiotics Smart Use project
BHA	Bureau of Health Administration
CME	Continuing Medical Education
CPD	Continuing Professional Development
CSMBS	Civil Servant Medical Benefits Scheme
DHO	District Health Office
DIC	Drug Information Centre
DPHO	District Public Health Office
DMSIC	Drug and Medical Supply Information Centre
DRA	Drug Regulatory Authority
DRG	Disease-related Group Costing (for inpatient treatment)
DTC	Drug and Therapeutics Committee
GDP	Good Dispensing Practice
EML	Essential Medicines List
EMIT	Emergency Medical Institute of Thailand
EDL	Essential Drug List
EML	Essential Medicines List
FDA	Food and Drug Administration
FEFO	First Expired First Out
FIFO	First in First out
GCP	Good Clinical Practice

GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPO	Government Pharmaceutical organization
GPP	Good Pharmacy Practice
HC	Health Centre
IPD	Inpatient Department
MO	Medical Officer
MOF	Ministry of Finance
MOH	Ministry of Health
MOL	Ministry of Labour
MOPH	Ministry of Public health
NDP	National Drug Policy
NF	National Formulary
NGO	Non-Governmental Organisation
NHC	National Health Committee
NHSO	National Health Security Office
NDP	National Drug Policy
NEML	National Essential Medicine List
NHP	National Health Policy
NLED	National List of Essential Medicines
NMP	National Medicines Policy
OPD	Outpatient Department
OPS	Office of the Permanent Secretary
OTC	Over-the-Counter
PV	Pharmacovigilance
PHO	Provincial Health Office

PLEASE	Project focusing on **P**harmacy andTherapeutics Committee, **L**abelling and leaflet, **E**ssential RUD tools, **A**wareness of RUD among prescribers and patients, **S**pecial population care, and **E**thics in Promotion
PM	Prime Minister
PTC	Pharmacy and Therapeutics Committee
QA	Quality Assurance
RDU/RUD	Rational Drug Use/Rational Use of Drugs
RUM	Rational Use of Medicines
SOP	Standard Operating Procedures
SSO	Social Security Office
SSS	Social Security Scheme
STG	Standard Treatment Guidelines
TOR	Terms of Reference
TRM	Traditional Medicines
UHCS	Universal Health Care Coverage Scheme
URTI	Upper Respiratory Tract Infection
VEN	Vital, Essential, Non-essential – method for classifying drug importance
VMI	Electronic management information system run by the GPO for the drugs and vaccines that they supply
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Thailand during 23 November – 4 December 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 [name of government department], facilitated by WHO/SEARO, would conduct the situational analysis.

The team members consisted of:

- WHO/SEARO: Dr Kathleen Holloway, Dr Anita Kotwani, Dr Budiono Santoso
- WHO/Thailand: Dr Nima Asgari
- Pharmacy Section, BHA, MOPH: Ms Pornpimon ChantrakunaparsMs Voranadda Srisuphan, , Dr Araya Sripairoj,
- IHPP, MOPH: Dr Chutima Akaleephan
- NHSO Chiang Mai: Mrs Siriporn Wohbah
- Thai FDA, MOPH: Ms Worasuda Yoongthong, Mrs Naphaphorn Puripunyavanich, Ms Kakanang Tosanguan, Ms Lalittanan Moolasart, Ms Juthathip Martro, Mr Kitti Sukantho, Mr Thanakrit Mongkolchaipak , Mr Sataporn Lumpaiboonsuk, Mr Yuthana Duangjai

The programme involved meetings with all the major government departments and other stakeholders involved in the management of medicines and visits to health facilities in two regions. A detailed program can be seen in section 3. During the visits to public health facilities and private pharmacies, drug stores were visited to collect data on stock availability for 40 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 4 December 2015 where findings were discussed and recommendations developed. Fifty-five participants attended the workshop and the list of participants 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

Thailand has a remarkable health delivery system where almost all patients are covered by insurance for their health services, including medicines. There is a well-functioning medicines public supply system as part of their health services delivery for the universal health coverage policy. Most of the needed essential medicines, over 90 %, are available in public hospitals with very small levels of stock out. The drug distribution is decentralized where the needed medicines are directly supplied to hospitals. The supplies for public health centers are taken care by the community hospitals. The availability of essential medicines in public health center facilities (even those classified for use at health centres) is less as compared to hospitals, possibly because some health centres are not using a substantial number of the medicines that are classified for use at that level in the national EML.

A substantial proportion of hospital expenditures has been accounted for by medicines not listed in the National Essential Medicines list, and most hospitals have their own hospital formularies serving as basis medicines supply. There is a need to promote the compliance with the national Essential Medicines List. The pharmaceutical services and management in hospitals are well organized to offer different functions supporting health care services. The clear system organization, along with the substantial presence of hospital pharmacists, are major reasons for the quality of services observed. In most health facilities the drug management information system is totally electronic. However, there is a need for unified information system for national monitoring of drugs management. The recommendations made during the last survey still need to be strictly implemented like harmonizing all electronic drug management, strengthen the Pharmacy section, MOPH and discourage use of non-EML drugs especially for CSMBS beneficiaries.

It was recommended to:

- Strengthen the mechanism for sharing information to ease drug management and monitoring by harmonizing the electronic drug management systems, especially GPO/VMI, health facility e-LMIS, MOPH monitoring system, MOF monitoring system, and NHSO.
- Strengthen the Pharmacy Section of MOPH to monitor compliance with standards in pharmaceutical care and procurement.
- Discourage the use of non-EML drugs through various means, possibly by limiting budget allocations, requiring co-payment for some non-EML drugs, devising clear criteria to classify the use of non-essential drugs, and monitoring and feedback to hospitals and prescribers on the use of non-EML drugs.
- Investigate the drug distribution system from community hospitals to health centers in order to improve availability of the needed medicines at health centers

2.3. Medicines Selection

Since the last situation analysis in 2011, there have been a number of revisions of the NEML which have been done every 1-2 years. However, there is plenty of room for promoting more use of the NEML at public facilities as well as private facilities. Substantial numbers of drugs items which do not belong to NEML are still being used and purchased at hospital facilities. The dissemination of the NEML and advocacy to comply with the NEML at hospital facilities needs to be strengthened. Effective incentives need to be devised to promote the use of the NEML. The concepts of essential medicines, the NEML, and rational use of medicines, need to be introduced in undergraduate training as well as in in-service training of the health workers. Although the medication system has been included in the hospital accreditation system, it does not include compliance to the NEML.

It was recommended to:

- Continue to update and revise the national Essential Medicines List (EML) in a transparent manner to improve acceptance, and disseminate to all health facilities:
    - To include medicines for all levels of care and classify them by facility level, prescriber type and therapeutic class as is being done currently.
- Monitor compliance with the national EML, including compliance with level of use by:
    - requiring every hospital to produce an annual report on drug consumption for MOPH, namely ABC analysis to identify high cost medicines and % budget spent on non-NEML drugs.
- Reduce the use of non-EML drugs, for instance, by differential reimbursement for vital, essential & non-essential drugs and co-payments for non-EML drugs.
- Promote understanding of Essential Drugs Concept and the national List of Essential Drugs (EML) through:
    - provision of feedback of local consumption data to prescribers by the Pharmacy and Therapeutics Committee, and to include them in undergraduate and postgraduate curricula.
- Devise a harmonized national essential drugs formulary, based on the national essential drug list (NEML), serving as a basis for all public procurement and insurance reimbursement.

2.4. Medicines use

Promoting rational, safe and cost effective use of medicines is a never-ending process. Interventions to promote rational use of medicines (drugs) should be part of the existing medicines and health care policy. There has been substantial progress since the last situation analysis in 2012 in Thailand with regard to promoting rational use of drugs. All hospitals have a functioning Pharmacy and Therapeutics Committee (PTC). Most PTC activities have been on medicines selection and procurement and it would now be important to expand PTC functions to undertake monitoring of prescribing (not just ABC analysis of consumption) and effective interventions for promoting rational use of drugs. Some standard treatment guidelines have been produced and distributed at health facilities. However, the use of these guidelines is sub-optimal and their use needs to be encouraged and monitored.

Some important projects such as ASU (Antibiotic Smart Use) and PLEASE (Pharmacy and Therapeutics Committee, Labelling and leaflet, Essential RUD tools, Awareness of RUD among prescribers and patients, Special population care, and Ethics in Promotion), which to some extent have produced good results, need to be institutionalized as part of the existing health care and medicines program. While many relevant activities to improve prescribing have been undertaken by different program, much more effort is still needed to promote rational and safe use of medicines by consumers and patients.

It was recommended to:

- Monitor medicines (drug) use
    - By ABC analysis of consumption, prescription audit and feedback for both outpatient and inpatient care - by hospital PTCs,
    - Use of existing hospital electronic patient data bases,
    - Reporting on selected drug use indicators to MOPH
    - Institutionalization of the PLEASE, ASU, and other drug use projects.
- Develop national Standard Treatment Guidelines (STGs) for primary & secondary care and implement them through:
    - publication online and dissemination of them free of charge to prescribers,
    - incorporation into undergraduate and continuing education.
- Incorporate components on rational prescribing and the essential medicines concept into the existing health professional education curricula.
- Strengthen the role and capacity of Pharmacy and Therapeutics Committee (PTC):
    - To monitor prescribing, encourage continuing medical education, undertake self-assessment, and report annually on activities to MOPH,
    - By strengthening the Pharmacy Section in the Office of the Permanent Secretary, MOPH, to review the PTC reports, and to train PTCs and take other actions, and
    - By considering inclusion of PTC activities in hospital accreditation.
- Develop systematic continuing professional development (CPD) by:
    - Thailand Medical Council considering to develop a new credit system for continuing medical education of doctors, obligatory for re-licensing (as already started for pharmacists & nurses),
    - including rational prescribing and the essential medicines concept in the curricula of health workers, and
    - Medical & pharmacist associations promoting the essential drugs concept through the lectures/seminars they organize.

- Undertake systematic public education through:
    - nationwide campaigns on the safe and prudent use of medicines,
    - devising core pharmaceutical messages e.g. "does my child need more than one drug?" or "coughs & colds do not usually need antibiotics",
    - giving messages through the Village Health Volunteers, community pharmacists, schools, NGOs, the media, and funded by insurance agencies.
- Strengthen an effective referral system by: encouraging the use of health centers and strengthening them in order to decrease the crowds in referral hospitals

2.5. Medicines Regulation

Thailand has a long history of implementing medicines regulation for protecting the public with a number of Drug Acts since early in the last century. The Drug Act BE 2510 (1967) was amended four times culminating with the Drug Act BE 2530 (1987). However, this Drug Act is too rigid not allowing for revision of fees and fines, which are too low and undermine the work of the FDA. For example, the FDA has to undertake more work to deal with poor applications for drug registration and cannot adequately punish pharmaceutical companies which publish misleading advertisements. The Drug Act was further revised with more flexible and effective provisions in 2003 but it has not yet been passed by Parliament and implemented. The Thai Food and Drug Administration (FDA), is an established regulatory authority responsible for implementing medicines regulation along with other Government Departments such as the Department of Medical Sciences.

Many aspects of the medicines regulatory system have been effectively implemented particularly the drug quality assurance system and the drug safety surveillance or pharmacovigilance system, etc. Nevertheless, there is room for further improvement. In the area of medicines registration the regulatory authority can aim for fewer brands of the same active pharmaceutical ingredient (API) in the market, along with 5-year duration of registration. The re-evaluation sub-committee could meet more regularly to re-evaluate the registration of irrational combination products. There is also a need to improve monitoring and control of drug promotional activities, as well as education and advocacy for consumers on the safety of medicines. Disallowing antibiotics, particularly 3rd and 4th generation systemic ones, from being sold without prescription at retail pharmacy stores would help to decrease their consumption and contain antimicrobial resistance.

It was recommended to:

- Work towards a new more flexible and effective Drug Act, as there are still gaps and many areas of disagreement.
    - Continuous consultation involving all relevant stakeholders will help to close the gaps and disagreement in different areas.

- Work towards having fewer brands of same drug (active pharmaceutical ingredient) in the market by:
    - Introducing 5-yearly re-registrations,
    - De-registering drugs not currently in the market,
    - Increasing the fee for registration and
    - re-evaluating drug registrations regularly.
- Monitor drug promotional activities in collaboration with MOPH & professional bodies & councils,
    - Consider banning medical representatives from public facilities except by appointment with the Pharmacy and Therapeutics Committee,
    - Require companies to disclose their marketing activities and budgets,
    - Increase the fines for publishing misleading adverts,
    - Institute a risk approach to monitoring advertisements,
    - Undertake a rapid survey for monitoring drug promotion in both public and private hospitals (include clinics and drug stores) to see whether they follow the ethical criteria,
    - Incorporate education on ethical drug promotion through universities and professional councils.
- Publish failed drug test results to convince prescribers about drug quality,

Consider an external WHO Assessment on Drug Regulatory Authority functionality

2.6. Medicines Policy and Coordination

For implementing the National Medicines Policy, relevant strategies have been devised for 2012 – 2016 on: access; rational use; development of the domestic industry; biological products; herbal medicines for self-reliance; and on strengthening the regulatory system. Each strategy is furthered divided into sub-strategies, tactics and actions. Relevant committees are formed and different government departments/agencies are designated for implementing the strategic actions identified. Effective implementation of the NEML is one important aspect of the NMP which needs to be improved especially at hospitals. Different stakeholders involved in implementing the NMP need to be systematically monitored. As implementation of the NMP obviously involves multiple government committees and Government departments/agencies, either within or outside the MOPH, there is a need to designate an executive government department/agency to coordinate actions and to execute recommendations of the statutory committee. As mentioned earlier in the situational analysis of 2012, there are chances of various working groups doing the same work and duplication of work may lead to some inconsistencies.

The Universal Health Care Coverage Scheme (UHCS) and organization of medicines management in Thailand is very impressive. A major reason for the successful implementation of much of Thailand's National Medicines Policy and pharmaceutical care may be the employment of many pharmacists in the health system at all levels (with the exception of health centres).If Thailand were able prepare one document that fully described their UHCS programme together with how their pharmaceutical services are organized, this could provide institutional memory of lessons learned and would also be very useful for other countries to learn from.

With regard to national drug policy, it was recommended to:

- Promote the use of the National Essential Drug List as a basis for public procurement and reimbursement,
- Define a common standard of compliance in using the National Essential Drug List for procurement, reimbursement and usage.
- Monitor the activities of stakeholders in implementing National Drug Policy,
- Work on having a unified management system for universal health coverage policy involving different insurance schemes.

With regard to coordination, it was recommended to:

- Decide on one permanent statutory committee to advise the Minister of Health on pharmaceuticals with wide membership including laypersons, professional bodies etc. This could be the National Drug Systems Development Committee.
- Appoint one executive department in MOPH to carry out the statutory committee recommendations
    - To coordinate actions between different departments within MOPH, other Ministries and national agencies, i.e. the Pharmacy Section in the Office of the Permanent Secretary, FDA, Bureau of Policy & Strategy, Ministry of Education; Ministry of Finance; Ministry of Industry; Ministry of Commerce,
    - To be responsible for rational use of drugs: EML, STGs, PTCs, monitoring drug use, continuing education, and public education.
- Streamline the committees and invest in their advice.
- Document the description of the pharmaceutical health care system in order to maintain institutional memory of lessons learnt and progress made in implementing universal health coverage policy.

3. PROGRAMME AGENDA

Day	Date	Time	Places visited
1	23.11.15 Monday	Am	Meeting with Team at WHO Country office, Thailand
		Pm	Meeting with SSS office, NHSO and The Comptroller General office by three teams. Travel to Chaing Mai
2	24.11.15 Tuesday	Am	Visit to Lumphun general Hospital (Team 1) and to Pa Sang Community Hospital (Team 2)
		Pm	Visit to Makhueajae Health Centrer (Team 1) and to Pa Sang Health Center (Team 2) Visit to Private Retail Pharmacies: Tirdsak (Team 1); Visit to Pure Big C and Smele (Team 2)
3	25.11.15 Wednesday	Am	Visit to Nakornping Regional Hospital
		Pm	Visit to Ban Saluangnok Health Center (Team 1) and to Doi Kaew Health Center (Team 2)
4	26.11.15 Thursday	Am	Visit to Jomthong General Hospital
		Pm	Visit to Mae-ai Health Center (Team 1) and Sankampaeng Community Hospital (Team 2) Visit to retail pharmacies: Boots
5	27.11.15 Friday	Am	Visit to Kitti Chiang Mai retail pharmacy (Team 1) and Chiang Mai University Public Pharmacy (Team 2)
		Pm	Travel back to Bangkok
6	28.11.15 Saturday	Am	Checking and completing the survey forms
		Pm	
7	29.11.15 Sunday	Am	Analysis of data from forms
		Pm	Visit to Rueanya private Retail Pharmacy
8	30.11.15 Monday	Am	Visit to FDA. Focus group Discussion on Regulation (Team 1) and with Departments of Medical Science, Disease Control, Bureau of health Administration, Health, Health service support.
		Pm	Focus Group Discussion at FDA with Policy group, national Sub-committee on RUM, EDL section
9	01.12.15 Tuesday	Am	Focus Group Discussion: The healthcare Accreditation Institute (Team 1) Pharmacy Council, Nursing Council (Team 2)
		Pm	Visit to Government Pharmaceutical Organization and GPO Drug Store (Team 1)
10	02.12.15 Wednesday	Am	Visit to Siriraj Hospital
		Pm	Visit to Charoenkrung Pracharak Hospital (Team 1) Visit to BKK Health Center (Team 2)
11	03.12.15 Thursday	Am	Preparation with workshop
		Pm	Meeting with Core Team to finalize the Presentation for the Workshop
12	04.12.15 Friday	Am	Workshop
		Pm	Workshop; Departure for Delhi

4. MEDICINE SUPPLY

4.1 Responsible Agents/Departments

Function/ Organisation	MOH	Other Agency	Name of Agency/MOH Department
Selection	✓		Subcommittee of the National List of Essential Medicines, with Food and Drug Administration acting as its secretariat
Quantification	✓		Hospitals make a 3 year plan and approved by Regional/Provincial Health Authority
Procurement	✓		Hospitals do their own procurement Community hospitals undertake procurement for health centers.
Pricing	✓		Price Negotiation Working Group
Storage	✓		Pharmacy Unit of Hospitals and health centers
Distribution	✓	✓	Suppliers supply medicines to health facilities/hospitals Community hospitals supply medicines to health centers
Monitoring & evaluation	✓		Pharmacy Section, Bureau of Health Administration, MOPH

4.2. Drug availability

In recent years, apparently there are no studies to investigate the availability of essential medicines in health facilities using selected drug indicator in Thailand. However, there are few studies investigating the availability and affordability of specific medicines for examples medicines for palliative care[1]or for non-communicable diseases[2]. In the 2012 situational analysis, availability of essential medicines was not reviewed. However, in this 2015 situational analysis, the availability of 40 essential medicines, jointly selected with the team members from the Government from the National Essential Medicines List (NEML), was assessed in both public and private facilities.

[1] Thongkhamcharoen R[1], Phungrassami T, Atthakul N. Palliative care and essential drug availability: Thailand national survey 2012. J Palliat Med. 2013 May;16(5):546-50. doi: 10.1089/jpm.2012.0520. URL: http://www.ncbi.nlm.nih.gov/pubmed/23822211\

[2] Nguyen et al. Journal of Pharmaceutical Policy and Practice 2015, 8(Suppl 1):P3. URL: http://www.joppp.org/content/8/S1/P3

The key essential medicines surveyed for availability consisted of:

Health Centres (34 medicines):

> Albendazole tab; amlodipine tab; amoxycillin tab; antacid; amitriptyline tab; antibiotic eye drops; atenolol tab; budesonide inhaler; cetirizine tab; clotrimazole cream; dexamethasone inj; diazepam inj; diclofenac inj; dicloxacillin tab; domperidone tab; enalapril tab; ferrous + folic tab; fluconazole tab; fluexetine tab; glipizide tab; hydrochlorthiazide; ibuprofen tab; metformin tab; metronidazole tab; norfloxacin tab; normal saline; ORS; omeprazole tab; paracetamol tab; permethrin; phenytoin cap; prednisolone tab; roxithromycin tab; salbutamol inhaler.

Referral (provincial, regional, general, university) hospitals, Community/District hospitals (6 additional medicines):

> Co-amoxyclav tab; ceftriaxone inj; cefazolin inj; meropenem/imipenem inj; risperidone tab; tramadol cap.

The team members interviewed the informants at the health facilities and checked the availability from the stores. Table 4.2.1 show some data on stock availability and stock-out.

- The averages of availability during the visits were , 97 % (95 – 100 %) in public general and referral hospitals, 92.5 % (90 – 95 %) in community hospitals, 69.1 % (50 – 82.4%) in health centres , 67.8% (55-80.0%) in private pharmacies, and 77.5 % in public pharmacies.

- The levels of stock out during the visits were 0.66 % (0 – 2.8 %) in public general and referral hospitals, 0 % in community hospitals, and 9.15 % (4.5 – 14.7 %) in health centres.

- There were lower levels of availability and relatively higher stock-outs of essential medicines at health centres. There seemed to be a kind of bottle-neck in distribution from community hospitals to health centres which needs to be systematically addressed.

- On discussions with pharmacy staff from the general and regional hospitals, there were often stock-outs of certain products such as antidotes and certain vaccines due to unavailability of suppliers at international levels.

Overall essential medicines availability was good. If medicines were unavailable it was more often due to non-use rather than stock-out since the % of medicines out of stock was much lower than might be expected from the % availability of medicines. For example, in health centres, up to 30% of medicines may not be used, since 69% of essential drugs were available but only 9% were out of stock, on average.

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

Public Referral Hospitals	Regional hospital	General hospital 1	General hospital 2		University hospital	Metropolitan hospital	Average
% EML/currently used items out of stock	0.5%	2.8%	0.0%		0.0%	0.0%	0.66%
% key EML drugs available	95.0%	97.5%	100.0%		97.5%	95.0%	97.0%
% prescribed drugs dispensed*	100.0%	99.0%	99.5%		100.0%	100.0%	99.7%
Community Hospitals	1	2	3				Average
% EML/currently used items out of stock	0.0%	0.0%	0.0%				0.0%
% key EML drugs available	92.5%	95.0%	90.0%				92.5%
% prescribed drugs dispensed*	100.0%	100.0%	100.0%				100.0%
Public primary health care centre	1	2	3	4	5	6	Average
% EML/currently used items out of stock*	14.7%	14.1%	6.7%	10.0%	4.5%	4.9%	9.15%
% key EML drugs available	50.0%	58.8%	70.6%	70.6%	82.4%	82.4%	69.1%
% prescribed drugs dispensed*	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Private pharmacies	1	2	3		4		
% key EML drugs available	60.0%	80.0%	75.0%		72.5%		
% prescribed drugs dispensed*	100.0%	100.0%	100.0%		100.0%		
Private pharmacies	5	6	7		8		Average
% key EML drugs available	55.0%	60.0%	70.0%		70.0%		67.8%
% prescribed drugs dispensed*	100.0%	100.0%	100.0%		100.0%		100.0%
Public pharmacies	1	2					Average
% key EML drugs available	77.5%	77.5%					77.5%
% prescribed drugs dispensed*	100.0%	100.0%					100.0%

* From the prescription audit done during the health facility survey

4.3 Annual aggregate data of medicines distribution / consumption

ABC analysis is a useful tool in pharmaceutical supply system to analyze consumption pattern and its monetary values. It may reflect the efficiency of procurement, uses and funding. ABC analysis of aggregate national, regional and provincial consumption data would be most useful, but this was not available. However the mission managed to obtain ABC analysis at institutional levels, i.e. hospitals and health centers.

Tables 4.3.1, 4.3.2, 4.3.3 and 4.3.4 show the top 20 items consumed by value at national, district/community hospital and health centre level, respectively. The results from all health facilities could not be presented here and in particular, the results from only two of the six health centres visited are presented. There are some important findings which would need further consideration.

Firstly, a substantial proportion of expenditures in referral and general hospitals is on non-EML medicines, indicating the need to promote the concept of essential medicines and rational drug use at these levels. Effective incentives for using essential medicines need to be explored. Thus the % of budget spent on EML medicines was 44.8% in the Siriraj university referral hospital, 62.5% in Charoenkrung Pacharak Bangkok municipal referral hospital and in these two hospitals the top 20 medicines consumed 25% and 21.5% of the budget, respectively. For all other facilities, the % of the budget spent on EML medicines was 75% in Lamphun General Hospital, 75% in Nakornping Regional hospital, 69% in Sankampaeng Community hospital, 96% in Pasang Community hospital and 99% and 90% for the two health centers depicted in Table 4.3.4.

Secondly, a substantial proportion of expenditures is on medicines for non-communicable diseases, at all level of health care, unlike in many other low and middle-income countries where expenditure on antibiotics tends to predominate. Expenditures on antibiotics in the referral and general hospitals were in the range of 8.2% to 11.0% and in the community hospitals and health centres in the range of 4-9%. Expenditure on vitamins was generally less than 5% except at one tertiary care hospital expenditure where it was 10.5% of the total budget, which may not be justified.

The WHO country profile shows that the top 10 causes of mortality in Thailand in 2012 were ischaemic heart disease (13.7%), stroke (10.3%), lower respiratory infections(9.4%), road injury (5%, chronic obstructive pulmonary disease (4.7%), HIV/AIDS (4.1%), diabetes mellitus (4.1%), liver cancer (3.8%), trachea, bronchus, lung cancers (3.5%) and kidney diseases (2.5%)[3]. Similarly, the ten leading burden of diseases in 2012 for Thailand were cardiovascular diseases and diabetes, other NCDs*, neuropsychiatric conditions, cancers, unintentional injuries, HIV, TB, malaria, chronic respiratory diseases, musculoskeletal diseases, acute respiratory infections, and maternal, neonatal, nutritional diseases.

