

Myanmar

Drug Policy and Pharmaceuticals in Health Care Delivery

Mission Report 19-26 October 2011

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Programme Agenda

Wednesday, 2011, Oct 19th

Morning: Arrive Yangon, Briefing with WR,
New Yangon General Hospital,
Afternoon: Central Medical Store Depot.

Thursday, 2011, Oct 20th

Morning: Myanmar Medical Association and Myanmar Medical Council,
Pharmacology Department of University of Medicines I,
Afternoon: Kungyangon Township Hospital, Daidanaw Sub-Centre,
Nat Sin Gone Rural Health Centre.

Friday, 2011, Oct 21st

Morning: Tharawaddy District Hospital,
Afternoon: Nagaphyugalay Rural Health Centre,
Tha Phyu Sub-Centre.

Saturday, 2011, Oct 22nd

Morning: Select Private Pharmacy & wholesaler, AA Private Pharmacy,
and Thet Paing Soe
Afternoon: Yangon General Hospital.

Sunday, 2011, Sept 23rd

Morning: Yangon to Nay Pyi Taw
Afternoon: Planning meeting for workshop with Dr Thida Hla.

Monday, 2011, Oct 24th

Morning: Department of Health and Essential Drugs Program, MOH,
Myanmar Food and Drug Administration Department
Afternoon: Leiway Township Hospital,
Tha Byay Pin Rural Health Centre.

Tuesday, 2011, Oct 25th

Morning: Presentation of findings by Dr. K.A.Holloway;
Plenary discussion of findings and group work;
Afternoon: Presentation of group work;
Plenary discussion of group work;
Development of recommendations.

Wednesday, 2011, Oct 26th

Nay Pyi Taw - Yangon

Thursday, 2011 Oct 27th

Morning: Myanmar – Delhi

Acronyms

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AHW	Auxiliary Health Worker
ANM	Auxiliary Nurse Midwife
CPD	Continuing Professional Development
CME	Continuing Medical Education
CMSD	Central Medical Store Depot
DoH	Department of Health
DIC	Drug Information Centre
DHO	District Health Officer (doctor)
DPHO	District Public Health Office
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committees
EDL	Essential Drug List
EDP	Essential Drug Programme
EML	Essential Medicines List
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
HA	Health Assistant
HQ	Headquarters
HP	Health Post
HPIC	Health Post in Charge
IPD	In Patient Department
LMIS	Logistics Drug Management Inventory System
MFDA	Myanmar Food and Drug Administration
MIC	Medicine Information Centre
MMA	Myanmar Medical Association
MMC	Myanmar Medical Council
MO	Medical Officer (doctor)
MOH	Ministry of Health
MPF	Myanmar Pharmaceutical Factory
MRA	Medicines Regulatory Authority
MTC	Medicines and Therapeutic Committee

NGO	Non-Governmental Organization
NDP	National Drug Policy
OPD	Out Patient Department
OTC	Over-The-Counter
RHC	Rural Health Centre
RUM	Rational Use of Medicines
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
VEN	Vital Essential Non-Essential – method for classifying drug importance
WHO	World Health Organization

Executive summary

A visit was made to Myanmar during October 19-26, 2011. The programme was arranged in agreement with the MOH to undertake a rapid situational analysis of the pharmaceutical situation - with a focus on medicines policy, health care delivery and use of medicines, and to conduct a 1-day workshop with national stakeholders. The workshop objectives were to: (1) review the findings of the WHO situational analysis, (2) identify the main priority problems, (3) formulate recommendations for medicines policy to address the problems, and (4) facilitate development of plans to review the national medicines policy and implement the policies recommended. Visits were made to public health facilities and private pharmacies in the Yangon and Nay Pi Taw Regions, the major MOH departments (including the Department of Food and Drug Administration), the clinical pharmacology department in the University of Medicine I, two university teaching hospitals, the Myanmar Medical Council and Association and the Myanmar Academy of Medical Sciences. It was found that Myanmar has an extensive health care system with trained health care personnel. However, there are a number of serious problems in the pharmaceutical sector concerning drug supply, selection, use, regulation, policy, information and coordination, as highlighted below, but there are sufficient resources and capacity to address many of the problems.

Drug Supply and selection

Medicines are supplied by the Central Medical Store Depot (CMSD), Department of Health, Division of Medical Care, MOH, to all public health care facilities. A 'push' system is used from the central level down to the district/township, drugs originally being supplied according to the number of facility beds but recently according to the previous year's consumption.

Since government expenditure on general drugs is less than 0.2 USD/capita/year, drugs cannot be supplied according to need and there are very frequent stock-outs such that CMSD drugs last only one month and are only used only for the very poor people. All other patients have to pay out-of-pocket for their drugs, either in private pharmacies or directly from health workers who purchase drugs from pharmacies themselves in order to sell to patients. There is a national Essential Medicines List (NEML) 2010 but due to budgetary constraints the CMSD is able to supply less than half the drugs on the NEML.

Referral hospitals generally have one or more private pharmacies operating within the hospital compound and doctors prescribe many non-EML drugs and by brand name. Most

pharmacies, particularly at district and township level, but even sometimes at the tertiary referral level, were managed by non-pharmacists. A manual system of drug inventory control was used and no monitoring of consumption was done.

It was recommended that an electronic logistic management inventory system be established at central, referral hospital and township level to improve stock control and quantification and that the CMSD publish an ABC analysis of consumption data annually. It was also recommended that the NEML be revised with drugs categorized by level of health facility and that each district and each referral hospital employ a pharmacist to manage drug supply, distribution and quantification and to monitor adherence to the NEML.

Drug use

Only a handful of drug use surveys done more than 10 years ago were identified. The consultant observed that prescribing was similar to what was previously published. High vitamin use was observed in all facilities and very high use of antibiotics for upper respiratory tract infection in all district/township level facilities. In tertiary facilities there was high use of non-EML drugs and prescribing by brand name. Although national standard treatment guidelines exist, few prescribers were using them or other sources of independent drug information. However, prescribers in the private sector and in tertiary hospitals were receiving pharmaceutical representatives on a daily basis. While, prescribing principles are taught at undergraduate pre-clinical level, this knowledge is later undermined by clinical studies and later work. Continuing Professional Development (CPD) is adhoc and does not include much on rational use of medicines. The MOH provides refresher training for government staff and the Myanmar Medical Association has developed a refresher course for private GPs. No hospitals have functional DTCs or undertake any prescription audit. There is no National Drug Information Centre.

