Thailand

Drug Policy and Use of Pharmaceuticals in Health Care Delivery

Mission Report 17-31 July 2012

30th August 2012

Kathleen A Holloway

Regional Advisor in Essential Drugs and Other Medicines

World Health Organization, Regional Office for South East Asia, New Delhi
## Contents

- Programme Agenda ................................................................. 3
- Acronyms ................................................................................. 5
- Executive Summary ................................................................. 6
- Terms of Reference ................................................................. 9
- Background ............................................................................... 9
- Medicines Supply ................................................................. 10
- Medicines Selection and consumption ...................................... 15
- Medicines use .......................................................................... 18
- Medicines Regulation ............................................................. 24
- Medicine Policy and health system issues ................................. 28
- Workshop ................................................................................. 32
- Recommendations ............................................................... 33
- References .............................................................................. 36
- Annex 1: Persons met during the mission .................................. 41
- Annex 2: Participants in the workshop ...................................... 46
- Annex 3: Consultant’s slide presentation given in workshop ......... 47
Programme Agenda

Monday, July 16th
Afternoon: Arrive Thailand

Tuesday, July 17th
Morning: Pharmacy Section, Bureau of Public Health Administration
Afternoon: National Sub-committee for Rational Use of Medicines under the National Drug System Development Committee and teams from the Health System Research Institute and Faculty of Medicine, Chulalongkorn Hospital, Chulalongkorn University.

Wednesday, July 18th
Morning: Thai National Food and Drug Administration
Afternoon: Pharmacists from Departments of Disease Control and Health on drug procurement and Bangkok Drug Mart pharmacy.

Thursday, July 19th
Morning: Medical Council and Pharmacy Council of Thailand
Afternoon: Institute of Medical Research and Technology Assessment and Bureau of Drug and Narcotic, Department of Medical Sciences, MOPH.

Friday, July 20th
Morning: National Health Security Office (NSHO)
Afternoon: Bangpood Health Centre, Pakhret District and Banya 2 pharmacy, Bangbuanthong District, in Nonthaburi Province. Drug Management System Information Centre (DMSIC), Pharmacy Section, Office of Permanent Secretary, MOPH.

Saturday, July 21st
Document review and preparation of the report

Sunday, July 22nd
Document review and preparation of the report

Monday, July 23rd
Morning: Royal College of Physicians of Thailand
Bang Si Thong Health Centre, Bang Kruai District
Afternoon: Bang Kruai Community Hospital, Nonthaburi Province
Phaesatchakorn Pharmacy, Bang Kruai District

Tuesday, July 24th
Morning: Ladsawai Health Promotion Hospital, Lamluka
Sub-district in Pratumthani province
Afternoon: Ladsawai 2 Health Centre and Virat Malmangmont Pharmacy in Pratumthani province
Wednesday, July 25th
  Morning: Pranangklao Provincial Hospital, Nonthaburi
  Afternoon: Travel to Phuket for 17th International Social Pharmacy Workshop

Thursday, July 26th
  Morning: Presentation at International Social Pharmacy Workshop
  Afternoon: Return to Bangkok

Friday, July 27th
  Morning: Government Pharmaceutical Organisation (GPO)
  Afternoon: Rajavithi Hospital, Bangkok

Saturday, July 28th
  Document review and preparation of the report

Sunday, July 29th
  Document review and preparation of the report

Monday, July 30th
  Morning: Samut Sakhon Provincial Hospital
  Afternoon: Kratum Baen Community Hospital, Samut Sakhon Province

Tuesday, July 31st
  Morning: Bureau of Policy & Strategy, Office of Permanent Secretary, MOPH
  Afternoon: Debriefing with stakeholders

Wednesday, August 1st
  Leave Thailand
### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>ABC analysis – method for measuring drug consumption</td>
</tr>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>CPD</td>
<td>Continuing professional development</td>
</tr>
<tr>
<td>CME</td>
<td>Continuing medical education</td>
</tr>
<tr>
<td>CSMBS</td>
<td>Civil Servant Medical Benefits Scheme</td>
</tr>
<tr>
<td>DG</td>
<td>Director General</td>
</tr>
<tr>
<td>DIC</td>
<td>Drug Information Centre</td>
</tr>
<tr>
<td>DHO</td>
<td>District Health Officer (doctor)</td>
</tr>
<tr>
<td>DPHO</td>
<td>District Public Health Office</td>
</tr>
<tr>
<td>DMSIC</td>
<td>Drug Management System Information Centre</td>
</tr>
<tr>
<td>DRA</td>
<td>Drug Regulatory Authority</td>
</tr>
<tr>
<td>DRG</td>
<td>Disease-related group costing (for inpatient treatment)</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutic Committees</td>
</tr>
<tr>
<td>EDL</td>
<td>Essential Drug List</td>
</tr>
<tr>
<td>EDP</td>
<td>Essential Drug Programme</td>
</tr>
<tr>
<td>EML</td>
<td>Essential Medicines List</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Authority</td>
</tr>
<tr>
<td>GLP</td>
<td>Food Laboratory Practice</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>GPO</td>
<td>Government Pharmaceutical Organisation</td>
</tr>
<tr>
<td>HC</td>
<td>Health Centre</td>
</tr>
<tr>
<td>HQ</td>
<td>Headquarters</td>
</tr>
<tr>
<td>IPD</td>
<td>Inpatient department</td>
</tr>
<tr>
<td>LMIS</td>
<td>Logistics Drug Management Inventory System</td>
</tr>
<tr>
<td>MIC</td>
<td>Medicine Information Centre</td>
</tr>
<tr>
<td>MO</td>
<td>Medical Officer (doctor)</td>
</tr>
<tr>
<td>MOF</td>
<td>Ministry of Finance</td>
</tr>
<tr>
<td>MOL</td>
<td>Ministry of Labour</td>
</tr>
<tr>
<td>MOPH</td>
<td>Ministry of Public Health</td>
</tr>
<tr>
<td>MRA</td>
<td>Medicines Regulatory Authority</td>
</tr>
<tr>
<td>MTC</td>
<td>Medicines and Therapeutic Committee</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
</tr>
<tr>
<td>NDP</td>
<td>National Drug Policy</td>
</tr>
<tr>
<td>NDRA</td>
<td>National Drug Regulatory Authority</td>
</tr>
<tr>
<td>NHSO</td>
<td>National Health Security Office</td>
</tr>
<tr>
<td>NMP</td>
<td>National Medicines Policy</td>
</tr>
<tr>
<td>OPD</td>
<td>Outpatient department</td>
</tr>
<tr>
<td>OPS</td>
<td>Office of the Permanent Secretary</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-the-counter</td>
</tr>
<tr>
<td>RUM</td>
<td>Rational use of medicines</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>SSO</td>
<td>Social Security Office</td>
</tr>
<tr>
<td>SSS</td>
<td>Social Security Scheme</td>
</tr>
<tr>
<td>STG</td>
<td>Standard Treatment Guidelines</td>
</tr>
<tr>
<td>TOR</td>
<td>Terms of Reference</td>
</tr>
<tr>
<td>UHCS</td>
<td>Universal Health Coverage Scheme</td>
</tr>
<tr>
<td>VEN</td>
<td>Vital Essential Non-Essential – method for classifying drug importance</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Executive summary

A visit was made to Thailand during 17-31 July, 2012. The programme was arranged in agreement with the MOPH. The TOR were to undertake a rapid situational analysis of the pharmaceutical situation, focusing on health care delivery and to conduct a half-day workshop with national stakeholders to discuss the findings and develop a roadmap for national action. Visits were made to public health facilities and private pharmacy stores in Bangkok and neighbouring provinces, the major MOPH departments (including the Office of the Permanent Secretary and the Food and Drug Administration), the National Health Security Office (NHSO), the Thai Medical and Pharmacy Councils, the Royal College of Physicians and Medicine faculty members from Chulalongkorn University Hospital. It was found that Thailand has an extensive health care system with many trained health care personnel, universal health coverage and an excellent drug distribution system. However, there are a number of problems in the pharmaceutical sector concerning drug selection, use, regulation, policy and coordination, as highlighted below. With the large number of trained staff available, there are sufficient resources and capacity to address most of the problems.

Drug Supply

Most drugs are procured by funds allocated centrally by the NHSO (the agency mandated by the 2002 National Health Security Act to serve as ‘purchaser’ of health care for 74% of the population in Thailand’s Universal Health Coverage scheme) or with funds received from other government or private insurance. All essential drugs were in stock in all health facilities visited. There is a requirement for all health facilities to procure 70-100% essential drug items, costing 60-90% of their individual budgets, according to a 3-year procurement plan at median drug prices, which are monitored by the MOPH. However, many hospitals have difficulty to stay within the regulations concerning procurement of essential drugs and use revenue from private insurance, out-of-pocket payments and other fee for service activities to purchase non-EDL drugs. Monitoring by the MOPH of procurement is made more difficult due to un-harmonized hospital electronic drug inventory systems. Several units in MOPH and also the Ministry of Finance are monitoring procurement with some duplication effort and without always sharing information.

*It was recommended that: all hospital electronic logistic management inventory systems be harmonized to ease drug management and monitoring; the Pharmacy Section of the MOPH be strengthened to monitor compliance with procurement regulations; and the use of non-essential drugs be discouraged by limiting central budget allocations, requiring co-payment for some non-essential drugs and providing feedback to hospitals and prescribers on their use of non-essential drugs.*

Drug Selection

There is a national essential drug list (NEDL) revised annually with 740 chemical entities. The selection process involves 17 different expert panels to make proposals, which are then screened by the concerned working group and reviewed by a health economic working group before final recommendation for decision by the NEDL sub-committee of the National Drug System Development Committee. Despite the process, there are concerns that very costly drugs are still being included in the
NEDL. All hospitals have their own formularies that include non-essential as well as essential drugs and use revenue from private insurance, out-of-pocket payments and fee for service activities to purchase non-essential drugs. Consumption data confirmed that about half of hospital drug budgets were being spent on non-essential drugs. Use of the NEDL as a reimbursement list results in greater compliance but does sometimes result in the use of some drugs meant for use at referral level being used at health centre level for patients initially treated at referral level but registered with the health centre for insurance purposes.

It was recommended that hospitals be required to produce an annual report for MOPH on drug consumption (with ABC analysis¹) to show use by therapeutic category and use of high cost drugs and non-essential drugs. It was also recommended that the essential drug concept be actively promoted through pre-service and in-service training and through Drug and Therapeutic Committees; to introduce safeguards with regard to the use of drugs meant for use at referral hospital being used at health centres; and to consider including compliance with the NEDL as part of hospital accreditation.

Drug use

The consultant conducted an outpatient prescription audit in 9 public health facilities and 4 pharmacy stores visited. As one would expect, the average number of drugs per patient, the use of non-essential drugs and brand names and the drug cost per patient increased with increasing level of facility (which must treat more complicated patients). Use of antibiotics for upper respiratory tract infection was quite high being over 50% and some ‘polypharmacy’² was observed in the treatment of upper respiratory tract infections and aches and pains. Results were similar to other studies found in the published literature. Although there are many Standard Treatment Guidelines (STGs) produced, they are often not consistent with the NEDL and few are accepted as the National Standard or are used. All hospitals have Drug and Therapeutic Committees (DTCs) but their focus is on the use of high cost non-essential drugs, mostly for inpatient use and few regularly monitor outpatient prescriptions. Neither undergraduate nor post-graduate education focuses on the essential drug concept or rational prescribing. Much prescribing for simple primary care conditions is done by private pharmacy stores.

It was recommended that prescription audit be undertaken for outpatient and inpatient care by hospital DTCs and that existing electronic database systems recording patient diagnosis and treatment be used. It was further recommended to: develop national standard treatment guidelines for primary and secondary care; expand the role of DTCs to include prescription audit and in-service education on prescribing; to consider development of a credit system for continuing medical education which should focus on prescribing; to strengthen the disciplines of clinical pharmacology and pharmacy; and to develop public education campaigns on the safe and prudent use of drugs.

¹ ABC analysis is a method of analyzing drug consumption to identify the top drugs that consume most of the budget – thus allowing judgment on whether expenditure is spent on the most needed drugs.
² Polypharmacy means the unnecessary use of multiple drug items
Drug Regulation

The FDA, under the MOPH, regulates a sector comprising 17,424 drug stores, wholesalers and distributors, approximately 150 manufacturers and about 30,000 drug products. The FDA has 96 staff members in the central office but no branch offices and works with Provincial Health Offices to undertake inspection of drug stores and other provincial functions. The major functions of the FDA cover pre-marketing and post-marketing surveillance, drug registration and monitoring of advertisements. There is an extensive system of pharmacovigilance and an excellent drug testing laboratory. However issues of concern are: life-long product registration resulting in too many brands being on the market; drug schedules that allow many drugs (including new generation antibiotics) to be sold by pharmacists without prescription; too few provincial staff to do sufficiently frequent drug store inspections; and insufficient monitoring of drug promotional activities. The FDA is currently awaiting a new drug act to take care of some of these issues.

It was recommended to work towards having fewer brands of the same drug on the market by: introducing 5-yearly re-registration and de-registering drugs not currently in the market; introducing a new prescription-only drug schedule for certain drugs such as new generation antibiotics; monitoring drug promotional activities in collaboration with MOPH and other bodies such as the professional associations and councils; and liaising with provincial health offices to increase drug store inspections. It was also recommended to consider making the FDA semi-autonomous.