The ABC analysis has also shown that medicines for chronic diseases like hypertension, diabetes, asthma, hyperlipidemia and kidney disease are consuming a lot of expenditure, such medicines being in the top 20 for all levels of health care. Anticipating more consumption in the upcoming years, it would be very helpful to devise clinical guidelines for non-communicable diseases, and disseminated and introduced to prescribers. Monitoring the use and consumption of NCD drugs would be very much needed. ABC analyses could be performed, not only at institutional levels but also at regional and national levels to identify areas where efficiency could be maximized.

[3] World Health Organization Geneva. Thailand Statistical Profile 2012. http://www.who.int/countries/tha/en/

Table 4.3.1: ABC analysis of top 20 items – University and Specialist hospitals Data 2014-2015

Rank	Charoenkrung Pacharak hospital (Bangkok Metropolitan)			Siriraj Hospital (University Hospital)		
	Item Name/Strength	Monetary Value	EML	Item Name/Strength	Monetary Value Million	EML
1	Atorvastatin Sandoz 40 mg tablet	6,561,240	Y	Atorvastatin tab	109.92	Y
2	PIPERTAZ 4.5 gram injection (piperacillin)	4,954,186	Y	Erythropoetin alpha inj	88.82	Y
3	EFREX PROTECS PFS 4000 IU Inj (epoetin alfa)	4,879,200	Y	Entecavir tab	82.27	N
4	Actos 30 mg tablet (pioglitazone)	3,525,222	Y	Tacrolimus cap	78.06	Y
5	PLAVIX F/C 75 mg tablet (clopidogrel)	3,415,907	Y	Rosuvastatin tab	72.92	N
6	MEPROPENEM 1 gm injection	3,351,401	y	Erythropoetin beta inj	70.59	Y
7	JANUVIA 100 mg tablet (sitagliptin)	3,027,903	N	Rituximab inj	68.09	N
8	Human Albumin 20 % 50 ml inj	2,905,050	N	Clopidogrel tab	65.56	Y
9	BLOPRES 16mg tablet (candesartan cilexetil)	2,649,855	N	Deferasirox tab	60.67	N
10	XARATOR F/C 40 mg tablet atorvastatin	2,618,436	Y	Donepezil tab	59.41	N
11	AMBES 10 mg tablet (amlodipine)	2,484,000	Y	Bortezomib inj	56.49	N
12	IMPLANON NXT 68 mg IMPLANT (etonogestrel)	2,446,020	Y	Imatinib tab	53.47	Y
13	MADIPLOT 20 mg tablet (manidipine)	2,441,205	N	Leuprorelin inj	46.50	Y
14	XATRAL XL P/R 10 mg tablet (alfuzosin)	2,419,056	Y	Trastuzumab inj	45.41	Y*
15	PARIET GASTRO RESISTANT 20 mg tab (rabenprazol)	2,408,162	N	Mycophenolate sodium oral	42.37	N
16	LORANTA 100 mg tablet (losartan)	2,187,829	Y	Mycophenolate mofetil oral	41.29	Y
17	ULTRAVIST 300 50 ml inj (iopromide)	2,141,070	Y	Pregabalin tab	39.39	N
18	0.9 %normal saline100 Ml Injection	2,098,056	Y	Alfuzosin tab	39.27	Y
19	ARCOXIA 60 mg tablet (etoricoxib)	2,043,486	N	Oxaliplatin inj	38.91	Y
20	OXALIPLATIN 50 mg/10 ml	2,030,325	Y	Losartan tab	38.64	Y
	% budget on top 20 drugs	60,587,609	21. 55 %	% budget on top 20 drugs	1198 M	24 9%
	% on Antibiotics	30,844,510	10.97 %	% on Antibiotics	396 M	8.2 %
	% budget on vitamins	6,009,921	2.14 %	% budget on vitamins	507 M	10.5%
	% budget on EML drugs	175,873,851	62.57 %	% budget on EML drugs	2155 M	44.8 %
	Per capita annual expenditure on medicines supplied (catchment population 360,405)		779.95	Per capita annual expend. on medicines supplied	-	-
	Total medicines budget	281 097 022	100 %	Total medicines budget	4810 M	100%

* Added to the EML in 2015.

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Table 4.3.2: ABC analysis of top 20 items – General and Regional hospitals Data 2014-2015

Rank	Lamphun General hospital			Nakornping Regional hospital		
	Item Name/Strength	Monetary Value	EML	Item Name/Strength	Monetary Value	EML
1	Erythropoietin alpha inj 4000 IU/0.4 ml	4,659,717	Y	1.5 % peritoneal dialysis low calcium 5 litre	13,028,701	Y
2	Manidipine HCL tab 20 mg	3,323,837	N	Mycophenolate Mofetil 250 mg caps	9,262,853	Y
3	Celecoxib, caps 200 mg	2,248,737	N	Oxaliplatin inj 50 mg	8,929,691	Y
4	Amlodipine, tab 10 mg	2,167,867	Y	Atorvastatin tab 40 mg	8,703,180	Y
5	Lopinavir + Ritonavir tab 200 mg + 150 mg	2,149,821	Y	Meropenem inj 1 G	7,508,016	Y
6	Brimonidine tartrate eye drop	2,133,950	Y	Erythropoetin inj 500 IU	6,183,384	Y
7	Sodium valproate tab 500 mg	2,005,923	Y	Sitagliptin tab 100 mg	5,438,425	N
8	Irinotecan inj 100 mg/5mL	1,902,415	N	Manidipine HCl tab 20 mg	4,989,390	N
9	Sevoflurane liq.250 ml	1,626,628	Y	Peginterferon alpha 2B 100 ug inj	4,981,096	Y
10	Meropenem powd 1 G inj	1,619,812	Y	Ezetimibe tab 10 mg	4,624,211	N
11	Simvastatin tab 20 mg	1,571,025	Y	Epoietin alfa inj 4000 IU	3,595,233	Y
12	Sodium Chloride 0.9% 1000 ml	1,568,061	Y	Sodium Valproate SR tab 500 mg	3,318,369	Y
13	Atorvastatin Ca tab 20 mg	1,517,981	Y	Amlodipine tab 5 mg	3,265,868	Y
14	Nicardipine HCl inj 10 mg/10mL	1,484,529	Y	Pregabalin caps 75 mg	3,251,225	N
15	Carvedilol tab 12.5.mg	1,465,616	Y	Piperacillin 4 G + Tazobactam 500 mg powd inj	3,240,602	Y
16	NVP+3TC+AZT (GPO) 200mg+150 mg +250 mg	1,405,584	Y	Sodium Chloride 0.9 % 1000 ml	3,206,965	Y
17	Letrozole tab 2.5 mg	1,404,524	Y	Entecavir tab FC 0.5 mg	3,102,881	N
18	Alfuzosin tab 10 mg	1,398,276	Y	Azatanavir sulfate caps 300 mg	3,025,526	Y
19	Sodium chloride 0.9 % 100 ml	1,341,475	Y	Lercanidipine tab 20 mg	2,873,292	N
20	Sitagliptin tab 100 mg	1,319,791	N	Alfuzosin SR tab 10 mg	2,819,664	Y
	% budget on top 20 drugs	38,315,569	25.3 %	% budget on top 20 drugs	105,348,572	31.8 %
	% on Antibiotics		8.25 %	% on Antibiotics		9.6 %
	% budget on vitamins		1.37 %	% budget on vitamins		2.4 %
	% budget on EML drugs		75 %	% budget on EML drugs		75.%
	Total budget	151,571,456	100 %	Total budget	331,149,755	100 %

Table 4.3.3: ABC analysis of top 20 items – Community /District Hospitals Data 2014-2015

Rank	Pasang Hospital			Sankampaeng Hospital		
	Item Name/Strength	Monetary Value	EML	Item Name/Strength	Monetary Value	EML
1	Simvastatin tab 20 mg	978,611	Y	AZT+Lamivudine+Nevirapine tab	829,511	Y
2	Salmeterol+Fluticasone	676,282	Y	Lopinavir+Ritonavir tab	729,983	Y
3	Amlodipine tab 10 mg	620,240	Y	Tenofovir tab	474,246	Y
4	Metformin tab 500 mg	525,325	Y	Amlodipine tab 5 mg	438,025	Y
5	N.S.S.0.9% in 1000ml	501,845	Y	Metformin tab 500 mg	306,155	Y
6	Rabies vaccine vero cell inj	464,526	Y	Losartan 50mg tab	293,853	Y
7	Carvediol 12.5mg tab	423,000	Y	Simvastatin tab 10 mg	283,253	Y
8	Losartan 50mg tab	397,600	Y	JE Vaccine	264,454	Y
9	Amlodipine tab 5 mg	349,635	Y	Influenza vaccine-1 dose	260,454	Y
10	Epoitin (prefill) 4000iu/0.4ml	318,535	Y	Influenza vaccine-4 dose	253,121	Y
11	Glipizide 5mg tab	289,307	Y	DT Vaccine	226,540	Y
12	Enalapril tab 5 mg	251,370	Y	Ipratropium+Femoterol inhalation	220,639	Y
13	N.S.S.0.9% in 100ml	242,224	Y	Fenofibrate 300mg cap	208,230	Y
14	Enalapril tab 20 mg	201,810	Y	Rabies Vaccine	206,554	Y
15	NPH+RI 70:30 100iu/0.4ml	180,612	Y	Lamivudine 150mg tab	205,823	Y
16	Theophylline SR tab 200mg	178,636	Y	Fluticasone+Salmeterol Acc Inhaler	203,583	Y
17	Ceftriaxone powder inj 1 G	174,392	Y	Fluticasone+Salmeterol MDI	176,550	Y
18	Aspirin tab 81mg	151,625	Y	Pioglitazone 30mg tab	171,506	Y
19	Hydralazine tab 25mg	146,940	Y	Aspirin tab 81mg	162,351	Y
20	Budesonide inhaler 200mcg/dose	146,622	Y	Analgesic cream	160,172	Y
	% budget on top 20 drugs	7,219,137	40.4%	% budget on top 20 drugs	6,075,003	72.03 %
	% on Antibiotics		6.03%	% on Antibiotics		NA
	% budget on vitamins		2.2%	% budget on vitamins		NA
	% budget on EML drugs		95.9%	% budget on EML drugs		68.79%
	Total drug budget	17,853,788	100%	Total drug budget	8,434,816	100%
	Per capita annual expenditure on medicines supplied (catchment population 57,811)	308.83		Per capita annual expenditure on medicines supplied (catchment population 74,542)	113.15	

Table 4.3.4: ABC analysis of top 20 items – Health centres Data 2014-2015

Rank	Makkhueajae Health Center, Lamphun			Health Center 52, Bangkok Metropolitan		
	Item Name/Strength	Monetary Value	EML	Item Name/Strength	Monetary Value	EML
1	Amlodipine tab 10 mg	88,303	Y	Simvastatin tab 10 mg	252,000	Y
2	Simvastatin tab 20 mg	39,982	Y	Metformin tab 500 mg	198,000	Y
3	JE Vaccine Inj 0.5.ml	38,590	Y	Manidipine tab 10 mg	82,500	N
4	Metformin tab 500 mg	26,942	Y	Atenolol tab 50 mg	70,000	Y
5	Glibenclamide tab 5mg	25,183	Y	Losartan tab 50 mg	69,600	Y
6	Losartan tab 50 mg	22,966	Y	Glipizide tab 5 mg	47,500	Y
7	Metformin tab 850 mg	22,790	Y	Enalapril tab 5 mg	45,200	Y
8	Gemfibrozil caps 300 mg	20,957	Y	Humulin (Insulin 70/30) inj	44,440	Y
9	Enalapril tab 5 mg	17,600	Y	Amoxycilline caps 500 mg	40,000	Y
10	Rabies vaccine Vero 0.5 ml	17,550	Y	Calcium Carbonate tab 100 mg	39,500	Y
11	MMR vaccine inj	16,965	Y	Sennoside tab 7.5 mg	33,480	Y
12	Simvastatin tab 40 mg	16,128	Y	Glibenclamidee tab 5 mg	30,000	Y
13	Enalapril tab 20 mg	14,977	Y	Coamoxiclav tab 875/125 mg	28,000	Y
14	Atenolol tab 50 mg	14,077	Y	Simvastatin tab 40 mg	28,000	Y
15	Methylsalicylate cream 15 % 15 G	12,700	Y	Amlodipine tab 5 mg	27,000	Y
16	Amoxycillin caps 500 mg	11,624	Y	Paracetamol tab 500 mg	26,000	Y
17	Sodium Chloride irrigation 1000 ml	11,405	Y	Hydrochlorothiazide tab 25 mg	22,500	Y
18	Allopurinol tab 100 mg	9,249	Y	Omeprazole caps 20 mg	21,600	Y
19	Aspirin tab 81 mg	9,019	Y	Humulin 70/30 inj	20,790	Y
20	Cough phylantus emblica syr	8,761	N	Allopurinol tab 100 mg	17,500	Y
	% budget on top 20 drugs	445,765	71.9%	% budget on top 20 drugs	1,143,610	73.8 %
	% on Antibiotics		4.1 %	% on Antibiotics		8.59 %
	% budget on vitamins		1.3 %	% budget on vitamins		5.51 %
	% budget on EML drugs		98.6 %	% budget on EML drugs		90.1 %
	Total drug budget	619,737	100%	1,549,940		100%
	Per capita annual expenditure on medicines supplied (catchment population 16712)	37. 1		Per capita annual expenditure on medicines supplied (catchment population 63 824)	24.28	

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

Public procurement for goods including medicines must comply with the regulations of the Office of Prime Minister 1992, which was amended in 2006. The regulation stipulates different methods of procurement which include price negotiation, price inquiry or selective tendering method, open competitive bidding, limited bidding and an e-auction.

In November 2014, a new e-procurement system was launched to replace those earlier bidding methods.

The procurement of medicines in Thailand is decentralized and undertaken by each health facility or hospital. Medicines to health centers are supplied by the community hospitals. Although there is no central procurement for medicines, there is a central mechanism for price negotiation. The price fixed by the central agency is the price at which facilities can buy those medicines.

Only a few high-cost & orphan medicines are supplied centrally by the Government Pharmaceutical Organization (GPO) on behalf of National Health Security Office (NHSO) and the controlled drugs are supplied by the Food Drug Administration (FDA) and GPO.

Another government policy on procurement since 1998, is on Measures on Drug Management Efficiency Development which focuses on the overall drug management cycle at hospitals, pooled procurement at provincial levels and reporting for purchasing price.

4.4.2. Provincial/District/Health facility Drug Procurement

Although the procurement of medicines is done by each health facility (except for health centers where their medicines supplies are provided by the regional, general, provincial and community hospitals), there is a mechanism for regional/provincial pooled procurement or price negotiations. In Chiang Mai province for example, the pooled procurement covers 200 medicines items and involves 51 hospitals in the province. The regional pooled procurement was started in 2005 on a voluntary basis as a pilot project and implemented nationwide in 2007.

For economy of scale, as much as possible, 156 items should be procured from the GPO, which undertakes procurement on behalf of all health facilities. Around 70-100% drug items prescribed by government owned facilities must be from the national EML (MOPH) and 60-100% budget must be spent on national EML medicines (all public hospitals) – depending on health facility level (60% in tertiary referral and regional hospitals, 70% in general and provincial hospitals, 80% in community hospitals, and 100% in health centres).

Medicines prices must be at or below the standard price as published by National Medicine Systems Development Committee. Hospital purchase must be according to a yearly procurement plan approved by the Hospital Pharmacy and Therapeutic Committee (PTC) Director and the Chief Provincial Health Office. If the order is more than 500 000 Baht per transaction, a competitive tender must be followed, which is mostly done for pooled procurement. Hospitals order medicines periodically from every week to every three months. In one big referral hospital, the reordering was done every day due to very fast moving and high consumption of some medicines.

The Ministry of Finance monitors all drug procurement transactions through an electronic on-line system (obligatory) and the MOPH monitors drug prices and EML compliance through a manual system (voluntary).

Each health facility makes a report on their consumption every three months for the district/provincial health offices.

4.5. Allocation of budget for medicines in the public sector

The major sources of funds for medicines are the NHSO (National Health Security Office) covering 48. 3 million people under the universal coverage policy, the SSS (Social Security Scheme for private employees) covering 11. 1 million people of private sector employees and the CSMBS (Civil Servant Medical Benefit Scheme) covering 4.7 million people of government employees and their families.

The NHSO covers outpatient & inpatient treatment costs of beneficiaries as well as preventive & promotive activities in public facilities only. NHSO allocates funds to hospitals on per capita basis according to registered populations for outpatient treatments, and according to diagnosis related grouping (DRG) for inpatient treatments. NHSO also reimburses some pre-agreed prevention and promotion activities.

The SSS covers outpatient and inpatient treatment for private sector employees whose salaries less than 15,000 Baht/month, using a tripartite contribution: 1.5% of salary automatically deducted, 1.5% from employer, 1.5% from government. After a continuous three months contribution an employee is eligible for this scheme. The allocation is based on capitation for outpatient services and based on diagnosis related grouping cost for in patients. Selected hospitals claim costs from Ministry of Labour

The CSMBS covers all treatments in any public hospital (private hospital for dialysis & emergency) and hospitals claim fee for service costs from Ministry of Finance (MOF).

A smaller proportion of budget for public health facilities is managed by the provincial health authority. This fund is used by the provincial health authority in the event of emergency or stock-outs encountered at public health facilities. In one of the province visited, the proportion of funds that was managed by provincial health office could be up to 20 %.

There is also funding from the NHSO for certain groups of medicines, namely the orphan drugs (antidotes, serum), vaccines and high cost medicines (cancer drugs).

For a General hospital under Bangkok Metropolitan Authority (BMA) for the fiscal year 2014-15, 63.37% of funding was from NHSO, 20.97% was from hospital working capital, 16.01% was from BMA budget and 0.35% was from BMA budget for HIV.

4.6. Drug quantification in the public sector

Quantification is based on past consumption and a 3-year procurement plan is developed for each facility. The 3-year procurement plan must comply with the existing regulation concerning purchase of essential drugs. The percentage of drug items purchased that must belong to the NEML is 100% for health centers, 90% for community hospitals, 80% for general and provincial hospitals and 70% for regional hospitals. In

each facility, there were obviously difficulties in complying with these regulations as each has their own hospital formulary with non-essential drugs listed.

Each facility, based on the 3-year procurement plan, devises a yearly procurement plan which has to be approved by the hospital director or by the chief of the local health authority (district or provincial). Hospitals should procure 3-monthly, but in reality reordering often has to be done more frequently, even weekly. One big referral hospital in Bangkok, mentioned that they order every day for medicines to cope with very high patient load and turnover of medicines.

4.7. Drug Management and Distribution in the public sector

4.7.1. Drug Storage and Distribution at the central national level

There is no national storage and distribution facility in Thailand. All medicines purchased by hospitals are directly distributed to health facilities by the supplier, except for drugs at health centers where the supply is from the Community Health Centers. Thus drug supply is mainly through a pull system with mainly decentralized procurement.

4.7.2. Drug Storage and distribution at the Provincial / District level

Medicines and vaccines stock management was considered good in most public facilities from regional hospitals to health centers. Storage facilities were air-conditioned and the space was commonly divided for different types of medicines, i.e. oral preparations, injectable and intravenous solutions, narcotics, medicines requiring refrigeration etc. There was a continuous 24 hours monitoring of the rooms as well as refrigerator temperature with an electronic system. All stores and wards followed the principles of FIFO (first in first out), and FEFO (first expired, first out). All short-dated items were tracked and expired items generally kept separately from non-expired stock. Especially for medicines purchased from GPO, there is a mechanism of redistribution of drugs approaching expiry.

From the annual plan, the consignment of medicines is actually planned for every three months. However, many hospitals have to make reorder with a shorter frequency either monthly, biweekly or weekly, because of high turnover of medicines. The stock out levels in most hospitals was minimized except for in health centers.

In most hospitals visited, there was a very well organized distribution system of medicines both for inpatients as well as for outpatient clinics. Under the Pharmacy Unit, there was a special pharmacy for inpatients as well as for outpatients. The distribution of medicines at the hospitals in Thailand may serve as a good model for hospital pharmacy management for other countries.

Pharmacists monitor medicines management in all sections of the hospital, including the wards where there is usually one nurse in charge of medicines. Hospital pharmacy units prepare for the wards daily dose dispensing for each patient. The medication nurses administer the medicines to patients guided by a checked sheet prepared by the pharmacy unit. All hospital drug stores are managed by pharmacists and health centers stores by nurses or store keepers.

The pharmacy unit at a referral hospital normally also undertakes different ranges of functions such as drug management and storage, drug distribution, oncologic preparations, total parenteral nutrition preparation, in-house production of certain preparations, etc. There was a lack of (storage) space in a few of the health facilities visited, especially in the referral hospitals.

Most of the health centers visited mentioned not having any problem in drug management as they are getting enough medicines from hospital. However, a few of them mentioned that they sometimes have a problem for chronic disease medicines which are for referred patients from the hospital. Some wanted more herbal medicines cream for muscle pain. The health center under the Bangkok metropolitan authority mentioned that medicines supplied by the GPO are always supplied in less quantity than ordered and that some medicines are out of stock for few months as a result. For example, Vitamin B_1, B_6 and B_{12} were out of stock for the last 3 months. However, they mentioned that they could request any quantity of medicine there being no cap for quantity.

All facilities visited had electronic LMIS and prescribing therefore it was easy to track the prescriptions and drug use including drug stock.

4.7.3. Pharmaceutical Human Resources

The pharmacist/pharmacy assistant staffing at the hospital level is relatively good where pharmacists are recruited to run the hospital drug management/logistics, drug dispensing services and pharmaceutical care/clinical pharmacy services. In referral hospitals, pharmacists are also responsible for more specific functions such as drug information services, pharmacovigilance, total parenteral nutrition, oncologic administration, hospital drug productions etc. In some hospitals, the available posts for pharmacists are not always fully occupied.

By contrast, the pharmacy staffing at health centers is far from ideal where no pharmacists/assistant pharmacists are employed. There were no available posts for pharmacist or assistant pharmacists for health centers. The pharmacist/pharmacy assistant from the community hospitals visits the health centers from time to time to supervise the drug management at health centers. The frequency of such supervisory visits varied from weekly to monthly to yearly. The drug store and pharmacy, including dispensing, at health centers is managed by nurses/nurse technicians plus store keepers. However, the health center at Bangkok under Bangkok metropolitan had a pharmacist to look after the store. If the health centers will be promoted for more patient services, to reduce the patient load on the community and regional, general and provincial hospitals, there would be a need to mobilize more clinical and pharmacy staff at health centers.

4.7.4. Traditional Medicine

Various aspects and practices of Thai traditional medicine have been promoted for health promotion and incorporated in the existing health care delivery system since the revival of Thai Traditional Medicines in 1978. These include traditional medicines products deriving from plants, Thai massage, hot herbal compresses and herbal steam baths, the practice of healthy body (Kayanamai) with good food and good physical exercise, healthy mind (Jitanamai) and healthy life style (Chevitanamai). There are over 2000

herbal products registered in Thailand and even some traditional medicines products are included in the current national essential medicines list[4].

Traditional medicines services are encountered in (community) hospitals and health centers that were visited by the team. Mostly they offered Thai massage, spa and some herbal products. A few traditional medicines practitioners are employed as hospital staff to run the Traditional Medicines Services. Traditional medicines products are also included in the hospital procurement and consume part of the hospital budget. In one of the health centers, herbal syrup for cough was one of the top 20 items as per expenditure consumed.

Pasang Hospital in Lamphun province has a manufacturing unit for traditional medicines and it manufactures 30 traditional medicines. The hospital distributes these traditional medicines to other hospitals in the region. The unit got GMP certificate in December 2014. For Pa-sang hospital, herbal drug dispensing value in fiscal year 2014-15 was 274,208 baht (0.83% of total medicines dispensing value). For the current fiscal year 2015-16 they plan to use at least 2% of the total medicines budget on traditional medicines.

4.8. Patient Flow in the Health Facilities

Health care delivery in health facilities is a complex process, where the patients should receive proper examination, proper diagnosis and cost effective treatment. With a high burden of patients coming to health facilities, and a limited number of technical staff, namely doctors, nurses, laboratory technicians and pharmacists, the process of services needs to be organized efficiently. The missions observed the flow of patients when seeking services at health facilities. In most facilities, the following process was followed:

1. Patient registration, where the identity of patients will be entered into the electronic registration system;
2. Measurement of vital signs such as blood pressure, body weight, height;
3. Screening for major complaints by nurse;
4. Laboratory examination, if any;
5. Screening by registered nurse for directing the patient to the prescriber;
6. Medical examination for diagnosis and prescribing by doctors. The prescription is printed and signed by prescribing doctor. Diagnosis is written on the prescription as well as on the patient's record.
7. Handing over of the printed signed prescription by the nurse to the patient.
8. Referral of patients either to the outpatient pharmacy to obtain the prescribed medicines or to the wards to be treated as inpatients.

[4] Chokevivat V and Chuthaputti A. The Roles of Thai Traditional Medicines in Health Promotion. Department for the Development of Thai Traditional and Alternative Medicine, Ministry of Public Health, Thailand, 2005.

9. Cashier for some patients who need to pay (if not registered with the facility).

Some of these steps are carried out by the same staff member at health centre level. The medical consultation is done individually and privately in an examination room. Record keeping is made electronically with patient diagnosis recorded according to the International Classification of Disease (ICD 9). In some but not all facilities, drug treatment was also recorded electronically. The flows as observed by the mission is similar to that described by Thumsamisorn A et al 2011[5]

In the biggest hospital of Thailand, Siriraj the number of OPD patients that visit each day is about 12000 who have appointments and about 500 without appointment. However, they have a large number of doctors and pharmacists to cope up the huge crowd.