It was recommended that a unit dedicated to regular monitoring of medicines use and implementing strategies to improve use be created within the MOH. This could be done by strengthening the Essential Drug Program. Other interventions recommended include: establishing Drug and Therapeutic Committees (DTCs) in all hospitals and requiring them to monitor drug consumption and report annually to MOH; establishing a National Drug Information Centre, distributing updated clinical guidelines and incorporating them into undergraduate and Continuing Professional Development (CPD) curricula; and developing public education programs on medicines use to be delivered through the sub-centre and rural health centre health workers.

Drug Regulation

The Myanmar Food and Drug Board of Authority (MFDBA) is highest authority of Food and Drug Regulations. The Myanmar Food and Drug Administration (MFDA) under the Department of Health (DoH) is responsible for enforcing the National Drug Law. Currently, the MFDA has no website. The MFDA has 42 technical staff to manage a sector consisting of 13,000 registered products, 7 manufacturers, more than 170 importers/wholesalers and 10,000 retail pharmacies (which require a pharmacist on the premises if they sell narcotics or a graduate if not). The MFDA relies on Food and Drug Supervisory Committees with local representation (but often no pharmacist) to inspect drug outlets as it has insufficient staff itself. Prescription-only drugs are often sold without prescription and many drugs are dispensed by unqualified personnel. There are many brands for the same active pharmaceutical ingredient available on the market so making inspection and supervision more difficult.

The MFDA does not undertake pharmacovigilance, leaving this to the Department of Medical Research (which reported 3 ADRs last year) and it is unable to actively monitor pharmaceutical drug promotion due to resource constraints. The MFDA has its own drug testing laboratory and tests several hundred samples per year but does not have the capacity to do all the testing that it feels is necessary. Drug registration is done manually and the problem of too many brands was recognized. However, the MFDA has difficulty to refuse registration of new brands of me-too molecules already existing on the market due to government policy not to refuse registration of me-too products that are produced according to GMP.

It was recommended that the manpower shortage be rectified as a matter of urgency; that the Standard Operating Procedures (SOPs) be revised for the various procedures and committees; that an electronic drug registration system be instituted and that staff be further trained on dossier evaluation for registration; that mechanisms aiming to reduce the number of me-too drugs registered be explored; that a unit be established to monitor all drug promotion activities; that the Drug Testing Laboratory be strengthened; and that a pharmacist be employed in each township/district to work with the F and D Supervisory Committees to enforce regulation.

Coordination

Many functions such as monitoring of medicines use, coordinating CPD, supporting DTCs, ensuring adherence to the NEML, implementing guidelines through wide distribution and incorporation into CPD and undergraduate curricula, and public education on medicines use are not undertaken by any MOH department. The National Drug Policy document, while

comprehensive, is not implemented in many aspects and the government wishes to update it and develop an implementation plan.

It was recommended that (1) a multidisciplinary mandated independent statutory committee (possibly a reformed Food and Drug Board of Authority) reporting directly to the Secretary of State or Minister of Health be established and (2) an executive unit (possibly a strengthened Essential Drug Program Division in the MOH) be established to carry out the recommendations of the statutory committee and to monitor medicines use and coordinate the implementation of strategies to improve use.

Terms of Reference

The objectives were:

- (1) to meet senior officials of the Myanmar Ministry of Health (MOH).
- (2) to undertake a rapid situational analysis of the pharmaceutical situation - with a focus on medicines policy, health care delivery and use of medicines.
- (3) to conduct a 1-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;
 - d) facilitate the development of plans to review the national medicines policy and implement the policies recommended.

Background

This mission was undertaken to conduct a national situational analysis with regard to the pharmaceutical sector and national medicines policy in order to aid MOH 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, SE/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 19-26 October, 2011, 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 1-day workshop with more than 80 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.

Myanmar has an extensive health care delivery system. Part of this health delivery system includes delivery of medicines, free to the patient, in the public sector. However, government has insufficient funds to supply the required quantity essential medicines to health facilities, which have been reporting many stock-outs. In addition, there have been concerns about irrational use of medicines. For these reasons and the prospect of a more liberal market in the future, the government is now wishing to update its National Drug Policy of 2001 and form an implementation plan. Therefore, the situational analysis was undertaken. It is hoped that the recommendations made will be incorporated into future plans of action. The words “medicine” and “drug” are used interchangeably in this report.

Medicines Supply

Drugs are procured and distributed by the Central Medical Store Depot (CMSD) of the Division of Medical Care under the Department of Health within the MOH and distributed to government health facilities. Government facilities consist of referral hospitals, district hospitals (100 beds), township hospitals (25-beds), station hospitals (16 beds), rural health centres and sub-centres (no beds). It is the policy that medicines are dispensed free of charge to patients in the public sector but in practice, medicines supplied by the CMSD cover so little of the need and are finished so quickly that they are generally reserved for use by poor patients, all other patients buying medicines from outside pharmacy shops. The structure of the services is such that within each township there is one township hospital under which there is 1-2 station hospitals and 3-4 RHCs, under each of which are 4-5 sub-centres.

Quantification

Public purchase by the CMSD is based on the past 3 year's consumption, 70% from government facilities (mostly Myanmar Pharmaceutical Factory – MPF) and 30% from outside companies. The central budget allocation has been estimated for each health facility according to the number of beds of the facility and past usage. Although drugs may be requested by facilities in practice allocated drugs are “pushed” from the centre to district level. The problem with this method is that it greatly under-estimates the need as there are very frequent stock-outs. In addition, the government budget has not covered the request of the CMSD.

It was estimated that government expenditure on general drugs (excluding the various vertical programs e.g. HIV/AIDS, TB, malaria) in 2010 was less than USD 0.2/capita/year – well below what is recommended by WHO. Furthermore, only 92 out of 341 items on the National List of Essential Medicines were procured. A further problem is that there is no electronic management inventory control system and no analyses of consumption e.g. ABC analysis has never been done.