Coordination

The MOPH, comprising 8 departments, is responsible for public sector health care delivery at province level and below, covering 90% of the public sector. There is a comprehensive national drug policy 2012-2016 developed by the National Drug System Development Committee (NDSDC), which is the highest committee addressing drug issues and developing drug policy. It is chaired by the Deputy Prime Minister and the secretary is the Chief of the FDA. The NDSDC has a number of sub-committees including ones responsible for the national list of essential drugs, rational use of medicines, developing national policy and estimating median drug prices for procurement. The sub-committee on rational use of medicines has seven sub-sub committees each dealing with a different strategy. In addition, the Prime Minister’s Office has become concerned about the rising expenditure and has instituted 6 official and 3 unofficial cabinet working groups to improve drug management and use. The Royal College of Physicians is heading one working group on guidelines which in itself is covering a number of drug policy issues. In all, rational use of medicines appears to be covered by 3 working groups or committees and there is a danger of duplication of work and inconsistency in objectives and recommendations. There are extensive electronic drug inventory and patient treatment computer systems but the information is not being fully utilized or shared between departments. Some functions are not achieved because of the requirement to collaborate across departments or ministries e.g. monitoring of prescribing at national level, developing national clinical guidelines acceptable to all, training on the essential drug concept and prescribing, public education and controlling pharmaceutical promotion.
It was recommended that (1) one multidisciplinary mandated independent statutory committee be chosen to report directly to the Minister of Health (this possibly being the current NDSDC) and (2) one executive unit (possibly the Pharmacy Section in the MOPH) be chosen to carry out the recommendations of the statutory committee and to monitor drug supply and use and to coordinate the implementation of strategies to improve use. It was also recommended to streamline all advisory committees.
Terms of Reference

The objectives were to:

(1) meet senior officials of the Thailand Ministry of Public Health (MOPH).

(2) undertake a rapid situational analysis of the pharmaceutical situation - with a focus on health care delivery and the use of medicines.

(3) conduct a half-day workshop with national stakeholders to:

   a) review the findings of the WHO situational analysis;
   b) identify the main priority problems to be addressed;
   c) formulate recommendations for medicines policy to address the problems.

Background

The mission was undertaken to conduct a national situational analysis with regard to the pharmaceutical sector, particularly supply and use of medicines, in order to aid MOPH in planning future action and also to plan for future WHO technical support.

The regional strategy to promote rational use of medicines (RUM), updated at the regional meeting of July 2010, recommends undertaking a situational analysis in order to plan for a more coordinated integrated approach to improving the use of medicines. The Regional Committee Resolution, SEA/RC64/R5, *National essential drug policy including the rational use of medicines*, also recommends undertaking a situational analysis to aid planning. This mission was undertaken during 17-31 July, 2012, for this purpose. During the situational analysis, a checklist/tool developed in HQ/WHO and now being revised in the region was used. This tool allows the systematic collection of information. The persons met during the fact finding mission can be seen in annex 1. An integral part of this mission was a half-day workshop with about 20 stakeholders that was held at the end of the mission to discuss and validate the findings and to form a road map for action. The participants of the workshop can be seen in annex 2.

Thailand has an extensive health system. Part of this health system includes delivery of medicines, free at the point of delivery, for the majority of the population, the health facilities claiming the costs from the insurance companies. However, the government is concerned at the escalating drug costs even though there is a requirement to use mostly essential drugs. In addition, there have been concerns about irrational use of medicines. For these reasons, the government invited WHO to undertake a situational analysis of the pharmaceutical sector in order to advise on future policy and facilitate the formation of a plan of action. It is hoped that the recommendations made as a result of the situational analysis will be incorporated into future plans of action.

The words “medicine” and “drug” are used interchangeably in this report.
**Medicines Supply**

Most drugs are procured by facilities using a budget allocated to them by the National Health Security Office (NHSO) on a per capita basis, using funds supplied by the MOF. The NHSO is the national agency which provides funds for the drugs used in the Universal Health Coverage Scheme which covers 74% of the population. A few drugs are supplied by the NHSO directly. Some drug costs for civil servants or for formally employed workers are reimbursed to the facilities by the MOF and MOL, respectively. Most patients are covered by the Universal Health Coverage Scheme and need pay nothing at the point of health care delivery. The hospitals can charge a mark-up of 10-30% on drugs dispensed to civil servants and formally employed workers and for which they are later reimbursed by MOF and MOL, respectively. The reimbursement margins form revenue which may be used by the hospitals to purchase more drugs, mostly non-EDL ones.

Funds allocated to facilities by the NSHO must be used to procure drugs according to a 3-year procurement plan that has been approved by the hospital Director or by provincial or central levels. The majority of funds must be spent on EDL drugs and there is some brief site inspection and central monitoring of purchases to ensure compliance. Since many physicians want to prescribe non-EDL drugs, there is great difficulty for the pharmacies to comply with their requests and stay within the regulations. Most manage this by using generated revenue to procure non-EDL drugs. All public facilities apart from health centres are staffed with pharmacists. Drug expenditure by the NHSO for the 47 million people covered by this scheme was 4730.28 Baht per capita. In 2008 total per capita drug expenditure was 5847.68 Baht. (MOPH 2011)

**Procurement**

All public facilities at the level of community hospital and above must procure most of their own medicines using the budget supplied by NHSO and revenue from other sources. Health Centres are supplied by Community Hospitals through a "pull" system. Facilities must purchase from the Government Pharmaceutical Organisation (GPO) if it manufactures those items. Thus the GPO supplies about 50-70% items, has economies of scale, and may sell at low prices. However, other drugs may also be purchased at relatively low prices in the public sector and there is a rule that all facilities can only purchase at the median price or below as published by Pharmacy Section of the Office of the Permanent Secretary. The pharmacy section estimates the median price by looking at previous purchase prices of health facilities, which they publish on their website: [http://DMSIC.moph.go.th](http://DMSIC.moph.go.th). The Pharmacy section monitors all procurement and prices according to national guidelines and regulations (MOPH 2007 and 2009).

Hospitals are supposed to purchase according to a 3-year procurement plan that they must develop. However, in reality, many hospitals purchase according to an annual plan. In theory, procurement plans should be reviewed by provincial health offices in the case of provincial and community hospitals and centrally in the case of general hospitals. However, in practice, the Director of each facility may approve the plan. If the amount to be procured is 100,000 Baht or more, a tendering process must be undertaken and a procurement committee formed. Thus, many hospitals procure lesser
amounts of medicines more frequently - often weekly. For some drugs, hospitals in a province or region may group together to undertake pooled procurement. In the case of one region, 4 provinces group together to purchase about 100 items, each province undertaking actual procurement of some of the items after having conducted the tendering process together. Drugs are delivered directly from the supplier to facility.

**Supervision of Procurement and Compliance with EDL regulation**

The Pharmacy Section monitors procurement - through the Drug Management System Information Centre (DMSIC). All hospitals are required to upload on-line the volumes and prices of all drugs procured. In this way the DMSIC is able to monitor prices. Since facilities are often using different electronic formats or manual systems it has not been possible for the DMSIC to monitor procurement of therapeutic categories or undertake ABC analysis of procurement. It was mentioned that some hospitals are not uploading all information on prices and volume but that the Pharmacy Section does not have the resources to correct the situation or deal with the data should all hospitals upload all information. In addition to uploading details of price and volume of drugs, hospitals also have to provide a 3-month summary report of the % of essential and non-essential drug items purchased and in stock. It was mentioned that, unlike for uploading information on volume and price for all drugs procured, all hospitals do send the 3-month summary reports. Although the Inspection Unit visits facilities, they do not have time to do physical stock checks and also the DMSIC is unable to reconcile the uploaded procurement data with the 3-monthly summary reports (due to lack of capacity) so the Pharmacy Section does not know precisely how well facilities are complying with the regulations. However, they mentioned that hospitals tend not to count some small amounts of non-essential drug items in order to show that they have complied with regulations. Furthermore, while most provincial and community hospitals generally do try to follow the regulations, the large hospitals do not follow the regulations to the same degree and have escalating drug costs and much greater use of non-EDL drugs. As a result the MOF has started monitoring all purchase for all items in all facilities. This duplicates the work on drugs for the 90% of public health facilities controlled by the MOPH but the DMSIC is hoping to collaborate with the MOF on this. The projects to have drug identity (ID) codes and harmonized logistic drug management inventory systems will ease supervision.

**Quantification**

Estimate of need is done on past consumption and a 3-year procurement plan must be developed. The plan must comply with regulations concerning purchase of EDL drugs. The % of drug items purchased that must belong to the EDL is 90% for community hospitals, 80% for general hospitals and 70% for regional hospitals. All provincial facilities must have 3 months buffer stock but Bangkok facilities must have just one month buffer stock due to easy logistics for re-stockage. Though hospitals should procure 3-monthly to cover 3 months consumption, they often make purchases more frequently, sometimes weekly.

**Distribution**

Drugs are delivered to hospitals directly from the GPO or other wholesalers. Community hospitals are responsible for drug distribution to health centres (HCs)
below them. Drugs are ordered by health centres weekly (sometimes monthly) and are collected by the health centres themselves from the community hospital. Many hospitals use an electronic management inventory system (VMI) which is run by the GPO for the drugs and vaccines that they supply and also for some other drugs that they import and distribute. For 19 programs, covering high risk high cost drugs, the VMI system operates such that stock is monitored by the GPO directly and each patient prescription audited. Once stocks reach below a certain level the GPO alerts the facility and sends more stock. However, for all other items (the majority) the hospital must initiate an order and manage drugs manually or by a different logistic management information system. There is currently an initiative to harmonise all the electronic drug management information systems used by different hospitals.

In addition to electronic drug inventory systems, all hospitals also have electronic health management information system to record patient diagnosis and treatment - which forms part of the health management information system. Information is sent via the provincial health offices to the Bureau of Policy and Strategy - which manages the health management information system. Although the data contains both diagnostic and drug data, so far the drug data has not been used. However, it was mentioned that ABC analyses and indicators of drug use could be analysed from this data.

Health Centres receive their medicines from the local community hospital but they do not receive any funds directly from the NHSO, rather the local community hospital handles their funds from the NHSO. The community hospitals send drugs to HCs as they demand. They also send funds received from the NHSO on behalf of the HCs to the HCs having first subtracted payment for the drugs provided to the HCs. The revenue provided to the HCs may be in the form of reimbursement for each NHSO patient seen (e.g. 60 Baht per patient seen by a nurse and 120 Baht per patient seen by a doctor who usually visits for a half day 1-3 times per week) or by lump sum e.g. 100,000 Baht per year. These funds, together with cash payments from uninsured patients and 1-2 other sources, form the revenue of the health centres which is used to pay electricity and water charges and other costs. All HCs operate a computer system which records the diagnosis and drug treatment of each patient, this data being used to estimate and negotiate the NHSO budget for the coming year. The data does not seem to have been used for prescription audit and feedback to improve prescribing.

**Manufacturing**

The Government Pharmaceutical Organisation (GPO) is a state enterprise under the MOPH established by Parliamentary Act in 1966 with the mission to manufacture drugs for the needs of the Thai population. It manufactures 200 drugs, including 132 essential drugs, and purchases a further 800 drugs. Purchases are made from other local Thai manufacturers and drugs are also imported from abroad. Currently GPO supplies about 1000 products (both essential and non-essential) to over 10,000 facilities including public and private hospitals and private drugs stores, including its own 10 pharmacy shops in Bangkok. It is fully GMP compliant and operates a strong quality assurance program. It was mentioned that some doctors are suspicious of the quality of some products when they are newly produced. This has sometimes resulted in hospitals buying other brands of a product instead of the GPO products by loosely interpreting the regulations and treating NHSO funds as non-government ones since
monies do not have to be returned at the end of the financial year to MOF. However, these suspicions can be overcome by sharing quality testing information with doctors. In addition to GPO there are a further 150 manufacturers in Thailand.

**Insurance**

Most people are covered by health insurance. Officially only 2% are not covered, although in one HC it was mentioned that 5% were not covered. There are 4 main public insurance systems.

**Universal Health Coverage Scheme (UHCS)**

The UHCS scheme covers 74% (47 million) of the population (IHPP/HISRO/WHO 2011), which includes all persons not in government service or formal employment. The scheme is tax-based and funds are issued by the MOF to the National Health Security Office (NHSO). The NHSO was established by the National Health Security Act in 2001 and serves as a ‘purchaser’ of health care services. In 2011, NHSO received 2497 Baht per person per year to cover the full cost of patient treatment. The NHSO sent 868 Baht per person per year directly to health facilities for them to procure drugs to cover outpatient drug costs. Another 1098 Baht per person per year was allocated for inpatient costs (based on disease-related group costing), but this was only sent to hospitals on receipt of a reimbursement claim.

Patients paid 30 Baht per visit at the initiation of the UHCS launched in 2001 when the Universal Health Security Act was passed and rolled out nationwide in 2002. Since late 2006, this 30 baht user fee was waived. The current government intends to reinstate the 30 Baht per visit user fee starting in September 2012. Any fees such as 30 Baht or mark-ups for reimbursed medicines from SSS or CSMBS or payments made from uninsured patients form hospital revenue, which can be used to procure non-EDL drugs and also pay overtime to staff. Some people say that a 30 Baht fee will help to reduce needless visits for minor ailments but it is unclear what it would cost to administer such a fee and whether it would be a cost-effective measure.

The NHSO and MOPH require that funds allocated to health facilities on a capitation basis for drug procurement must be spent mostly on EDL drugs. Depending on the health care level, 60-90% of all items procured using NHSO funds must belong to the national EDL and an annual procurement plan must be approved by the province. This scheme operates only in public facilities and only when patients are registered in the concerned catchment area. Patients should go to health centres first and only attend hospitals on referral. However, in practice many patients go directly to community hospitals. Patients must pay out-of pocket if they attend a facility where they are not registered, unless referred. For 96 expensive items, procurement is done centrally by the NHSO (and not locally by the hospitals) to allow economies of scale, and then sent to the health facilities directly.

The NHSO currently operates 13 branches and has a staff of 800. There are various projects operated by the NHSO to monitor drug consumption and compliance with the EDL regulations and referral system. However, drug costs are still escalating, doctor shopping (whereby patients visits multiple providers for the same illness) still occurs in some provinces and too many non-EDL drugs are still used. It was mentioned that the NHSO budget will be frozen for the next 2 years.
Social Security Scheme (SSS)
This scheme covers all persons (8 million) who are employed in the formal economic sectors but do not belong to the government civil service. This involves tripartite contributions from the employer, employee and government, amounting to 4.5% of the salary, which is automatically paid into a fund run by the Ministry of Labour (MOL). The patients pay some co-payment and the facility claims reimbursement from the MOL. This scheme only operates in selected hospitals (both public and private).