At most other hospitals (regional, general, provincial and community) doctors generally saw 30-60 patients per day. At community hospitals there was generally a traditional medicine doctor assisted by a few other traditional medicine staff for message and acupuncture. A few doctors mentioned that in a month they have to write a prescription for about 2-5 medicines for outside purchase from a private retail pharmacy.

Health centers had a very good set up in terms of space, computer and furniture but there was no doctor. At some health centers the doctor visits in the morning for few hours once or a few days per week. The prescribing is thus generally done by a registered nurse or technician nurse. Generally 20-40 patients visit per day at health centers. Most of the health centres visited had either a traditional medicine doctor or another traditional medicine staff to undertake massage and related procedures.

4.9. Insurance

Most people are covered by health insurance, and probably less than 1 % that are not covered by insurance. There are four major government insurance schemes in Thailand providing benefit package which include also medicines.

Universal Health Care Coverage Scheme (UHCS) is the biggest public insurance scheme covering 48.3 million people run by the National Health Security Office (NHSO). The NHSO provides a benefit package which includes medicines. It covers outpatient costs based on capitation for registered patients and inpatient costs based on diagnosis-related groups (DRG). The NHSO also provides cash payments to hospitals to treat high cost specific diseases (e.g. haemophilia, HIV, cancer) and for good performance (e.g. antibiotic control). This scheme operates when patients are registered in the concerned catchment area. Patients should go to the health centre or their local community hospital outpatient department first and only attend regional, general or provincial hospitals on referral,. Patients do not have to pay anything at the point of care if they attend a facility where they are registered but must pay out-of pocket if they attend a facility where they are not registered, unless referred. In an emergency a patient can visit any hospital. Generally only EML medicines are provided.

Social Security Scheme (SSS) provides insurance coverage for private employees for 11 million people. The premium contribution consists of 1.5 % salary automatically deducted, and the same amount of contribution from the employer as well as from the Government. Selected hospitals claim costs from

[5] Thumsamisorn A, Chinda1 T, Rittippant N , and Dumrongsiri A. Investigation of patient and Medicines Flow in Thai Hospital**.** *EPPM, Singapore, 20-21 Sep 2011*

Ministry of Labour receiving 1460 Baht/person/year as the capitation fees. There are 241 hospitals that are registered under SSS. If the beneficiary has one of the high risk diseases then calculations are done for risk adjusted capitation. In 2014 SSS had spent 33 billion Baht on 11.7 million beneficiaries. In a critical emergency a patient can visit any hospital and may get non-EML medicines without any copayment within 72 hours of treatment. However it is hard to communicate and set criteria to separate a critical emergency from other levels of emergency (i.e. urgent emergency or emergency) which are not eligible for reimbursement. As the result some patients must make a co-payment if the treatment is given beyond 72 hours or for a case that is not judged to be a critical emergency.

Civil Service Medical Benefit Scheme (CSMBS) provides insurance coverage for civil servants and their families - 4. 7 million people in total. The hospitals claim fee for service charges of the insured and their families from the MOF, patients not generally having to pay anything at the point of care. Patients can go for treatment to any public facility, but if they visit a facility which is not in their catchment area, they must pay and get the money reimbursed. For certain procedures, for example, Thai message, they can get reimbursement if it is advised by a doctor. Civil servants can also visit contracted private hospitals for certain treatments but they may need to make a co-payment if the treatment exceeds the benefit package. Non-EML drugs are also covered.

Migrant workers insurance, with a premium contribution of 1300 Baht per person per year, covers treatment at public hospitals.

Private insurance schemes exist, where patients have to pay their hospital bills in cash, and get reimbursement from the insurance company.

The public health care delivery system in Thailand consist of 48 specialized hospitals, 26 regional hospitals, 71 provincial hospitals, 734 community/ district hospitals and 9768 health centers which are under the MOPH. In addition, there are 11 university hospitals, 25 regional hospitals and 60 other public hospitals, and 365 community medical centers providing services for the publics[6].

4.10. Drug Manufacturing

Drug manufacturing is quite active in Thailand. There were one hundred fifty eight (158) pharmaceutical manufacturers registered and complying with the GMP regulations in 2013, according to the Thai Food and drug Administration[7]. The biggest medicines manufacturer is the Government Pharmaceuticals Organization (GPO), a state owned company, producing more than 300 different pharmaceutical products (90 % essential medicines) and medical devices. The GPO also produces medical apparatus and health supplements to cover a broad range of health system needs. The range of products manufactured by the GPO includes 240 pharmaceutical products (antiretroviral drugs, medicines for treatment of specific and general diseases and generic medicines for household use), biological products (8 types of vaccines and

[6] National Health Security Office, 2014.

[7] http://www.fda.moph.go.th/fda-net/html/product/drug/fda_drug/gmpenglish.htm

serum) and 30 herbal medicines products[8]. The GPO also supplies 156 essential medicines to public facilities for NHSO scheme.

Since 2003, the Thai FDA under MOPH has enacted regulations on "Good Pharmaceutical Practice (GMP) for pharmaceutical products". Since then, all pharmaceutical companies have had to comply with GMP guidelines to ensure that the drugs produced comply with the quality standards and are safe to consumers. The Thai FDA has implemented GMP inspection and monitoring to ensure that manufacturers comply with GMP standards. Manufacturers who are unable to comply with the GMP principles can no longer proceed with the drug business. Though most end-users generally seemed happy with the quality of products, Siriraj hospital mentioned that, for few generic medicines, they requested the Department of Pharmacology of the Medical School to do bioequivalence studies to confirm the manufacturer claims.

4.11. Drug Management in the private sector

There are over 11 000 licensed private pharmacies in Thailand. The mission visited 7 private pharmacies (including two chain pharmacies) in the Chiang Mai and Bangkok areas. The main findings are as follows:

In a radius of 1 km, usually there were 3 to 6 pharmacies, either owned by a chain pharmacy or by an individual pharmacist. These pharmacies usually received 50 – 200 clients daily, and dispensed the needed medicines, mostly for self-medication (90-95%) and a small amount for patients from private doctors (5-10%). Many patients, particularly with chronic diseases such as hypertension or diabetes, visited the retail pharmacies with old near complete strips of medicines for a refill. Many patients with minor conditions such as muscle pain, cough and cold and skin conditions, also consulted the pharmacy. These private pharmacies help improve distribution, access and availability of the needed medications to the people, including essential medicines.

The pharmacies stocked 200 to 3000 products, mainly allopathic but also some herbal products, depending on the preference of their clients or sales. The daily sales (medicines and other items) were between 8,000 to over 200,000 Bahts. Usually herbal medicines were also stocked by these retail pharmacies. The drug management was good and a few pharmacies had an electronic information system. All pharmacy shops visited had computers though not all had up to date information on the stock of medicines in the computer. The storage was clean, and medicines were stored by their therapeutic classes, and applying FEFO (first expired first out) and FIFO (first in first out) principles. Generally these pharmacies had 2-4 wholesalers from whom they got medicines. The wholesalers have liaison with companies which supply them medicines. Retail pharmacies generally gave orders weekly and for some medicines monthly. In case of emergency, retail pharmacies sometimes contacted directly the company representatives and got the supply same day or next day.

All the pharmacies visited were manned by pharmacists and assistant pharmacists. In general, the dispensing practice was hygienic, clean and safe. The dispenser was a pharmacist, assistant pharmacist or pharmacy students doing their internship. At a few pharmacies other helping staff were also available. The majority of medicines including antibiotics, amitriptyline, nortriptyline and fluoxetine were available without prescription. However, for schedule IV drugs including medicines for cancer, narcotics and

[8] Government Pharmaceutical Organization. A Company profile

psychotic drugs like diazepam, a prescription was needed. Drugs like alprazolam and lorazepam were not available at retail pharmacies but only in hospitals.

The dispensing communication, in general was short, mostly less than one minute and generally no label was put on the dispensed medication, though pre-printed labels were available at most pharmacies. The short dispenser-client contact is a lost opportunity for conveying relevant consumer education messages to promote healthy life style and rational use of medicines. Brief educational and advocacy messages on relevant issues could be devised and be disseminated through the dispensing points.

Recently Thailand has started a pilot project on pharmaceutical care for chronic diseases wherein pharmacists at retail pharmacies will monitor the blood glucose level and blood pressure and also provide knowledge about medication including how to use inhalers etc. The pharmacies have been provided forms to be filled-in and the filled forms to be returned to insurance/government and for each form some money is provided to the pharmacist. This project has just started and one of the retail pharmacies visited was on the pilot project.

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

Thailand has a remarkable health delivery system where almost all patients are covered by insurance for their health services, including medicines. There is a well-functioning medicines public supply system as part of their health services delivery for the universal health coverage policy. Most of the needed essential medicines, over 90 %, are available in public hospitals with very small levels of stock out. The drug distribution is decentralized where the needed medicines are directly supplied to hospitals. The supplies for public health centers are taken care by the community hospitals. The availability of essential medicines in public health center facilities (even those classified for use at health centres) is less as compared to hospitals, possibly because some health centres are not using a substantial number of the medicines that are classified for use at that level in the national EML.

A substantial proportion of hospital expenditure has been accounted for by medicines not listed in the National Essential Medicines list, and most hospitals have their own hospital formularies serving as basis medicines supply. There is a need to promote the compliance with the national Essential Medicines List. The pharmaceutical services and management in hospitals are well organized to offer different functions supporting health care services. The clear system organization, along with the substantial presence of hospital pharmacists, are major reasons for the quality of services observed. In most health facilities the drug management information system is totally electronic. However, there is a need for unified information system for national monitoring of drugs management. The recommendations made during the last survey still need to be strictly implemented like harmonizing all electronic drug management, strengthen the Pharmacy section, MOPH and discourage use of non-EML drugs especially for CSMBS beneficiaries.

4.13. Medicines Supply: Recommendations

- Strengthen the mechanism for sharing information to ease drug management and monitoring by harmonizing the electronic drug management systems, especially GPO/VMI, health facility e-LMIS, MOPH monitoring system, MOF monitoring system, and NHSO.
- Strengthen the Pharmacy Section of MOPH to monitor compliance with standards in pharmaceutical care and procurement.
- Discourage the use of non-EML drugs through various means, possibly by limiting budget allocations, requiring co-payment for some non-EML drugs, devising clear criteria to classify the use of non-essential drugs, and monitoring and feedback to hospitals and prescribers on the use of non-EML drugs.
- Investigate the drug distribution system from community hospitals to health centers in order to improve availability of the needed medicines at health centers.

5. MEDICINE SELECTION

5.1. National Essential Medicines List (NEML)

Box 5.1. summarises characteristics the national essential medicine list (NEML)

Box 5.1: Summary of the National Essential Medicines List of Thailand

- Responsible government department or agency: Division of NDP, FDA
- Date of publication of latest EML: 2015 web based only; Last printed version 2013
- Previous publication dates: updates on the web every 1-2 years
- Number of active pharmaceutical ingredients (APIs): 688
- Number of formulations for all APIs: 1034
- Number of traditional medicine products: 74 (50 TRM and 24 herbal)
- Categories by level of use:
    - Essential and complementary? Essential
    - Facility type Yes Prescriber type Yes
- Number of persons involved in drafting the latest national EML:
    - Core team: 25 member for sub-committee including two advisors
    - Experts: 23 Working groups on different therapeutic category of EML
    - Advisory Committee: National Committee of Drug System Development ; 37 members including the Chair – Deputy Prime Minister
- Specialties represented:
    - Major specialties: All
    - General practice? Yes (in the Liaison Committee but not the NEML subcommittee)
- Geographic representation of experts? Yes
- Consistency with national STGs? Unknown

5.2. Other Medicine Lists

5.2.1. Central level

There is a Nurse Practitioners' List of prescribable medicines, a subset of medicines from the NEML, which is compiled by the FDA. It contains 63 allopathic and 5 herbal medicines.

5.2.2. Peripheral level

Every hospital has its own formulary and another formulary that should be used for the health centers under its jurisdiction. For non-communicable and other specific diseases, hospitals sometimes also distribute the needed medicines to health centers for continuing treatment. Medical specialists from the (community) hospitals visit the health centers twice weekly to see these patients.

It is not exactly clear the reasons why every hospital, has its own formulary. This may reflect little faith in the NEML by the prescribers at the hospital level. To address this problem, there is guidance on the use of the NEML and the purchase of essential medicines by health facilities (see section 5.3), which aim to improve compliance to NEML.

The hospital formularies are developed by the Hospital Pharmacy (Drug) and Therapeutics Committee (PTC) consisting of various clinical specialties and pharmacists. Most hospitals have their Pharmacy and Therapeutics Committee. The selection of medicines in the hospital formularies are also claimed to be based on needs, safety, efficacy and cost effectiveness. Most of the hospital formularies also include medicinal products that are not listed in the NEML. The average percentage of drug items in the hospital formularies that did not belong to NEML was 26.3 % (10. 6 % to 41. 9 %) in the referral hospitals and 11.2 % (5.9 % - 20 %) in the community hospitals.

Why is compliance to the NEML not 100 % at hospitals? During discussion with a national expert, it was mentioned that the primary cause for noncompliance was irrational use of medicines by prescribers, demanding additional drugs other than those listed in the NEML. There was also often pressure from beneficiaries or government employees to use drugs outside the NEML. The specialists at the hospitals have their own drug preferences outside the NEML. Whatever the reasons, there was an obvious need to advocate the use of NEML at hospitals. Indeed, during the team visit to hospitals and health facilities, it was rare to see a copy of the NEML at the prescribers' or dispensers' desks.

5.3. Development / updating of national EML

Thailand has developed and implemented National Essential Medicines List (NEML) since 1981, serving initially as a basis for the medicine supply in the public sector[9], and later also as a basis for medicines reimbursement when Universal Coverage Policy came into being in 2001. The NEML is updated every 1-2 years. So since the last situation analysis in 2011, there have been some revisions. The last printed version was published in 2013 and the latest version of the NEML (2015) is published in the Royal Gazette and on the web.

The current version of the NEML consists of six hundred eighty eight (688) active ingredients and one thousand and thirty four (1034) formulations with six (6) categorizations, as follows:

- Category A for all health facilities, to use as first line treatment,
- Category B for alternative treatment to first line,
- Category C for use by well-trained doctors approved by the hospital director,
- Category D for costly drugs that are intended for specialist use for some specific conditions,
- Category E1 for special government projects (e.g. HIV/AIDS, TB drugs), and
- Category E2 for high cost but important drugs for particular groups of patients (e.g. anti-cancer drugs) and which require insurance approval.

The responsible agency to develop and to update the NEML is the Sub Committee on National Essential Medicines, which is under the National Committee of Drug System Development. The National Committee of Drug System Development is chaired by the Deputy Prime Minister, and the secretary is the Secretary General of Thai FDA. The Secretary of the NEML subcommittee is the Director of the Bureau of Drug Control of the Thai FDA. The role and function of the Sub Committee of the NEML is to select and to update the national essential medicine list (NEML).

The selection process starts with 23 National Expert Panels, each representing different drug groups. The panels select medicines based on criteria, which include health needs, safety, efficacy, availability and prices. A Screening Working Group, the “Liaison Committee” of 20 experts then independently reviews and coordinates all the recommendations of the national Expert Panels, also taking into account cost-effectiveness and equity analyses by the Health Economic Working Groups, and a National Affordability analysis by the Price Negotiation Working Group. The National Subcommittee on the NEML makes the final decision based on the recommendations from the Liaison Committee. If there are discrepancies between reviews, the National Sub Committee will seek independent reviews on cost effectiveness, equity and national affordability from other organizations such as Health Intervention and Technology Assessment Program (HITAP).

[9] Yoongtong et al. National drug policies to local formulary decisions in Thailand, China and Australia: Drug Listing Changes and Opportunities. VALUE IN HEALTH 15 (2012), s 126 – 131.

5.4. Implementation of EML

There are a number of policies which aim to ensure the implementation or use of the NEML. The procurement rules require that hospitals procure medicines listed in the NEML. Thus, based on the number of drugs items, the percentage of NEML drugs in their formularies should be at least 100% for health centers and community hospitals, 80% for general hospitals and to 70% for referral hospitals. Similarly, based on the budget allocation, the percentage of the budget that should be spent on NEML drugs is 90% for Health Centers, 80% for Community hospitals, 70% for general, provincial and regional hospitals and 60% for tertiary referral hospitals. The percentages of prescribed drugs which belong to NEML were 90% or over at the health centers and community hospitals and slightly less than 90 % at the referral hospital (table 5.4.). However the percentage of prescribed drugs that belong to EML was only 50 % (40 – 70 %), at both the private and public pharmacies, indicating of low compliance and acceptance by prescribers and consumers. At none of the facilities was a copy of the NEML available.

To promote the use of NEML, the Pharmacy Section of the MOPH undertakes monitoring of the compliance of purchase to NEML of all hospitals every three months. However, they do not have legal power to enforce any changes. The Government insurances also encourage the use of NEML, especially the NHSO and SSS (but not the CSMBS), where the budget allocation for medicines is based on capitation for outpatients and Diagnostic Related Grouping for inpatients. Using the NEML means more cost savings for the hospitals.

During the visits to health facilities, most of the prescribers were usually more familiar with their own hospital formularies than with the NEML. One national expert from a medical school mentioned that the essential medicines concept and rational use were rarely introduced in the undergraduate training of prescribers or in their in-service training. The team hardly found any copies of the NEML or of Standard Treatment Guidelines in the health facilities visited.

The medication management system which includes the hospital formulary and procurement systems, medication storage and medication use, have been included in the hospital accreditation system, but none cite anything about the NEML[10]. This may explain, partly why prescribers are more familiar with their hospital formulary than with the NEML.

Table 5.4.1 show some data on EML implementation.

[10] Health Care Accreditation Institute (Public Organization). Hospital and Health Care Standard, Version April 2011.

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

Public Referral Hospitals	Regional hospital	General hospital 1	General Hospital 2		University hospital	Metropolitan hospital	Average
% key EML items available*	95.0%	97.5%	100.0%		97.5%	95.0%	97.0%
% items on supply list that are non-EML	26.44 %	20 %	10.6 %		41.9 %	32.7%	26. 3%
% prescribed drugs belonging to the EML**	96.6%	83.4%	93.9%		81.5%	80.5%	87.2%
Community Hospitals	1	2	3				Average
% key EML items available*	92.5%	95.0%	90.0%				92.5%
% items on supply list that are non-EML	20%	7.7%	5.9 %				11.2%
% prescribed drugs belonging to the EML**	96.2%	90.7%	83.2%				90.0%
Public primary health care centre	1	2	3	4	5	6	Average
% key EML items available*	50.0%	58.8%	70.6%	70.6%	82.4%	82.4%	69.1%
% items on supply list that are non-EML	2.5%	-	1.4%	4%	-	-	
% prescribed drugs belonging to the EML**	96.6%	83.4%	93.9%	81.5%	80.5%	87.2%	93.8 %
Private pharmacies	1	2	3		4		
% key EML items available*	60.0%	80.0%	75.0%		72.5%		
% items on supply list that are non-EML	-	-	-		-		
% prescribed drugs belonging to the EML**	40.0%	56.4%	40.4%		50.0%		
Private pharmacies	1	2	3		4		Average
% key EML items available*	55.0%	60.0%	70.0%		70.0%		67.8%
% items on supply list that are non-EML	-	-	-		-		
% prescribed drugs belonging to the EML**	40.0%	-	77.3%		43.6%		49.7%
Public pharmacies	1	2					Average
% key EML items available*	77.5%	77.5%					77.5%
% items on supply list that are non-EML	-	-					
% prescribed drugs belonging to the EML**	55.1%	56.8%					55.9%

* Please see the same indicator recorded in table 4.2.1.

** From prescription audit – please see the same indicator recorded in table 6.3.1.

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

Since the last situation analysis in 2011, there have been a number of revisions of the NEML which have been done every 1-2 years. However, there is plenty of room for promoting more use of the NEML at public facilities as well as private facilities. Substantial numbers of drugs items which do not belong to NEML are still being used and purchased at hospital facilities. The dissemination of the NEML and advocacy to comply with the NEML at hospital facilities needs to be strengthened. Effective incentives need to be devised to promote the use of the NEML. The concepts of essential medicines, the NEML, and rational use of medicines, need to be introduced in undergraduate training as well as in in-service training of the health workers. Although the medication system has been included in the hospital accreditation system, it does not include compliance to the NEML.

5.6. Drug Selection: Recommendations

- Continue to update and revise the national Essential Medicines List (EML) in a transparent manner to improve acceptance, and disseminate to all health facilities:
    - To include medicines for all levels of care and classify them by facility level, prescriber type and therapeutic class as is being done currently.
- Monitor compliance with the national EML, including compliance with level of use by:
    - requiring every hospital to produce an annual report on drug consumption for MOPH, namely ABC analysis to identify high cost medicines and % budget spent on non-NEML drugs.
- Reduce the use of non-EML drugs, for instance, by differential reimbursement for vital, essential & non-essential drugs and co-payments for non-EML drugs.
- Promote understanding of Essential Drugs Concept and the national List of Essential Drugs (EML) through:
    - provision of feedback of local consumption data to prescribers by the Pharmacy and Therapeutics Committee, and to include them in undergraduate and postgraduate curricula.
- Devise a harmonized national essential drugs formulary, based on the national essential drug list (NEML), serving as a basis for all public procurement and insurance reimbursement.

6. MEDICINE USE

6.1. Responsible Agents/Departments

Function/ Organisation	MOPH	Other Agency	Name of Agency/MOH Department
Monitoring medicines use in hospitals	✓		- No specific monitoring of medicines use nationwide - PTC in some hospitals may undertake medicines use monitoring - Consumption expenditures are reported every three months to Provincial Health Office/Pharmacy Section of the Bureau of Health Administration, MOPH
Monitoring medicines use in Primary care	x	x	- No specific drug use monitoring done at primary care levels-
Development of national STGs	✓	✓	- Department of Medical Services MOPH - Royal College of Physicians - MOPH Vertical Program
Development of national formulary			No national formulary
Drug Information Centre	✓	✓	No national drug information center; but there are drug information centers at the University hospitals, Referral hospitals, School of Pharmacies, Thai FDA
Provision of independent drug information		✓	Drug information centers at University Hospitals, Referral Hospitals, School of Pharmacies
Monitoring Hospital DTCs	✓		Pharmacy Section of the Bureau of Health Administration MOPH
Monitoring Hospital quality of care	✓	✓	Department of Medical Services MOPH Department of Health Service Support, Bureau of Sanatorium and Art of Healing Health Care Accreditation Institute NHSO
Monitoring DTCs in provinces/districts	✓		Provincial/district health offices
Undergraduate education for health professionals		✓	Medical Council, Pharmacy Council, Thailand Nursing and Midwifery Council, Dental Council
Continuing medical education for health professionals		✓	Pharmacy Council, Medical Council, Dental Council, Thailand Nursing and Midwifery Council
Public education on medicines use	✓		Department of Health Services Support, MOPH
Implementing generic policies		✓	Thai FDA NHSO, SSS

6.2. Past prescription surveys

Table 6.2.1 shows recent prescribing surveys that have been done. Only three surveys have been done since 2011, including the last situational analysis.

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

Indicators	Ref 1[11]	Ref 1	Ref 1	Ref 1	Ref 2[12]	Ref 3[13]
Year of survey*	2012	2012	2012	2012	2011 - 2012	2013
Facility type	Referral hospitals	Community Hospitals	Health Centre	Drug stores	Referral hospital	Hospital
Public / private	Public	Public	Public	Private	Public	
Average number of drugs per patient	4.13	3.25	2.74	1.56		
% patients prescribed antibiotics	23.1	44.6	28.5	17.3		
% patients prescribed injections	5.5	3.1	5.3	0.8		
% drugs prescribed by generic name	67.4	87.9	91.8	4.0		
% prescribed drugs belonging to the EML	78.3	84.2	84.3	46.5		
% patients prescribed vitamins	18.3	9.6	14.2	5.3		
% URTI patients prescribed antibiotics	-	62.4	53.6	-	74 % (pre) 13 % (post)	30.2 %
% diarrhoea cases treated with ORS					78 % (pre) 19.1 % (post)	13.6 %
Average cost per prescription (USD)	1145.26	82.58	65.32	87.91		

* Year of survey refers to the year the survey was done not the publication date of the report;
AB=antibiotics; URTI=Upper respiratory tract infection; EML=essential medicines list; STG=Standard Treatment Guidelines.

[11]Holloway K. Thailand. Drug Policy and Use of Pharmaceuticals in Health Care Delivery. Mission Report, 30 August 2012, World Health Organization, Regional Office for South East Asia, New Delhi.

[12]Boonyasiri A & Thamlikitkul V. Effectiveness of Multifaceted Interventions on Rational Use of Antibiotics for Patients for Patients with Upper Respiratory Tract Infections and Acute Diarrhoea. *J Med Assoc Thai 2014; 97 (Suppl. 3): S13-S19. http://www.jmatonline.com/index.php/jmat/article/view/5313*

[13]Vandepitte WP, Ponthong R, Srisarang S. Treatment Outcomes of the Uncomplicated Upper Respiratory Tract Infection and Acute Diarrhea in Preschool Children Comparing Those with and without Antibiotic Prescription. *J Med Assoc Thai. 2015 Oct;98(10):974-84. http://europepmc.org/abstract/med/26638589*

Apart from the earlier situation analysis undertaken by the World Health Organization in 2012 (table 6.2.1), there are two important studies with high relevance to promoting rational use of medicines. One study was to demonstrate the effectiveness of multifaceted interventions on rational use of antibiotics for outpatients with acute respiratory infections and acute diarrhea under the Social Security Health Benefit Scheme and Universal Health Care Coverage Scheme at Siriraj Hospital[14]. Combined interventions consisting of prescribers training, provision of clinical practice guidelines, provision of preprinted medical record form, provision of information brochures on the causes and the needs as well as the risks of using antibiotics for acute respiratory conditions and acute diarrhea for the patients and/or their families, was shown to effectively reduce the use of antibiotics in these conditions. Another important study was to show that there was no difference of clinical outcome in pediatric patients with uncomplicated upper respiratory tract infections and with acute diarrhea, whether they were treated with or without antibiotics[15].