Distribution

Medicines are distributed from the centre to the concerned facility – twice a year for hospitals and once a year for Rural Health Centres and sub-centres. It was mentioned by some RHCs and sub-centres that antibiotics such as cotrimoxazole and amoxicillin had not been supplied for over 2 years. Until recently a revolving drug fund operated in all health facilities whereby drugs were charged to patients and the funds received used to purchase medicines.. One of the reasons given for failure was that health facilities were constrained to

buy generic drugs from Yangon and the price of these was more expensive than what could be purchased locally. Now, most patients must buy their medicines from pharmacy shops. However, in some RHCs and sub-centres with no pharmacy nearby, the health worker is buying medicines from the nearby town and selling them to patients in the health facility. There is weak supervision of this process and it was noticed that not all such purchased medicines were on the national EML for the level of facility concerned. Only in Leiway Township hospital, in Nay Pi Taw province was an official revolving drug fund still operating – but for 71 drugs only, not for the 100 or so items supplied by the CMSD or for another 25 items supplied by various projects. It was noticed that some tertiary hospital category drugs (e.g. tranexamic acid) and non-EML drugs (e.g. multivitamin infusion, Zinc+B Complex tablets) were being used at township level and the system of supervision was unclear.

It was generally observed that many drugs were out of stock, i.e. not on the CMSD shelves, in many health facilities, particularly antibiotics (e.g. amoxicillin, cotrimoxazole, metronidazole, tetracycline, chloramphenicol), contraceptives and paracetamol. Also some drugs not supplied by the CMSD for the concerned category of health facility were available in some health facilities. For example, norfloxacin, ciprofloxacin, amlodipine and ranitidine tablets were available at some sub-centres (bought by the health worker locally). In hospitals many non-EML drugs were prescribed (e.g. roxithromycin, multivitamin infusion, Zinc+BComplex tablets) and in some district/township hospitals complementary medicines recommended for the tertiary level (e.g. atorvastatin, levofloxacin) were also prescribed.

Procurement

Central procurement is done by tender for the 30% of drugs not procured from the Myanmar Pharmaceutical Factory (MPF). The procurement committee consists of the Director General of the Department of Health, the Director of the Myanmar Food and Drug Administration, Deputy DG of the division of Medical Care, the Chief of the CMSD and the Director of Finance within the MOH. The vertical disease control programs and other projects procure and distribute their own medicines and store them separately in their own warehouses.

This lack of a wider outside membership in procurement decisions means that the procurement system is open to undue influence from various sources when choosing bids. It is not clear how many manufacturers are actually involved in the tendering since there are only a few operating in Myanmar. However, it was mentioned that local manufacturing capacity is insufficient and that the government is planning to encourage outside factories to start up in Myanmar. If this were to occur, it would be important to have a wider

representation on the procurement committee. Where local purchase occurs, it is decided upon by the Medical Superintendent in consultation with the other doctors. At RHC and sub-centre level, any purchase is done by the health worker from local pharmacy shops.

Human resources

It was noted that there was no pharmacist in many hospitals, townships or districts. Often the duties of managing the drug store fell to a non-pharmacist. Myanmar produces 100 graduate pharmacists per year but only 10% find employment in the public sector. Even the CMSD only has a few pharmacists, most of whom are in junior positions. However, the activities of drug procurement, quantification, storage and distribution involve technical activities that only pharmacists have been trained to undertake – particularly at the central, provincial and district levels. Furthermore, there is a need for monitoring of drug consumption, prescription audit and supervision of drug management in all facilities from sub-centre to district/township level. Currently this is not done but could be done by a trained pharmacist based at district/township level.

Possible Solutions

1. Strengthen the CMSD:
 - to produce annual report on consumption with analysis;
 - To establish an electronic inventory management system to allow (1) better estimation / forecasting of drug need and stock control, and (2) ABC analysis of consumption for feedback to prescribers.
2. Employ at least 1 pharmacist per district & per referral hospital:
 - to be in charge of drug storage, distribution, procurement & quantification and to monitor consumption – all of which are all technical functions.
3. Increase the budget for general drugs from less than 0.2 USD/capita/year to at least 2.0 USD/capita/year.

Medicines Selection and Consumption

Myanmar published the 6th edition of its National Essential Medicines List (NEML) subdivided by tertiary level and other levels in 2010. The current list contains 341 essential medicines (including complementary anti-neoplastic agents). Unlike previous lists, the revised list has not been sub-divided by level of facility beyond a division between the tertiary level and all other levels below the tertiary level. There are also complementary drugs which are defined as those requiring the presence of specialists or specialist diagnostic equipment.

This lack of categorization by level of facility is a disadvantage because it no longer distinguishes which types of health worker can use which types of drug. It was observed that drug use is similar between different levels of health facility below the tertiary level. The Essential Drug Program (EDP) under the Division of Medical Care coordinated the development of the NEML. There was a core NEML committee consisting of the Deputy Director Generals, respectively, of the Divisions of Medical Care, Public Health, Disease Control, CMSD, MFDA, plus one physician and one surgeon. The chief of the EDP unit was the secretary of this core committee. It is not clear how many other experts, if any, were involved in development process.

The selection criteria used are not publicly available. Lack of transparency concerning the experts involved and the criteria used for selection may result in doctors not giving much credence to the NEML.

As mentioned previously, the CMSD procures a subset of 92 drugs from 341 essential medicines in the 2010 NEML, for use mostly by very poor patients in the public sector. In most hospitals, patients must go outside to purchase medicines. However in the tertiary referral hospitals visited in Yangon, one private pharmacy operated in the 220-bedded New Yangon General Hospital (4 specialties) and 4 private pharmacies operated in 1500-bedded Yangon General Hospital (25 specialties) premises. A non-pharmacist was in charge of the pharmacy in New Yangon General Hospital. There was no Drug and Therapeutic Committee in either hospital. Each pharmacy stocked more than 2000 items, according to whatever drugs and brands the hospital doctors chose to prescribe. In one of the pharmacies there were 11 different brands of cefixime. Yangon General Hospital mentioned that most CMSD drugs are used for primary health care problems in staff.