Civil Servant Medical Benefit Scheme (CSMBS)
This scheme covers 5 million civil servants and is funded by MOF. The CSMBS allows 100% reimbursement of all drugs (whether on the NEDL or not) and treatment from any hospital, public or private. The patient pays nothing at the point of delivery all costs being claimed by the facility directly from the MOF. The costs of this scheme are rising dramatically. It was suggested hospitals prefer to dispense non-EDL drugs for these patients because the profit margin is higher and the revenue can be used to buy non-EDL drugs for use in other patients. This is particularly so since MOF funds from the NHSO must be mostly used for EDL drugs according to the regulations. Currently there are no limits on CSMBS claims for reimbursement. While this scheme may cover only a minority of the population it covered 66% of drug costs in one regional hospital.

Compulsory Migrant Health Insurance Scheme
There is an estimated 2-4 million migrants in Thailand, although the actual figure is unknown as many are unregistered and migrant flows in and out of Thailand are dynamic. An estimated 80-90% are from Myanmar and the remaining 10-20% are largely from Cambodia and Lao. Registered migrant with a work permit are, in theory, required to purchase insurance through the Compulsory Migrant Health Insurance scheme. The fee includes an annual fee of 600 Baht for medical screening and 1300 Baht per year which covers treatment at public hospitals (and 2 private hospitals). An extra fee is charged per family member. The majority of registered migrants in Thailand do not purchase insurance or purchase it only for the first year. Overall, the majority of migrants are unregistered and have uneven access to health services; some receive services from health facilities on humanitarian grounds (although the health facility is not reimbursed) and many pay ‘out-of-pocket’ for services received. The government is proposing several new options for financing health care for migrants, but no sustainable or coherent approach has been determined as of August 2012.

In summary, many hospitals have difficulty to stay within the regulations concerning NEDL drugs. They use revenue from private insurance, out-of-pocket payments, and CSMBS to purchase non-EDL drugs. Monitoring by Pharmacy Section of Office of Permanent Secretary MOPH is mostly based on hospital summary reports only and is under-resourced. Half of hospitals do not send actual procurement data and the Pharmacy Section does not have the capacity to demand that they do so. In addition, un-harmonized electronic drug inventory systems create increased communication difficulties between the GPO and hospitals (for stock management) and between the Pharmacy Section and hospitals (for monitoring procurement prices). Furthermore, there is some duplication of effort and information is not shared. For example, MOF
as well as MOPH is monitoring procurement prices of drugs. ABC analysis can be
done easily on existing computer systems in most facilities and also by the Bureau of
Policy and Strategy within the Office of the Permanent Secretary but the information
is not shared with Pharmacy Section.

**Possible Solutions**

1. Harmonize all electronic drug management inventory systems, including those
   used in health facility drug stores, other health facility departments and the GPO
   a. Will ease drug management and monitoring

2. Strengthen the Pharmacy Section, MOPH
   a. to monitor compliance with procurement regulations and prices
   b. to have capacity to liaise with MOF on monitoring and avoid duplication
      of effort

3. Discourage use of non-EDL drugs by:
   a. Limiting budget allocations, particularly for CSMBS
   b. Requiring co-payment for non-EDL drugs
   c. Monitoring and feedback to hospitals and prescribers on non-EDL drug
      use
Medicines Selection and Consumption

There is a National Essential Drug List (NEDL) published in hardcopy in 2008. However, there have been minor revisions published on the website electronically annually. The current NEDL has about 740 active pharmaceutical ingredients that are divided into 5 categories:

A 1st line drugs used in health centres
B 2nd line alternative drugs for use in health centres
C Drugs for use by well trained physicians on signature of a hospital director
D Drugs for use by specialists on signature of a hospital director
E1 Drugs for use in government projects e.g. resistant HIV or TB, Haemophilia
E2 High risk, costly drugs for use by a senior specialist, e.g. anti-cancer drugs.

The selection process starts with 17 national expert panels which select and propose drugs for their section of the NEDL. The screening working group then coordinates the results from the 17 working groups and this is followed by review by the health economic working group that reviews the drugs from the point of view of cost-effectiveness, affordability and equity. Finally, the sub-committee of the NEDL selects a final list and submits it for approval to the National Drug System Development Committee. Although, the process tries to select drugs according to evidence of efficacy, safety and cost-effectiveness and makes members sign conflict of interest statements, it was mentioned that there are still some problems of lobbying (not of the committee but of individual physicians) by interested parties and too many expensive drugs being approved. Drugs are only generally deleted from the list if there are safety concerns.

Hospitals have their own formularies which include EDL and non-EDL drugs. They procure non-EDL drugs with revenue generated and 10-30% of the NHSO allocation. It was mentioned by one hospital, where half the items were non-EDL ones, that drug company representatives often visited the procurement department with suggestions for adding new non-EDL drugs to the hospital formulary and that these new drugs were considered for addition to the hospital formulary for a trial period. This was done when existing EDL drugs caused side-effects or were ineffective. This suggests that physicians have little faith in the NEDL. Indeed the national sub-committee on RUM felt that many physicians did not believe in a NEDL.

The public sector is required to follow the NEDL for the majority of its purchasing as follows:

<table>
<thead>
<tr>
<th>Hospital type</th>
<th>No.items</th>
<th>% items on EDL</th>
<th>% cost on EDL items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional hospital</td>
<td>700</td>
<td>70%</td>
<td>60%</td>
</tr>
<tr>
<td>General hospital</td>
<td>550</td>
<td>80%</td>
<td>70%</td>
</tr>
<tr>
<td>Community hosp</td>
<td>350</td>
<td>90%</td>
<td>80%</td>
</tr>
<tr>
<td>Health Centre</td>
<td>100</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

However, the national RUM sub-committee stated that in reality non-EDL drugs consumed half of the expenditure of many hospital drug budgets. In addition, some specialist hospitals run by other MOPH departments may not follow these rules. One specialist hospital, which does not treat UHC patients, mentioned that half the items may not belong to the NEDL. Private pharmacies were not aware which drugs were
on the NEDL. Table 1 shows the top 20 drugs by value in a regional, provincial and district (community) hospital.

### Table 1: Annual Drug Consumption in 3 hospital types in 2011

<table>
<thead>
<tr>
<th>No.</th>
<th>Regional Hospital Drug name</th>
<th>Value</th>
<th>Provincial Hospital Drug Name</th>
<th>Value</th>
<th>Community Hospital* Drug Name</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rosuvastatin 10mg</td>
<td>20,348,383</td>
<td>Rosuvastatin 10mg</td>
<td>10,327,438</td>
<td>Sitagliptin 100mg</td>
<td>4,493,179</td>
</tr>
<tr>
<td>2</td>
<td>Epoetin β 5000 IU inj</td>
<td>18,290,708</td>
<td>Valsartan 160mg</td>
<td>8,754,828</td>
<td>Rosuvastatin 100mg</td>
<td>3,980,413</td>
</tr>
<tr>
<td>3</td>
<td>Imatinib mesylate 100mg</td>
<td>16,408,392</td>
<td>Sitagliptin 100mg</td>
<td>8,009,865</td>
<td>Imipenem+ Cilastin inj</td>
<td>1,782,620</td>
</tr>
<tr>
<td>4</td>
<td>Celecoxib 200mg</td>
<td>16,276,034</td>
<td>Celecoxib 200mg</td>
<td>7,641,260</td>
<td>Esomeprazole 20mg</td>
<td>1,657,195</td>
</tr>
<tr>
<td>5</td>
<td>Atorvastatin 20mg</td>
<td>15,961,438</td>
<td>Clopidrogel 75mg</td>
<td>7,363,898</td>
<td>Clopidogrel 75mg</td>
<td>1,633,716</td>
</tr>
<tr>
<td>6</td>
<td>Meropenem 1g inj</td>
<td>14,032,065</td>
<td>Meropenem 500mg + Cilastatin 500mg inj</td>
<td>7,273,090</td>
<td>Bisoprolol 5mg</td>
<td>1,577,764</td>
</tr>
<tr>
<td>7</td>
<td>Rituximab 500mg inj</td>
<td>10,741,254</td>
<td>Atorvastatin 20mg</td>
<td>6,989,240</td>
<td>Erythropoietin α inj</td>
<td>1,569,855</td>
</tr>
<tr>
<td>8</td>
<td>Esomeprazole 20mg</td>
<td>10,680,284</td>
<td>Ertapenem 1g inj</td>
<td>6,547,919</td>
<td>Pregabalin 75mg</td>
<td>1,290,420</td>
</tr>
<tr>
<td>9</td>
<td>Imipenem+ Cilastin inj</td>
<td>10,378,208</td>
<td>Meropenem 1g inj</td>
<td>6,425,858</td>
<td>Tazocin 4.5g inj</td>
<td>1,234,352</td>
</tr>
<tr>
<td>10</td>
<td>Lansoprazole 30mg</td>
<td>9,638,079</td>
<td>Valsartan 160mg + Amlodipine 5mg</td>
<td>6,407,433</td>
<td>Irbesartan 300mg</td>
<td>1,216,988</td>
</tr>
<tr>
<td>11</td>
<td>Sulbactam+ Cefoperazone inj</td>
<td>9,452,179</td>
<td>Atorvastatin 10mg</td>
<td>6,342,958</td>
<td>Pioglitazone 30mg</td>
<td>1,117,704</td>
</tr>
<tr>
<td>12</td>
<td>Paclitaxel 260mg inj</td>
<td>9,141,461</td>
<td>Epoetin α 5000 IU inj</td>
<td>5,309,361</td>
<td>Meropenem 1g inj</td>
<td>1,055,733</td>
</tr>
<tr>
<td>13</td>
<td>Manidipine 10mg</td>
<td>9,096,296</td>
<td>Epoetin β 5000 IU inj</td>
<td>5,266,352</td>
<td>Celecoxib 200mg</td>
<td>1,036,477</td>
</tr>
<tr>
<td>14</td>
<td>Mycophenolate mofetil 250mg</td>
<td>8,975,608</td>
<td>Pioglitazone 30mg</td>
<td>5,118,880</td>
<td>Seretide 25/125 inhaler</td>
<td>1,012,220</td>
</tr>
<tr>
<td>15</td>
<td>Sodium Rabeprazole 20mg</td>
<td>8,260,639</td>
<td>Irbesartan 300mg</td>
<td>4,973,615</td>
<td>Telmisartan 40mg</td>
<td>1,001,540</td>
</tr>
<tr>
<td>16</td>
<td>Candesartan Cilexetil</td>
<td>7,980,933</td>
<td>Glimepiride 2mg + Metformin 500mg</td>
<td>4,873,430</td>
<td>Berodual inhaler</td>
<td>959,815</td>
</tr>
<tr>
<td>17</td>
<td>Ezetimibe 10mg</td>
<td>7,657,034</td>
<td>Aripiprazole 15mg</td>
<td>4,670,550</td>
<td>Exforge 160/5mg</td>
<td>933,657</td>
</tr>
<tr>
<td>18</td>
<td>Pregabatin 75mg</td>
<td>7,575,905</td>
<td>Manidipine 20mg</td>
<td>4,640,359</td>
<td>Simvastatin 20mg</td>
<td>929,230</td>
</tr>
<tr>
<td>19</td>
<td>Cilostazol 100mg</td>
<td>7,495,601</td>
<td>Entacapone 200mg</td>
<td>4,511,634</td>
<td>Tamsulosin 0.4mg</td>
<td>894,214</td>
</tr>
<tr>
<td>20</td>
<td>Capecitabine 500mg</td>
<td>7,415,038</td>
<td>Ezetimibe 10mg</td>
<td>4,412,948</td>
<td>Calcitonin 200 IU spray</td>
<td>858,853</td>
</tr>
<tr>
<td></td>
<td>1.3% items 22% budget</td>
<td>8 ED drugs 13% budget</td>
<td>12 NED drugs 9% budget</td>
<td>8 ED drugs 13% budget</td>
<td>12 NED drugs 9% budget</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 NED drugs 9% budget</td>
<td>11 NED drugs 15% budget</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 9 months consumption only during 2011-12; ED=Essential Drugs; NED=Non-essential Drugs (red, italics);
Table 1 indicates that indeed many hospitals are finding it difficult to stay within the NEDL. About half the total budgets in these 3 hospitals were spent on non-essential drugs. The percentage of budget spent on antibiotics in two of these hospitals was reported to be 12-14%. This is in contrast to some health centres (HCs) where it was found that about 25% of the budget was spent on antibiotics. It was also noticed that in some HCs, drugs normally reserved for use at hospital level were being used to continue treatment of patients whose treatment had been initiated at the referral hospitals. Since the NEDL is, in effect also an insurance reimbursement list, some of the focus of an NEDL in ensuring that certain drugs are restricted by level of facility is lost. It may be prudent to institute some safeguards concerning the use of potent medicines by nurses at HCs in the follow up treatment of some complex patients.

Possible Solutions

1. Harmonize the electronic drug management inventory system in all hospitals
   a. To ease reporting to the Pharmacy Section, MOPH

2. Require every hospital to produce an annual report on drug consumption for MOPH
   a. ABC analysis to identify high cost medicines and % of budget spent on non-EDL drugs

3. Establish hospital accreditation criteria that require the concerned hospital to be within the rules of procuring NEDL drugs The accreditation criteria could be made in consultation with the offices operating the various health coverage schemes (which could require that only NEDL drugs are used) and with the Thai Medical Council (which could require that the NEDL approach and criteria are included in medical and pharmacy curricula).