These two studies provided a good evidence that no antibiotic treatment was needed in upper respiratory infections and in acute diarrhea, and the lessons from these two studies could be disseminated or replicated at other hospitals and health facilities to promote rational use of antibiotics.

6.3. Current prescribing practices

A prescription survey in public facilities was done by reviewing 30 consecutive prescriptions from prescribers on the day of the visit to each facility. Prescription data was collected for general /primary health care patients as far as possible. In hospitals, data was not collected for specialist clinics but did include some patients from general medicine and paediatric clinics. Where possible, in the larger hospitals, prescriptions were examined prospectively as patients came to the OPD pharmacy after consultation with OPD doctors. However, for some facilities the data could not be collected for the day of the visit because either there were not many patients during the visit (in health centres) or the OPD hours were over by the time team visited the facility. In these two circumstances data was collected for the last 30 patients from the OPD registers or data from the computer which were usually well maintained with diagnosis and drugs prescribed. Information on the number of items prescribed, generics, antibiotics, injections, vitamins, EML drugs, traditional medicines, number of drugs dispensed, cost per prescription were recorded. The percentage of generics, the average drugs per prescription, the percentage of antibiotics, the percentage of injections, the percentage of vitamins and the percentage of prescribed drugs belonging to EML were calculated. In addition, information on the antibiotic treatment of the last thirty (30) upper respiratory tract infections (URTI) cases was also collected from the patient records/prescriptions. The dispensing survey was undertaken by interview and observation at the pharmacies and health facilities at the point when the medicines were dispensed to patients. The results of the survey are summarized in table 6.3.2.

Important findings on prescribing practices, among others, are as follows.

[14] Boonyasiri A & Thamlikitkul V. Effectiveness of Multifaceted Interventions on Rational Use of Antibiotics for Patients for Patients with Upper Respiratory Tract Infections and Acute Diarrhoea. *J Med Assoc Thai 2014; 97 (Suppl. 3): S13-S19. http://www.jmatonline.com/index.php/jmat/article/view/5313*

[15] Vandepitte WP, Ponthong R, Srisarang S. Treatment Outcomes of the Uncomplicated Upper Respiratory Tract Infection and Acute Diarrhea in Preschool Children Comparing Those with and without Antibiotic Prescription. *J Med Assoc Thai. 2015 Oct;98(10):974-84. http://europepmc.org/abstract/med/26638589*

The pattern of poly-pharmacy was obvious in this assessment, patients receiving multiple drugs, at hospitals. The average number of drugs per case at referral hospitals was 3.18 (2.7 – 4.0), and at community hospital was 3.65 (2.68 – 4.64). At the health centers, the pattern of poly pharmacies was less with an average number of drugs per case was 2.78 (2.0 – 3.3). Compared with earlier situation analysis in 2012, there was a slight reduction but there was still room for improvement especially in one hospital where the average number of drugs per case was 4.0.

The average percentage of antibiotics prescribed at the referral hospitals was 14.0 % (6.7 % - 18.3 %), at the community hospitals was 11.9 % (8.3 – 16.0 %) and at the health centers was 11.3 % (6.7.% - 20 %). Again as compared to earlier situation analysis in 2012, there is improvement. However, the percentage of URTI cases which were prescribed with antibiotics remained high, with an average at referral hospitals of 52.1 % (37. 8% - 80.6 %), at community hospitals 20.0 (13.3 % - 30.0 %), and at the health centers 46.6 % (23.3 % - 76.7 %). These figures are similar to those found in the NHSO reporting of antibiotic use in URTI in 900 hospitals (personal communication from Nithima Sumpradit FDA). There was an obvious need for focused intervention on the use of antibiotics for URTI cases. As earlier mentioned, an intervention study of multi-facetted interventions to improve the quality use of antibiotics, undertaken at referral hospitals, had successfully reduced the use of antibiotics in URTI cases from 73 % to 13 % during the few months of intervention, though whether this improvement would be maintained over some years is unknown, and probably a repeat of the intervention package would be needed to maintain the reduced antibiotic use.

The prescription of vitamins was relatively substantial with an average percentage at referral hospitals of 10 % (0 – 15 %), at community hospitals 13.5 % (11.6 % - 16.0%), and at the health centers 13.1 % (3.3 % - 26.7 %). The impact is obvious from economic point of view as in some facilities the expenditure on vitamins was amongst the top 20 medicines.

The prescribing patterns can also be influenced by the prescriber type and the patient load for each prescriber. In all the public hospitals visited, the prescribers were doctors but at the health centers, some qualified nurses were prescribing. At some health centers doctors from community hospital visit regularly. Doctors at the health centers are specialists in primary health care. The patient load per prescriber was not high at the health centers (10-30) and hospitals (30-60) visited, all prescribers having sufficient time to undertake patient consultation.

Table 6.3.2 show some data on health facility prescription survey.

Table 6.3.2: Results of prescription audit from health facility survey

Public referral hospitals	Regional hospital	General hospital 1	General Hospital 2	Univ. hospital	Metropolitan hospital	Average
Average number of drugs per patient	4.0	3.32	3.05	2.7	2.82	3.18
% patients prescribed antibiotics	6.7%	18.3%	18.3%	10.0%	16.7%	14.0%
% patients prescribed injections	8.3%	8.3%	3.3%	0.0%	8.3%	5.6%
% patients prescribed vitamins	10.0%	15.0%	15.0%	10.0%	0.0%	10.0%
% drugs prescribed by generic name	91.9%	85.0%	95.6%	75.3%	43.8%	78.3%
% prescribed drugs belonging to EML	96.6%	83.4%	93.9%	81.5%	80.5%	87.2%
% URTI patients prescribed AB	80.6%	46.7%	37.8%	50.0%	45.6%	52.1%
Average cost per prescription	1320.90	416.88	237.80	513.20	725.64	642.88
% patients treated with TRM medicine	0.0%	8.3%	0.0%	3.3%	0.0%	2.32%
% prescribed drugs dispensed	100.0%	99.0%	99.5%	100.0%	100.0%	99.7%
Public Community hospitals	1	2	3			Average
Average number of drugs per patient	3.64	2.68	4.64			3.65
% patients prescribed antibiotics	11.3%	8.3%	16.0%			11.9%
% patients prescribed injections	8.8%	11.6%	16.0%			12.1%
% patients prescribed vitamins	15.0%	11.6%	16.0%			13.5%
% drugs prescribed by generic name	97.6%	92.5%	82.8%			91.0%
% prescribed drugs belonging to EML	96.2%	90.7%	83.2%			90.0%
% URTI patients prescribed AB	30.0%	13.3%	16.7%			20.0%
Average cost per prescription	242.60	90.43	252.04			195.02
% patients treated with TRM medicine	18.8%	0.0%	4.0%			7.6%
% prescribed drugs dispensed	100.0%	100.0%	100.0%			100.0%
Public primary health care centres	*1*	2	3	4	5	6	Average
Average number of drugs per patient	2.1	2.0	3.0	3.3	3.06	3.2	2.78
% patients prescribed antibiotics	6.7%	4.3%	20.0%	20.0%	16.7%	0.0%	11.3%
% patients prescribed injections	6.7%	13.0%	0.0%	0.0%	3.3%	0.0%	3.8%
% patients prescribed vitamins	3.3%	8.7%	26.7%	23.3%	10.0%	6.7%	13.1%
% drugs prescribed by generic name	96.8%	100.05	85.6%	97.0%	95.7%	96.9%	94.2%
% prescribed drugs belonging to EML	92.1%	95.7%	85.6%	97.0%	95.7%	96.9%	93.8%
% URTI patients prescribed AB	23.3%	-	50.0%	76.7%	42.9	40.0%	46.6%
Average cost per prescription	29.06	37.76	54.85	131.00	139.16	156.43	91.40
% patients treated with TRM medicine	6.75	39.15	23.3%	0.0%	10.0%	0.05	13.2%
% prescribed drugs dispensed	100%	100%	100%	100%	100%	100%	100%

Table 6.3.2 on prescribing consolidation sheet continued

Private-for-profit pharmacies	1	2	3	4	
Average number of drugs per patient	1.67	1.33	2.14	1.82	
% patients prescribed antibiotics	3.7%	3.3%	9.1%	7.3%	
% patients prescribed injections	0.0%	0.0%	0.0%	0.0%	
% patients prescribed vitamins	7.4%	13.3%	13.6%	12.2%	
% drugs prescribed by generic name	2.2%	12.5%	14.9%	2.7%	
% prescribed drugs belonging to the EML	40.0%	56.4%	40.4%	50.0%	
Average cost per prescription	157.03	158.97	386.41	148.51	
% patients treated with TRM medicines	11.15	0.0%	18.25	12.2%	
% prescribed drugs dispensed	100.0%	100.0%	100.0%	100.0%	
Private-for-profit pharmacies	1	2	3	4	Average
Average number of drugs per patient	1.0		2.2	1.3	1.64
% patients prescribed antibiotics	26.7%		0.0%	10.0%	8.6%
% patients prescribed injections	0.0%		0.0%	0.0%	0.0%
% patients prescribed vitamins	0.0%		0.0%	3.3%	7.1%
% drugs prescribed by generic name	16.7%		9.1%	3.3%	8.8%
% prescribed drugs belonging to the EML	40.0%		77.3%	43.6%	49.7%
Average cost per prescription	154.57		263.00	62.03	190.07
% patients treated with TRM medicines	0.0%		0.0%	20.0%	8.8%
% prescribed drugs dispensed	100.0%		100.0%	100.0%	100.0%
Public Pharmacies	1	2			Average
Average number of drugs per patient	1.63	1.47			1.55
% patients prescribed antibiotics	3.0%	20.0%			11.5%
% patients prescribed injections	0.0%	0.0%			0.0%
% patients prescribed vitamins	13.3%	10.0%			11.6%
% drugs prescribed by generic name	8.1%	63.6%			35.8%
% prescribed drugs belonging to the EML	55.1%	56.8%			55.9%
Average cost per prescription	241.60	199.33			220.46
% patients treated with TRM medicines	16.7%	13.3%			15.0%
% prescribed drugs dispensed	100.0%	100.0%			100.0%

The prescription survey in the private retail pharmacies showed that average number of drugs purchased per patient was 1.64 (1.0-2.14) and that 8.6%% bought antibiotics and 7.1% bought vitamins. This lower use is not surprising since most purchases were over-the-counter with no prescription for minor ailments. Not surprisingly, only 49.7% of the purchased medicines were from the national EML since shops were selling those non-EML medicines which patients cannot get free from public health facilities. Only 8.8% drugs dispensed/prescribed were by generic name. On average each patient spent Baht 190.07 per purchase. Two public pharmacies were also surveyed, one in Chiang Mai run by the university and the other in Bangkok run by the GPO. At these public pharmacies the average number of drugs purchased per patient was 1.55, 11.5% patients bought antibiotics and 11.6% bought vitamins. The percentage of purchased medicines belonging to the national EML was 55.9%, which is slightly higher than purchases from private retail pharmacies. The percentage of medicines prescribed/dispensed by generic medicines was 35.8% which is higher than in the private retail pharmacies. On average each patient spent Baht 220.46 per purchase which is surprisingly higher than the amount spent at the private retail pharmacies. May be patients go to buy expensive medicines at public pharmacies.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

Dispensing was done by pharmacists or qualified assistant pharmacists at the hospitals but by trained nurses or public health personnel at Health Centers. At all hospitals there were enough pharmacists, pharmacy assistants and other helpers to deal with all the works of preparing medicine packets, labelling and dispensing to patients.

The dispensing practice was hygienic and no counting by hand was observed in any facility. The labeling used was computer generated with self-adhesive paper that was stuck to a zip plastic bag. The information in the label contained patient name, drug name, strength and frequency of administration. The label may also contain warning/indication or any other specific direction.

The dispenser-patient interaction time was short in most cases, with an average duration of less than a minute. In all public facilities, all of the prescribed medicines were dispensed (100 %), indicating a very good access to the needed medicines at all the facilities. There was no generic substitution of therapeutic substitution at any of the pharmacies observed. Dispensing records were all kept in the computer, although copies of the prescriptions were also kept in most of the facilities. Diagnosis was not always written by doctors in the prescriptions, nor was it always recorded in the computer.

6.4.2. Health Facility Inpatients (wards)

In the wards of public hospitals, medication nurses administered the prescribed medicines to patients with the supervision of the inpatient pharmacies.

In the hospital ward, medication nurses dispense/administer the prescribed medicines to patients using a check list that has been prepared by the pharmacy staff.

All documents were kept in the ward with patient's prescribing sheet. The nurse transcribes from the individual patient's prescription sheet to the individual patient's dispensing sheet. The pharmacist transcribes the information from the dispensing sheet to print a label and paste it onto the dispensing sheet. There was a good liaison between IPD pharmacist and medication nurse on prescribing and dispensing instructions. Patients' trays all had the oral medicines with dispensing sheets in one trolley and the injectables in another trolley. The nurse crosschecks with dispensing sheet before giving medicines to patients. Intravenous fluids are taken from the cupboard in the ward and whose stock is electronically kept in the computer.

The ward store only has medicines for emergencies such as injectables, narcotics etc.

6.4.3. Private retail pharmacies

Dispensing at private retail pharmacies was generally done, or supervised, by a qualified pharmacist. Medicines were dispensed as strips or in bottle containers and generally put in a polythene bag or envelop but no labelling was done. However, at two private retails pharmacy shops, during the time of data collection, and on asking about labels the pharmacist started issuing labels. At public pharmacies hand written labels were issued with the generic name, strength, size and frequency of the dose recorded. In case of antibiotics they mentioned the duration of the treatment as well.

The dispenser-patient interaction was generally less than one minute. No computerized records of individual patient transactions were available to see in some retail pharmacies though all had computers. At one retail pharmacy, for each transaction a slip was written so that later they could record it in the computer. At chain pharmacies all the patient transactions were recorded in the computer with the patient's name and all medicines bought. Antibiotics were dispensed without prescription.

6.5. Policies to promote rational use of medicines

Rational use of drugs (medicines) (RUD/RUM) is one of the four strategies of the National Drug Policy 2011 in Thailand. Under the Rational Use of Drugs Strategy, there are seven sub-strategies, namely (1) Regulatory Mechanism of RUD, (2) RUD curriculum and education, (3) RUD tools and system, (4) RUD in general population and in community, (5) Generic drugs (6) Antimicrobial resistance, (7) Ethics in drug prescription and promotion. For 2014 – 2016, there is an implementation plan which includes, (1) RUD hospital, (2) RUD Education, (3) Good Governance in drug system, and (4) RUD in the Thai citizen.

A pilot project is currently implemented, known as the PLEASE project, consisting of important elements of the RUD strategy, namely Pharmacy and Therapeutics Committee (P), Labelling and leaflet (L), Essential RUD tools (E), Awareness of RDU among prescribers and patients (A), Special population care (S), and Ethics in Promotion (E). The network was launched in October 2014, involving seventy one (71) hospitals. There were ten RDU modules implemented in the undergraduate curricula of doctors, dentist, pharmacists, veterinary doctors and nurses. The implementation of Ethical Criteria for Drug Promotion by stakeholders would be monitored by MOPH to promote good governance. A working group was appointed in September 2014 to develop a system and content for public education utilizing all channels of

communication in the public and private sectors, and to implement other strategies following WHO recommendations.

Another important program is the Antibiotics Smart Use (ASU) programme, which was introduced in 2007 in Thailand as a model to promote the rational use of medicines, starting with antibiotics. The program's first phase consisted of assessing interventions intended to change prescribing practices; the second phase examined the feasibility of programme scale-up. Currently the programme is in its third phase, which centers on sustainability[16]. To change antibiotic prescription practices, multifaceted interventions at the individual and organizational levels were implemented; to maintain behavior change and, to scale up the program, interventions at the network and policy levels were used. For instance, at Siriraj Hospital, the multifaceted interventions of this program have reduced the use of antibiotics in URTI and acute diarrhea.[17]

6.5.1. Monitoring and supervision of prescribing/dispensing by supervisors

There was no routine systematic data collection of prescribing and dispensing practices at health facilities for monitoring and supervision purposes. Some health facilities may become the site of a special study on drug use, and data on prescribing and dispensing were collected at times, but it was not intended as a routine drug use monitoring and supervision. Some hospitals may monitor the use of certain medications for their internal monitoring of, for instance, expensive medicines or high-risk medicines. There was no national monitoring system for prescribing and dispensing, although all the information is available electronically. Only procurement of medicines at health facilities and compliance to national EML was monitored through the provincial/district health offices and reported to the Pharmacy Section of the Bureau of Health Administration.

6.5.2. Standard Treatment Guidelines (STGs)

Standard treatment guidelines are important in promoting rational prescribing. MOPH develops and disseminates treatment protocols for a number of diseases for special programmes, such as malaria, TB and HIV/AIDS, non-communicable diseases, asthma, chronic obstructive pulmonary disease, hypertension, dengue hemorrhagic fever, acute respiratory infections, acute diarrhea, snake bites etc. These treatment protocols were found in the consulting rooms of the health facilities visited. The Royal College of Physicians also has a working group on standard treatment guidelines. The Department of Medical Services has developed standard treatment guidelines for about 50 diseases and disseminated them to health facilities. However, none were seen at the health facilities visited and it is not clear how these guidelines are introduced during pre-service or in-service training, and whether the compliance of the prescribers in using the standard treatment guidelines, is monitored.

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[16] Nithima Sumpradit et al Antibiotics Smart Use: a workable model for promoting the rational use of medicines in Thailand. *Bull World Health Organ* 2012;90:905–913 **|** doi:10.2471/BLT.12.105445 http://www.scielosp.org/scielo.php?pid=S0042-96862012001200010&script=sci_arttext

[17] Boonyasiri A & Thamlikitkul V. Effectiveness of Multifaceted Interventions on Rational Use of Antibiotics for Patients for Patients with Upper Respiratory Tract Infections and Acute Diarrhoea. *J Med Assoc Thai 2014; 97 (Suppl. 3): S13-S19.* *http://www.jmatonline.com/index.php/jmat/article/view/5313*

University hospitals may produce their own clinical guidelines. The importance of treatment guidelines cannot be overlooked. Clinical guidelines on common conditions in children such as acute respiratory infections and acute diarrhea, introduced with a training workshop and educational outreach, have been proven effective in reducing the use of antibiotics by nurses working at primary health care in Thailand[18], but dissemination treatment guidelines alone without monitoring and follow up supervision is unlikely to change prescribing.

6.5.3. National Formulary

There is no national formulary booklet, only the national List of Essential Medicines. However, a hospital formulary is available in all hospitals which is used for the procurement and reimbursement from insurers. The National Drug Policy Office developed 3 series of national formularies - for gastrointestinal disease, neurologic disease, and E2 category drugs. However, the later series of national formularies were paused due to lack of staff.

6.5.4. Drug information Centre

There is no National Drug Information Centre in Thailand. However, in some university hospitals and referral hospitals and schools of pharmacy, there is a Drug Information Centre providing information services to the users mostly at those hospitals and the health centers under their jurisdiction. For example, the Drug Information and Poison Control Information Center at Siriraj Hospital provides 24-hour services and is manned by pharmacists. They receive almost 20,000 queries on drugs per year and information was given on 2,226 cases of poisoning last year. The users consist of nurses, doctors, pharmacists and even patients from the hospital and outside the hospital. They use international references such as Micromedex. The types of questions they encountered are on dosage and administration, on drug compatibility and stability, on use and efficacy and on availability. Funding for the Drug Information Center comes from the hospital. The drug Information and Poison Control Center also publishes the Siriraj *PharmLetter* every month, and 2000 copies are distributed to prescribers, pharmacists, nurses at Siriraj Hospital.

The Drug Information Center at Mahidol University School of Pharmacy offers drug information services such as (1) Data search for information on a specific medicine, (2) Answering any queries regarding a medicine, (3) Distribution of D.I.C bulletin and D.I.C newsletters to members and (4) Distribution of the series of the book entitled 'New Drugs in Thailand'[19].

[18] Pagaiya N & Garner P. Primary care nurses using guidelines in Thailand: a randomized controlled trial. *Tropical Medicine and International Health, Vol. 10 (5) : 471 – 477, 2005. URL:http://www.ncbi.nlm.nih.gov/pubmed/15860094*

[19] http://www.pharmacy.mahidol.ac.th/eng/service.php?code=1&lang=EN

6.5.5. Independent drug information

Drug information services provided by the hospital pharmacies, especially at the referral hospital were the most accessible sources of drug information. In public hospitals, clinical protocols published by MOPH, hospital formularies are always available and serve as part of drug information, but the NEML was not available. Standard treatment guidelines/protocols were seen in health centers, published by the provincial health authority. Some forms of clinical guidelines were also available at health facilities such as for Dengue Hemorrhagic Fever, for hypertension, for asthma, for diabetes, for snakebites etc. Other references are also used at hospitals such as Drug Information Handbook, AB X guidelines, Handbook of Injectable Drugs, Micromedex, drugs in Pregnancy and Lactation etc.

Most of the prescribers had access to internet and some doctors mentioned that they also look for drug information in the internet when needed. Medical representatives also visit health facilities, mainly the referral hospitals, providing information on their products at the hospital pharmacies as well as with doctors. MIMS was still used as an important source of drug information, especially at the private pharmacies. Generally medical representatives do not visit public facilities for promotion and training purposes.

6.5.6. Drug (Pharmacy) and Therapeutics Committees

There were functional Pharmacy (Drug) and Therapeutic Committees (PTC) at all the hospitals visited, even at the community hospitals. This is an achievement to promote effective drug management and safe and rational use of drugs. They are tasked to manage the procurement plan and compliance to the NEML. The scope of functions of the PTC may vary between hospitals, but may cover support of effective and efficient medicine management through medicines selection, and promoting safe and rational use of medicines. In big hospitals the PTCs may have various sub-committees for different activities. For instance at Siriraj University Hospital, the mission included: policy establishment and implementation; monitoring services for medication safety and cost containment; promoting rational use of medicines; and hospital formulary management. Their PTC therefore was divided into three subcommittees, namely Adverse Drug Reaction Monitoring Sub Committee, Rational Drug Use Sub Committee, and Formulary Management Sub Committee. At Nakornping Regional Hospital, the responsibilities of the PTC were to: provide direction and support an efficient medication management system; develop a hospital formulary; handle the use of non-formulary medication if urgently needed; identify high alert drugs and design appropriate management for minimizing risks; develop measures to prevent medication errors and monitor ADRs; and undertake Drug Utilisation Evaluation. Similarly the referral hospital of Bangkok Metropolitan Administration, Charoenkrung Pracharak Hospital had a PTC with 13 doctors, 6 pharmacists and one nurse plus a medication error committee, a rational drug use committee, an adverse drug reaction committee, a risk management committee, an infection control committee, a patient care team, a medical staff organization and a nursing organization. At this hospital three meetings had been held in the last one year and many activities performed.

The organization of PTC usually consists of clinical specialists representing different clinical expertise, nurses and pharmacists and chaired by hospital Deputy Director or Hospital Director. The chief of the pharmacy department/unit serves as secretary of the PTC. As earlier mentioned at referral hospitals they are divided into different subcommittee. The hospital PTC usually has a meeting 2 or 3 times in a year.

PTCs have indeed implemented activities relevant to their mission. In one general (provincial) hospital, Lamphun, the important activities undertaken during 2015, included: the addition of membership for the RDU subcommittee and functions to develop/adapt clinical guidelines; adaptation of clinical criteria of pharmaceutical promotion; approved Clinical Guidelines for Antimicrobial use; revision of the medicines list and budget for 2016, establishment of a Drug and Medical Supply Subcommittee for Lamphun District health System to serve 18 health centers etc.

In some hospitals, PTCs actively undertake medicines utilization and monitoring for certain medication for instance certain antibiotics, dangerous and expensive medicines. Such drug utilization and monitoring was mostly done internally and shared within the hospitals. For example, at Pasang Community (District) Hospital, 13 medicines (expensive antibiotics and other medicines) were chosen for monitoring and reported annually to the PTC. From the ADR monitoring at Pasang hospital, if an ADR event happened in a patient, there would be an ADR stamp on the first page of the patient OPD card with the drug name, date and the ADR symptoms on it. This is to prevent a repeated ADR. PTC activities also involve patient counselling for in and outpatients, undertaken by the pharmacists.

From discussions with members of the PTCs, most PTCs seemed to be quite active. They were often faced with various limitations, but they were operational. They would need also to focus on activities to promote rational prescribing at the hospitals. It interesting to learn the results of surveys on the performance of PTCs that had been undertaken[20],[21]. From these studies it was found that barriers to PTCs' performance included: over-stretched committee staffs; inadequate budgetary considerations; poor communication and performance monitoring; erratic national directives; and lack of standard criteria for drug selection.

[20]Umnuaypornlert and Kitikannakorn N. Performance of Pharmacy and Therapeutics Committees of Public Hospitals in Rural Thailand. *Mahidol University Journal of Pharmaceutical Sciences 2014; 41 (1), 11-18.* *https://scholar.google.com/scholar?cluster=12675397128381992984&hl=id&as_sdt=0,5&as_vis=1*

[21] Sudchada P, Umnuaypornlert A, Kitikannakorn N. A Survey of Practical Policies to Promote Rational Drug Use (RDU) of Pharmacy and Therapeutics Committee (PTC) in Thailand.
Srinagarind Med J 2012: 27(2). http://thailand.digitaljournals.org/index.php/SMJ/article/view/11916

6.5.7. Undergraduate education on medicines use

In Thailand, there are 21 recognized medical schools -19 public and 2 private [22], fourteen dental schools[23], nineteen pharmacy schools[24] and seventy eight recognized nursing and midwife undergraduate education institutions[25]. The undergraduate for medical, dental and pharmacy education is 6 years, whereas for nurse and midwifery for 4 years and all students must pass the final examination held by their respective schools/universities. The licensing of these professionals is undertaken by each council respectively, i.e. Medical Council, Dental Council, Pharmacy Council and Nurse and Midwifery council. The Councils set the contents of the curricula and manage the examinations for licensing (which are separate from the university exams).