Table 1 shows the top 20 general drugs procured from the Myanmar Pharmaceutical Factory (MPF) and other sources by the CMSD in 2010. This procurement list only covers about 62% of the total purchase and does not include specialist hospital drugs and drugs used by the vertical disease control program drugs. It can be seen that out of 97 items the top 20 drug items (20.6% items) consume 68.8% of the budget. It was also found that antibiotics consume 15.8% of the budget and vitamins 18.8% of the budget. Of all vitamin expenditure 46.3% was on multivitamins and vitamin B Complex. Thus expenditure on vitamins and antibiotics is high. Three of the top 20 items are not on the NEML. The supply of non-EML drugs (e.g. multivitamin infusions and roxithromycin) by the CMSD undermines efforts to persuade specialist doctors to follow the NEML.

Table 1: Top 20 drugs procured in 2010 by CMSD

SN	Drug Name	Amount (Kyat)	% of budget
1	Inj ASV Viper (Liq)	75 000 000	9.8%
2	Tab Ethambutol 400mg	57 960 000	7.6%
3	Oral Rehydration Salts 20.5gm	42 000 000	5.5%
4	Dextrose 5% solution x 500mls	40 500 000	5.3%
5	Tab Chlorofos*	30 618 000	4.0%
6	Water for injection x 5ml	29 948 233	3.9%
7	Tab Paracetamol 500mg	28 175 000	3.7%
8	Tab Vitamin B Complex (Burplex)	28 000 000	3.7%
9	Tab Vitamin B1 10mg (Bevit)	24 176 000	3.2%
10	Dextrose 5% in Sodium Chloride 0.9% solution 500ml	22 500 000	2.9%
11	Tab Vitamin C (Cevit)	19 500 000	2.6%
12	Inj Artemether	19 383 000	2.5%
13	Inj Streptomycin Sulphate x 10ml	17 354 742	2.3%
14	Tab Vitamin A + B Complex (Vitazone)*	17 224 000	2.3%
15	Cap Doxycycline 100mg	16 500 000	2.2%
16	Tab Vitamin B2 (Ribovit)	12 310 000	1.6%
17	Dextran-40 500mls	11 650 000	1.5%
18	Tab Iron and B Complex (Furamin BC)*	11 040 000	1.4%
19	Tab Folic Acid	10 712 500	1.4%
20	Ringer Lactate Solution x 500mls	10 500 000	1.4%
21	Subtotal of top 20 drugs	525 051 475	68.8%
22	Other drugs	237 718 720	31.2%
Total budget		762 770 195	100%

* Non-EML drugs

A prescription audit (see section on rational use) found that the proportion of prescribed drugs belonging to the NEML was 59% in drug retail shops (reflecting private practice), 62% in tertiary hospitals, 94% in district/township hospitals and 98% in RHCs and sub-centres. These results show that the NEML is followed by the districts, townships and primary care facilities to a large extent but not so much by the specialist hospital doctors or doctors in private practice.

It was also found that, within the public sector, many doctors in district/township hospitals were prescribing drugs recommended for tertiary level use (e.g. tranexamic acid) and that many non-doctor health workers in RHCs and sub-centres were prescribing some drugs (e.g. norfloxacin, ciprofloxacin, amlodipine and ranitidine) that one might expect only doctors to prescribe, although there is now no distinction of drugs for different categories of health worker or facility at district level or below.

Possible solutions

1. Ensure consistency between the NEML, other lists such as that used by CMSD and National Standard Treatment Guidelines.
2. Require stricter adherence to the NEML by tertiary referral hospitals:
 - Referral hospitals should develop their own formularies from within the NEML, monitor adherence and justify the quantity of non-EML drugs used (which should not normally be more than 10-20% of the budget);
 - Drug and Therapeutic Committees or specialist boards, established by specialist associations, could provide guidance on what specialist non-EML drugs are reasonable to purchase.
3. Continue to regularly update the NEML and increase the transparency and inclusiveness of the process to improve acceptability to prescribers by:
 - Publishing the selection criteria and the list of experts involved in the selection process;
 - Categorizing drugs by level of facility and/or level of prescriber to ensure that drugs are prescribed by prescribers who are trained to use such medicines.
4. Improve use of the NEML by:
 - Widely disseminating the NEML to all facilities and including it in pre-service and in-service training curricula in order to further sensitize doctors to the utility of following the NEML.

Medicines Use

No studies of prescribing in Myanmar were found in the published literature. Two studies on prescribing in primary care, dating from 1994, were found in the WHO archives. One study examined diarrhoea treatment in children and found that half of all cases were treated with antibiotics but that only 30% received ORS (MOH 1994).

The other study was associated with an intervention involving the training of health workers and found that compliance with guidelines was 89% for the trained health workers and 12% for untrained ones (Myint et al 2000). In addition, the % patients treated with vitamins was 58% for trained health workers and 3% for untrained ones.

The consultant undertook a rapid prescribing survey in the outpatient departments in 10 public facilities (serving mostly acute patients) and 2 private pharmacies (serving acute and chronic patients). In each facility the prescribing in 30 patient encounters was examined.

In the public facilities at district level and below, the OPD register was examined and data on diagnosis was also obtained, so allowing matching of diagnosis with drug treatment. In two tertiary referral hospitals and also one district hospital (where there was a hospital pharmacy due to operation of a revolving drug fund), 30 patient bills were examined and data on drug cost per prescription was obtained. In the two private pharmacies 30 patient bills from computerized records were examined. The two private pharmacies' data concerned mainly private outpatient prescription data and thus injection usage was very low.

The lower rate of antibiotic use seen in the private retail shops reflects the higher proportion of chronic cases and lower proportion of acute cases as compared to what is seen in primary health care. The results are shown in table 2.