4. Work towards reducing the number of NEDL drugs
   a. Consider differential reimbursement for vital, essential and non-essential drugs and co-payments for non-EDL drugs

5. Consider introduction of safeguards to ensure that drugs meant for use at referral hospital level are not used by HCs without adequate supervision by the concerned referral hospital.

6. Promote understanding of the Essential Drugs Concept
   a. Feedback local consumption data to prescribers
   b. Should be done by DTCs
Medicines Use

In most of the public facilities visited, doctors were seeing about 50 patients per day, although many of the patients were follow-up ones. The number of patients seen per day tended to be higher in hospitals as compared to primary care units. Thus, most doctors are generally not overburdened and can give adequate consultation time to patients. Dispensing was generally done by pharmacy staff who also seemed to have adequate time to dispense medicines to patients.

Prescribing

Only a few studies of drug use in Thailand over the last 10 years were found in the literature. Table 2 summarizes the baseline data from these studies. In addition some of these studies and others have been done in association with interventions to improve the use of medicines. Regulation without accompanying education or punitive action for contravention and education alone had little impact in pharmacy shops (Karolinska Inst et al 2000). Implementation of an EDL in Chulalongkorn University hospital did result in a reduction in the number of drugs prescribed per person, an increase in generic prescribing and a decrease in the cost per prescription (Limpanasithikul et al 2002). Implementation of clinical guidelines in a public hospital did result in a decrease in the use of antibiotics for upper respiratory tract infection from 74% to 44% (Thamlikitkul et al 2004). However in another study clinical guidelines were found to have very little effect (Pagaiya & Garner 2005).

Table 2: Summary of baseline drug use in primary care in Thailand as reported in studies conducted from 2000 onwards

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Av. no. drug/Px</td>
<td>2.52</td>
<td>3.76</td>
<td>3.24</td>
<td>3.8*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Pm with ABs</td>
<td></td>
<td>34-38</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Pm with INJs</td>
<td></td>
<td>2.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% generic drugs</td>
<td>28.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% diarrh. given ABs</td>
<td>85.6</td>
<td></td>
<td>83-97</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% diarrh. given ORS</td>
<td>6-33*</td>
<td>91.3</td>
<td>67-83</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% URTI given ABs</td>
<td></td>
<td>74.0</td>
<td>60.3</td>
<td>60.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Pm compliant with STGs</td>
<td>25-37*</td>
<td>15</td>
<td></td>
<td>36.26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Px=prescription; AB=antibiotic; INJ=Injection; EML=Essential Medicines List; ORS=oral rehydration solution; VIT=vitamin; URTI=upper respiratory infection; STG=Standard Treatment Guideline; *= results from private pharmacy
The consultant undertook a rapid prescribing survey in the outpatient departments in 9 public facilities and 4 drug stores (serving mostly acute patients). In each facility the prescribing in 30 patient encounters was examined by reviewing prescriptions in the outpatient dispensary - either the paper prescriptions or the results entered into the electronic computer system. In the case of drug stores, results were obtained from electronic bills in 3 stores and by observation in one store. The results are shown in table 3.

Table 3: Drug use indicator survey

<table>
<thead>
<tr>
<th>Drug use indicator</th>
<th>Referral Hospital</th>
<th>Community Hospital</th>
<th>Health Centre</th>
<th>Drug Store</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=3</td>
<td>n=2</td>
<td>n=4</td>
<td>n=4</td>
</tr>
<tr>
<td>Av. no. drugs / patient</td>
<td>4.13</td>
<td>3.25</td>
<td>2.74</td>
<td>1.56</td>
</tr>
<tr>
<td>% patients with Antibiotics</td>
<td>23.1</td>
<td>44.6</td>
<td>28.5</td>
<td>17.3</td>
</tr>
<tr>
<td>% patients with Injections</td>
<td>5.5</td>
<td>3.1</td>
<td>5.3</td>
<td>0.8</td>
</tr>
<tr>
<td>% patients with Vitamins</td>
<td>18.3</td>
<td>9.6</td>
<td>14.2</td>
<td>5.3</td>
</tr>
<tr>
<td>% URTI cases with Antibiotics</td>
<td>-</td>
<td>62.4</td>
<td>53.6</td>
<td>-</td>
</tr>
<tr>
<td>% prescribed generic drugs</td>
<td>67.4</td>
<td>87.9</td>
<td>91.8</td>
<td>4.0</td>
</tr>
<tr>
<td>% prescribed NEDL drugs</td>
<td>78.3</td>
<td>84.2</td>
<td>84.3</td>
<td>46.5</td>
</tr>
<tr>
<td>Av. drug cost / patient (Baht)</td>
<td>1145.26</td>
<td>82.58</td>
<td>65.32</td>
<td>87.91</td>
</tr>
</tbody>
</table>

URTI = upper respiratory tract infection

It can be seen that the higher the facility level the greater the drug use and cost as might be expected since the complexity of cases rises with facility level. However, part of the increased costs in referral hospitals compared to other facilities is due to the lower use of essential drugs and prescribing by generic name. Antibiotic use was highest in community hospitals as expected since the majority of bacterial infections will be treated in these facilities. However, antibiotic use for upper respiratory tract infection (URTI) was high in both community hospitals and health centres. One might expect a small minority of URTI cases to receive antibiotics but in fact over half of such cases received them. The use of essential drugs and prescribing by generic name was lowest in drug stores, where the cost per drug item was higher than in health centres or community hospitals. This is of concern since drug stores are delivering primary care to a substantial proportion of the population. In general the results were similar to those found in the literature as shown in table 2.

A number of inappropriate outpatient prescribing practices were observed. Common cold cases, which might require no medicines at all, often received bromhexine (non-EDL), antihistamine (chlorpheniramine, cetirizine, cinnarizin [non-EDL]), paracetamol + antibiotic + vitamin (B Complex, Multivitamin, Vitamin B1-6-12 [non-EDL]). Aches and pains, which might require one analgesic, often received 2-3 analgesics - paracetamol/aspirin and diclofenac/ibuprofen and analgesic balm + tolperisone (non-EDL) or norgesic (non-EDL combination of paracetamol + orphenadrine). Some hypertension cases were prescribed lorazepam or alprazolam. It was also noticed in hospital OPD that cash-paying or CSMBS patients compared to
UHCS patients receive fewer NEDL drugs (69% vs 87%), fewer generics (60% vs 75%) at greater cost (1768 Baht vs 523 Baht).

Standart Treatment Guidelines (STG) and Formulary

There are a few national Standard Treatment Guidelines (STGs) for certain diseases e.g. national disease control programs and some communicable diseases produced by the Dept of Disease control. The Department of Medical Services runs not only 29 large hospitals but also a program to develop standard treatment guidelines and so far they have developed guidelines for about 50 diseases. The Dept is attempting to harmonise STGs on the same condition produced by different departments. Even so, there was no standard format for STGs to follow nor are they required to follow any rules, such as recommendation of NEDL drugs only. Thus in some guidelines non-EDL drugs are recommended. The Dept staff mentioned that they distributed 1000-10,000 copies to all provinces and hospitals depending on demand but that few doctors used the STGs in practice. The Royal College of Physicians is also now leading a working group on the production of national STGs according to a recent Cabinet decision. Some university hospitals produce their own guidelines. However, for all practical purposes there are no current national STGs for most conditions. There was a hospital formulary 2006 seen in the department of pharmacy.

Education and Information

Undergraduate education
There are 22 medical and 18 pharmacy schools. Medical undergraduate education lasts 6 years and pharmacy undergraduate education has just changed to 6 years. The Medical Council sets what should be in the curricula and also manages the final central examination system. The Consortium of Medical Education fine tunes courses and teaching methods. 40 hours of pharmacology is taught in the first 3 years of medical education and another 20 hours in various other courses. However, no clinical pharmacology is taught and teaching on clinical prescribing is left to university hospital senior clinicians. Many universities do not teach about the NEDL or STGs. Pharmacy undergraduate education for all students is the same for the first 4 years and students have 6 weeks clinical attachment in each of a community pharmacy and a hospital pharmacy in the 4th year. In the 5th year pharmacy students choose either pharmacy care or scientific pharmacy depending whether they wish to later work in the health care setting or in industry. Pharmacy care students do receive some teaching on diagnosis of common mild conditions e.g. 1 hour on cough and cold and 3 hours on skin conditions. The 6th year pre-registration year is spent in an external attachment either in the health care or manufacturing settings depending on what branch of pharmacy was chosen in the previous year. Doctors and pharmacists must currently work 2-3 years in the rural area after qualification although this rule may change for pharmacists in a few years as the rural areas now have enough pharmacists.

Continuing Professional Development
Continuing Professional Development (CPD) or continuing medical education (CME) is voluntary and organized on an adhoc basis, most meetings being sponsored by the pharmaceutical industry. There is also an adhoc system for CME for pharmacists run
by various Pharmacy Associations. The Community Pharmacy Association runs one lecture a month sponsored by a pharmaceutical company. Both the Medical and Pharmacy Councils are working towards a points credit system for approved CME activities and a change in the law is currently being considered to make 20-30 hours of CME per year obligatory for all doctors and pharmacists.

**Health Professional Councils**

There are independent councils for nurses, pharmacists and doctors. The Medical Council acts according to the Medical Profession Act 1982 and there are similar acts for pharmacists and nurses. The Act specifies the legal responsibilities of the Medical Council which includes: registration and licensing of doctors; curricula specification and approval for medical students and postgraduate specialties (through 79 specialist boards); medical school specification and approval; CME requirements; and developing and enforcing professional ethics. The 13 Royal Colleges and specialist associations may initiate specialist curricula and exams but they must go through the Medical Council for ratification. The Medical Council Board consists of 52 members, half elected and the other half appointed by virtue of their senior positions - Deans, Directors of Military Medical Departments, Permanent Secretary MOPH, DG Department of Health and Director of Department of Medical Services. Each member serves for 2 years. Last year the Medical Council received 300 complaints mostly from the public of which 15 resulted in the practitioner’s license being revoked.

The Pharmacy Council has similar responsibilities with regard to pharmacists. Their Board includes unelected representation from the Thai FDA and the various pharmacist associations as well as Deans of Pharmacy schools and military pharmacists. Both Councils are considering the development of obligatory CME and mentioned the problem of unethical drug promotion. While the FDA has representation on the Pharmacy Council Board, the arrangement was not reciprocal. The Pharmacy Council felt that there were some issues of quality and regulation for which they could play a useful role if they sat on the FDA Board.

**Independent Drug Information**

There is no National drug info centre. In private pharmacies, the main source of information is the local MIMS. However, some pharmacies also had a Handbook on Pharmacotherapy with some prescribing information.

**Public Education**

There is a system of Village Community Volunteers but they have not been used for delivering targeted messages on drug use to the public. Relevant messages could include “don’t take antibiotics without seeing a health worker first” or “medicines are not needed for simple coughts and colds” or “ask your doctor whether your child really needs more than 2 medicines”.

**Drug and Therapeutic Committees (DTC)**

Every hospital has a DTC to manage the 3-year procurement plan and ensure compliance with NEDL policy. They decide on all non-EDL drugs that may be purchased. Other functions include monitoring ADRs. However, there is very little other action to promote rational use of medicines or the essential drug concept.
Monitoring and Supervision

There is some supervision of health centres by community hospitals but it is focused on compliance with the NEDL and not on prescribing. As mentioned previously (see drug supply), both health centres and community hospitals send data from their electronic databases on patient treatment to the provincial health office for compilation and sending to the Bureau of Health Policy and Strategy in the MOPH. However, the data used is mostly on patient numbers and diseases – as needed for the health management information system – and not on drugs. Thus, outpatient prescribing could be monitored using existing electronic data systems but is not. The NHSO monitors some drug use – mainly in special projects – and operates a pay-for-performance system to reward hospitals that perform well in some areas e.g. reduced use of antibiotics.

Private Pharmacies

All drugs are sold OTC apart from controlled drugs. There is no "Prescription-only" drug schedule although pharmacies are divided into those with a pharmacist always present which may sell "prescription-only"-type drugs and those where a pharmacist is not always present which may only sell "OTC"-type drugs. In addition there is a separate regulation for a further category of Special Controlled Drugs which stipulates that systemic steroids and oncology drugs cannot be sold without prescription. Since there is no strict drug scheduling (apart from for narcotics) pharmacists undertake prescribing for mild conditions and are taught to do so in pharmacy school. It was observed that some private pharmacists took a patient history and did simple diagnostic procedures (e.g. examination of the throat) prior to selling medicines. Some pharmacies are accredited by the Pharmacy Council if they follow Good Pharmacy Practices - but the accreditation is voluntary and seems to confer no financial or other advantage.

Many doctors work in their own private clinics in the evenings after finishing work in public facilities. In general they dispense their own medicines and this is where they earn money. Currently there is an act being considered to develop a prescription-only drug schedule but there is already much resistance to it. The pharmacists say that they will support such schedules if the doctors are forced to write prescriptions (in order that patients still buy drugs from them) but not otherwise. However, doctors say that they must continue to dispense medicines because patients are unwilling to pay consultation fees and thus they need dispensing fees.