Many medical schools have embarked on problem-based learning curricula. The six years curricula is divided into three phases, 1 year pre-medical phase, 2 years pre-clinical phase and 3 years clinical phase. Pharmacology is taught during the pre-clinical years and some schools have implemented problem-based pharmacotherapy teaching. Prescribing is taught during the clinical years. During the entire course very little exposure is provided to the students on the National Essential Medicines List and its application. Many medical schools do not incorporate into their undergraduate curricula the essential medicines concept, rational use of medicines and standard treatment guidelines. At some medical schools which implement problem-based learning, the teaching curricula are based on the human system and not on the pharmacology discipline.

The curriculum of pharmacy was changed in 2008 to six years, culminating in a Doctorate of Pharmacy. In 2014 the Thai Pharmacy Council made the 6-year program a compulsory requirement for licensure[26]. The Doctor of Pharmacy program is expected to produce pharmaceutical care pharmacists and to provide more clinical experiences during training. After the 5th year, students may opt either for clinical pharmacy and pharmaceutical care, or industrial pharmacy and pharmaceutical sciences. Clinical Pharmacy attachments at retail pharmacies can provide good practical experience but also exposure to the use of non-essential medicines that are usually sold at such pharmacies. The Doctor in Pharmacy Program has been found to be suitable for hospital settings. However, there was concern regarding the suitability of the Pharm D graduates for community hospitals and primary health care settings because of their insufficient training in health promotion and disease prevention[27]. It was also felt that they may need more exposure to the essential medicines concept and policy and rational drug use.

To promote the inclusion of rational use of drugs (RUD) into the undergraduate curricula, the MOPH in collaboration with the professional councils has developed modules on rational drug use. Ten modules were developed for inclusion in the medical, dental, pharmacy and veterinary doctor curricula, due for

[22] http://www.tmc.or.th/en_home.php

[23] http://www.dentalcouncil.or.th/eng/inter_license.php

[24] Chanakit E et al. A Survey of Pharmacy Education in Thailand. *American Journal of Pharmaceutical Education 2014; 78 (9) Article 161.* URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4453078/

[25] http://www.tnc.or.th/en

[26] Chanakit E et al. A Survey of Pharmacy Education in Thailand. *American Journal of Pharmaceutical Education 2014; 78 (9) Article 161.* URL:http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4453078/

[27] Chanakit et al. Hospital pharmacists' perceptions of the suitability of doctor of pharmacy graduates in hospital settings in Thailand. *BMC Medical Education (2015) 15:181 DOI 10.1186/s12909-015-0471-6.* http://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-015-0471-6

implementation in the strategic plan of 2014 – 2016. Modular topics included: Concept and Principles of RUD, Good Prescribing Practice, Communications for RUD, Patient Safety, Drug Resistance and Rational Use of Antimicrobial Agents, Ethics and Rational Use, Accessibility, Equity and Cost Effectiveness for RUD, Inter-professional Teamwork for RUD, Information sources for RUD, and Always Improving in RUD. These modules aim to serve as harmonized undergraduate curricular content on RUD for all health professionals. The impacts of these modules on the competence of students need to be evaluated.

6.5.8. Continuing Medical Education on medicines use

Each of the different professions has its own continuing professional development (CPD) or continuing medical education (CME).

For medical doctors, there are scientific meetings organized by academic institutions and medical associations, usually with participation of a pharmaceutical company as sponsor. However, CME is not a compulsory requirement for renewal of the professional license and the Medical Council has not developed any compulsory CPD program for its members. The Medical Council does oversee and approve all postgraduate specialist training curricula developed by the 14 Royal Colleges of Medical Specialists or other institutions.

For pharmacists, there is a compulsory requirement to earn CPD 100 credit units in five years. One credit unit is equivalent to a one hour lecture/seminar. The pharmacists' association organizes a monthly lecture or seminar on current relevant topics related to pharmaceutical care and pharmaceutical sciences. The Pharmacy Council has developed a compulsory CPD program for its members and oversees what programs run by different institutions are acceptable for CPD.

For nurses and midwives, there is a compulsory requirement to earn CPD 50 credit units in five years, accumulated evenly year by year (i.e. 10 credits unit per year). It is not clear whether related topics on medicines such as the National Essential Medicines List, rational use of drugs etc. are included in the CPD lectures. The Nursing Council oversees a compulsory CPD program for its members which must be undertaken in accredited institutions using approved curricula.

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

As in many other countries, public education on the safe and prudent use of medicines could be considered as less than robust. There are few programme activities addressed to consumers. Some hospital pharmacy departments have outreach community programmes for public education concerning the quality and safe use of medicines. Some hospital pharmacy unit staff undertake patient counselling for outpatients as well as for inpatients. However, such activities need to be institutionalized. Village health volunteers potentially can deliver suitable messages on rational of drugs such as the safe and prudent use of antibiotics, rational use of medicines and self-medication. Focused messages could be developed and field-tested prior to wide implementation. Pharmacists or assistant pharmacists at public and private pharmacies potentially could deliver relevant messages to their clients on rational and safe use of medicines.

A special working group has been appointed in September 2014 by MOPH with the task of developing a system of, and content for, public education on the safe and prudent use of medicines, using all channels of communication in the public and private sectors. During the visits to retail pharmacies, it was observed however, that it was very easy for patients to buy antibiotics and medicines for chronic diseases over-the-counter without prescription.

6.5.10. Generic Policies

Promoting generic prescribing is one way to control medicines expenditure in many health care settings including for the insurance reimbursement. Thailand has been widely known as an active country to promote generics policy, especially with regards to generic HIV/AIDS medicines. The current survey indicated relatively high generic prescribing. The average percentage of drugs prescribed by generic name in the public sector was 78.3 % (43.8 % - 95. 6%) in referral hospitals, 91.0 % (82.8 % - 97.6 %) in community hospitals, and 94.2 % (85.6 % - 100 %) in health centers,. By contrast, generic prescribing at retail pharmacies was low, the average percentage of drugs being prescribing by generic name being 35.8% in public pharmacies and 8.8% in private ones. Nevertheless these figures are somewhat higher as compared to the previous situation analysis in 2012, where generic prescription was only 67.4 % at referral hospital, 87.9 % at community hospital, 91 % at health centers, and 4 % at the pharmacies.

Another survey in district hospitals in 2009 showed that the average generic prescribing was 73.9 %[28]. As the insurance payment is based on capitation for outpatients and on Diagnostic Related Grouping for inpatients, generic prescribing will help in controlling medicines expenditure. Allowing generic substitution has been implemented at some public hospitals, especially at the referral hospitals.

A survey amongst hospital pharmacists in 2010[29], indicated that most pharmacists agreed that generic substitution could reduce national and hospital expenditures (88.1% and 95.5% respectively). However, they also recommended that notification and meeting among relevant healthcare providers should be set up prior to implementation of generic substitution, and, due to concerns of safety and efficacy of generic drugs, 84.7% of respondents strongly agreed that patients should be monitored after substitution. Respondents also felt that the top three drugs that could not be generically substituted were cardiovascular drugs, neurological drugs and chemotherapeutic agents. Thus, allowing generic substitution, promoting generic prescribing at hospitals (where generic prescribing is still limited), and promoting generic drugs to patients and the general population would help to deal with the increasing costs of medicines.

[28] Plianbangchang et al. Physicians' generic drug prescribing behavior in district hospitals: a case of Phitsanulok, Thailand. *Pharmacy Practice (Internet) 2010 Jul-Sep;8(3):167-172. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4127051/*

[29] Sukhontarat et at. Evaluating Pharmacists' Perception on Generic Substitution. The 4th Annual Northeast Pharmacy Research Conference of 2012 *"Pharmacy Profession in Harmony",* Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand.

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

Promoting rational, safe and cost effective use of medicines is a never-ending process. Interventions to promote rational use of medicines (drugs) should be part of the existing medicines and health care policy. There has been substantial progress since the last situation analysis in 2012 in Thailand with regard to promoting rational use of drugs. All hospitals have a functioning Pharmacy and Therapeutics Committee (PTC). Most PTC activities have been on medicines selection and procurement and it would now be important to expand PTC functions to undertake monitoring of prescribing (not just ABC analysis of consumption) and effective interventions for promoting rational use of drugs. Some standard treatment guidelines have been produced and distributed at health facilities. However, the use of these guidelines is sub-optimal and their use needs to be encouraged and monitored. Some important projects such as ASU (Antibiotic Smart Use) and PLEASE (Pharmacy and Therapeutics Committee, Labelling and leaflet, Essential RUD tools, Awareness of RUD among prescribers and patients, Special population care, and Ethics in Promotion), which to some extent have produced good results, need to be institutionalized as part of the existing health care and medicines program. While many relevant activities to improve prescribing have been undertaken by different program, much more effort is still needed to promote rational and safe use of medicines by consumers and patients.

6.7. Medicines use: Recommendations

- Monitor medicines (drug) use
    - By ABC analysis of consumption, prescription audit and feedback for both outpatient and inpatient care - by hospital PTCs,
    - Use of existing hospital electronic patient data bases,
    - Reporting on selected drug use indicators to MOPH
    - Institutionalization of the PLEASE, ASU, and other drug use projects.
- Develop national Standard Treatment Guidelines (STGs) for primary & secondary care and implement them through:
    - publication online and dissemination of them free of charge to prescribers,
    - incorporation into undergraduate and continuing education.
- Incorporate components on rational prescribing and the essential medicines concept into the existing health professional education curricula.
- Strengthen the role and capacity of Pharmacy and Therapeutics Committee (PTC):
    - To monitor prescribing, encourage continuing medical education, undertake self-assessment, and report annually on activities to MOPH,

- By strengthening the Pharmacy Section in the Office of the Permanent Secretary, MOPH, to review the PTC reports, and to train PTCs and take other actions, and
- By considering inclusion of PTC activities in hospital accreditation.

- Develop systematic continuing professional development (CPD) by:
  - Thailand Medical Council considering to develop a new credit system for continuing medical education of doctors, obligatory for re-licensing (as already started for pharmacists & nurses),
  - including rational prescribing and the essential medicines concept in the curricula of health workers, and
  - Medical & pharmacist associations promoting the essential drugs concept through the lectures/seminars they organize.
- Undertake systematic public education through:
  - nationwide campaigns on the safe and prudent use of medicines,
  - devising core pharmaceutical messages e.g. "does my child need more than one drug?" or "coughs & colds do not usually need antibiotics",
  - giving messages through the Village Health Volunteers, community pharmacists, schools, NGOs, the media, and funded by insurance agencies.
- Strengthen an effective referral system by: encouraging the use of health centers and strengthening them in order to decrease the crowds in referral hospitals.

7. MEDICINE REGULATION

7.1. Responsible Agents/Departments

Regulatory function	DRA	Other Agency	DRA/MOH department/Name of Agency
Drug Schedules	✓		Standard & Regulation Division, Bureau of Drug Control, FDA
Licensing & Inspection of drug outlets	✓		Post Marketing Control Division, Bureau of Drug Control, FDA
Drug registration	✓		Pre Marketing Control Division, Bureau of Drug Control, FDA
Pharmacovigilance	✓		Health Product Vigilance Center, FDA
Drug quality testing		✓	Bureau of Drugs and Narcotics, Department of Medical Sciences, MOPH
Drug promotion	✓		Section of Drug Advertisement, Pre Marketing Control Division, Bureau of Drug Control, FDA. Rural & Local Consumer Protection, Promotion Division, FDA
Drug pricing		✓	Ministry of Commerce
Health professional licensing/accreditation		✓	Medical, Dental, Pharmacy and Nursing Councils of Thailand
Health facility/hospital licensing/accreditation	✓	✓	Health Accreditation Institute (Public Organization) Department of Medical Services, MOPH

7.2 Pharmaceutical sector

A summary of Thailand's pharmaceutical sector is shown in box 7.2.

Box 7.2: Summary of Thailand's pharmaceutical sector

- Number of products on the market:
  - Allopathic: 22 201, biologicals 702, narcotics 150
  - Traditional: 13 266; Veterinary : 2994, biologicals 646
- Number of manufacturers:
  - Allopathic: 175 (mostly local manufacturers); Traditional: 825
- Number of wholesaler & retailer outlets:
  - Allopathic: 14500 normal (1100 accredited by Pharmacy Council) and 3525 "ready packed"
  - Traditional: 2180; Veterinary : 700
- Enforcement of regulations in last fiscal year:
  - 120 manufacturers inspection, 1600 retailers inspection (Bangkok)
  - Enforcement: No. prosecutions : 1416 (422 for medicines); Value of fines : 18,045,100 Bahts (4,802,800 Bahts for medicines)
  - Number of people sentenced to be imprisoned: 58 cases during 2011-13

7.3 Current Medicines Legislation (key documentation)

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
Drugs Act BE 2510 (1967), amended four times, the last time in 1987, is still in effect. Attempts to revise the Drug Act of BE 2530 (1987) are painstaking and time consuming. When it becomes effective, many features will be change accordingly.	1967/1987
The draft new Drugs Acts BE 2546 (2003), not yet passed by Parliament and implemented	2003
Psychotropic substances Act 1975	1975
Narcotics Act 1979	1979

b) Coverage:

Area / Activity Covered?	Y/N	Document Name
Establishment and functioning of National Drug Regulatory Authority	Y	
Medicines marketing authorisation	Y	
Medicines scheduling	Y	
Licensing of medicines handling premises, personnel & practices	Y	
Licensing of prescribers	Y	Pharmacy and Medicines Councils
Mandatory CME for prescriber licence renewal	N	
Licensing of pharmaceutical personnel	Y	Pharmacy Acts
Mandatory CME for pharmacy licence renewal	Y	
Regulatory inspections/ enforcement activities	Y	
Medicines quality	Y	
Medicines packaging & labelling	Y	
Medicines promotion	Y	
Post-market surveillance/ pharmacovigilance	Y	
Collection of fees	Y	Under regulation act
Clinical trials	Y	Clinical trial register but not under FDA
Generic substitution	N	Hospital policy
TRIPS-related issues	Y	
Transparency and accountability	Y	Civil Service Act
Banning of unsafe medicines	Y	

The currently operating Drug Act of 1967/1987 was described by all respondents met as too old and too rigid. Fees and fines are too low but cannot be changed without a new Act or amendment. Low fees and fines have negative consequences. The low fees for drug registration have resulted in poor quality applications and the low fines for improper drug promotional activities have resulted in companies being happier paying fines than obeying the rules.

There are substantial changes in the draft new Drug Act (2003). When the draft new Drug Act becomes effective, many legal provisions will be changed accordingly, for example:

- Reclassification of medicines into 3 new categories: prescription only, pharmacy dispensing and household remedy.
- Physicians will be no longer allowed to compound medicines for their patients.
- Manufacturers who are unable to comply with GMP principles will no longer be able to proceed with drug manufacturing business.
- GMP requirements may be revised and approved by the Drug Committee and declared by the minister of public Health, without any need of approval from the Parliament, as currently required in the 1987 law.
- Government-owned enterprises or agencies will no longer be exempted from the requirements of licensing and product registration.
- Pharmaceutical products will be registered in either of the two channels: one for general medicines and the other for Thai traditional medicines.
- Products licenses will have to be renewed every five years.
- The Drug Committee will be authorized to withdraw any products if later evidence proves that the products are not scientifically efficacious.
- The Food and Drug Administration will be able to declare certain changes for its services related to licensing, registration, dossier evaluation and approval processes, including expenses for testing the products.
- Product liability will be implemented for the first time. Consumers will be able directly to sue and get compensation from drug manufacturers if there is any serious harm occurring to them after consumption, provided that the product indications are strictly followed.
- Any deviation of statements in advertisements from those permitted will have to be made known to the public through further apology advertisements along with the correct statements.
- The amount of fines will be increased up to ten-fold, compared to the previous ones.
- A pharmacist will be allowed to work in as many pharmacies as he/she can[30].

However, there has been objection to various parts of the draft new 2003 Act by different stakeholders, including the medical profession, the pharmacy profession and the pharmaceutical industry. While many differences have been resolved it was mentioned that the pharmaceutical industry is still objecting to increasing stringency in post-marketing surveillance, ethical criteria for drug promotion, cost information transparency and the patent status of various products to be freely accessible. Some aspects of the proposed new law, such as allowing a pharmacist to work in as many pharmacies as he/she can, would have to be carefully monitored.

[30] http://www.fda.moph.go.th/fda_eng/frontend/theme_1/info_data_main.php?ID_Info_Main=4

7.4 National Regulatory Authority for medical products

A summary of the national regulatory function is shown in box 7.4.

Box 7.4.: Summary of the Food and Drug Administration's regulatory functions

- Name of National Drug Regulatory Authority: Food and Drug Administration (FDA)[31], Thailand
  - Total number of technical staff: 344; All posts filled[32]
  - Executive/senior experts: 28
  - Pharmacists, nutritionist an Food technologists: 277
  - Professionals in other fields: 27
  - Lawyers: 12
  - Total number of non-technical staff: 144; All posts filled
- Website address: www.fda.moph.go.th
- Number of quality-control (drug testing) laboratories: One central laboratory under the Department of Medical Sciences, and one Regional Laboratory per region
- Annual report of activities and regulation enforcement in 2014:
  - 120 manufacturing inspections, 1600 retail outlet inspections (in Bangkok by the FDA in Bangkok), 422 prosecutions and fines worth 4 million Bahts for offences.
  - Unknown how many inspections and prosecutions were done in the provinces as they as handled by the Provincial Health Offices.
- Annual Budget last fiscal year: 21,936,562 USD (1 USD = 36.36 Baht)[33]
  - Position in hierarchy of government structure)? Under the Ministry of Public Health
- Decentralised capacity?
  - No branch offices. Some functions outsourced to the Provincial Health Office (PHO), with a new online reporting system for Provincial Health Office Activities.
  - Functions carried out by the PHO include: inspection of wholesalers, retailers and traditional medicine manufacturer (but allopathic medicine manufacturers done centrally); licensing, post-marketing surveillance, monitoring of advertisements in newspapers (but package inserts done centrally).
- Written SOPs for key procedures?
  - Product dossier evaluation — Written Thai SOP
  - Registration of medicines — Written Thai SOP
  - Inspection of manufacturing premises — Written Thai SOP
  - Inspection of retail premises — Written Thai SOP
  - Sampling for quality control testing — Written Thai SOP
  - Medical product recall or withdrawal — Written Thai SOP

[31] http://www.fda.moph.go.th/eng/index.stm
[32] http://www.fda.moph.go.th/fda_eng/frontend/theme_1/about_us.php?ID_About_Us=18

[33] http://www2.bot.or.th/statistics/ReportPage.aspx?reportID=123&language=th

The Food and Drug Administration of Thailand is the responsible agency for overall health products administration including drug administration[34]. The organizational infrastructure of the FDA consists of two main groups. Firstly, the Health Product Control Division group, which consists of the Bureau of Cosmetics and Hazardous Substances Control, and the Bureaus of Drug Control, Food Control, Medical Devices Control, Narcotics Control and Import Export Inspection. Secondly, the Support Division Group consisting of three divisions, namely Division of Public and Consumers Affairs, Division of Rural and Local Consumers Health Products Protection Promotion, Division of Technical and Planning, and Office of the Secretary. The missions of the FDA are: (1) To regulate and monitor health products to meet safety, efficacy and quality standards, (2) To promote Good Manufacturing Practice in the production and quality control of health products to ensure consumer safety and to encourage exports, (3) To undertake research and to develop the effectiveness of the consumers protection system for health products, (4) To promote and support the capability of consumers and society to be able to protect themselves and be self-reliant with regard to health products, and (5) To encourage and enable all stakeholders and non-governmental parties to share in their consumer protection role.

Based on the interview with FDA staff, the FDA, especially the Bureau of Drug Control, manages a pharmaceutical sub sector consisting 23 053 allopathic, 13266 traditional medicines and 3640 veterinary products, 175 allopathic 825 traditional medicines manufacturing plants, and 18025 allopathic, 280 traditional medicines and 700 veterinary wholesale/retail outlets.

7.4.1 Technical committees to advise the drug regulatory authority

The Drug Committee is officially appointed by the Minister of Public Health every two years, with specific designations, (1) to advise the Minister on both regulatory and technical aspects related to the administration of pharmaceutical control, (2) to approve or withdraw pharmaceutical registration, standard specifications, criteria and guidelines, including suspension or withdrawal of licenses to manufacture, import, distribute or sell medical products. Membership of the committee consists of fourteen regular members, five of whom are ex-officio members appointed based on their positions in pharmaceutical-related organizations, and the others being appointed from among pharmaceutical and medical experts.

The committee then appoints 26 (though only 19 mentioned on the web) subcommittees[35] to assist with their tasks, as follows:

1. Subcommittee for GMP PIC/S Membership;
2. Subcommittee on rules, procedures and condition under Drug Act B.E.2510 (1967);
3. Subcommittee on pharmacovigilance and drug safety in human;
4. Subcommittee on product reclassification;
5. Subcommittee on risk management of veterinary drugs;
6. Subcommittee on developing measures to solve quality problem of approved drugs;
7. Subcommittee on strengthening standard of local pharmaceutical plants;

[34] http://www.fda.moph.go.th/eng/index.stm
[35] http://www.fda.moph.go.th/eng/drug/laws.stm

8. Subcommittee on GMP inspection of foreign pharmaceutical plants;

9. Subcommittee on developing standard of drug stores;

10. Subcommittee on human drug re-evaluation;

11. Subcommittee on new drug registration for human use;

12. Subcommittee on pharmaceutical standard and regulation of cell and tissue therapy;

13. Subcommittee on registration of modern medicines for veterinary use;

14. Subcommittee on herbal drug registration;

15. Subcommittee on registration of radiopharmaceuticals;

16. Subcommittee on re-evaluation of epoetin products;

17. Subcommittee on registration of biological products for human use;

18. Subcommittee on bioequivalence;

19. Subcommittee on drug shortage surveillance and management;

20. Subcommittee on generic drug registration for human use;

21. Subcommittee on registration of traditional drugs;

22. Subcommittee on guideline for biosimilars;

23. Subcommittee on antimicrobial reclassification;

24. Subcommittee on regulatory requirement to import or manufacture unlicensed drugs for clinical studies;

25. Subcommittee on modern drug appeals;

26. Subcommittee on traditional and herbal drug appeals.

7.4.2 Regulation of Traditional Medicine

The regulation of Traditional Medicines is the responsibility of Food and Drug Administration, covering the registration of traditional/complementary medicines products, licensing of traditional/complementary medicines manufacturers, and post marketing surveillance of traditional/complementary medicines products for quality and safety. The Bureau of Drugs and Narcotics, Department of Medical Sciences, undertake pre and post marketing quality analysis of herbal products. There are currently 13,266 traditional medicines products, 825 traditional manufacturing plants, and 2,180 traditional medicines wholesale/retail outlets.

There are four types of traditional and alternative medicines in Thailand, i.e. (1) Thai traditional medicines based on Thai Traditional Medicines principles and textbooks, (2) Traditional Chinese medicines, (3) Herbal medicines from single herbs, normally in modern dosage forms and (4) Single herbal preparations from standardized extracts. The development and promotion of traditional medicines in Thailand is the responsibility of another department, i.e. the Department of Thai Traditional and Alternative Medicines, under the Ministry of Public Health and established in 2002.

7.5 Drug Schedules

According to the Drug Act BE 2530 (1987), medicines are classified into two major groups, modern and traditional drugs. The modern drugs are classified into four different categories, namely:

I. Household remedies, which do not require license to sell;

II. Ready-packed drugs that can be sold in drug stores by nurses or other medical professionals (and under which no more drug products are being listed in this category);

III. Dangerous drugs, which can be sold without prescription but must be dispensed by pharmacists; and

IV. Specially controlled drugs, such as narcotics, psychotic drugs including diazepam and drugs for cancer treatment, whose sale requires a prescription. Drugs like alprazolam and lorazepam are meant only for hospital use and not meant to be available or sold at retail pharmacies at all.

Antibiotics are not prescription-only drugs in Thailand and are sold at retail pharmacies without prescription. The mission observed the sale of antibiotics and other “dangerous drugs” without prescription in a number of the retail pharmacies visited.

As earlier mentioned, the draft new Drug Act BE 2546 or 2003) is not yet passed by Parliament and implemented. According to the new 2003 Drug Act, medicines would be reclassified into 3 new categories (1) Prescription only medicines, whose sales require prescription; (2) Pharmacy dispensing medicines, which can be sold without prescription but must be dispensed by pharmacists; and (3) Medicines for household remedies.

7.6 Regulation and inspection of drug outlets

The Drug Act requires that any party who wishes to sell, manufacture or to import drugs into Thailand must obtain a license from the licensing authority. The annual licence fees for various outlets are as follows:

- License to manufacture modern medicines - 8,000 Baht,
- License to import modern medicines - 10,000 Baht,
- License to sell modern medicines – 1,500 Baht,
- License as a wholesaler of modern medicines – 1,000 Baht,
- License to sell medicines in sealed packages which are classified as neither dangerous nor specially controlled drugs – 1,000 Baht,
- License to sell modern veterinary medicines – 1,000 Baht,
- License to manufacture traditional medicines – 1,000 Baht,
- License to sell traditional medicines – 300 Baht,
- License to import traditional medicines – 5,000 Baht.