Table 2: Prescribing survey undertaken by the consultant

Drug use indicator	Referral hospital N=2	District/Township hospital* N=3	RHC and Sub-centre N=5	Private Drug Retailer N=2
Av. no. drugs / prescription	2.8	2.7	2.1	2.3
% Prescriptions with antibiotics	27%	56%	31%	9%
% Prescriptions with injections	32%	25%	5%	1%
% Prescriptions with vitamins	27%	25%	36%	38%
% drugs prescribed by generic name	4%	51%	75%	11%
% prescribed drugs on the EML	62%	94%	98%	59%
% Upper Respiratory Tract Infection cases given Antibiotics	-	100%	72%	-
% prescribed drugs dispensed	89%	60%	90%	99%
Av.drug cost/prescription (Kyats)	5665	1241	-	4363

*A district hospital has about 100 beds and a township hospital 25 beds. One of the Township hospitals was operating a Revolving Drug Fund.

It can be clearly seen that the higher the level of facility, the greater the number of drugs prescribed per patient and the lower the % of drugs prescribed by generic name or from the NEML. Indeed prescribing by generic name is very low in the tertiary referral hospitals and in the private sector. About 40% of drugs prescribed at tertiary level and in the private sector are non-EML drugs. Antibiotic use is extremely high at district level and below, 72-100% of upper respiratory tract infection cases receiving antibiotics. The drug cost per prescription was much higher in the referral hospitals and private sector as compared to the township hospital operating a revolving drug fund.

In most of the public facilities visited, doctors and paramedical prescribers were seeing about 10 outpatients per day. In hospitals, doctors were generally seeing a further 10 patients who would be admitted. Thus, doctors are generally not overburdened and can give adequate consultation time to patients. Dispensing was generally done by paramedical staff some of whom may have to dispense medicines to 100 patients per day in the big tertiary hospitals. In the two private pharmacies and one hospital with a RDF, where the dispensing process was seen, it was observed that the patient-dispenser contact time was often less than one minute, so allowing little time to give patients proper instruction on how to take their

medicines. There was no labeling apart from writing the number of tablets and the frequency per day on the strip packaging.

Standard Treatment Guidelines (STG) and Formulary

There are national Standard Treatment Guidelines, aimed at primary care, published for 4 different categories of health workers e.g. Medical Officers (MOH 2006), Health Assistant, Midwife and Voluntary Health Worker. While many district facilities have these guidelines, few prescribers were using them or other sources of independent drug information. One paediatrician stated that she used quinine for cerebral malaria in children rather than arthemether as recommended in the national STGs because she did not trust the guidelines. Yangon General Hospital had developed and published its own standard treatment guidelines (YGH 2011). It is not known how compliant prescribers are with the recommendations made in YGH guidelines. The Myanmar Medical Association and the Myanmar Pharmaceutical Association have produced a Myanmar Pharmaceutical Index in 2010 which contains information on all the drugs registered. However few doctors or facilities had this book.

Undergraduate education

Pharmacology is taught in the 3rd year of MB.BS but the pharmacology department has little input into the clinical teaching of the 4th and 5th years. Thus, whatever prescribing principles they learn at that time are likely to be undermined by their later clinical studies and work with senior consultants.

Continuing Professional Development

Continuing Professional Development (CPD) is organized with the teaching hospitals for in-service staff. The MOH vertical disease control programs run refresher training for district level staff from time to time. In addition, supervisory visits are made by township staff to RHCs and from RHCs to sub-centers monthly. However, there is very little focus on prescribing and none has utilized prescription audit and feedback. Outside of teaching hospitals, CPD for doctors is adhoc and not mandatory. In the private sector, many doctors are not undertaking any form of CPD.

The Myanmar Medical Association (MMA), which is the only body totally independent of government, runs 3 projects on Continuing Medical Education (CME) for private practitioners. Firstly, they run weekend courses over a period of 2 years in Yangon and Mandalay. Secondly, they run similar weekend courses in each of their 28 of their 78

township branches (out of a total of 330 townships in Myanmar). Thirdly, they run a distance learning project. So far they have trained 200 doctors in Yangon and Mandalay and 20-30 doctors per branch and 3000 doctors are undertaking distance learning. It is not clear how much attention is given to general prescribing skills in these courses. However, it was generally agreed during a discussion with the Myanmar Medical Association (MMA), the Myanmar Medical Council (MMC) and the Myanmar Academy of Medical Sciences (MAMS), that clinical pharmacology hardly exists in Myanmar, there being very little teaching on general prescribing to undergraduates and little post-graduate study or work, such as surveys on drug use. They stated that most doctors were getting their information from the pharmaceutical industry, receiving daily visits from company representatives.

Myanmar Medical Council (MMC) and Myanmar Medical Association (MMA)

The MMC are partially independent of government but there are plans for them to become totally autonomous. The MMC is responsible for licensing doctors with general or temporary licenses. There are plans to have licenses for specialists but this has not started. Licenses must be renewed every 2 years. Currently this is just a formality but they are planning to start a credit system for relicensing. The MMC also supervises the curricula of the one military and four government universities undertaking MB.BS courses. Many Myanmar-trained doctors emigrate overseas. Some foreign doctors come to work in Myanmar and they are granted temporary licenses according to recommendations of the Medical Council in their own country. Most of these doctors are specialists. They are currently considering starting a licensing exam for foreign doctors. The MCC also investigates 2-3 complaints per year against doctors – mostly in the private sector as government deals with complaints in the public sector.

The MMA is a member-based organization and is the only fully independent association of doctors. It has 12,000 members out of a total of 30,000 doctors in the country. The MMA has developed CME courses aimed at private GPs (as described above). The MMA, together with the MMC and the MAMS form a “think-tank” to recommend policies to government.

Independent Drug Information

Sources of independent drug information are few. Some teaching hospitals were receiving journals and producing newsletters but this is not generally the case elsewhere. There is no Drug Information Centre (DIC) run by MOH.

Public Education

There have been no public education campaigns to improve the use of medicines. In the sub-centres and RHCs there are staff who undertake public education on maternal child health, treatment of childhood illness, vaccination and so on. While some staff have distributed messages not to demand injections, the focus of their messages has generally not been on medicines use. Many health workers felt that patient demand was a problem and that public education was needed. Relevant messages could include “don’t take antibiotics without seeing a health worker first” or “medicines are not needed for simple coughs and colds” or “ask your doctor whether your child really needs more than 2 medicines”.