Possible Solutions

1. Monitor drug use
   a. ABC analysis, prescription audit and feedback for outpatient as well as inpatient care - by hospital DTCs
   b. May use the existing hospital electronic patient databases and report on selected drug use indicators to MOPH
c. Develop selected prescribing indicators to monitor outpatient and inpatient treatments
d. Could be integrated into the existing reporting system to Bureau of Policy and Strategy, MOPH, via the provincial health offices
e. Should involve the NHSO the social security office (SSO), the office managing the civil servants medical benefits scheme, and the office managing the compulsory migrant health insurance scheme who can contribute financially and intellectually to the development of indicators and national monitoring systems

2. Standard Treatment Guidelines
   a. Develop national STG for primary and secondary care
   b. Disseminate STG directly free of charge to every doctor
   c. Incorporate STGs into undergraduate and continuing medical education

3. Expand the role of DTCs
   a. To monitor prescribing, encourage continuing medical education, and report annually on activities to MOPH
   b. Requires strengthening the MOPH to review the reports
   c. Consider including DTC activities in hospital accreditation for training medical students and also treating insured patients
   d. Could be paid for by funding sources from the NHSO, SSO, and possibly funds from the other schemes in the country

4. Continuing professional development (CPD)
   a. Thailand Medical and Pharmacy Councils to consider developing a credit system for continuing medical education and making CPD obligatory for re-licensing
   b. Curricula should include prescribing and the essential drugs concept
   c. Medical and pharmacist associations could promote the essential drugs concept through the lectures they organise

5. Strengthen clinical pharmacology and pharmacy
   a. Establish post-graduate studies on clinical pharmacology and clinical pharmacy and encourage these students to analyse drug consumption and do prescription surveys

6. Public Education
   a. Core pharmaceutical messages e.g. "does my child need more than one drug?" or "coughs and colds do not usually need antibiotics"
b. Could be given through the Village Health Volunteers, schools and NGOs. Perhaps Thai Health, NHSO and other public monies could pay for this.
Medicines Regulation

Drug regulation is done according to the Drug Act 1967, which has been amended 4 times, the last time being in 1987. A new Drug Act has been in the pipe-line for some time. In particular, a new Act is required for more punitive action for contraventions and also to introduce a re-evaluation fee for registered drugs.

The Thai national Food Drug and Drug Administration, under the MOPH, implement the Act and regulations. The main activities of the FDA consist of:

- Pre-marketing and post-marketing surveillance
- Surveillance program on product safety
- Surveillance system on advertisement
- International affairs regarding pharmaceuticals
- Database on registered pharmaceuticals

The Bureau of Drug Control within the FDA is the main body responsible for drug regulation and consists of 4 divisions - System Development; Standards establishment; Pre-Marketing Control; Post-Marketing Control; and 1 section of Administration. There are 96 staff members in the central office and no branch offices. The central FDA works with Provincial Health Offices to undertake inspection of pharmacies and certain other functions in the provinces. The FDA regulates a sector comprising 17,424 drug stores (MOHP 2011), wholesalers and distributors, approximately 150 manufacturers and about 30,000 drug products. 94% of all locally manufactured drugs are GMP compliant. (MOPH 2011)

Regulation of outlets and drug schedules

The FDA is responsible for issuing licenses to all drug outlets. Each outlet must be re-registered annually and ideally there should be annual inspections. Even with this task delegated to Provincial Health Offices, there is insufficient staff to undertake annual inspections of all drug stores. There are no OTC or Prescription-only drug schedules. Instead drugs are divided into 4 categories:

1. Household Remedy drugs - which include about 50 drugs recommended as household remedies. This includes paracetamol packaged as 8 tablets
2. Ready-packed drugs -- which includes about 10 drugs which are similar to those in the household remedy list but which are sold in larger quantities e.g. paracetamol sold in greater quantities than 8 tablets.
3. Dangerous Drugs - which include antibiotics and other drugs that would normally be considered as prescription-only in many countries
4. Specially-controlled drugs - which are very risky for patients and/or are costly e.g. anti-cancer drugs.

Category 1 drugs may be sold in a general store where there is no pharmacist. However, all the other drugs may only be sold in drug stores where there is a pharmacist present at all times. However it was mentioned that many drug stores sell "Dangerous Drugs" even though no pharmacist is present in the pharmacy. Narcotic and controlled drugs have a separate drug schedule and are controlled by a separate division. Only drug stores with special licenses may sell narcotic and controlled drugs
and also specially-controlled drugs. In addition, there are 3 categories of traditional medicines - traditional medicine made according to the traditional medicine pharmacopoeia, home remedies and modified herbal medicine which has been produced using modern technology. The annual license fee for a drug store able to sell dangerous drugs is 2000 Baht.

There has been discussion about making a prescription-only drug schedule, particularly for antibiotics. However, this move is opposed by the both the medical and pharmacy professions. Doctors do not want to give up dispensing and pharmacists do not want to give up prescribing if doctors do not give up dispensing.

**Drug Registration**

For “me-too” generic products (new products with the same active pharmaceutical ingredient as in products already registered), the only requirement for registration is bio-equivalence studies and submission of a dossier concerning the specifications and quality assurance of the product. GMP inspections may be done. For new originator brands, ACT/ASEAN technical guidelines for registration are followed. The first stage involves in-house review by a pharmacist and the second stage external review by pharmacists and physicians. A sub-committee meets to decide on the efficacy, safety and quality of the product and makes a recommendation to the National Drug Committee of the FDA for final approval. Generally, a conditional approval is given initially together with a safety monitoring program and limited distribution. Once the drug has been used for some time, unconditional approval is given. This approval incurs a fee but the product is then registered forever. Only if safety issues occur is a re-evaluation of the product, with regard to continued registration, undertaken. Unfortunately, the company is not obliged to pay for any re-evaluation, which may be costly. Generally the FDA negotiates with the manufacturer to withdraw unsafe products voluntarily.

The Department of Medical Sciences has a drug testing laboratory to test the quality of drugs at the request of the FDA. The lack of any criteria to limit the registration of me-too branded generic drugs has resulted in about 30,000 registered products and multiple brands. For example, in MIMS (2005), 101 brands of paracetamol (alone or in combination), 49 brands of chlorpheniramine and 41 brands of amoxicillin were found.

**Pharmacovigilance**

The National Centre for Pharmacovigilance (NHPCV) is situated in the Technical and Planning Division of the FDA. There are 9 pharmacists and 6 support staff. The national centre has a network of 12 regional centres that collect adverse event reports from the facilities under them. Every hospital Drug and Therapeutic Committee (DTC) is involved in monitoring adverse drug reactions (ADRs). Monitoring is based on spontaneous reporting, targeted spontaneous reporting (as in a vertical disease control program) 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 recall. Outbreaks of ADRs are referred to the Bureau of Epidemiology to investigate the cause of the problem. Currently, erythropoietin is undergoing re-evaluation because of a high incidence of adverse events. The NHPCV
is a member of the WHO International Drug Monitoring Program, operates vigibase on-line and reported more than 60,000 ADRs (mostly mild reactions) in 2011. The website is http://www.fda.moph.go.th

**Drug Testing Laboratory**

The Bureau of Drug and Narcotic in the Department of Medical Sciences runs an ISO approved drug testing laboratory and is a WHOCC. The laboratory tests about 2500 drug samples per year, consisting of:

- 1000 samples for the Thai FDA post-marketing surveillance program focused mainly in pharmacy shops,
- 1000 samples for their own post-marketing surveillance program of generic drugs in hospitals and
- 500 samples for operating an external QA program for 12 public regional drug testing labs, 40 private pharmaceutical company labs and labs in various ASEAN countries (1-2 samples sent to each lab per year).

They mentioned that about 10% of all specimens failed quality testing mainly due to poor dissolution and instability. The FDA would like them to test more samples but they are operating to full capacity. Their work as a WHOCC involves training laboratory staff and testing drug samples from Asian countries, providing technical consultancy in Asian countries, and collaborating with WHO/HQ on developing international standards. In addition they produce reference substances for use in Asian laboratories. The laboratory participates in an external QA program run by WHO and also the European Directorate of Quality Medicines and is also currently in the process of applying for WHO pre-qualification for the UN program.

**Drug Promotion**

There is pre-approval of advertisements for all drugs and also some post-marketing surveillance. Some respondents felt that the control of advertisements was good, mentioning that there are even some advertisements of antibiotics on TV! Unfortunately, the concerned FDA expert was not available for comment. It was mentioned by all respondents that frequent visits of drug company representatives to clinical doctors and procurement pharmacists in the public sector was detrimental to good practices. Both the Medical and Pharmacy Councils mentioned the problem of unethical drug promotion by pharmaceutical companies influencing prescribing and that PREMA, an association of international manufacturing companies and TPMA, an association of local manufacturing companies, was now trying to do self-regulation of drug promotional activities. However, it was mentioned that the punishments were too small to stop unethical practices.

**Drug Pricing**

Drug prices in the private sector are set by the industry - manufacturers and retailers. Most retailers aim to have at least a 10% mark-up and prices are often set according to what the market will bear and sometimes after bargaining between the retailer and customer. Prices in the public sector are negotiated between industry and purchasers including NHSO and local facilities.
**Possible Solutions**

1. Work towards having fewer brands of the same drug (active pharmaceutical ingredient) in the market
   a. Introduce 5 yearly re-registration and re-evaluation
   b. De-register all drugs not currently in the market

2. Monitor drug promotional activities in collaboration with MOPH and professional bodies and councils
   a. Consider banning medical representatives from public facilities except by appointment with the DTC
   b. Ban inappropriate financial incentives or promotional holidays
   c. Require companies to disclose their marketing activities and budgets to the FDA

3. Publish information on the FDA website on drug testing results
   a. to convince prescribers about drug quality

4. Increase staff at provincial health offices
   a. to inspect drug stores, monitor drug promotion and do post-marketing surveillance

5. Consider introducing a new prescription-only drug schedule for certain drugs that should only be used in hospitals e.g. new generation antibiotics

6. Consider regulations to improve patient knowledge of drugs e.g. information leaflet and requiring that all packaging has the generic name in large font and the brand name in small font.

7. Consider making the FDA semi-autonomous
Medicine Policies and Health system issues

Thailand has an extensive health care system in which most patients receive health care free at the point of delivery and the costs are claimed by the facility directly from one of the various schemes currently operating. Only a minority of patients pay out-of-pocket for health care. Government facilities are obliged to procure mostly essential drugs and to treat the majority of patients with essential drugs under the UHCS. There is monitoring and supervision of procurement and consumption of essential drugs and also extensive electronic data collection systems on patient treatment, although much of the data is not analysed. Continuing medical education is adhoc with little focus on rational prescribing or on the NEDL. Moreover, STGs and the EDL concept are not a strong feature of most pre-service medical, nursing or pharmacy curricula. There is a national medicines policy document 2011 which covers many aspects of the pharmaceutical sector. The various medicine policies that are in place, as found by the WHO consultant during the mission, and that may impact on drug use, are shown in table 4.

Table 4: Medicine Policies in place in Thailand

<table>
<thead>
<tr>
<th>Drug Policy</th>
<th>State of implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Drug Policy</td>
<td>Many aspects are being implemented</td>
</tr>
<tr>
<td>Monitoring the use of medicines</td>
<td>Monitoring of consumption centrally &amp; locally to ensure most drugs procured and used are on the NEDL</td>
</tr>
<tr>
<td>Essential Drug List</td>
<td>2012 NEDL on the web, but the last printed version was 2008.</td>
</tr>
<tr>
<td>Standard Treatment Guidelines</td>
<td>50 national STGs on different diseases produced by the Department of Medical Services, but many of these STGs are not consistent with the NEDL and are not used</td>
</tr>
<tr>
<td>Formulary</td>
<td>National Formulary published</td>
</tr>
<tr>
<td>Generic Policies</td>
<td>None</td>
</tr>
<tr>
<td>Regulation of drug promotion</td>
<td>Pre-approval of advertisements</td>
</tr>
<tr>
<td>Monitoring ADRs</td>
<td>Extensive system for monitoring adverse drug reactions (ADRs)</td>
</tr>
<tr>
<td>Payment for medicines</td>
<td>For the majority of patients, who are insured, all medicines are received free of cost at the point of delivery, facilities claiming reimbursement from one of the health coverage schemes</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>96% of the population is covered by one of the three main health coverage schemes (UHCS, SSS, CSMBS).</td>
</tr>
<tr>
<td>Revenue from medicines</td>
<td>Hospitals get revenue on mark-ups for medicines dispensed and also for treating non-insured patients or patients who are not registered with the facility.</td>
</tr>
<tr>
<td>Medicine Pricing policies</td>
<td>Price negotiation between government and manufacturers in the public sector</td>
</tr>
<tr>
<td>Undergraduate medical training</td>
<td>NEDL and STGs are not part of the curricula. No training on problem-based pharmacotherapy.</td>
</tr>
<tr>
<td>Continuing medical education</td>
<td>CPD/CME is adhoc and generally does not focus on prescribing or include the NEDL and STGs. Most meetings are sponsored by the pharmaceutical industry.</td>
</tr>
<tr>
<td>Drug Info Centre</td>
<td>No national medicines information centre but information units in some hospitals and the FDA</td>
</tr>
<tr>
<td>Public education on medicines use</td>
<td>System of public education through village health volunteers but this system has not been used to spread messages on prudent and safe use of medicines</td>
</tr>
<tr>
<td>DTCs</td>
<td>Drug and Therapeutic Committees (DTCs) in all hospitals</td>
</tr>
<tr>
<td>National Strategy on AMR</td>
<td>National strategy on antimicrobial resistance (AMR) published in 2011</td>
</tr>
</tbody>
</table>
Coordination and Management

The MOPH is responsible for public sector health care delivery at province level and below, covering 90% of the public sector. It is headed by the Health Minister, the Deputy Health Minister, followed by the Permanent Secretary and 4 deputy permanent secretaries. Under the MOPH, there are 8 departments:

- Office of the Permanent Secretary
  - with 76 provincial offices
- Food and Drug Administration
- Department of Medical Services
- Department of Health
  - with 12 regional offices
- Department of Disease Control
  - with 12 regional offices
- Department of Mental Health
- Department of Health Services Support -
  - medical registration division is responsible for licensing private hospitals
- Department of Medical Science
- Department of Traditional Medicine

There are 12 regions, 76 provinces and about 10-12 districts per province. In each province, is a Chief Medical Officer and a Health Office and at least 1 provincial hospital and in big provinces there is the regional hospital also. There is at least 1 community hospital per district and about 15-20 health centres, staffed only by nurses, under each community hospital. Regional hospitals have 700-1000 beds, provincial (general) hospitals 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.