The Bureau of Drug Control is the licensing authority for the manufacturing, import and sales of drugs within the Bangkok metropolis and its territories. Provincial Public Health Offices are the licensing authorities for the manufacture and import of traditional drugs and sales of drugs in other provinces outside Bangkok. Each outlet should be re-licensed annually and ideally inspected annually, though staff are insufficient to do this throughout the country.

At the time of survey, there were in the FDA 30 qualified inspectors for doing outlet and GMP inspection as well as post-marketing surveillance. In 2014 inspections were carried out for 120 manufacturers over all Thailand, and 1600 wholesaler/outlets within the Bangkok area. It is unknown how many inspections were undertaken by the Provincial Health Offices, though the Rural and Local Consumer Health Products Division collects such information from the PHOs. There are 1,018 pharmacists employed by the PHOs who undertake many activities including inspection of pharmacy and food outlets.

7.7 Drug Registration

The Thai FDA, Bureau of Drug Control, is responsible for drug registration[36]. According to the draft new Drug Act (2003), not yet fully implemented, from the registration perspective, general medicines are further defined into:

- Generics (me-too medicines), which are pharmaceutical products with the same active ingredients and the same dosage forms as those the original products, but manufactured by different manufacturers. The registration requires only dossiers on product manufacturing and quality control along with product information. Local manufacturers are inspected regularly while foreign manufacturers are inspected on a case by case but mostly rely on GMP certification by the Drug Regulatory Authority of the manufacturing country.

- New medicines, which are products of new chemicals, products with new indications, new combinations, or products with a new delivery system or new dosage form. The registration of new

[36] http://www.fda.moph.go.th/eng/drug/pre.stm

medicines requires a complete set of product dossiers, demonstrating evidence of safety, efficacy and quality.

- New generics, which are medicines with the same active ingredients, dose, dosage forms as those new compounds (medicines) registered after 1992. Registration of such new generics requires dossiers of bioequivalence studies in addition to the required dossiers for generics. GMP inspection may or may not be done.

The registration requirements are available and can be assessed through the internet. The Evaluation Subcommittee meets and decides on the safety, efficacy and quality of the products and makes recommendations to the National Drug Committee of the FDA for final approval for registration. It was mentioned that approval may be granted by the FDA chief without necessarily going through the National Drug Committee. Generally, for a new drug, a conditional approval is given initially together with a safety surveillance program and limited distribution for 2 years. Once the medicines have passed this period, unconditional approval is granted. The approval incurs a fee but the products will be registered forever. Only if safety issues occur, may re-evaluation be undertaken with regard to continued registration. The company is not obliged to pay any fee for a re-evaluation. Generally the FDA negotiates with the manufacturers to withdraw products voluntarily.

It was mentioned that the Re-evaluation Sub-committee was not meeting as regularly as needed in order to re-evaluate all drugs, specifically to undertake review of post-marketing quality testing results, serious adverse drug reactions and review of all irrational combinations. All withdrawn drugs are available online[37]. In 2015, drug formulations that combined with camphor or sodium camphosulphonate injection were withdrawn due to possible side-effects on the central nervous system which may lead to death. However, a request for re-evaluation of serratiopeptidase, a registered product of more than 10 indications, has not yet been acted upon by the sub-committee, even though the company has conducted a world-wide withdrawal including Thailand.

There are currently, 23,053 allopathic medicines, 13,266 traditional medicines, and 3,640 veterinary products registered. There are extensive SOPs for medicines registration. The registration fees for medicines are relatively low, being 2000 Baht for new and old allopathic molecules and 500 Baht for traditional medicines. The annual licence fee for manufacturing premises is 8000 Baht.

7.8 Pharmacovigilance

The National Center of Pharmacovigilance (NHPCV) is situated in the Technical and Planning Division of the FDA. It has a network of 12 regional centers that collect adverse event reports from the facilities under them. Every Hospital Pharmacy and Therapeutics Committee (PTC) is active in monitoring adverse drug reactions (ADRs) from the respective hospitals. Monitoring is based on spontaneous reporting, targeted spontaneous reporting (such as in the vertical disease public health programs) and intensive cohort monitoring and cohort event monitoring. If there are serious safety concerns, the product is referred for re-evaluation of the product registration and possible withdrawal. Outbreaks of ADRs are referred to the Bureau of Epidemiology to investigate the cause of the problem. The NHPCV is a member of the WHO International Drug Monitoring Program, operates vigibase, and reported more than 49 000 ADRs in 2014.

[37] http://drug.fda.moph.go.th/zone_law/law010.asp

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

Year	2011	2012	2013	2014	2015
No. ADRs	60 680	55 302	56 386	49 722	34 329 (not complete yet)
No. of TRM ADRs	138	132	185	184	95 (not complete yet)

7.9 Drug Promotion

Advertisements need to be approved by the FDA before dissemination through whatever channel or media. There is a mechanism for both pre-market approval and post market surveillance of drug promotion materials, the Pre-marketing Division giving pre-market approval and the Compliance and Enforcement Management Centre undertaking post-marketing surveillance. Advertisements of dangerous drug and specially controlled drug are permitted only for health professionals but not for general public. However, medicines classified as household remedies may be advertised directly to the general public.

Based on the discussions with the FDA team, generally the FDA conducts post marketing surveillance of 4000 cases of drug promotion per year. The fines are considered too small, i.e. 100,000 Baht being the maximum, which the companies do not mind paying. There is plenty of room for improvement in the post-market surveillance of drug advertisement. There is no system for monitoring of companies representative activities. From the survey the team conducted in various hospitals and facilities it was found that pharmaceutical company representatives still visited pharmacies and doctors at the hospitals and this would need to be addressed to avoid their impact on prescribing practices. The International Manufacturing Companies Association and the Association of Domestic Manufacturing Companies are collaborating for self-regulation in pharmaceutical promotion.

The control of drug advertisements has recently focused on the internet as it was estimated that 85 % of such advertising was undertaken without FDA approval.

7.10 Drug Price controls

There is no direct drug price control, but there is price negotiation between industry and the purchasers at the central (NHSO) and at the provincial levels (Provincial Public Health Office) and price monitoring by Ministry of Trade/Commerce. Monitoring of procurement prices in public hospital purchases is done regularly by the Pharmacy Unit of the Bureau of Health Administration, MOPH.

The drug pricing mechanism in Thailand can be explained as follows. In the private sector, a market mechanism operates with free competition among products with similar ingredients (generics) and among drugs under the same category. There is no price cap or maximum retail price. Most retailers in the private sectors aim to have at least a 10 % mark up, and prices are often set up according what market will bear and sometimes even after bargaining between the retailers and the customers.

In the public sector, there is a price negotiation mechanism whereby a median price is established for essential drugs. The standard price list has been effective from 1986 and guides the purchasing committees in price negotiations. The government has also established a new policy for the procurement of drugs, whereby hospitals have to use not less than 70% of the government allocated money to buy the essential drugs. The mission was also informed that although in theory the Ministry of Commerce could have a direct drug price control, under the Price Fixing and Antitrust Act, but in reality there was no price control.

7.11 Drug Testing Laboratories

The Bureau of Drugs and Narcotics, under the Department of Medical Sciences, MOPH, is the responsible agency for quality testing of pharmaceutical products. The Bureau runs a pharmaceutical quality control laboratory with ISO accreditation and is designated as a WHO Collaborating Center. In 2012 the Bureau of Drugs and Narcotics was prequalified for the UN prequalification program.

Since 2007 the Bureau of Drugs and Narcotics, under the Department of Medical Sciences, MOPH, in cooperation with government hospitals and the Provincial Health Offices has continuously collected samples of pharmaceutical products used in hospitals for quality assurance after such products have been purchased and delivered. This program is under the Universal Health Coverage Policy, which includes 60 items. The quality of pharmaceutical products has been published on the website of the Department of Medical Sciences and in the Green Book[38], to facilitate purchasing decisions or to be used for other beneficial purposes. With regards to the pharmaceutical products which were sub-standard, the Food and Drug Administration was informed.

The Bureau has 154 staff consisting of 73 pharmacists, 34 scientist and 47 supportive staff. The science staffs are qualified in chemistry, biochemistry and microbiology. They have a national laboratory, 14 regional quality control laboratories and drug testing kits at the border areas. In 2014, the total number tested was 3528 sample with a failure rate of 6 %. The products that “pass” the test are published, and those that “fail” are not published in the Green Book.

Quality testing of finished pharmaceutical products and active pharmaceutical ingredients (APIs) is undertaken both during the pre-market period for registration, and post market for quality surveillance. They undertake quality testing of finished pharmaceutical products and active pharmaceutical ingredients (API), both during the premarket period for registration, and during the post-market period for quality surveillance. They also undertake quality testing of herbal products. The national laboratory also produces the ASEAN reference substances and undertakes identification/analysis of narcotics in biological samples.

Table 7.11.1 shows the number of quality tests performed and the results for the last 5 years.

[38] http://dmsc2.dmsc.moph.go.th/webroot/drug/index.stm\

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		4,605		4,605		438 (9.5%)
2011		4,645		4,645		227 (4.9%)
2012		5,170		5,170		235 (4.5%)
2013		4,970		4,970		307 (6.2%)
2014		3,528		3,528		205 (5.8%)

7.12 Drug Recall

The FDA and PHOs are authorized to order product recalls by Ministerial Regulation No. 20 B.E 2525 (1982) issued pursuant to the Drug Act B.E.2510 (1967). Manufacturers and importers must recall products within 15 days if the product has been found to cause serious health problems or within 30 days if the product is suspected of causing serious health problems. After review of the details of the individual case, the FDA or PHO will decide to correct the problem, for example by revision of the labelling or by destruction. Products are referred for investigation and recall by hospitals and PHOs or from the DMS. Voluntary recall is done by manufacturers on their own initiative after discovering problems but they have to report these to the FDA. There are SOPs covering recall procedures.

It is not known how many recalls were initiated in the last years and for what reasons - whether ADRs, quality or labelling issues, etc.]

7.13 Clinical Oversight

The Thai FDA regulates medicinal drugs that are manufactured in Thailand or imported into Thailand for use in clinical trials. The clinical trials must be approved by the FDA listed ethical committee before filing the manufacture or import permit form. Usually the application form and its required attachments need 20-60 working days to process for approval. The FDA requires all manufacturers or import permit holders to follow conditions in manufacturing or importing of investigational drugs as follows:

- All products must comply with GMP;
- Use only of products that are specified in the clinical trial protocol only;
- Regulation of the conduct of clinical trials according to GCP and GLP;
- Reporting of ADRs according to the specified guideline;

- Submission of progress reports annually and submission of end-of-trial reports;
- Facilitation of the Thai FDA inspectors in the GCP inspection.

The Thai FDA can suspend or terminate the clinical trial or the use of the drugs in clinical trials as deemed necessary.

There is a national clinical trials registry online[39] and there are currently several hundred clinical trials ongoing[40].

7.14 Licensing and accreditation of health professionals

There are independent professional councils for medical, dental, nursing and midwifery and pharmacists. Each with different Acts specifying the legal authorities of the council, the Professional Act BE 2511 (1968) for the Medical Council, the Dental Act B.E. 2537 (1993) for Dental Council, Professional Nursing and Midwifery Act B.E.2528 (1984) for Nursing and Midwifery Council, and a number of Pharmaceutical Acts for Pharmacy Council. These professional Councils have the legal power to issue or to suspend licenses, to recognize training institutions and their curricula.

The Thai **Medical Council** was established under the Medical Professional Act in 1968[41]. According to the Medical Profession Act BE 2525 (1982), the Medical Council of Thailand has the legal authorities/duties to register and to issue licenses to applicants applying to be medical practitioners, to suspend or to revoke license to be the medical practitioner, to recognize the degree, certificate in medicines or the professional diploma of various institutions, to recognize the various curricula for the medical training of the medical institutions, and to recognize the academic standard of the institutions providing training, to issue the diploma in the boards of medical specialty in the various fields of medical practice and to issue other certificates of special training in the medical profession. Fourteen (14) Royal Colleges of medical specialists can initiate training curricula but they have to be approved by the Medical Council. The Thai Medical Council Committee members consist of top executives from health care providers and users, Deans from medical schools, Director of the medical department of the army, air force, navy, police, the Permanent secretary MOPH, Director General Department of Health, Director General Department of Medical Services and elected doctors from private and public sectors. Unfortunately, the mission was not able to have much discussion with the Medical Council members.

Many doctors work in their own private clinics in the evenings after finishing work in public facilities and generally they dispense their own medicines, which is where they earn money. They may be easily influenced by promotional activities and may not undertake much CME. It is due to these private doctors dispensing activities that pharmacists have been unwilling to relinquish their prescribing activities.

The Thai **Pharmacy Council** has similar authorities with regard to pharmacist profession, i.e. licensing of pharmacist profession and recognizing pharmacy training institutions and their training curricula. Their committee includes Thai FDA officials, representatives from pharmacist associations, Deans of Pharmacy

[39] http://www.clinicaltrials.in.th/
[40] https://www.centerwatch.com/clinical-trials/listings/location/international/Thailand/
[41] http://www.tmc.or.th/en_home.php

Schools and military pharmacists. The Pharmacy Council develops a compulsory CPD program for their members.

Discussion with Pharmacy Council members revealed that there are about 32,000 members who have licenses. Recently the degree in pharmacy has been upgraded to six years to get a Pharm D degree. Previously the pharmacy degree was for five years. There are 19 schools of Pharmacy in the country. Pharm D has two specializations – Pharmaceutical care and Industrial Pharmacy. In some pharmacy schools the initial 4 years of teaching is the same and only the last two years have specialization. But in some schools from the first year onwards separate classes and teaching is done for both the courses. About 1,800 students per year pass out from various pharmacy colleges and around 1500 get their license; some do not apply as they are doing further studies and few do not clear the exam. At present there is one exam by the Pharmacy Council for licensing. However, they are planning to have two exams the first exam after students have cleared 4 years which will be common for all and later another exam for the two specializations of the Pharm D course. Postgraduate degrees in pharmacy can be divided into, first the regular ones through academic masters and doctoral programs (PhD), and second the Practice Specialist (under the Councils College of Pharmacotherapy) with a 4-year residency training.

The Pharmacy Council charges 5,000 baht for the license exam and for license renewal 500 baht every five years. From this year, they have started a compulsory CME system, requiring 100 credits in 5 years (ideally >10 credits per year) for renewal of the pharmacy license. Credits can only be attained by attending seminars and courses run by universities and associations and which are approved by the Pharmacy Council.

From 2013 onwards, the Pharmacy Council has been accrediting pharmacy shops for Good Pharmacy Practice (GPP). As per the GPP accreditation criteria:

- Pharmacists should always be in the store from start to close;
- All products should be of good quality;
- Good storage;
- Good prescribing/dispensing including patient counselling;
- Record keeping for non-communicable disease drugs, homecare, prolonged use of antibiotics.

In addition there is a second accreditation of pharmacies by the FDA mandated by Ministerial Regulation which stipulates minimum requirements. All new drug stores registered after 25 June 2014 have to be accredited while old drug stores, registered before 25 June 2014, have to gradually change step by step and achieve accreditation within 8 years by 2022. Apparently, the Pharmacy Council accreditation criteria are superior to the FDA accreditation criteria. However accreditation by the Pharmacy Council is not yet compulsory and does not seem to confer much financial advantage. It is not clear whether it is enforceable by law since the FDA mentioned that accreditation was not done being done. It was mentioned that pharmacy data was being collected by inspectors at the time of writing and that pharmacies must be accredited to work with the NHSO on various pilot projects such as screening for hypertension and diabetes mellitus.

Last year the Pharmacy Council received about 50 complaints, of which 20 were for Ghost Pharmacists (where there is no pharmacist in the pharmacy) and 30 were for wrong practice. The council suspends the license for some period depending upon the complaint but it is minimum six months.

The Thai **Nursing and Midwifery Council**[42] , according to the Professional Nursing and Midwifery Act B.E.2528 (1984), has the authority to (1) arrange for the registration and licensing of nurses and / or midwifery practitioners; (2) suspend or revoke a nursing and / or midwifery license; (3) approve the curriculum of an institute before forwarding to the Ministry of University Affairs for accreditation; (4) accredit curriculum at certificate level of an institute that wants to offer education related to professional nursing and midwifery; (5) accredit training courses of an institute that wants to offer education, related to professional nursing and midwifery; (6) endorse accreditation of academic institutions that offer teaching and training; (7) approve the degree, certificate equivalent to degree, certificate or specialist certificate issued by an educational institute that offers a program in this field, (8) issue a letter of approval or certification of specialization or other forms of certification to those who practice the profession of nursing and / or midwifery; (9) function according to the objectives of the Nursing and Midwifery Council. The committee member of the Thai Nurse and Midwifery Council consist of nineteen (19) appointed members representing Ministry of Public Health, Ministry of Education, Ministry of Defense, Ministry of Interior, Bangkok Metropolitan and the Thai Red Cross, sixteen elected members, the President and the Secretary General.

The nursing and midwifery basic course is 4 years with a bachelor degree. Previous short courses have now been discontinued though there is still a one year course for nursing aids who must practice under a nurse. The 4 year bachelor nurse must practice for 2 years before taking further courses such as the nurse practitioner course of 4 months or a master's program of 2 years. Nurse practitioners can prescribe and order 19 drugs like paracetamol, antihistaminics etc. and in addition to traditional medicines. Nursing aids get enrollment with the Nursing Council but do not get a license. There are 180 000 registered nurses with the Council.

The Nursing Council runs a licensing exam, the fees being 3800 baht for initial licensing. License renewal is five-yearly, members paying 1050 baht that includes 500 baht for the membership fee, 500 baht for the license and 50 baht for the card. For renewal they are supposed to take 50 CNEU (Continuing Nursing Education Units). In 2014 the Council received 15 case complaints, and in 2015, 18 case complaints pertaining to violation of nursing standards or inappropriate practice behavior.

7.15 Licensing and accreditation of health facilities and pharmacies

According to the Drug Act, any party who wish to manufacture, to import and to sell medicinal products, requires licensing from the Licensing Authority. The Thai FDA has the legal authority to issue a license for manufacturers, importers, wholesaler and pharmacies. Licenses are issued for nine different business areas, i.e. (1) manufacturing of modern medicines, (2) importation of modern medicines, (3) selling of modern medicines, (4) wholesale of modern medicines, (5) sales of modern medicine of sealed packages, (6) selling of veterinary medicines in sealed package, (7) manufacturing of traditional medicines, (8) selling traditional medicines, and (9) importation of modern medicines.[43] The team was informed that, while the Pharmacy Council is undertaking accreditation of pharmacies according to Good Pharmacy Practice (GPP), there was no legally enforceable accreditation of pharmacies based on GPP in actual practice, although a recent

[42] http://www.tnc.or.th/en
[43] http://www.fda.moph.go.th/eng/drug/pre.stm

Ministerial Regulation has initiated a step-by-step approach to achieving GPP by 2022 to be enforced by the FDA.

The Healthcare Accreditation Institute (HAI) is an autonomous public organization, responsible for accrediting hospitals using the Hospital and Healthcare Standard[44]. The institute has undertaken hospital accreditation for 20 years, with 50 % funding from Government and 50% from accreditation fees paid by the hospitals.. They have 80 full time staff and 110 part-time surveyors. Thai hospitals are required to get accredited or to pursue accreditation if they want to participate in public health insurance or welfare schemes such as the UHCS and the SSS. More than 700 hospitals, over 500 public and 200 private ones, have been accredited. The hospital accreditation program serves as a mechanism to encourage systematic total hospital quality improvement, using the principles of self-assessment, quality assurance, and customer-focused continuous quality improvement (CQI) and total quality management (TQM). The standards are divided into four parts, i.e. (1) overview of the organization management system, (2) Key hospital system, (3) Patient care process, and (4) Performance results. The medication system is included under the key hospital system. The Healthcare Accreditation Institute also collaborates with professional associations like the Medical Association and Pharmaceutical Association in undertaking assessments.

The licensing of private hospitals, clinics of general practitioners or specialists is done by the Department of Medical Services, MOPH. In Bangkok there are 100 private hospitals and 4000 clinics (80 % GP). In other provinces licensing is taken care of by the Provincial Health Offices. Overall in Thailand there are some 320 private hospitals and 17,500 private clinics (including GP, dental, physiotherapy, traditional medicine, medical technology, nurse, and midwife clinics). Licenses must be renewed every year. The HAI have checklist for hospital/clinic inspection covering facilities available and equipment, whether for GP private clinics or hospitals, such as ventilation, infection waste, needle disposal and expired drugs in the facility etc. There is no restriction on the number of facilities to be opened.

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

Thailand has a long history of implementing medicines regulation for protecting the public with a number of Drug Acts since early in the last century. The Drug Act BE 2510 (1967) was amended four times culminating with the Drug Act BE 2530 (1987). However, this Drug Act is too rigid not allowing for revision of fees and fines, which are too low and undermine the work of the FDA. For example, the FDA has to undertake more work to deal with poor applications for drug registration and cannot adequately punish pharmaceutical companies which publish misleading advertisements. The Drug Act was further revised with more flexible and effective provisions in 2003 but it has not yet been passed by Parliament and implemented. The Thai Food and Drug Administration (FDA), is an established regulatory authority responsible for implementing medicines regulation along with other Government Departments such as the Department of Medical Sciences.

Many aspects of the medicines regulatory system have been effectively implemented particularly the drug quality assurance system and the drug safety surveillance or pharmacovigilance system, etc. Nevertheless, there is room for further improvement. In the area of medicines registration the regulatory authority can aim for fewer brands of the same active pharmaceutical ingredient (API) in the market, along with 5-year

[44] The Healthcare Accreditation institute (Public Organization). Hospital and Healthcare Standard, April 2011.

duration of registration. The re-evaluation sub-committee could meet more regularly to re-evaluate the registration of irrational combination products. There is also a need to improve monitoring and control of drug promotional activities, as well as education and advocacy for consumers on the safety of medicines. Disallowing antibiotics, particularly 3rd and 4th generation systemic ones, from being sold without prescription at retail pharmacy stores would help to decrease their consumption and contain antimicrobial resistance.

7.17 Medicines regulation: Recommendations

- Work towards a new more flexible and effective Drug Act, as there are still gaps and many areas of disagreement.
    - Continuous consultation involving all relevant stakeholders will help to close the gaps and disagreement in different areas.
- Work towards having fewer brands of same drug (active pharmaceutical ingredient) in the market by:
    - Introducing 5-yearly re-registrations,
    - De-registering drugs not currently in the market,
    - Increasing the fee for registration and
    - Re-evaluating drug registrations regularly.
- Monitor drug promotional activities in collaboration with MOPH & professional bodies & councils,
    - Consider banning medical representatives from public facilities except by appointment with the Pharmacy and Therapeutics Committee,
    - Require companies to disclose their marketing activities and budgets,
    - Increase the fines for publishing misleading adverts,
    - Institute a risk approach to monitoring advertisements,
    - Undertake a rapid survey for monitoring drug promotion in both public and private hospitals (include clinics and drug stores) to see whether they follow the ethical criteria,
    - Incorporate education on ethical drug promotion through universities and professional councils.
- Publish failed drug test results to convince prescribers about drug quality,
- Consider an external WHO Assessment on Drug Regulatory Authority functionality.

8. MEDICINE POLICY AND COORDINATION

8.1. National Medicines Policy

Thailand has implemented National Medicines Policies (NMP) since 1981, along with the development of National Essential Medicines List (NEML) in the same year[45]. The NEML served as a basis for medicines procurement at public facilities since 1986 with a Prime Minister Office regulation. Later after the implementation of the universal coverage policy in 2001, the NEML basically served as a basis for reimbursement, although there were also local hospital formularies used in public hospitals. The latest NMP is the National Drug Policy BE 2554 (2011). The following information is taken from the printed document on National Drug Policy BE 2554 (2011) and Strategies for the Development of a National Drug System (2012 – 2016).

The vision of the National Drug Policy BE 2554 (2011) is universal access to medicines for all, rational use and national self-reliance. The goals of the policy are: (1) to provide people with a standard of preventive health care and treatment that ensures quality, safety and efficacy of medicines; (2) to promote a system for rational use of drugs and access to essential medicines in an equitable, sustainable and timely manner; (3) to establish an effective surveillance mechanism; and (4) to develop national industry to a level of national self-reliance.

There is a strategic plan for 2012 – 2016 implementation which covers four strategies, these being: (1) Access to Medicines; (2) Rational Use of Medicines; (3) Development of the Domestic Pharmaceutical Industry, Biological Products and Herbal Medicines for Self-Reliance; (4) Strengthening Regulatory System to completely assure Quality, Efficacy and Safety of the Registered Medicines. Each strategy consists of different sub strategies, each with its specific objective. For each sub strategy, there are different (government) organizations designated for the implementation.

Under strategy 1 on Access to Medicines, there are four sub-strategies, as follows:

- Sub Strategy 1: To coordinate collaborative network for accessibility of medicines,
- Sub strategy 2: To support patients' groups to access medicines and participate in health care promotion,
- Sub strategy 3: To control domestic drug pricing to commensurate with the living cost of the people, and
- Sub Strategy 4: Taking advantage of and/or alleviating legal obstacles preventing access to medicines.

Under strategy 2 on Rational use of Medicines, there are seven sub strategies, as follows:

- Sub-strategy 1: To develop a regulatory system and monitoring mechanism to ensure rational use of medicines,
- Sub-strategy 2: Systematic development of human resources in health services,
- Sub strategy 3: To develop mechanism and tools for facilitating rational use of medicines,
- Sub-strategy 4: To strengthen the capacity of the people's sector in the rational use of medicines,
- Sub-strategy 5: To encourage manufacture and quality control of generic medicines,

[45] Yoongtong et al. National drug policies to local formulary decisions in Thailand, China and Australia : Drug Listing Changes and Opportunities. *Value in Health* 15 (2012), s 126 – 131 URL: http://www.sciencedirect.com/science/article/pii/S1098301511035406

- Sub-strategy 6: To develop preventive and problem solving systems and mechanisms caused by antimicrobial use and drug resistance,
- Sub-strategy 7: To promote the ethics of prescribers and stopping unethical sales promotion of drugs.