Supervision and training for district level staff

Most facilities are visited monthly by a supervisor from the next level of facility above them. However, supervision of prescribing does not appear to be undertaken. Most prescribers did not feel that their prescribing may be sub-optimal.

Drug and Therapeutic Committees (DTC)

There is no national DTC and there are no Drug and Therapeutic Committees in any of the hospitals or district/township health authorities. Most hospitals had no formulary list and did not carry out many of the functions that a DTC may be expected to undertake such as managing a formulary system, prescription audit, monitoring of adverse drug reactions or coordinating CPD on prescribing. Any local purchase of drugs is decided by the concerned health worker in that facility. Only in the Township Hospital running a RDF was there a committee that decided on drug selection and purchase.

Private prescribers/dispensers

Most public sector hospital doctors do private practice after office hours and some dispense medicines from their own clinics. In district and township hospitals, many doctors actually live in government accommodation on the hospital compound and conduct private practice in this accommodation. A consultation generally costs Kyat 3000/-. Some doctors mentioned that the profit-motive may lead to the prescribing and dispensing of many newer branded products which many patients cannot afford. In Yangon, most private doctors buy their own drug for dispensing from Mingalar Market.

Of the two private pharmacies visited, one saw about 100-150 patients per day (half with prescriptions) and the other 300 per day (30% with prescriptions). Both were owned by doctors, only one employing a pharmacist at a junior level. The pharmacy managers and other staff had learnt pharmacy management “on-the-job”. The smaller pharmacy stocked about

2000 products and bought drugs from about 150 wholesalers. The larger pharmacy (which also had a wholesaler branch) stocked about 4000 products and purchased drugs from more than 50 importers. Both pharmacies received their drug orders within 1-2 days of making the order.

The retail pharmacies mentioned that they sold some drugs such as vitamins with a 5% mark-up but other drugs with a 10% mark-up. In addition, wholesalers are generally only allowed a mark-up of 5-7% when selling to the retail sector – so overall the mark-up for patients is nearly 20% officially. However, the mark-up may be much more in remote less supervised areas.

The two private pharmacies mentioned that they mainly supplied drugs to patients attending private clinics which also had their own pharmacies but that they managed to attract some of the patients away from these clinic pharmacies by charging lower prices. It was stated that daily takings range from Kyats 1-20 Lakhs / day according to shop size – but that actual profit is generally less than 10%.

All private pharmacies mentioned receiving daily visits from drug company representatives and that this was their main source of information along with MIMS and CIMS and the Myanmar Pharmaceutical Index. One pharmacy had an old copy of the British National Formulary. None of the staff in either pharmacy were familiar with the NEML. The wholesaler part of the larger pharmacy mentioned that they supplied 200 private hospitals through out Myanmar and that they had a team of 27 representatives, each one seeing about 10 doctors per day and each doctor monthly. Thus one can see that this wholesaler alone is promoting and selling drugs to thousands of doctors throughout Myanmar.

Possible Solutions

1. Monitor drug use including:

- ABC analysis of consumption data both centrally and in each referral hospital and district/township to identify high consumption drugs and to make comparisons between districts/townships and between primary and hospital care;
- adherence to the NEML;
- Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above);
- Use of clinical pharmacology and clinical pharmacy students to undertake drug use studies (see recommendation 9).

2. Annual publication (ideally as a statutory requirement) in all major hospitals and districts/townships of drug consumption analysis and prescription audit, with analysis of all publications in the MOH/EDP.
3. Establish functional DTCs in all major hospitals with an obligation to:
 - monitor drug use;
 - develop their own formulary from within the NEML, monitor compliance and justify non-EML use;
 - coordinate CPD in their institutions;
 - report annually to MOH on their activities so enabling MOH to know what is and is not going on and what needs to be done (requires MOH capacity to review these reports).
4. Develop an accreditation system for hospitals which includes a functional DTC as one of the criteria.
5. Develop and regularly update national STGs, for both primary care and hospitals, disseminate them to all doctors, and incorporate them into both undergraduate and postgraduate CPD curricula.
6. Include prescription audit into the MMA CME program being conducted in Yangon, Mandalay and 28 branches of MMA.
7. Encourage the MMA and MMC to develop a credit system to encourage voluntary CPD and to incorporate prescription audit and feedback and ethics into CPD.
8. Disseminate to the public of core pharmaceutical messages through the RHC and sub-centre health workers, community midwives and the media, e.g. does my child need more than one drug?
9. Strengthen pharmaceutical disciplines in the university system:
 - clinical pharmacology (to teach general prescribing at undergraduate and post-graduate levels) in all university hospitals teaching medical students;
 - clinical pharmacy (which includes the skills of drug monitoring, prescription audit DTC management, drug evaluation) into all pharmacy courses.
10. Establish a National Drug Information Centre.
11. Employ more pharmacists such that every township and referral hospital has a pharmacist who can undertake monitoring of drug use, prescription audit and act as the secretary of a DTC.

Medicines Regulation

There is a National Drug Law 1992 (Myanmar government 1992). It is not clear if this encompasses all the regulations or not – but no drug schedules are described. In practice, all medicines (with the exception controlled drugs) are available over-the-counter without prescription. The Myanmar Food and Drug Board of Authority (MFDBA) is highest authority of Food and Drug Regulation/ Control. The Myanmar Food and Drug Administration, DOH is responsible for enforcing the National Drug Law. Currently the MFDA has no website, although they plan to start one.

The MFDA has difficulty to enforce all aspects of the National Drug Law due to a shortage of human and financial resources. Currently there are 42 technical and 10 office staff to manage a pharmaceutical sector of 13,000 registered products (although about 3000 are currently not circulating in the market), 170 drug importers, 10,000 registered drug retail shops and 7 government manufacturers. The MFDA has a central office in Nay Pyi Taw (capital) and a branch office in Mandalay. It is planning to open another branch office in Yangon (where the majority of drug importing and transactions occur and where the central office used to be before the capital shifted to Nay Pyi Taw). There is a Central Food and Drug Supervisory Committee which oversees all the activities of the MFDA.