Within the Office of the Permanent Secretary is the Pharmacy Section which mainly focuses on developing guidelines on implementation drug policy, mainly drug management and monitoring prices. There is also an Inspection section which inspects hospitals 6 monthly for many aspects of quality of care and whether various regulations are followed - including compliance with regulations concerning the procurement of NEDL drugs. 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. It is not clear how much overlap there is between the Pharmacy Section in the Office of the Permanent Secretary and other players, such as the FDA, the national drug system development committee and the prime ministers’ cabinet’s working groups.

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 NEDL.
There are also 5 semi-autonomous bodies funded directly by the MOF:
1. National Health Security Office (NHSO)
   - This body holds the budget for drugs and vaccines under the Universal Health Coverage Scheme (formerly 30 Baht scheme) which covers 74% of the population.
2. Health System Research Institution (HSRI)
   - Undertakes research on health systems including drugs
3. Thai Health Promotion Foundation (ThaiHealth)
   - Funds many projects on health promotion and promoting RUM
4. National Health Committee (NHC)
   - Develops national health policy including drug policy
5. Emergency Medical Institute of Thailand (EMIT)
   - Runs the emergency medical system

National Drug Policy

There is a comprehensive national drug policy 2012-2016 published in 2011 developed by the National Drug System Development Committee (formerly the National Drug Committee), which is the highest committee addressing drug issues and developing drug policy. It is chaired by the Deputy Prime Minister and the secretary is the Chief of the FDA. The NDP has as its goal "Universal Access to medicines for all, rational use of medicines and national self-reliance". There are 4 elements, each with objectives and sub-strategies, as follows:
- Access to medicines
- Rational use of medicines
- Development of domestic pharmaceutical industry, biological products and herbal medicines for self-reliance
- Strengthening the regulatory system to completely assure quality, efficacy and safety or registered medicines

Under the national drug system development committee there are 4 sub-committees, one responsible for developing and updating the national EDL, another for promoting rational use of medicines, another for developing national policy and another on median drug prices. It is not clear if there are other committees to address the other aspects of drug policy e.g. development of domestic industry. Under the sub-committee on rational use of medicines there are seven sub-sub-committees each dealing with a different strategy - as follows:
- To develop a regulatory system and monitoring mechanism to ensure RUM
- To develop human resources in health service
- To develop mechanisms and tools to facilitate RUM e.g. NEDL, STGs, Formulary, DTCs, drug information, regulatory mechanism for prescriptions and a national supervisory system
- To strengthen community capacity in RUM
- To encourage manufacture and quality control of generic medicines
- To develop AMR containment systems
- To promote ethical prescribing and stop unethical drug promotion
Each strategy has tactics and some have targets but the monitoring systems to ensure and monitor compliance are still in development.

Recently the Prime Minister’s Office has become concerned about the rising expenditure and has instituted 6 official and 3 unofficial cabinet working groups to improve drug management and use. These groups are similar to the long standing groups described above and manned by the same people, but there are some differences. The official cabinet groups cover: promotion of generic and NEDL-drugs; drug prices; guidelines (headed by the Royal College of Physicians of Thailand), National Drug Code; Disease-related costing for inpatients (DRG); and Audit (for the above 5 groups). The more recently added unofficial groups cover AMR, RUM and Promotion of Traditional Medicine. Thus there appear to be multiple groups working on various aspects of drug policy. Some of these groups are working in a complementary way. However, there is also fragmentation. For example, the Cabinet working group on drug prices is negotiating lower drug prices for non-EDL drugs with the view to allowing more of such drugs to be used. This is in contradiction to the subgroup working to encourage the use of NEDL-drugs. Despite all the working groups, budget for the infrastructure needed to implement all the policies and monitor progress, particularly prescription audit, is lacking. In addition, the Royal College of Physicians mentioned that the working group on guidelines does not only concern clinical guidelines but a plethora of other issues concerning drugs for which there are 8 sub-committees covering various aspects of drug policy, sometimes with overlapping terms of reference.

Possible Solutions

1. Decide on one Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership including laypersons, professional bodies, etc.
   a. Could be National Drug Systems Development Committee

2. Appoint one executive department in MOPH to carry out the statutory committee recommendations
   a. To coordinate action:
      i. Between departments in MOPH (Pharmacy Section in Office of Permanent Secretary, FDA, Bureau of Policy & Strategy) etc
      ii. With Ministry of Education (health professional education and school education); Ministry of Finance (health budgets), Ministry of Industry (manufacturing); Ministry of Trade (drug pricing)
   b. To be responsible for rational use of drugs: NEDL, STGs, DTCs, monitoring drug use, CPD, public education
   c. Could be the Pharmacy Section of the Office of the Permanent Secretary

3. Streamline the committees and invest in their advice
Workshop

At the end of the mission, a half-day workshop was held on July 31st with about 20 national stakeholders to discuss the consultant’s findings and to develop recommendations. The participants in the workshop can be seen in annex 2. The consultant’s presentation at the workshop can be seen in annex 3.

Objectives of workshop

- Review the WHO fact finding results
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems

Agenda

- Presentation of the findings by the WHO consultant and discussion of the findings with identification of main problems and possible solutions
- Discussion of recommendations focused on 5 main categories as specified below:
  - Drug supply
  - Drug selection
  - Promoting rational drug use
  - Drug regulation
  - Drug Policy and coordination

There was a lively discussion and the stakeholders agreed with the many of the consultant’s findings and most of the consultant’s recommendations. During the workshop, recommendations were agreed by consensus in plenary discussion. Following the workshop, the recommendations were edited (for language and coherence) and circulated to all the stakeholders. The following conclusions and recommendations were agreed by all stakeholders and incorporate all comments from the workshop participants.
**Recommendations**

**A. Drug Supply**

1. Harmonize all electronic drug management inventory systems, including those used in health facility drug stores, other health facility departments and the GPO
   - Will ease drug management and monitoring

2. Strengthen the Pharmacy Section, MOPH
   - to monitor compliance with procurement regulations and prices
   - to have capacity to liaise with MOF on monitoring and avoid duplication of effort

3. Discourage use of non-EDL drugs by:
   - Limiting budget allocations, particularly for CSMBS
   - Requiring co-payment for non-EDL drugs

4. Monitoring and feedback to hospitals and prescribers on non-EDL drug use

**B. Drug Selection**

5. Harmonize electronic drug management inventory system in all hospitals
   - To ease reporting to the Pharmacy Section, MOPH

6. 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-EDL drugs

7. Establish hospital accreditation criteria that require the concerned hospital to be within the rules of procuring NEDL drugs. The accreditation criteria could be made in consultation with the offices operating the various health coverage schemes (which could require that only NEDL drugs are used) and with the Thai Medical Council (which could require that the NEDL approach and criteria are included in medical and pharmacy curricula).

8. Work towards reducing the number of NEDL drugs
   - Consider differential reimbursement for vital, essential and non-essential drugs and co-payments for non-EDL drugs

9. Consider introduction of safeguards to ensure that drugs meant for use at referral hospital level are not used by HCWs without adequate supervision by the concerned referral hospital.

10. Promote understanding of the Essential Drugs Concept
    - Feedback local consumption data to prescribers
    - Should be done by DTCs
C. Rational use of medicines

11. Monitor drug use
   • ABC analysis, prescription audit and feedback for outpatient as well as inpatient care - by hospital DTCs
   • May use the existing hospital electronic patient databases and report on selected drug use indicators to MOPH
   • Develop selected prescribing indicators to monitor outpatient and inpatient treatments
   • Could be integrated into the existing reporting system to Bureau of Policy and Strategy, MOPH, via the provincial health offices
   • Should involve the NHSO, the social security office (SSO), the office managing the civil servants medical benefits scheme, and the office managing the compulsory migrant health insurance scheme who can contribute financially and intellectually to the development of indicators and national monitoring systems

12. Standard Treatment Guidelines
   • Develop national STG for primary and secondary care
   • Disseminate STG directly free of charge to every doctor
   • Incorporate STGs into undergraduate and continuing medical education

13. Expand the role of DTCs
   • To monitor prescribing, encourage continuing medical education, and report annually on activities to MOPH
   • Requires strengthening the MOPH to review the reports
   • Consider including DTC activities in hospital accreditation for training medical students and also treating insured patients
   • Could be paid for by funding sources from the NHSO, SSO, and possibly funds from the other schemes in the country.

14. Continuing professional development (CPD)
   • Thailand Medical and Pharmacy Councils to consider developing a credit system for continuing medical education and making CPD obligatory for re-licensing
   • Curricula should include prescribing and the essential drugs concept
   • Medical and pharmacist associations could promote the essential drugs concept through the lectures they organise

15. Strengthen clinical pharmacology and pharmacy
   • Establish post-graduate studies on clinical pharmacology and clinical pharmacy and encourage these students to analyse drug consumption and do prescription surveys

16. Public Education
• Core pharmaceutical messages e.g. "does my child need more than one drug?" or "coughs and colds do not usually need antibiotics"
• Could be given through the Village Health Volunteers, schools, and NGOs. Perhaps Thai Health, NHSO and other public monies could pay for this.

D. Regulation and Monitoring of quality of medicines

17. Work towards having fewer brands of same drug (active pharmaceutical ingredient) in the market
   • Introduce 5 yearly re-registration and re-evaluation
   • De-register all drugs not currently in the market

18. Monitor drug promotional activities in collaboration with MOPH and professional bodies and councils
   • Consider banning medical representatives from public facilities except by appointment with the DTC
   • Ban inappropriate financial incentives or promotional holidays
   • Require companies to disclose their marketing activities & budgets to the FDA

19. Publish information on the FDA website on drug testing results to convince prescribers about drug quality

20. Increase staff at provincial health offices to inspect drug stores, monitor drug promotion and do post-marketing surveillance

21. Consider introducing a new prescription-only drug schedule for certain drugs that should only be used in hospitals e.g. new generation antibiotics

22. Consider regulations to improve patient knowledge of drugs e.g. information leaflet and requiring that all packaging has the generic name in large font and the brand name in small font.

23. Consider making the FDA semi-autonomous

E. Coordination and Management

24. Decide on one Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership including laypersons, professional bodies.
   • Could be National Drug Systems Development Committee

25. Appoint one executive department in MOPH to carry out the statutory committee recommendations
   • To coordinate action:
   • Between departments in MOPH (Pharmacy Section in Office of Permanent Secretary, FDA, Bureau of Policy & Strategy) etc
With Ministry of Education (health professional education and school education); Ministry of Finance (health budgets), Ministry of Industry (manufacturing); Ministry of Trade (drug pricing)

- To be responsible for rational use of drugs: NEDL, STGs, DTCs, monitoring drug use, CPD, public education
- Could be the Pharmacy Section of the Office of the Permanent Secretary