Under strategy 3 on the Development of the Domestic Pharmaceutical Industry, Biological Products and Medicinal Herbs for Self-reliance, there are four sub-strategies, as follows:

- Sub-strategy 1: To develop and revise rules and regulations to promote domestic investment and advancement of the pharmaceutical manufacturing industry,
- Sub-strategy 2: To strengthen research and development as well as incremental innovation of the Pharmaceutical industry into commercial products,
- Sun-strategy 3: To supply resources to support the domestic pharmaceutical manufacturing industry and marketing,
- Sub-strategy 4: To assure prescribers and the public confident in quality and efficacy of locally manufactured medicines.

Under strategy 4 on Strengthening Regulatory System to Completely Assure Quality, Efficacy and Safety of the Registered Medicines, there are three sub-strategies, as follows:

- Sub-strategy 1: Efficient improvement of regulatory capacity and transparency in accordance with good governance,
- Sub-strategy 2: Advancement of post-marketing surveillance and early warning systems,
- Sub-strategy 3: Re-evaluation of the registered pharmaceutical products that have negative impacts on consumers and the general public.

There are some important points to note. Firstly, the National Medicines Policy (NMP) does not stand alone as a normative policy document, but is accompanied by strategic plan, sub strategies and actions for implementation. Secondly, the role of different government departments and agencies are clearly shown in each sub strategy. However, there is a need to define which organizational unit is designated to coordinate the implementation. Thirdly, the NMP specifically addresses health sector objectives namely access and equity, quality as well as rational use of medicines as part of the health delivery system. However, it also addresses industrial and economic objectives such as domestic industrial development, self-reliance, and research and development and innovation. Fourthly, transparency and good governance in medicines sector to improve access, quality and rational use are emphasized and translated into program monitoring and evaluation. Fifthly, the roles of consumers in promoting access and to medicines and in promoting health have been well defined in the policy document. However, it is less clear how this issue is translated into actions.

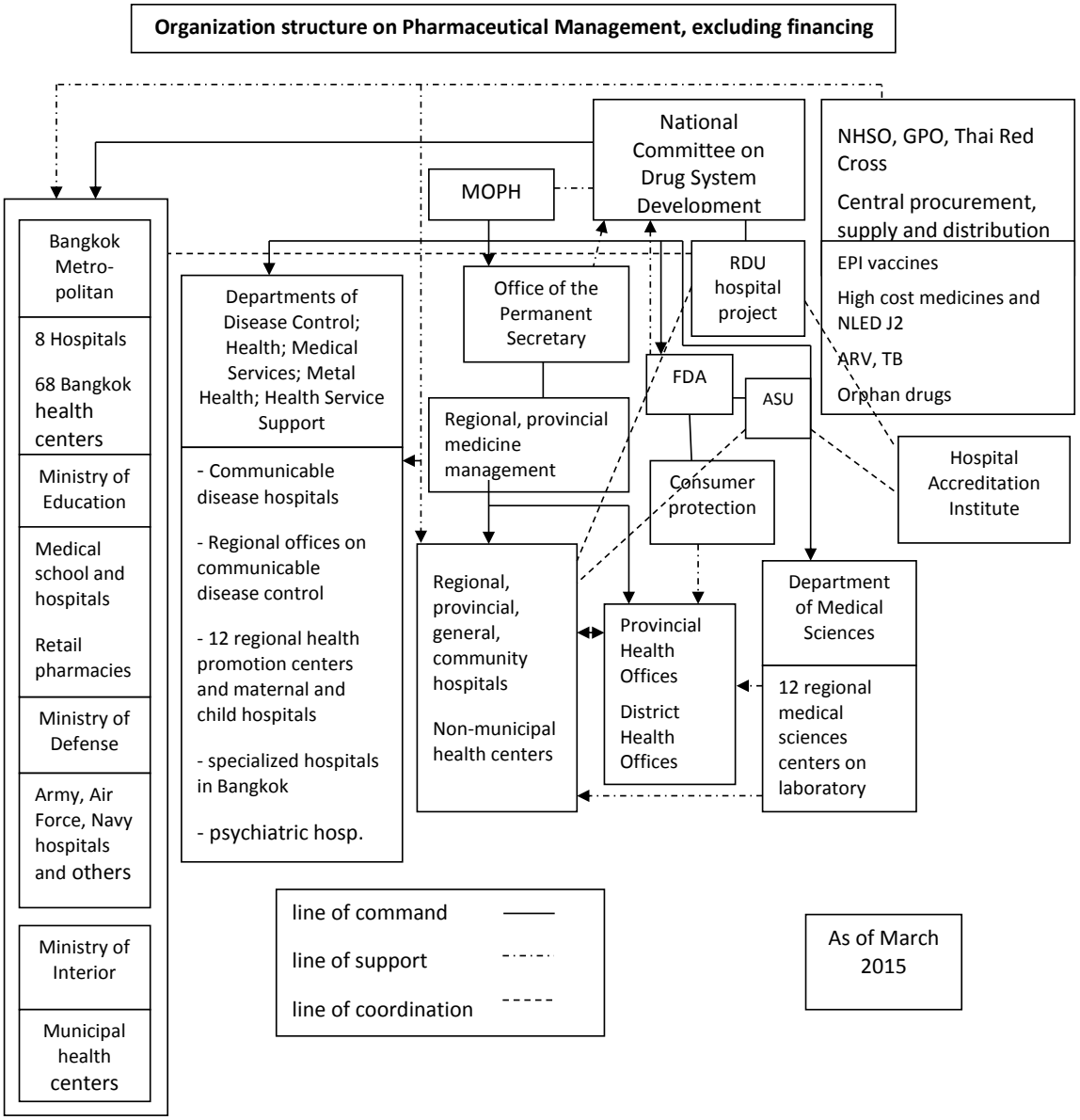
At the time of writing a new National Medicines policy and strategic plan for 2017-2021 was being drafted.

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

Policy	Implementation status
National Medicines Policy (NMP)	NMP updated document 2011 with a strategic plan for implementation 2014 - 2016
National Essential Medicines List (EML)	NEML updated annually and published online; latest printed version in 2013. It is used as the basis for procurement and reimbursement
National Standard Treatment Guidelines (STGs)	Treatment protocol for MOPH special programs, such as malaria, TB and HIV/AIDS, non-communicable diseases, asthma, chronic obstructive pulmonary disease, hypertension, dengue hemorrhagic fever, acute respiratory infections, acute diarrhea, snake bites etc. are available. STGs for about 50 diseases from the Department of Medical Services, but these guidelines were not seen at the health facilities.
National Formulary manual	There no national formulary but individual hospitals may have their own formulary manual
National government unit dedicated to promoting rational use of medicines	Subcommittee on Promoting Rational Drug Use of the National Committee on Drug System Development
Monitoring medicines use	Only NEML compliance is monitored. Otherwise, there is no robust national monitoring system though in some hospitals, the Pharmacy & Therapeutics Committee monitor the use of certain medications.
Pharmacy (Drug) & Therapeutic Committees (PTCs/DTCs)	PTCs exist in all hospitals
National Drug Information Centre (DIC)	No national DIC, but drug information centers/services are available at referral hospitals, schools of pharmacy
Generic Policies	Exist in public health facilities
Health insurance	Three insurance schemes (UHCS, SSS and CSMBS) covering 99 % population.
Payment for medicines by patients	No out-of-pocket payment at public facilities
Provider revenue from medicines	No provider revenue from medicines
Undergraduate training on pharmacology & prescribing	Incorporated in the undergraduate curricula of doctors and pharmacists
CME training on pharmacology & prescribing	No specific CME on these topics
Public education on medicines use	Public education through village health workers but very little on the use of medicines
Pharmacovigilance	Extensive national system on ADR monitoring
Regulation of drug promotion	Premarket approval but inadequate post-market surveillance
National strategy to contain Antimicrobial Resistance	AMR sub strategy exists together with a National Sub Committee to coordinate action
Over-the-counter availability of prescription-only medicines including antibiotics	Some antibiotics and other “dangerous” medicines (considered prescription-only in other countries) are available OTC in pharmacies but no controlled drugs requiring a prescription were available OTC.

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

8.3.1 Ministry of Health Organogram



8.3.2 Coordination within the Ministry of Public Health

The Ministry of Public Health is responsible for health promotion, disease prevention and control, medical care services and rehabilitation and other affairs[46]. It is headed by the Health Minister, the Deputy Health Minister, followed by the Permanent Secretary and four Deputy Permanent Secretaries.

The vision is "to *be the core agency in developing the health system with quality, efficiency and equality; with participation of the people, communities and all sectors for good health of all Thai people in order to achieve a good and sustainable society following the King's Sufficiency Economy philosophy".*

The MOPH missions are: (1) to determine national and international health policy and strategy, concordantly with ongoing changes; (2) to develop an efficient and equitable integrated health service system for both normal situations and emergencies with emphasis on basic rights, specialized services and emergency medicine, surveillance system, disease prevention and control and health threats; (3) to promote participation of all sectors to raise health consciousness, promote health and improve health behaviors; (4) to develop a health management system and mechanism to meet the quality standards, in line with Sufficiency Economy Philosophy; and (5) to determine health research and knowledge management direction policy.

Within the MOPH, there are nine departments/agencies:

1. Office of the Permanent Secretary with 76 provincial offices,
2. Food and Drug Administration,
3. Department of Medical Services,
4. Department of Health with 12 Regional Offices,
5. Department of Disease Control with 12 Regional Offices,
6. Department of Mental Health,
7. Department of Health Services Support, with a medical registration division responsible for licensing private hospitals,
8. Department of Medical Sciences with 12 Regional Centers for Laboratory Analysis
9. Department of Traditional Medicines.

There are 12 Regions, 76 provinces and about 10 – 12 districts per province. In each province, there is a Chief Medical Officer, a Provincial Health Office and at least one provincial hospital, plus a Regional Hospital in big provinces. There is at least one community hospital per district and about 15 – 20 primary health centers under each community hospital. Primary health centers are staffed by nurses usually but sometimes also by Primary Health Care by doctors. Regional Hospitals have 700 – 1000 beds, provincial (general) hospital 500 – 700 beds and district (community) hospitals 10 – 120 beds depending on the size of the population. The MOPH also runs 12 large hospitals in Bangkok.

In addition to the MOPH system, metropolitan authorities, the military, universities and the private sector also run hospitals. The Department of Maternal and Child Health, the Department of Mental Health and the Department of Disease Control also run specialist hospitals and clinics. The hospitals that are not under the MOPH do not always follow the NEML.

[46] http://eng.moph.go.th/index.php/about-us/authority-and-function

The Pharmacy Section, within the Office of the Permanent Secretary, mainly focuses on developing MOPH guidelines on implementation of drug policy, particularly monitoring prices and NEML compliance of MOPH's hospitals. The Inspection Section, in the Office of the Permanent Secretary, inspects MOPH hospitals every 6 months for many aspects of quality of care and whether various regulations are followed, using standardized check lists. However, their reports are quite general and lack detail.

The MOPH also has other departments including the FDA that play a role in developing drug policy and there are various committees. According to the 2008 Prime Minister Regulation on National Committee on Drug System Development, the Thai FDA, under the MOPH, serves as the secretariat of the National Committee on Drug System Development. This committee is chaired by the Prime Minister and is responsible for national drug policy development and evaluation, development of national essential drug list and standard price for procurement, rational use of drugs, and antimicrobial resistance. The Bureau of Drug Control is also a key responsible unit since February 2015.

It is not clear how much overlap there is between the Pharmacy Section in the Office of the Permanent Secretary, the FDA, the national drug system development committee and the prime ministers' cabinet's working groups.

8.4. Coordination beyond the Ministry of Public Health

8.4.1. National Committee on Drug System Development (NDSDC)

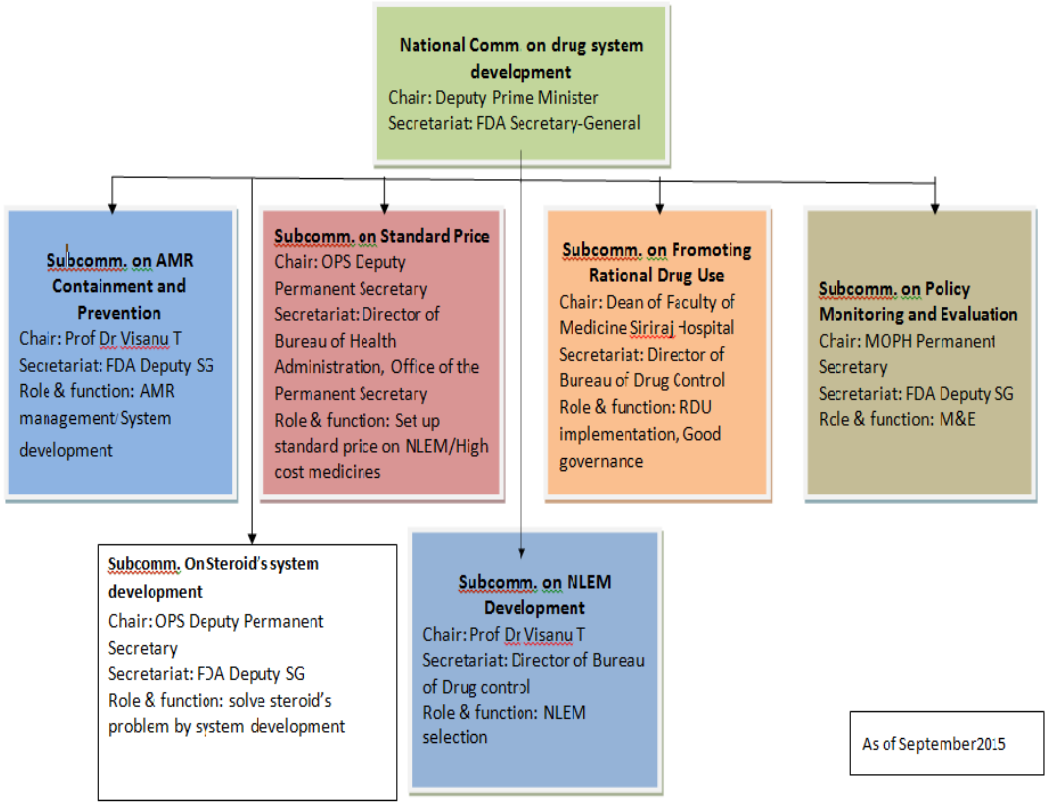
Medicines related issues including the NMP become the policy issues not only of the health sector but also the cabinet and the non-health sectors. At the national level, under the cabinet there is a National Committee on Drug System Development, chaired by the deputy Prime Minister with the Secretary General of FDA as the secretary. This national committee consists of six subcommittees on different priority areas:

1. Subcommittee on Antimicrobial Containment and Prevention. The primary function is the management of AMR containment and prevention program. Professor Visanu T, a leading national expert from Siriraj Hospital, is appointed as the chairperson and the Deputy Secretary General of Thai FDA as the Secretary.
2. Subcommittee on Steroid System Development. The main function is to solve the problems on steroid misuse. The Deputy of the Permanent Secretary of the MOPH is the Chairperson and the Deputy Secretary General of Thai FDA is the secretary.
3. Subcommittee on Standard Price. The primary function to set up standard prices for essential medicines and high cost medicines. The Deputy Permanent Secretary of MOPH is the Chairperson and the Director of the Bureau of Health Administration is the secretary.
4. Subcommittee on the Development of National Essential Medicines List (NEML) with primary function to develop and revise the NEML. Professor Visanu T is appointed as the Chairperson and the Deputy of FDA Secretary General as the Secretary.
5. Subcommittee on Promoting Rational Drug Use. The primary function is to promote rational drug use and to manage the Good Governance Program. The Dean of the Medical Faculty Siriraj Hospital is the Chairperson and the Director of Bureau of Drug Control of Thai FDA is the secretary.
6. Subcommittee on Strategy Development, Monitoring and Evaluation. The primary function is the monitoring and evaluation of implementation. The Chairperson is the Permanent Secretary of the MOPH and the secretary is the Deputy of Secretary General of Thai FDA.

The appointment of the National Committee on Drug System Development and its Sub-committees clearly indicates a strong commitment from the Government on NMP implementation and on strengthening the coordination mechanism (see Figure 8.4.1). The appointment of MOPH high ranking officials in each subcommittee would enhance effective implementation and coordination between different organizational units within the MOPH. Moreover, it also reflects the serious response of MOPH on priority medicine issues such as AMR and irrational use of medicines. However, there is a possible risk of overlapping and duplication of work by various MOPH technical units on specific areas, for example, on medicines price negotiation.

In addition to the National Committee on Drug System Development and the Subcommittee on Antimicrobial Containment and Prevention, there also now exists an AMR strategic coordinating committee. A new Draft AMR action plan has been written and is waiting for final approval. It is not clear how the new AMR strategic coordinating committee relates to the existing Subcommittee on Antimicrobial Containment and Prevention.

Figure 8.4.1: National Committee on Drug System Development



8.4.2. Other Ministries / Agencies with medicines-related functions

The Ministry of Finance funds five semi-autonomous bodies which have roles that are related to drug policy and/or medicines management:

1. National Health Security Office (NHSO). This body holds the budget for drugs and vaccines under the Universal Health Coverage Scheme which covers 74% of the population.
2. Health System Research Institution (HSRI), which undertakes research on health systems including drugs.
3. Thai Health Promotion Foundation (Thai Health) which funds many projects on health promotion and promoting RUM.
4. National Health Commission (NHC) which develops national health policy including drug policy, and
5. National Institute for Emergency Medicine (NIEM)

Other Ministries also play a role in influencing how medicines are managed:

- The Ministry of Commerce is legally responsible for regulating prices of all commodities including pharmaceuticals. In practice they have not intervened pharmaceutical markets and most actions have been taken on appeals from patients. Under the law they have a power to monitors drug prices, set prices at any level of the supply chain, and request for cost structure. In addition it also legally responsible for limiting importation and exportation of specific goods.
- The Ministry of Industry e.g. The Board of Investment of Thailand has a role on giving privileges for investment e.g. waivers or reductions of duties and taxes on imports of machinery.
- The Ministry of Education is in charge of universities and schools and can play role in changing the study curricula at every educational level e.g. primary school, secondary school, undergraduate studies. This particularly concerns the curricula for health professionals and medical schools.

The National Committee on Drug System Development, chaired by the deputy Prime Minister, plays a vital role in coordinating with these other ministries. However, another way that Thailand is achieving success in coordination and policy implementation is the dedication of a number of professionals, both doctors and pharmacists, who are working in a synergistic way to push policy reforms through different channels. For example with regard to promoting rational use of antibiotics and containing antimicrobial resistance, there is a push through the National Health Assembly (bottom-up approach), the FDA (top down approach), the Health Systems Research Institute (HSRI), the NEML committee and the AMR sub-committee.

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

For implementing the National Medicines Policy, relevant strategies have been devised for 2012 – 2016 on: access; rational use; development of the domestic industry; biological products; herbal medicines for self-reliance; and on strengthening the regulatory system. Each strategy is furthered divided into sub-strategies, tactics and actions. Relevant committees are formed and different government departments/agencies are designated for implementing the strategic actions identified. Effective implementation of the NEML is one important aspect of the NMP which needs to be improved especially at hospitals. Different stakeholders involved in implementing the NMP need to be systematically monitored. As implementation of the NMP obviously involves multiple government committees and Government departments/agencies, either within or outside the MOPH, there is a need to designate an executive government department/agency to coordinate actions and to execute recommendations of the statutory committee. As mentioned earlier in the situational analysis of 2012, there are chances of various working groups doing the same work and duplication of work may lead to some inconsistencies.

The Universal HealthCare Coverage Scheme (UHCS) and organization of medicines management in Thailand is very impressive. A major reason for the successful implementation of much of Thailand's National Medicines Policy and pharmaceutical care may be the employment of many pharmacists in the health system at all levels (with the exception of health centres). If Thailand were able prepare one document that fully described their UHCS programme, together with how their pharmaceutical services are organized, this could provide institutional memory of lessons learned and would also be very useful for other countries to learn from.

8.6. Medicines policy and coordination: Recommendations

With regard to national drug policy, it was recommended to:

- Promote the use of the National Essential Drug List as a basis for public procurement and reimbursement,
- Define a common standard of compliance in using the National Essential Drug List for procurement, reimbursement and usage.
- Monitor the activities of stakeholders in implementing National Drug Policy,
- Work on having a unified management system for universal health coverage policy involving different insurance schemes.

With regard to coordination, it was recommended to:

- Decide on one permanent statutory committee to advise the Minister of Health on pharmaceuticals with wide membership including laypersons, professional bodies etc. This could be the National Drug Systems Development Committee.

- Appoint one executive department in MOPH to carry out the statutory committee recommendations
    - To coordinate actions between different departments within MOPH, other Ministries and national agencies, i.e. the Pharmacy Section in the Office of the Permanent Secretary, FDA, Bureau of Policy & Strategy, Ministry of Education; Ministry of Finance; Ministry of Industry; Ministry of Commerce,
    - To be responsible for rational use of drugs: EML, STGs, PTCs, monitoring drug use, continuing education, and public education.
- Streamline the committees and invest in their advice.
- Document the description of the pharmaceutical health care system in order to maintain institutional memory of lessons learnt and progress made in implementing universal health coverage policy.

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10. PERSONS MET DURING THE SITUATIONAL ANALYSIS

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2	Mr. Wattana Boonyaraktanya	Standard and Welfare Office, The Comptroller's General Department
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5	Ms. Ratsamee Wimolsantirungsri	Lumphun Hospital, Lumphun
6	Ms. Anchaphorn Kamsarn	Lumphun Hospital, Lumphun
7	Mr. Sompong Kamsarn	Lumphun Hospital, Lumphun
8	Mr. Narit Maneethong	Lumphun Hospital, Lumphun
9	Miss Yupin Nampoonsak	Pasang Hospital, Lumphun
10	Mr. Narit Maneethong	Chief of Makhueajae Health Centre, Makhueajae Health Centre, Lumphun
11	Dr. Pokin Sakarinkhul	Makhueajae Health Centre, Lumphun
12	Mr. Wittaya Pinkasan	Makhueajae Health Centre, Lumphun
13	Ms. Pimchanok Khonk	Makhueajae Health Centre, Lumphun
14	Ms. Pawarisa Lomnasak	Makhueajae Health Centre, Lumphun
15	Mr. Tirdsak Yanaroad	Tirdsak Pharmacy, Lumphun
16	Mrs Jansri Mulawong	Pasang Health Center, Lumphun
17	Mr Suttipong Banluewong	Pure Big C Drug Store, Lumphun
18	Ms. Piyatida Taejaroenkul	Nakornping Hospital, Chiang Mai
19	Ms. Chanokporn Uttama	Nakornping Hospital, Chiang Mai
20	Miss Punnee Klowuttaiwatt	Nakornping Hospital, Chiang Mai
21	Ms. Kobgan Akasin	Nakornping Hospital, Chiang Mai
22	Mrs. Rasanaa Thanatipamont	Nakornping Hospital, Chiang Mai
23	Mr. Manop Kantee	Nakornping Hospital, Chiang Mai
24	Mrs. Wanna Sawats	Saluangnok Health Center, Chiang Mai
25	Ms. Achara Boonsuk	Saluangnok Health Center, Chiang Mai
26	Mrs. Sangjan Phaphirom	Doi Kaew Health Centre, Chiang Mai
27	Miss Sirikul Rattana	Jomthong Hospital, Chiang Mai
28	Miss Prapha Butta	Jomthong Hospital, Chiang Mai
29	Miss Dolruethai Banjerdjin	Jomthong Hospital, Chiang Mai
30	Miss Naphaporn Sittidej	Jomthong Hospital, Chiang Mai
31	Mrs. Pakawadee Kannika	Jomthong Hospital, Chiang Mai
32	Mrs. Arnanprapha Chaimongkol	Jomthong Hospital, Chiang Mai
33	Mrs. Kittinapha Suphawong	Jomthong Hospital, Chiang Mai
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35	Mrs. Sakorn Jaiphayom	Jomthong Hospital, Chiang Mai
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43	Mr. Nattapat Noiman	Sankampaeng Hospital, Chiang Mai
44	Mr. Issara Nanawichit	Chiang Mai Public Health Office,
45	Miss Parinda Tositarat	Boots pharmacy, Central Festival, Chiang Mai
46	Miss Panicha Kittirungsri	Kitti Chiang Mai Pharmacy, Chiang Mai
47	Miss Siriwipha Suwapha	Kitti Chiang Mai Pharmacy, Chiang Mai
48	Dr. Purida Wienthong	Chiang Mai University Pharmacy,
49	Assist. Prof. Dr. Siritree Suttajit	Chiang Mai University Pharmacy,
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59	Dr.Ornsiri Serirat	Department of Medical Services, MOPH
60	Dr.Chariya Sangsajja	Director of Bamrasnaradura Infectious Diseases Institute, Bangkok and Department of Disease Control, MOPH
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70	Dr.Siriorn Sinthu	Thailand Nursing and Midwifery Council
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74	Mr.Pisan Asanee	Acting Director of Logistics Department, The Government Pharmaceutical Organization
75	Miss Patcharee Wattanasiritanawong	The Government Pharmaceutical Organization
76	Mr Chatuphon Charoenkitpaiboon	The Government Pharmaceutical Organization
73	Mrs. Kruawan Laopiyasakul	GPO Drug Store, The Government Pharmaceutical Organization
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80	Ms. Premjit Suttipoom	Siriraj Hospital, Bangkok
81	Miss Ajjima Sarapakdi	Siriraj Hospital, Bangkok
82	Miss Ploypan Pothisuntorn	Siriraj Hospital, Bangkok
83	Mr. Preeda Benjamakaskul	Siriraj Hospital, Bangkok
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87	Mrs.Chawaporn Leelavethaphong	Chief of Pharmacy Department, Charoenkrung Pracharuk Hospital, Bangkok
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114	Miss Juthathip Laoharuengchaiyod	Division of National Drug Policy, Bureau of Drug Control, FDA, MOPH
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38	Miss Lalittanan Moolasart	Div NDP, BDC, FDA, MOPH
39	Miss Juthathip Martro	Div NDP, BDC, FDA, MOPH
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44	Mr.Thanakrit Mongkolchaipak	Div NDP, BDC, FDA, MOPH
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50	Miss Kasinee Juthasawat	The Government Pharmaceutical Organization
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52	Dr. Kathleen Holloway	WHO/SEARO
53	Dr. Budiono Santoso	WHO/SEARO
54	Dr. Anita Kotwani	WHO/SEARO
55	Dr. Nima Asgari-Jerhandeh	Acting WR Thailand

12. WORKSHOP SLIDE PRESENTATION

Medicines in Health Care Delivery in Thailand Situational Analysis: 23 Nov – 4 Dec 2015

WHO/SEARO: *Dr Kathleen Holloway, Dr Anita Kotwani, Dr Budiono Santoso*

Pharmacy Section, BHA, MOPH: *Pornpimon Chantrakunapars, Dr Araya Sripairoj, Ms Voranadda Srisuphan*

IHPP, MOPH: *Dr Chutima Akaleephan*
NHSO Chiang Mai: *Mrs Siriporn Wohbah*

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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.