The Chairman of this committee is the Director General of the Department of Health, the Secretary is the Director of the MFDA and members include the chief of the Division of Public Health, chairman of the City Development Committee, and representation of the departments of police, general affairs and the Livestock, Breeding and Veterinary Department. An equivalent supervisory committee exists at each administrative level of state, region, district and township. A pharmacist is generally not available at township level but there is always a pharmacist present at State level or above. The township hospital medical superintendant is a member of the township supervisory committee, which undertakes inspection of all drug outlets in their area. Township supervisory committees are responsible for issuing and revoking licenses for drug outlets in their areas (authority delegated to them by the MFDA).

Regulation of outlets and drug schedules

By law a diploma pharmacist is only required to be present in a retail pharmacy if controlled drugs are sold. All pharmacies are supposed to receive a visit at least 4 times a year by the relevant local supervisory committee and need to renew their license once every 3 years. If controlled drugs are sold, they should be visited monthly and renew their license annually. There is a checklist for retail pharmacy inspection which covers many issues such

premises and storage conditions, stock management, drug labeling, presence of banned or expired drugs, knowledge of the retailer and documentation on controlled drugs.

Township committees are supposed to examine all these things and report quarterly to the central level. In practice, township medical officers mentioned that they undertook inspections to verify that record keeping for controlled drugs was being done properly and that they could only cursorily look at storage and a random selection of drugs and submitted report to central food and drug supervisory committee. They could not look in depth at all aspects of the retail outlet due to lack of time. It was also mentioned that with the shortage of inspectors and lack of transport and funds together with the large number of pharmacies it was not possible to inspect annually all distributors and outlets. Each local committee sends in a report quarterly detailing the number of retail shops opened, the number closed down and the presence of any problems. Last year 50 illegal shops were closed down. In Yangon, 135 retail pharmacies were inspected and 37 were found to be selling unregistered drug and 4 selling counterfeit drugs. In such circumstances the Yangon F & D Supervisory Committee may revoke the retail pharmacy license for 3-6 months but only with the agreement of the Central F & D Supervisory Committee. There are OTC, prescription-only drug, natural health care products and controlled drugs. There are 3 categories of product which may be freely sold without prescription, excluding controlled drugs. Antibiotics are freely available without prescription and traditional practitioners are also prescribing them and other allopathic drugs. The MFDA mentioned that it is difficult to take punitive action for the selling of prescription-only drugs without prescription.

Drug Promotion

There is very little monitoring of drug promotional activities. There is legal provision for pre-approval of the advertising of OTC medicines and pre-approval for package information inserts for all medicines at the time of registration. It is not clear how the monitoring is done nor how pre-approvals are given since there is no dedicated committee to undertake this function.

There is a reliance on competitor importers to inform on their rivals and then the Institute of Medicine 1 in Yangon is asked to review the concerned advert. Monitoring of other drug promotional activities is not undertaken. It was mentioned that multivitamins are advertised on television and that this was unethical and should be screened by the MFDA.

Pharmacovigilance

National pharmacovigilance is undertaken by the Department of Medical Research. It was stated that 3-4 ADRs were reported in 2010. The MFDA also distributed the ADR forms

to Heads of State/ Regional/ Teaching Hospitals, Drug Advisory Committee members and the MMA. Most hospitals were not undertaking any pharmacovigilance. The National Poison Control Centre monitors poisoning and stated that they would like to start up ADR monitoring. It was stated that last year there were 100 cases of poisoning admitted to hospitals in Lower Myanmar, of which 70 cases were due to drug poisoning and 40 cases due to paracetamol poisoning.

Drug Quality

The MFDA has its own Drug Testing Laboratory. Approximately, 150 pre-market and 15 post-market drug samples are tested per month. Of 124 samples from retail shops that were tested last year, two were found to be counterfeit, three were substandard and 12 were unregistered. Of all the pre-market drugs tested last year, there was an 8-10% failure rate. Currently, the lab is not able to do any bio-equivalence testing. Many specialist doctors stated that they preferred to prescribe by brand name because they did not trust the quality of generic products and did not feel that the MPF followed Good Manufacturing Practice (GMP).

Drug registration

Product registration for old molecules already on the market only requires review of all specifications within a dossier by the MFDA, as per ASEAN guidelines. There is no system to limit the number of me-too products that are registered and there are up to 70 brands of paracetamol and more than 50 brands of some drugs such as amoxicillin. New molecules require a review by the Technical Advisory Committee once information about the product is gathered by MFDA staff. New molecules will only be considered for registration if they are already registered in the UK, USA, Australia, Thailand, Indonesia or Singapore. Registration lasts 1-3 years and the registration fee is USD 300 for old and new molecules alike. All revenue is sent to the Treasury. Membership of the Technical Advisory Committee for registration includes the DG Department of Health, MFDA staff, all the Heads and Professors of Clinical Subjects from Institutes of Medicines 1 and 2, and representatives from the University Pharmacy and Veterinary Departments. The committee meets quarterly.

Drug Pricing

Basic ground prices for drugs – imports and drugs manufactured by the MPF - are decided by the Myanmar Pharmaceutical Medical Products and Entrepreneur Association in collaboration with the Ministry of Commerce. Wholesalers are then allowed a 5-7% mark-up and retailers a further 5% mark-up for vitamins and 10% for other drugs. In remote areas

transport fees will also be added. There appears to be little supervision of prices charged. Currently, about USD 600 million worth of drugs is imported every year and it was stated that the prices of imported drugs are at least four times that of locally produced drugs.