26. Streamline the committees and invest in their advice.
References


## Annex 1: Persons met & places visited during the situational analysis

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Duangta Palakornul</td>
<td>Chief Pharmacist, Pharmacy Section, Bureau of Public Health Administration, Office of the Permanent Secretary</td>
</tr>
<tr>
<td>Assoc Prof Kitti Pitaknitinun</td>
<td>Senior Pharmacist, Pharmacy Section, Bureau of Public Health Administration &amp; Pharmacy Council</td>
</tr>
<tr>
<td>Worasuda Yoongthong</td>
<td>Thai Food and Drug Administration, National List of Essential Medicines Office, National Sub-committee RUM</td>
</tr>
<tr>
<td>Napapon Puripanyana</td>
<td>Thai Food and Drug Administration, National Sub-committee on RUM</td>
</tr>
<tr>
<td>Pornpit Silkavute</td>
<td>Health System Research Institute, National Sub-committee on RUM</td>
</tr>
<tr>
<td>Dr Pisonthi Chingtrakul</td>
<td>Faculty of Medicine, Pharmacology, Chulalongkorn University</td>
</tr>
<tr>
<td>Nithima Sumpradit</td>
<td>International Health Policy and Planning, Thailand</td>
</tr>
<tr>
<td>Yuppadee Javroongrit</td>
<td>Expert Pharmaceutical Standards, Thai Food &amp; Drug Administration.</td>
</tr>
<tr>
<td>Tharnkamol Chanprapaph</td>
<td>Drug Control Division, Thai Food &amp; Drug Administration.</td>
</tr>
<tr>
<td>Wimon Suwankesawong</td>
<td>Pharmacovigilance, Technical &amp; Planning Division, Thai Food and Drug Administration.</td>
</tr>
<tr>
<td>Anchalee Jiruknatee</td>
<td>Essential Drugs Section, Thai Food and Drug Administration.</td>
</tr>
<tr>
<td>Nipat Susaensamran</td>
<td>Essential Drugs Section, Thai Food and Drug Administration.</td>
</tr>
<tr>
<td>Wannisa Theantawee</td>
<td>Essential Drugs Section, Thai Food and Drug Administration.</td>
</tr>
<tr>
<td>Prat Teekapakvisit</td>
<td>OPD pharmacist, Bumrasnaradura Institute, Specialist Hospital under Dept Disease Control, MOPH</td>
</tr>
<tr>
<td>Siriwat Techathawat</td>
<td>Pharmacist, Bureau of General Communicable Diseases, Dept Disease Control, MOPH</td>
</tr>
<tr>
<td>Sujin Junrugsra</td>
<td>Pharmacist, Bureau of Health Promotion, Dept Health</td>
</tr>
<tr>
<td>Phusit Prakongsai</td>
<td>Director, International Health Policy Program, Thailand</td>
</tr>
<tr>
<td>Dr Prasobsri Ungthavorn</td>
<td>Vice-President, Medical Council of Thailand</td>
</tr>
<tr>
<td>Chongmas Nitsingkarin</td>
<td>Pharmacist-owner of Bangkok Drug Mart Pharmacy and President of Community Pharmacy Association, Thailand</td>
</tr>
<tr>
<td>Somnuk Aramtiyamrong</td>
<td>Director, Institute of Medical Research &amp; Technology Assessment, Dept Medical Services, MOPH</td>
</tr>
<tr>
<td>Somkiat Potisat</td>
<td>Research &amp; Technology Assessment, Dept Medical Services, MOPH</td>
</tr>
<tr>
<td>No.</td>
<td>Name</td>
</tr>
<tr>
<td>-----</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>22</td>
<td>Sooksri Ungboriboonpisal</td>
</tr>
<tr>
<td>23</td>
<td>Wiyada Akarawut</td>
</tr>
<tr>
<td>24</td>
<td>Nidapan Ruangrittinon</td>
</tr>
<tr>
<td>25</td>
<td>Netnapis Suchonwanich</td>
</tr>
<tr>
<td>26</td>
<td>Duangtip Hongsamoot</td>
</tr>
<tr>
<td>27</td>
<td>Wasan Saenwian</td>
</tr>
<tr>
<td>28</td>
<td>Napaporn Wattanapaiboonsuk</td>
</tr>
<tr>
<td>29</td>
<td>Worрапorn Promaksorn</td>
</tr>
<tr>
<td>30</td>
<td>Noppadol Sahasoontaravuti</td>
</tr>
<tr>
<td>31</td>
<td>Wichit Nantharattanpont</td>
</tr>
<tr>
<td>32</td>
<td>Prof Kriang Tungsanga</td>
</tr>
<tr>
<td>33</td>
<td>Wittaya Chansiripotha</td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>34  Uaychai Jirachaithorn</td>
<td>Chief of Pharmacy, Bang Kruai Community Hospital, Nontaburi</td>
</tr>
<tr>
<td>35  Mrs Sakul Thongplene</td>
<td>Acting Director, Bang Sri Thong HC, Bang Kruai District</td>
</tr>
<tr>
<td>36  Vipaporn Kerdxn</td>
<td>Nurse, Bang Sri Thong HC</td>
</tr>
<tr>
<td>37  Dr Prapum Plumpanupat</td>
<td>Deputy Director, Pranangklao Provincial Hosp, Nonthaburi</td>
</tr>
<tr>
<td>38  Mrs Nonlapan Pumleng</td>
<td>Clinical Pharmacy Pranangklao Provincial Hosp, Nonthaburi</td>
</tr>
<tr>
<td>39  Mrs Warnwilai Naranong</td>
<td>Clinical Pharmacy Pranangklao Provincial Hosp, Nonthaburi</td>
</tr>
<tr>
<td>40  Mr Surin Srimorrorrat</td>
<td>Drug Information, Pranangklao Provincial Hosp, Nonthaburi</td>
</tr>
<tr>
<td>41  Mr Pattipong Dissayadesh</td>
<td>Pranangklao Hospital, Procurement Pharmacist.</td>
</tr>
<tr>
<td>42  Pranisa Korron</td>
<td>Community Hospital Pharmacist, Lamluka District, Pratumthani Province</td>
</tr>
<tr>
<td>43  Mrs Sirigun Piriayon</td>
<td>Director, Ladsawai 1 HC, Lamluka District</td>
</tr>
<tr>
<td>44  Dr Khajorpong Tounwong</td>
<td>Doctor, Ladsawai 1 HC, Lamluka District</td>
</tr>
<tr>
<td>45  Somjit Phathaireagrunruang</td>
<td>Director, Ladsawai 2 HC, Lamluka District</td>
</tr>
<tr>
<td>46  Vipaporn Wangsaen</td>
<td>Nurse, Ladsawai 2 HC, Lamluka District</td>
</tr>
<tr>
<td>47  Luckchaya Surarnt</td>
<td>Nurse, Ladsawai 1 HC, Lamluka District</td>
</tr>
<tr>
<td>48  Virat Maluangmont Songermbhesaj</td>
<td>Pharmacist-Owner of Urat Mal Pharmacy, Pratumthani province</td>
</tr>
<tr>
<td>49  Sukhum Vivattipong</td>
<td>Deputy Managing Director, Government Pharmaceutical Organisation (GPO)</td>
</tr>
<tr>
<td>50  Somchai Srichalnak</td>
<td>Deputy Managing Director, GPO</td>
</tr>
<tr>
<td>51  Sit Thirapakchumanunt</td>
<td>Advisor (Expert) GPO</td>
</tr>
<tr>
<td>52  Chakkrit Prapaipittayakhum</td>
<td>Director Biological Products, GPO</td>
</tr>
<tr>
<td>53  Dr Onsiri Serirat</td>
<td>Deputy Director, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>54  Mr Aree Tongreian</td>
<td>Chief Pharmacist, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ms Weena Promprasert</td>
<td>Pharmacist, Inventory Section, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>Ms Amporn Huntrakul</td>
<td>Drug Information Service, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>Panyachat Gausukpaiboon</td>
<td>Pharmacist, Inpatient Section, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>Chidchonnee Kosolpanadurong</td>
<td>Pharmacist, Non-sterile compounding unit, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>Jirapurn Chidovit</td>
<td>Pharmacist, Sterile compounding unit, Rajavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>Dr Seroch Mekavothinkul</td>
<td>Deputy Director, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Mr Amnouy Praukpakpoon</td>
<td>Chief Pharmacist, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Ms Vanicha Piyaranathanawat</td>
<td>In-patient pharmacist, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Ms Janira Hunpradit</td>
<td>Out-patient pharmacist, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Mr Noppawoot Kittichayarak</td>
<td>In-patient pharmacist, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Ms Wanisa Sriroek</td>
<td>Out-patient pharmacist, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Ms Pranee Sangtanu</td>
<td>Procurement pharmacist, Samut Kakhon Prov Hosp</td>
</tr>
<tr>
<td>Ms Thitima Payaksiri</td>
<td>Warehouse pharmacist, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Dr Apichat Chutanunta</td>
<td>Internal Physician, Samut Kakhon Provincial Hospital</td>
</tr>
<tr>
<td>Anchalee Laddaglom</td>
<td>Chief Pharmacist, Krathum Baen Community Hospital, Samult Kakhon Province</td>
</tr>
<tr>
<td>Dr Apichat Charoenthumsukjui</td>
<td>Deputy Director, Krathum Baen Community Hospital</td>
</tr>
<tr>
<td>Mathee Sywannarak</td>
<td>Pharmacist, Krathum Baen Community Hospital</td>
</tr>
<tr>
<td>Hathaikan Kannapai</td>
<td>Pharmacist, Krathum Baen Community Hospital</td>
</tr>
<tr>
<td>Yaowanun Ponyaprateep</td>
<td>Pharmacist, Krathum Baen Community Hospital</td>
</tr>
<tr>
<td>Ms Tabtim Tongwijit</td>
<td>Bureau of Policy &amp; Strategy, Office of Permanent Secretary, MOPH</td>
</tr>
<tr>
<td>Mr Somlak Sirichunwijit</td>
<td>Bureau of Policy &amp; Strategy, Office of Permanent Secretary</td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>76 Niyada Kiatying-Angsulee</td>
<td>Director, Social Research Institute, Chulalongkorn University, Bangkok</td>
</tr>
<tr>
<td>77 Paitip Langruangrong</td>
<td>Pharmacist, DMSIC, Pharmacy Section, Office of Permanent Secretary, MOPH</td>
</tr>
<tr>
<td>78 Pornipimon Chankuanpars</td>
<td>Pharmacist, Pharmacy Section, Office of Permanent Secretary, MOPH</td>
</tr>
<tr>
<td>79 Chawalit Tantinimitkul</td>
<td>Formerly NPO WCO Thailand</td>
</tr>
<tr>
<td>80 Dr Maureen Birmingham</td>
<td>WR Thailand</td>
</tr>
</tbody>
</table>
Annex 2: Participants of Workshop on the Pharmaceutical Situation

<table>
<thead>
<tr>
<th>SN</th>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr Kathleen Anne Holloway</td>
<td>WHO SEARO</td>
</tr>
<tr>
<td>2</td>
<td>Dr Maureen E Birmingham</td>
<td>WHO Thailand</td>
</tr>
<tr>
<td>3</td>
<td>Mr Chawalit Tantinimitkul</td>
<td>WHO Thailand</td>
</tr>
<tr>
<td>4</td>
<td>Dr Mukta Sharma</td>
<td>WHO Thailand</td>
</tr>
<tr>
<td>5</td>
<td>Ms Patanong Jongsirielrd</td>
<td>Bureau of Health Administrative, Office of Permanent Secretary for Public Health, MoPH</td>
</tr>
<tr>
<td>6</td>
<td>Dr Pisonthi Chongtrakul</td>
<td>Committee to Promote Rationale Drugs Use</td>
</tr>
<tr>
<td>7</td>
<td>Ms Napaporn Puripanyawanich</td>
<td>Committee to Promote Rationale Drugs Use</td>
</tr>
<tr>
<td>8</td>
<td>Asst. Prof. Niyada Kiatying-Angsulee, PhD</td>
<td>Director Social Research Institute &amp; Chair Social Pharmacy Research Unit Chulalongkorn University</td>
</tr>
<tr>
<td>9</td>
<td>Ms Wimon Suwankesawong</td>
<td>Head of Health Product Vigilance Center (HPVC), Technical and Planning Division, FDA</td>
</tr>
<tr>
<td>10</td>
<td>Mr Sujint Kunraks</td>
<td>Department of Health, MoPH</td>
</tr>
<tr>
<td>11</td>
<td>Mrs. Netnapsis Suchonwanich</td>
<td>National Health Security Office (NHSO)</td>
</tr>
<tr>
<td>12</td>
<td>Ms Weena Promprasert</td>
<td>Rachavithi Hospital, Bangkok</td>
</tr>
<tr>
<td>13</td>
<td>Ms Chutima Jameekornikul</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>14</td>
<td>Ms Petcharat Pongcharoensuk</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>15</td>
<td>Ms Jittapak Boonson</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>16</td>
<td>Mr. Tharnkamol Chanprapaph</td>
<td>Drug Control Division Food and Drug Administration Ministry of Public Health</td>
</tr>
<tr>
<td>17</td>
<td>Mrs. Rumpai Kaewwician</td>
<td>Bureau of Policy and Strategy, MoPH</td>
</tr>
<tr>
<td>18</td>
<td>Dr Phusit Prakongsai</td>
<td>International Health Policy Program, Thailand (IHPP)</td>
</tr>
<tr>
<td>19</td>
<td>Dr Nithima Sumpradit</td>
<td>International Health Policy Program, Thailand (IHPP)</td>
</tr>
</tbody>
</table>
Annex 3: Slide presentation given by consultant to stakeholders in the 1-day workshop

Medicines supply and use in Thailand:
WHO mission: 17-31 July 2012
Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Background
- Irrational use of medicines in all countries of region
  - Increasing demand for medicines but limited budget in Thailand
- July 2010 regional meeting in SEARO attended by 9 countries, including Thailand
  - Recognised the need for a comprehensive health system approach to promote rational use of medicines
  - Recommended countries to undertake a national situational analysis to identify the major problems and possible solutions in order to develop a national action plan
- Regional Resolution: SEA/RC64/R5
  - Recommended countries to undertake national situational analyses & WHO to develop a tool for countries to do such analyses
- Situational analysis
  - Workshop to develop recommendations to incorporate into a national plan of action

Objectives of the workshop / debriefing
- Review the WHO fact finding results
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems
  - for use by MOPH, WHO, partners

Agenda of the workshop
- Presentation by WHO with discussion of findings, identification of main problems and possible solutions
- Discussion of solutions and development of recommendations for MOPH, WHO and partners to follow with regard to:
  - Drug supply and selection
  - Promoting rational drug use
  - Drug regulation
  - Drug policy and coordination

Mission 17-31 July, 2012
17 July: Pharmacy Section, Office of the Permanent Secretary, National sub-committee for RUM under National Drug System Development Committee with teams from Health System Research Institute & Faculty of Medicine, Chulalongkorn University.
18 July: FDA, MOPH Procurement officers; private drug store in Bangkok.
19 July: Medical & Pharmacy Councils, Dept Medical Services, MOPH.
20 July: NHBO; Health Centre and private drug store in Northaburi.
23 July: Royal College of Physicians of Thailand; Health Centre, District Hospital & private pharmacy store in Nonthaburi province.
24 July: Health Promotion hospital, Health Centre and private drug store in Phatthalung province.
25 July: Pra Nang Khao (Provincial) Hospital, Northaburi.
26 July: 17th International Social Pharmacy workshop, Phuket.
27 July: GPO, Rachavithi Hospital, Bangkok.
30 July: Provincial and community hospitals in Samut Sakhon province.
31 July: Workshop.