Universal Health Coverage Policy

- Universal health coverage
  - All people have access to the health services they need without the risk of financial hardship when paying for them.
- Universal health coverage requires
  - An efficient health system that provides all the population with access to good quality services, health workers, medicines and technologies.
  - A financing system to protect people from financial hardship and impoverishment from health care costs.
- Thailand is in the forefront of UC policy in Asia
  - Thailand's UC system provides a model to other countries.
- Medicines are essential element of health care
  - How is the pharmaceutical system organized in Thailand for UC?

Agenda of the workshop

09.00 – 09.15 am
- Opening session by Deputy general

09.15 – 10.15 am
- Presentation by situational analysis team with discussion of findings, identification of main problems & possible solutions

10.15 – 10.30 am
- Tea break

10.30 – 11.00 am
- Group work to discuss solutions and develop recommendations for future action

11.00 – 12.30 pm
- Presentation of group work with plenary discussion and finalization of recommendations

12.30
- Lunch

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 2012
- To report on the findings and develop an action plan in a workshop of government officials and other stakeholders.

Mission 23 Nov–4 Dec., 2015: week 1

- 23 Nov: meeting with the core team, visits to Social Security Office, Comptroller's Office, National Health Security Office; travel to Chiang Mai
- 24 Nov: visits to general hospital, community hospital, 2 health centres and 2 private pharmacies in Lamphun province
- 25 Nov: visits to regional hospital and 2 health centres in Chiang Mai province
- 26 Nov: visits to general hospital, 2 community hospitals, 1 health centres and 2 private pharmacies in Chiang Mai province
- 27 Nov: visits to 1 private and 1 public pharmacy in Chiang Mai; travel to Bangkok
- 28 Nov: preparation for the workshop

Mission 23 Nov–4 Dec., 2015: week 1

- 23 Nov: meeting with the core team, visits to Social Security Office, Comptroller's Office, National Health Security Office; travel to Chiang Mai
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- 27 Nov: visits to 1 private and 1 public pharmacy in Chiang Mai; travel to Bangkok
- 28 Nov: preparation for the workshop

Drug Supply

- Pull system with mainly decentralised procurement and centralised negotiation for prices and suppliers:
  - Purchase by individual hospitals, often weekly / daily
  - Community Hospitals purchase for Health Centres
  - Pooled procurement for some drugs in provinces, regions
  - Some high-cost & orphan drugs supplied centrally by NHSO/GPO and controlled drugs supplied by FDA/GPO
- Funds for purchase received from:
  - NHSO, SSS (Ministry of Labour) and CSMBS (Ministry of Finance) at central level
  - Out-of-pocket payment (fees for service) from patients with private or no insurance
- No change since last situational analysis 2012

Methods

- 2-week data collection using WHO/SEARO situational analysis tool
- Interviews with concerned government officials & stakeholders & document review
- Visits to public health facilities & private pharmacies
  - Stock-check for availability of 40 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 and management
  - Health system & health care factors

Selected 40 key essential medicines to measure drug availability

Health Centres (34 drugs)

- Albendazole tab; amlodipine tab; amoxycillin tab; antacid; amitriptyline tab; antibiotic eye drops; atenolol tab; budesonide inhaler; cetirizine tab; clotrimazole cream; dexamethasone inj; diazepam inj; diclofenac inj; dicloxacillin tab; domperidone tab; enalapril tab; ferrous + folic tab; fluconazole tab; fluexetine tab; glipizide tab; hydrochlorthiazide; ibuprofen tab; metformin tab; metronidazole tab; norfloxacin tab; normal saline; ORS; omeprazole tab; paracetamol tab; permethrin; phenytoin cap; prednisolone tab; roxithromycin tab; salbutamol inhaler.

Community, general & referral hospitals (extra 6 drugs)

- Co-amoxyclav tab; ceftriaxone inj; cefazolin inj; meropenem/imipenem inj; risperidone tab; tramadol cap.

General findings

- Extensive health care system, with substantial infrastructure, trained hardworking health care personnel and good health indicators
- Very good system of health care delivery with respect to medicines areas based on UHC system
- Much progress in improving use of antibiotics since last situational analysis in 2012
- Some problems remain in drug management, particularly concerning compliance with the EML, drug use, information and coordination
  - can be addressed by existing resources and capacity.

Drug Availability

- Situational analysis Nov-Dec. 2015
  - Availability of key EML drugs: 95-100% (40 drugs) in hospitals and 50-82% (34 drugs) in health centres
  - Few stock-outs, but some non-availability of EML drugs: 0-3% in hospitals; 5-15% in health centres
  - Non-availability due to some EML drugs not being on local formularies and therefore not ordered or used
  - All prescribed drugs are dispensed and each outpatient received 2 - 3 drugs on average
- Situational analysis July 2012
  - Availability not measured but no stock-outs reported
  - Each outpatient received 2 - 4 drugs on average

National Health Security Office (NHSO)

- Covers 48.3 million people (78% population)
  - Covers outpatient & inpatient treatment costs of beneficiaries as well as preventive & promotive activities
- Allocates funds to hospitals in different ways:
  - Per capita basis according to registered populations and outpatient treatments based on use of essential drugs
  - Reimbursement of hospital claims for inpatient treatments based on disease related group (DRG) costs
  - Reimburses prevention & promotion activities
  - On-top cash payments to hospitals to treat high cost specific diseases (e.g. haemophilia, HIV, cancer) and for good performance (e.g. antibiotic control)
- Requires internal accounting between hospitals
  - Patients must pay out-of-pocket if they attend a facility where they are not registered, unless referred
  - Costs of referred unregistered patients claimed by the treating hospital from the hospital where the patient is registered

Stock Management

- Stock management good in all facilities
  - All stores and wards following FEFO,
  - All short-dated items tracked and expired items generally kept separately from non-expired stock
- Electronic LMIS and prescribing in all facilities visited
  - Some prescribers still writing prescriptions by hand
  - Local prescription data not always appropriately used
- Pharmacists monitoring medicines management in all sections of the hospital, including the wards where there is usually one nurse in charge of medicines
- All hospital drug stores managed by pharmacists and health centre stores by nurses
- Lack of storage space in a few of the health facilities visited

Other insurances

- SSS
  - Covers outpatient and inpatient treatment for private sector employees with salaries <15,000 Baht/month (11.1 million people)
  - Tripartite contribution:1.5% of salary automatically deducted, 1.5% from employer, 1.5% from government
  - Per capita allocation of funds to selected hospitals which claim costs from Ministry of Labour
- CSMBS
  - Covers all treatments in any public hospital (private hosp for dialysis & emergency) for civil servants and their families (4.7 million people)
  - Hospitals claim fee for service costs from Ministry of Finance
  - Escalating drug costs
- Migrant Worker Insurance
  - 1300 Baht per year covering treatment at public hospitals
- Private Insurance
  - Patients pay cash and get reimbursed by their insurance
- Uninsured persons
  - Includes <1% of the population who must pay out-of-pocket

Drug Supply problems

- Many hospitals have difficulty to stay within the regulations concerning NEML drugs
- Monitoring of NEML compliance & prices by Pharmacy Section of Office of Permanent Secretary MOPH is based on summary reports from some hospitals only and is under-resourced
- Non-harmonized electronic drug inventory systems between GPO & hospitals (stock management) and Pharmacy Section (monitoring prices & NEML compliance) and MOF (monitoring transactions)
  - ? Some duplication of effort by GPO, MOPH, FDA, MOF and information not always shared ?

Procurement

Done locally according to govt. regulation

- 156 items from GPO if possible – for economies of scale
- 70-100% drug items must be from the national EML (MOPH) 60-100% budget must be spent on national EML medicines (all public hospitals) – depending on health facility level
- Prices must be at or below the standard price as published by National Medicine Systems Development Committee
- Purchase must be according to yearly procurement plan approved by Hosp PTC/Director & Chief Prov. Health Office
- Competitive tender if order is >500,000 Baht per transaction (mostly done for pooled procurement, not by hospitals)
- MOF monitors all drug procurement transactions through electronic on-line system (obligatory)
- MOPH monitors drug prices and EML compliance through manual system (voluntary)

Drug Supply: suggested solutions

- Strengthening the mechanisms for sharing information to ease drug management & monitoring
  - Harmonize electronic drug management systems
  - GPO/VMI, health facility e-LMIS, MOPH monitoring system, MOF monitoring system, NHSO, MOPH
- Strengthen the Pharmacy Section, MOPH
  - to monitor compliance with standards in pharmaceutical care and procurement
- Discourage use of non-EML drugs by:
  - Limiting budget allocations
  - Requiring co-payment for some non-EML drugs
  - Monitoring and feedback to hospitals & prescribers on the use of non-EML drugs

National Essential Medicines List (NEML)

- Updated annually
- On the web, but was last printed in 2013
- 688 active ingredients & 1034 formulations - with 6 categories:
- A for first-line treatment
- B for alternative treatments to first-line
- C for use by well trained doctors approved by the hospital director
- D for specialist use for specific conditions
- E1 govt. projects
- E2 high cost/risk drugs for specialist use – requires insurance authorisation

ABC Analyses: drug consumption in Chiang Mai & Lamphun

Facility type	No. items in formulary	Top 20 drugs		% total budget			
		% budget	No. non-EML items	EML drugs	ABs	VIT	TRM
Referral Hospital	587-745	24-35	1-6	71-89	8-12	1-2	
	Amlodipine, alfuzosin, atorvastatin, erythropoetin, meropenem, piperacillin + tazobactam, simvastatin, sodium valproate, saline iv						
Comm-unity Hospital	312-256	40-72	0-1	92-96	6	2	
	Amlodipine, aspirin, enalapril, ipatropium + fenoterol nebuliser solution, losarten, insulins, metformin, rabies vaccine, saline iv						
Health Centre	95-168	72-81	0-3	67-99	4-7	1-2	2-33
	Amlodipine, aspirin, allopurinol, amoxycillin, enalapril, glipizide, hydrochlorthiazide, losarten, metformin, paracetamol, simvastatin						

Selection process

- 22 sub-committees (one for each drug group) select drugs based on selection criteria of health needs, efficacy, safety, availability, prices
- Liaison committee independently reviews recommendations of 22 sub-committees
- For discrepancies, central committee requests independent review for cost-effectiveness, equity & national affordability
- Central committee for NEML makes the final decision

Top 20 drugs by value in 74 hospitals 2015

No	Drug name	Baht	No	Drug name	Baht
1	Meropenem 1g inj.	115,971,656	13	Sitagliptin phos. 100mg	57,347,158
2	Atorvastatin 40mg	110,702,261	14	Tigecylcine 50 mg inj	57,030,807
3	Imipenem + cilastin 1g inj.	94,589,161	15	Celecoxib cap 200 mg	54,070,043
4	Sod. valproate 50mg	88,634,430	16	Pregabalin 75 mg	50,192,256
5	Erythropoetin 4000 IU	81,443,107	17	Simvastatin 20 mg tab	48,347,238
6	Erythropoetin 5000 IU	76,570,345	18	Pregabalin 75 mg cap	46,795,634
7	Alfusozin 10mg tab	75,488,419	19	Simvastatin 20 mg tab	46,655,907
8	Clopidrogel 75mg tab	73,373,859	20	Ertapenam 1g inj.	45,118,977
9	N. Saline 500ml inj.	67,563,569	21	Piperacillin 4g + Tazobactam 0.5g inj.	43,798,989
10	N. Saline 100ml inj.	66,668,266	22	Sevoflurane100%,250ml	43,298,780
11	Human albumen 20% 50ml inj.	59,743,456	23	Erythropoietin alfa 5000 IU inj.	42,423,041
12	Trastuzumab 440mg	58,935,099	24	Manidipline 20 mg tab	42,171,910

Implementation of NEML

- Procurement rules require hospitals to procure EML drugs
  - Items: 90% HCs & Comm Hos; 80% Gen Hos; 70% Ref Hos
  - Budget: 90% HCs; 80% Comm Hos; 70% Gen Hos; 60% Ref Hos
- MOPH monitors compliance with procurement rules but can take no action
- Govt. insurance systems give preference to EML drugs
- Each hospital decides its own formulary and also the formulary that should be used for the health centres under its jurisdiction. Sometimes provinces also decide on a formulary for use at health centres.
- Hospitals distribute higher level drugs sometimes to health centres for specific patients initiated on treatment
- 2015 general OPD prescribing survey: >80% of prescribed drugs belong to the EML in all public sector facilities

Drug selection suggested solutions

- Require every hospital to produce an annual report on drug consumption for MOPH
  - ABC analysis to identify high cost medicines and % of budget spent on non-EML drugs
- Work towards reducing the use of non-EML drugs
  - Consider differential reimbursement for vital, essential & non-essential drugs & co-payments for non-EML drugs
- Promote understanding of Essential Drugs Concept and the national List of Essential Drugs (NEML)
  - Feedback local consumption data to prescribers
  - Should be done by PTCs
  - Include in undergraduate and postgraduate curricula

Drug use indicator prescription survey

Drug use indicator	Referral hospital n=5	Community hospital n=3	Health Centre n=6	Drug Store n=9
Av. no. drugs / patient	**3.18**	3.65	2.78	1.62
% patients with Antibiotic	**14.0**	**11.9**	**11.3**	**9.2**
% patients with Injection	5.6	12.1	3.8	0.0
% patients with Vitamins	**10.0**	13.5	13.1	8.1
% URTI cases with AB	52.1	**20.0**	**46.6**	-
% prescribed generic drugs	**78.3**	91.0	94.2	14.8
% prescribed EML drugs	**87.2**	**90.0**	**93.8**	51.1
Av. drug cost / Px (Baht)	642.88	195.02	91.4	196.83

Drug use (1)

- Monitoring of drug use weak with little feedback to prescriber
  - OPD patient records all computerized with diagnostic and treatment information, entered by the doctor or the pharmacist, but diagnosis not always recorded
  - IPD patient records and individual patient dispensing sheets record diagnosis & treatment, and…
  - Good liaison between IPD pharmacist and medication nurse on prescribing and dispensing instructions, so ….
  - Drug use monitoring could easily be done by PTCs & required as part of on-line reporting to MOPH
- Private pharmacy prescribing and dispensing
  - Much prescribing for simple diseases is done by pharmacists who use many non-EML drugs
  - Many NCD patients get drugs refills direct from pharmacy

Drug use (2)

- Over-crowding in referral hospitals
  - Health centres under-used
- Standard Treatment Guidelines
  - National protocols for some diseases in all consulting rooms
  - Dept Medical Services, MOPH, has developed some STGs
  - Royal College of Physicians has STG working group
  - Few STGs/protocols found in health facilities
- Hospital Pharmacy & Therapeutic Committees (PTC)
  - Meet regularly to discuss the formulary & non-EML purchase
  - Develop hospital formulary (can include some non-EML drugs)
  - Do DUE on high-cost drugs; but rarely on general prescribing
  - Monitor ADRs and medication errors
  - Report some activities to MOPH online, but MOPH (Pharmacy Section in BHA) capacity to monitor and take action is limited

Drug use (3)

- Undergraduate education
  - Doctors: Pharmacology taught in pre-clinical studies but little time given to NEML or problem-based pharmacotherapy teaching & prescribing taught by senior clinicians who often do not follow the NEML
  - Pharmacists: Prescribing for simple conditions is taught and clinical pharmacy attachments could provide good practical experience, but many non-EML drugs sold in pharmacies.
- Continuing Education
  - Doctors: Not obligatory & topics chosen on an adhoc basis, often in association with sponsored meals or conferences, & there is a lack focus on rational use of drugs.
  - Pharmacists: New system whereby every pharmacist will need 100 credits every 5 years to get re-licensed, starting in 2015.
  - Nurses: CNE obligatory & some refresher training provided by MOPH but little focus on rational prescribing.

Drug use (4)

- Community / public education
  - Has any nationwide public education campaigns on safe use of medicines been done?
  - Have village health volunteers (under Dept of Health Service Support) been used to spread messages on safe & prudent medicines use?
  - Has public education been done via the media (consumer information unit in the FDA)?
- Independent drug information
  - Some university hospitals & pharmacy faculties provides Drug Information Centre services
- Drug promotion
  - Pharmaceutical representatives visit doctors & pharmacists in both public & private sectors

Projects to promote rational use

- Rational Drug Use Hospital Project in about100 hospitals, started in March 2015
  - Pharmacy and Therapeutics Committee
  - Labeling/leaflet
  - Essential rational drug use tools
  - Awareness of rational drug use
  - Special population care
  - Ethics in prescription
- Antibiotic smart use project
  - Monitor antibiotic use in URTI, diarrhoea, wounds
- NHSO monitoring of antibiotic use
  - Monitor antibiotic use in URTI, diarrhoea

Possible solutions for improving use (1)

- Monitor drug use
  - Institutionalize the PLEASE, ASU, and other drug use projects
  - ABC analysis, prescription audit and feedback for outpatient as well as inpatient care - by hospital PTCs
  - May use the existing hospital electronic patient databases & report on selected drug use indicators to MOPH
- Standard Treatment Guideline
  - Develop national STGs for primary & secondary care
  - Implement STGs by publishing online, disseminating free of charge to prescribers & incorporating into undergrad & continuing education
- Strengthen the role & capacity of PTCs
  - To monitor prescribing, encourage continuing education, undertake self-assessment, and report annually on activities to MOPH
  - Requires strengthening the Pharmacy Section, BHA, MOPH to review the reports, train PTCs and take other actions
  - Consider including PTC activities in hospital accreditation

Drug regulation (2)

- Drug Quality Assurance
  - National drug testing lab under Department of Medical Sciences (WHOCC) plus 14 regional labs and drug testing kits in border areas
  - 3,528 samples tested and 6% failed in 2014
  - "Pass" tests published, "failed" tests not published in "green" book
- Drug Schedules
  - Household remedy drugs (modern 60, TRM 24) – sold in any store
  - Dangerous drugs (including antibiotics and considered as prescription-only elsewhere) sold in pharmacies by pharmacists
  - Specially-controlled drugs only sold with a doctor's prescription
  - Unscheduled (non-dangerous) drugs which are not categorized (unannounced by MOPH) can be sold by any health professional
- Drug Price Controls
  - No direct price controls but price monitoring and negotiation between industry and purchasers in the public sector

Possible solutions for improving use (2)

- Continuing professional development (CPD)
  - Thailand Medical Council to consider making the new credit system for continuing medical education of doctors obligatory for re-licensing (as already started for pharmacists & nurses)
  - Curricula should include prescribing & essential drugs concept
  - Medical & pharmacist associations could promote the essential drugs concept through the lectures/seminars they organise
- Public Education
  - Conduct nationwide campaigns on safe use of medicines
  - Core pharmaceutical messages e.g. "does my child need more than one drug?" or "coughs & colds do not usually need antibiotics"
  - Could be given through Village Health Volunteers, community pharmacists, schools, NGOs, the media, & insurance agencies can pay
- Referral system
  - Strengthen the referral system to encourage the use of health centres and decrease the crowds in referral hospitals

Drug Regulation (3)

- Drug Registration
  - New products for old molecules registered upon receipt by the FDA of evidence of adequate quality, but some hospitals re-review quality evidence
  - New molecules registered after technical evaluation for efficacy, safety & quality by evaluation expert team +/- subcommittee
  - Life registration unless no manufacture or importation for 2 years or recommendation to deregister from re-evaluation subcommittee
  - Fees too low, no processing fee, & poor quality dossiers received
- Drug promotion
  - Pre-approval of labels, package inserts, adverts – 30,921 last year
  - Post-approval monitoring – 4,000 adverts reviewed/year
  - Fines too low to prevent companies from issuing misleading adverts
- Adverse Drug Reaction Monitoring
  - 49,722 ADRs reported from hosps in 2014 & reported to WHO/Upsala

Drug regulation (1)

- FDA executes:
  - Drug Act 1967, amended 4 times, lastly in 1987
  - Psychotropic substances Act 1975 and Narcotics Act 1979
  - FDA is under MOPH
  - Many people want a new Drug Act
- FDA manages a sector consisting of:
  - 23,053 allopathic; 13,266 TRM; and 3,640 veterinary products
  - 175 allopathic and 825 TRM manufacturing plants
  - 18,025 allopathic; 2,180 TRM; & 700 veterinary wholesale/retail outlets
- FDA staffing
  - 651 staff, including 367 pharmacists (Drug Control 168 pharmacists)
  - Collaboration with Prov. Health Offices, each with 7-12 pharmacists
- SOPs/Checklists
  - Extensive set of SOPs for most procedures
- Regulation & enforcement in 2014
  - 120 manufacturer inspections; 1,600 retail outlet inspections (Bangkok)
  - 422 prosecutions and fines worth 4 million Baht for offences

Possible solutions to improve regulation

- Work towards a new more flexible Drug Act
  - Many gaps, but still many areas of disagreement
- Work towards having fewer brands of same drug (active pharmaceutical ingredient) in the market
  - Introduce 5 yearly re-registration
  - De-register all drugs not currently in the market
  - Increase the fee for registration
- Monitor drug promotional activities in collaboration with MOPH & professional bodies & councils
  - Consider banning medical representatives from public facilities except by appointment with the PTC
  - Require companies to disclose their marketing activities and budgets
  - Increase the fines for publishing misleading adverts
  - Institute a risk approach to monitoring adverts
- Publish failed drug test results
  - to convince prescribers about drug quality
- External WHO Assessment on DRA functionality

National Drug Policy

- National Drug Policy BE 2554 (2011) & Strategies for the Development of a National Drug System 2012-2016
- Vision: universal access to medicines for all, rational use of medicines & national self reliance
- Four Strategies with objectives & sub-strategies:
  - Access to medicines:
    - health care promotion, patient group support, pricing controls, alleviating legal obstacles to access
  - Rational use of medicines (RUM):
    - Monitoring of use, development of mechanisms to facilitate RUM, generic policies, control of drug sales promotion
  - Developed domestic pharmaceutical industry for self-reliance:
    - Revise rules to promote domestic investment, strengthen R & D
  - Strengthened regulatory system to assure quality, efficacy and safety of registered medicines:
    - Re-evaluation of registered products, strengthen post-marketing surveillance, improved capacity & transparency

Possible solutions for coordinating structure and national policy

- Decide on one Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership incl. laypersons, professional bodies …
  - Could be National Drug Systems Development Committee
- Appoint one executive department in MOPH to carry out the statutory committee recommendations
  - To coordinate action between different departments, Ministries
    - Pharmacy Section BHA, FDA, Bureau of Policy & Strategy, etc
    - MOE; MOF; Min. of Industry; Min. of Commerce
  - To be responsible for rational use of drugs: NLEM, STGs, PTCs, monitoring drug use, continuing educ., public education
- Streamline the committees & invest in their advice
- Document a description of the pharmaceutical health care system in order to maintain institutional memory of lesson learnt and progress made in implementing UHC

Coordination: MOPH Structure

- Under MOPH, there are 9 departments:
  - Office of the Permanent Secretary (OPS) with 76 provincial offices
  - Departments of Health, Disease Control, Medical Services, Food & Drug Administration, Medical Sciences, Thai Traditional & Complementary Medicine, Health Services Support, Mental Health
  - Departments sometimes do not share information with each other
- 90% of public hospitals & health centres are run by MOPH (mostly Office of the Permanent Secretary)
  - 10% government hospitals are run by other MOPH departments, Ministries, municipal authorities, agencies
  - Hospitals under other Ministries, agencies do not follow MOPH rules
- Other public organisations
  - NHSO, Health System Research Institution (HSRI), Thai Health Promotion Foundation, National Health Committee, Emergency Medical Institute of Thailand, Healthcare Accreditation Institute
  - Each body develops health policy or undertakes research

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

Coordination: Committees & working groups

- National Drug Systems Development Committee
  - Several subcommittees including ones on RUM, NEDL, AMR, Prices, Policy Strategy Development, M & E, Steroid Devel. Sys.
- 2012 many working groups were reported
  - Cabinet Working Groups: Promotion of NEDL & generic drugs; Price negotiation for non-EDL drugs; National drug code; Disease Related Group; STGs; Audit; Antimicrobial resistance; Traditional Medicines; RUM.
  - Royal College of Physician Working Groups: Evaluating drug use; Standards of clinical care; Promoting RUM; Medical supplies & Reimbursement.
  - Risk of duplication of effort & policy inconsistency
  - Current status????
- Full description of excellent UHC pharmaceutical system not published