Mission findings
- Extensive health care system, with substantial infrastructure, trained health care personnel, universal coverage and good health indicators, but...
- Problems in the pharmaceutical sector concerning:
  - Drug use, information and coordination, but...
- Sufficient resources and capacity to address the problems
Drug Supply

• 100% essential drug availability in all facilities visited
• Decentralised Drug Procurement:
  – Purchase by individual hospitals, often weekly
  – Community Hospitals purchase on behalf of Health Centres
  – Pooled procurement for some drugs in provinces & regions
  – Some high risk costly drugs supplied centrally by NHSO
• Purchase with govt funds according to MOH regulation
  – from GPO if possible – so allowing economies of scale
  – include 70-100% drug items from EDL – depending on hosp level
  – be at or below the median reference price
  – according to 3-year procurement plan approved by Hosp Director
  – allow for buffer stock of 3 months at province & 1-month at district
  – all procurement orders sent to MOH for price monitoring
• Funds for purchase received from:
  – NHSO, SSS (MOL) and CSMBs (MOF) at central level
  – Fee for service from patients with private or no insurance

Drug Supply problems

• Many hospitals have difficulty to stay within the regulations concerning EDL drugs
  – Use revenue from private insurance, out-of-pocket payments, and
  – CSMBs to purchase non-EDL drugs
• Monitoring by Pharmacy Section of Office of Permanent Secretory MOH is mostly based on
  hospital summary reports only and is under-resourced
  – Half hospitals do not send actual procurement data & Pharmacy
    Section does not have the capacity to demand that they do so
• Un-harmonized electronic drug inventory systems
  – creates increased communication difficulties between GPO &
    hospitals for stock management and between Pharmacy Section
    & hospitals for monitoring procurement prices
• Some duplication of effort and info not shared
  – MOF as well as MOH is monitoring procurement prices of drugs
  – ABC analysis can be done easily on existing computer systems in
    most facilities but the info is not shared with Pharmacy Section

National Health Security Office (NHSO)

• Covers 48 million people (74% population)
• Allocates funds on a per capita basis to hospitals
  based on their registered populations and covers:
  – Outpatient treatment based on use of essential drugs
  – Inpatient treatment based on disease related group (DRG) costs
  – Prevention & Promotion
• On-top cash payments to hospitals
  – to treat high cost specific diseases e.g. haemophilia, HIV, cancer
  – For good performance e.g. antibiotic control
• Requires internal accounting between hospitals
  – The health facility where the patient is registered must pay cash
  – outpatient treatment given by another hospital after referral
  – The budget for inpatient treatment is kept centrally at the NHSO &
    distributed according to “claims” made by the treating hospital
  – Un-referred patients registered with another facility must pay cash

Other insurance

• SSS
  – Covers outpatient and inpatient treatment for 10 million private
    sector employees
  – 3% of salary automatically deducted & co-payment sometimes
    required
  – Per capita allocation of funds to selected hospitals which claim
    costs from Ministry of Labour
• CSMBs
  – Covers all treatments in any hospital of 5 million civil servants
  – 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
  – Patient pays cash and gets reimbursed by his/her insurance
• Uninsured persons
  – Includes 4% of the population who must pay out-of-pocket

National Essential Drug List (NEDL)

• National Essential Drug List (NEDL) updated annually
  – On the web, but was last printed in 2008
  – 749 chemical entities – more than double the number on the WHO
    model list - with 5 categories:
    – A/B for primary care;
    – C/D for use by well trained doctors approved by the hospital director;
    – E1/E2 (high cost/risk drugs & govt projects) for senior specialist use
• Selection process
  – 17 national expert panels select and propose
    drugs based on selection criteria of health needs, efficacy, safety,
    compliance and quality
  – Screening working group coordinates results from 17 working groups
  – Health Economic Working group examines proposed drugs for cost-
    effectiveness, equity & national affordability
  – Sub-committee for NEDL makes the final decision
  – “Problems of lobbying & approval of too many high-priced drugs”
Use of the NEDL

- Government promotes use of Essential Drugs
  - MOPH regulations require that 70-100% of procured items belong to the NEDL and that 60-90% of budgets are spent on EDL drugs
  - NHISO and SSS promote use of EDL drugs by budget allocations

- Public hospital formularies
  - All public hospitals have Drug and Therapeutic Committees that develop their own formularies that include both EDL and non-EDL drugs
  - All hospitals have difficulty to comply with procurement regulations on essential drugs
  - half of provincial and regional hospital budgets may be spent on non-EDL drugs
  - possible under-reporting of low volume non-EDL drug items to Pharmacy Section in MOPH

Possible solutions for selection / NEDL

- Harmonize electronic inventory management system in all hospitals
  - To ease reporting to the Pharmacy Section, MOPH

- 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-EDL drugs

- Work towards reducing the number of EDL drugs
  - Consider differential reimbursement for vital, essential & non-essential drugs & co-payments for non-EDL drugs
  - Consider separation of the NEDL & reimbursement lists

- Promote understanding of the Essential Drugs Concept
  - Feedback local consumption data to prescribers
  - Should be done by DTCs

Top 20 (2%) drugs items by value (Baht) 2011

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Value</th>
<th>Drug Name</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ezetimibe 10mg</td>
<td>6,407,433</td>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
</tr>
<tr>
<td>Amlodipine 5mg</td>
<td>4,511,634</td>
<td>entacapone 200mg</td>
<td>4,640,359</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>meropenem 1g inj</td>
<td>4,670,550</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>manidipine 20mg</td>
<td>4,640,359</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>eritapenem 1g inj</td>
<td>4,511,634</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>irbesartan 300mg</td>
<td>4,573,615</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>simvastatin 20mg</td>
<td>4,511,634</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>pioglitazone 30mg</td>
<td>4,511,634</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>valsartan 160mg</td>
<td>4,511,634</td>
</tr>
<tr>
<td>valsartan 160mg+</td>
<td>6,425,858</td>
<td>atorvastatin 20mg</td>
<td>4,511,634</td>
</tr>
</tbody>
</table>

Top 20 (3%) drugs items by value (Baht) 2011-12

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Value</th>
<th>Drug Name</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcitonin 200 IUspray</td>
<td>1,216,988</td>
<td>irbesartan 300mg</td>
<td>1,234,352</td>
</tr>
<tr>
<td>Tamsulosin 0.4mg</td>
<td>1,234,352</td>
<td>tazocin 4.5g inj</td>
<td>1,234,352</td>
</tr>
<tr>
<td>Simvastatin 20mg</td>
<td>1,234,352</td>
<td>pregabalin 75mg</td>
<td>1,234,352</td>
</tr>
<tr>
<td>Seretide 25/125 inhaler</td>
<td>1,234,352</td>
<td>celecoxib 200mg</td>
<td>1,234,352</td>
</tr>
</tbody>
</table>

Drug use indicator prescription survey

<table>
<thead>
<tr>
<th>Drug use indicator</th>
<th>Referral hospital</th>
<th>Community hospital</th>
<th>Health Centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ar. no. drugs / patient</td>
<td>4.13</td>
<td>3.25</td>
<td>2.74</td>
</tr>
<tr>
<td>% patients with Antibiotics</td>
<td>23.1</td>
<td>44.6</td>
<td>28.5</td>
</tr>
<tr>
<td>% patients with Infections</td>
<td>5.5</td>
<td>3.1</td>
<td>5.3</td>
</tr>
<tr>
<td>% patients with Vitamins</td>
<td>18.3</td>
<td>9.6</td>
<td>14.2</td>
</tr>
<tr>
<td>% URTI cases with AB</td>
<td>62.4</td>
<td>73.6</td>
<td></td>
</tr>
<tr>
<td>% prescribed generic drugs</td>
<td>67.4</td>
<td>87.9</td>
<td>91.8</td>
</tr>
<tr>
<td>% prescribed EDL drugs</td>
<td>78.3</td>
<td>84.2</td>
<td>84.3</td>
</tr>
<tr>
<td>Ar. drug cost / Px (Baht)</td>
<td>1145.26</td>
<td>82.58</td>
<td>63.32</td>
</tr>
</tbody>
</table>

Some common practices observed:

- Common cold cases
  - Many cases receive bromhexine (non-EDL), antihistamine (chlorpheniramine, cetirizine, cinnarizin [non-EDL], paracetamol & antibiotic + vitamin B Complex, Multivitamin, Vitamin B1 & 6-12 [non-EDL])
- Aches & pains
  - Many cases receive 2-3 analgesics: paracetamol/artistin and diclofenac/ibuprofen and analgesic balm + tolperisone (non-EDL) or norgesic (non-EDL)
- Hypertension
  - Use of torazepam & alprazolam

- Hospital OPD
  - Cash-paying or CSMBS patients compared to NHSO patients receive fewer EDL drugs (69% vs 87%), fewer generics (60% vs 75%) at greater cost (1768 Baht vs 523 Baht)
Drug use policies

- Private practice prescribing
  - Much prescribing for simple diseases is done by community pharmacists who are often unfamiliar with the NEDL.
  - Many doctors practice privately in evenings, dispensing drugs.
- Standard Treatment Guidelines
  - Department Medical Services, MOPH, has produced STGs for about 50 diseases but experiences difficulty harmonizing between various stakeholders & their STGs are sometimes not harmonized with NEDL & often not used by teaching hospitals or doctors.
  - Royal College of Physicians has STG working group by Cabinet order.
- Hospital Drug & Therapeutic Committees
  - Meet regularly to discuss the formulary & non-EDL drug purchase.
  - DUE on high cost non-EDL drugs but not on general prescribing.
  - Electronic databases with diagnosis & treatment data in all facilities but only used for reporting morbidity, not drug use.
- Drug promotion
  - Frequent pharmaceutical representatives visits to doctors & pharmacists in both public & private sectors.

Possible solutions for improving use (1)

- Monitor drug use
  - ABC analysis, prescription audit, feedback for outpatient as well as inpatient care - by hospital DTCs.
  - May use the existing hospital electronic patient databases & report on selected drug use indicators to MOPH.
  - Could be integrated into the existing reporting system to Bureau of Policy & Strategy, MOPH, via the provincial health offices.
- Standard Treatment Guidelines
  - Develop national STG for primary & secondary care.
  - Disseminate STG directly free of charge to every doctor.
  - Incorporate STGs into undergraduate & continuing medical education.
- Expand the role of DTCs
  - To monitor prescribing, encourage continuing medical education, and report annually on activities to MOPH.
  - Requires strengthening the MOPH to review the reports.
  - Consider including DTC activities in hospital accreditation.

Drug use policies

- Undergraduate education
  - Doctors: Pharmacology taught in pre-clinical studies but little patient-based pharmacy teaching & prescribing taught by senior clinicians who often do not follow the NEDL, or STGs.
  - Pharmacists: Prescribing for simple conditions is taught and clinical pharmacy attachments could provide good practical experience, but the NEDL and STGs may not be used.
- Continuing Medical Education
  - Doctors/pharmacists: Not obligatory and topics are chosen on an ad hoc basis, often in association with sponsored meals or conferences, & there is a lack focus on rational use of medicines.
  - Nurses: Some refresher training is provided by MOPH but there may be a lack of focus on rational prescribing.
- Community / public education
  - Any nationwide public education campaigns on drug use done?
  - Any use of village health volunteers (under Dept of Health Service Support) to spread messages to communities on safe & prudent medicines use?

Possible solutions for improving use (2)

- Continuing professional development (CPD)
  - Thailand Medical & Pharmacy Councils to consider developing a credit system for continuing medical education & making CPD obligatory for re-licensing.
  - Curricula should include prescribing & essential drugs concept.
  - Medical & pharmacist associations could promote the essential drugs concept through the lectures they organise.
- Strengthen clinical pharmacology & pharmacy
  - Establish post-graduate studies on clinical pharmacology & clinical pharmacy and encourage these students to analyse drug consumption and do prescription surveys.
- Public Education
  - 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 the Village Health Volunteers, schools, NGOs & the media and insurance companies could pay for this.

Educational drug use policies

- Undergraduate education
  - Doctors: Pharmacology taught in pre-clinical studies but little patient-based pharmacy teaching & prescribing taught by senior clinicians who often do not follow the NEDL or STGs.
  - Pharmacists: Prescribing for simple conditions is taught and clinical pharmacy attachments could provide good practical experience, but the NEDL and STGs may not be used.
- Continuing Medical Education
  - Doctors/pharmacists: Not obligatory and topics are chosen on an ad hoc basis, often in association with sponsored meals or conferences, & there is a lack focus on rational use of medicines.
  - Nurses: Some refresher training is provided by MOPH but there may be a lack of focus on rational prescribing.
- Community / public education
  - Any nationwide public education campaigns on drug use done?
  - Any use of village health volunteers (under Dept of Health Service Support) to spread messages to communities on safe & prudent medicines use?

Drug Regulatory Issues

- Extensive pharmacovigilance.
  - Excellent drug testing laboratory (WHOCC) that regularly tests samples.
- Product registration is for life.
  - Too many brands on the market (>100 brands of paracetamol, >40 brands of amoxicillin & chlorpheniramine).
- Drug schedules allow many drugs (including new generation ABIs) to be sold by pharmacists without doctor’s prescription.
  - A prescription-only drug schedule is opposed by both doctors & pharmacists.
- Too few provincial staff to regularly inspect drug stores.
  - Pre-approval of drug adverts done but insufficient monitoring of other drug promotional activities.
Possible solutions to improve regulation

- 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
- Monitor drug promotional activities in collaboration with MOPH & professional bodies & councils
  - Consider banning medical representatives from public facilities except by appointment with the DTC
  - Ban inappropriate financial incentives or promotional holidays
  - Require companies to disclose their marketing activities and budgets
- Publish information on website on drug testing results
  - to convince prescribers about drug quality
- Increase staff at provincial health offices
  - to inspect drug stores, monitor drug promotion and post-marketing surveillance
- Consider making the FDA semi-autonomous

Coordination: 
Committees & working groups

- National Drug Systems Development Committee
  - Several subcommittees including ones on RUM, NEDL
- Cabinet Working Groups
  - 6 official & 3 unofficial subgroups on: Promotion of NEDL & generic drugs, Price negotiation for non-EDL drugs; National drug codes; Disease Related Group; STGs; Audit; Antimicrobial resistance, Traditional Medicine, RUM
- Royal College of Physician Working Groups on guidelines
  - Subgroups on: Evaluating drug use; Standards of clinical care; Promoting RUM; Medical supplies & Reimbursement
- Risk of duplication of effort & inconsistency of recommendations

National Drug Policy

- 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
  - **Development of 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

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, Thai Food & Drug Administration, Medical Sciences (rare drug testing lab), Thai Traditional Medicine, Health Services Support, Mental Health
  - Departments do not always 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 municipal authorities or other agencies & do not follow MOPH rules
- Five semi-autonomous bodies
  - NHSO, Health System Research Institution (HSRI), Health Promotion Funds, National Health Committee, Emergency Medical Institute of Thailand
  - Each body develops health policy or undertakes research

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 departments in MOPH (Pharmacy Section in Office of Permanent Secretary, FDA, Bureau of Policy & Strategy) etc
  - To be responsible for rational use of drugs: NEDL, STGs, DTCs, monitoring drug use, CPD, public education
  - Streamline the committees & invest in their advice

Group Discussion

- Discussion to draft recommendations with practical steps including:
  - Who will do it?
  - Resources needed?
- Topics:
  - Drug supply and selection
  - Promoting rational drug use
  - Drug regulation
  - Drug policy and coordination