Possible Solutions

1. Strengthen the MFDA by:
 - Appointing sufficient staff, particularly inspectors and graduate pharmacists, one per district, to deal with all the required activities;
 - Training existing staff for certain specialist activities such as dossier evaluation for drug registration, Good Manufacturing Practices, Good Laboratory Practices, Pharmacovigilance in community and hospital pharmacies;
 - Amending the current regulations to increase punitive action.
2. Revise and update the standing operating procedures (SOPs) so as to improve:
 - the way in which many procedures are conducted;
 - how various committee meetings are currently managed, particularly with regard to membership and possible conflict of interest in members who sit on many committees.
3. Improve the process of drug registration by:
 - installing an electronic system for drug registration to ease the process;
 - reviewing the criteria for drug registration so as to reduce the number of applications of me-too products;
 - raising the registration fee so as to reduce the number of brands of the same active pharmaceutical ingredient being registered;
 - publishing the number of products approved by the technical advisory committee and the number of products approved without review by the committee.
4. Strengthen the drug testing laboratory to test more samples per year and to include bio-equivalence testing.
5. Start a unit within the MFDA dedicated to monitoring drug promotional activities, starting with pre-approval of adverts and package inserts for all medicines (not just OTC ones) and gradually expanding the system to monitor all promotional activities – all of which would require establishing an adverts approval committee.
6. Review the drug schedules to consider whether there should be an extra drug schedule consisting of drugs that should be only available on prescription in specialist centres and

not available even with prescription in ordinary pharmacies, e.g. oncological drugs, anti-TB drugs and very new antimicrobials. Such a schedule could prevent misuse in the private sector, particularly of newer antimicrobial drugs, where misuse will lead rapidly to antimicrobial resistance.

Medicine Policies and Health system issues

There is an extensive health care system where patients are supposed to receive free health care. However, many patients have to pay out of pocket as many essential medicines are not supplied by the government and often there are shortages of those medicines that are supplied. Very few patients have health insurance. Most MOH officials felt that there was inadequate supervision of many medicine-related activities. There is a national drug (medicines) policy (NMP) document (Myanmar government 2001) which attempts to describe a full set of pharmaceutical policies. The current NMP has 13 objectives covering the areas of:

- Drug supply, availability and affordability
- Rational use of Drugs
- Manufacture of Drugs
- Drug Regulation
- Human Resources for Drug Management
- Adequate financial resources for drug management

Details of the individual objectives can be found in annex 3. However, the NMP does not have a section on monitoring and evaluation and is also lack details with regard to many of the components. In addition, there is no implementation plan. Many people complained that the NMP was only on paper and nothing was implemented. The current government wishes to update / draft a new NMP. Myanmar has not participated in the global surveys of the pharmaceutical sector conducted by WHO through questionnaires sent to MOHs in 2003 and 2007. Thus, many aspects of the pharmaceutical sector are not known in detail. 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 3.

Table 3: Medicine Policies in place in Myanmar

Drug Policy	State of implementation
National Medicines Policy	Official document 2001, with some aspects implemented but many not implemented.
Monitoring the use of medicines	Very little monitoring of consumption centrally or locally.
Essential Medicines List	6 th Edition of National List published in 2011. Only some of the drugs are included in public sector procurement.
Standard Treatment Guidelines	National STGs for PHC for 4 different levels of health worker e.g. Medical Officer (MO), Health Assistants, etc. STGs for MO published in 2006. Some teaching hospitals have published their own STGs e.g. Yangon General hospital 2011.
Formulary	Myanmar Pharmaceutical Index published in 2010 but no National Formulary Manual published by government.
Generic Policies	Generic substitution in the private sector allowed.
Regulation of promotion of medicines	Government regulation exists for pre-approval for package information inserts for all drugs and adverts in OTC drugs, but there is no dedicated committee to work on this.
Monitoring of ADRs	Done by the Department of Medical Research but very few ADRs reported (3-4 last year).
Payment for medicines	All medicines should be received free of cost in all public facilities but the stock-outs are so severe that most patients must buy their medicines out-of-pocket from private pharmacies.
Health Insurance	Public health insurance does not cover a significant proportion of the population.
Revenue from medicines	Officially, revenue from medicines is not used to pay salaries in the public sector but many public sector workers are buying medicines locally to prescribe and sell in their health facilities due to chronic stock-out of essential drugs.
Medicine Pricing policies	No strict pricing policies used in either the public or private sectors.

Drug Policy	State of implementation
Undergraduate medical training	National EML and STGs are not part of the curricula although some teaching hospitals have their own STGs. No training on problem-based pharmacotherapy.
Continuing medical education	Some CPD provided to township level staff by MOH vertical disease control programs and some courses run for private GPs by the MMA but little focus on prescribing.
Medicines Information Centre	No national medicines information centre.
Public education on medicines use	No public education campaigns on medicines use done in the past 2 years though some health workers have taught communities not to demand injections.
DTCs	No Drug and Therapeutic Committees (DTCs) in any hospital
National Strategy for containing AMR	No national strategy to antimicrobial resistance (AMR). Antibiotics frequently available over-the-counter without prescription.

Coordination and Management

While some aspects of the national drug policy have been implemented, many have not. One of the possible reasons for non-implementation of many parts of the NMP may be the existing MOH structure and the lack of any particular department or division to ensure coordination between all the concerned departments/divisions within not only the Department of Health and other departments of the MOH, but also with other relevant ministries such as the Ministry of Finance. For example, the NEML is developed by the EDP and used in procurement by the CMSD both these units being within the Medical Care Division of the Department of Health (DoH), MOH. However, MOF does not provide enough funds for the CMSD to procure all the needed essential drugs. The Department of Medical Science in the MOH is responsible for health worker education and medical schools but hospitals are often not using the MOH STGs but rather are using their own STGs (as in Yangon General Hospital). It is not clear which division/unit is taking charge of monitoring drug consumption

and prescribing, coordinating training and supervision with regard to general prescribing or organizing public education on medicines use.

The MOH currently consists of 4 technical Directorates each with a Director General:

- (1) Department of Medical Sciences, responsible for health worker education,
- (2) Department of Traditional Medicine,
- (3) Department of Medical Research,
- (4) Department of Health (DoH).

Within the Department of Health there are 10 divisions, each headed by a Deputy Director General, as follows:

- Medical Care;
 - Includes the Essential Drug Program (EDP), Hospital Administration and Central Medical Supply Depot (CMSD).
- Myanmar Food and Drug Administration.
- National Health Laboratory;
 - Includes drug quality testing.
- Public Health;
 - Deals with nutrition, women and child health, reproductive health, school health, elderly, community health and basic health services.
- Occupational Health.
- Planning;
 - Deals with human resources.
- Disease Control;
 - Deals with the vertical disease control programs such as TB, HIV/AIDS and malaria, which have their own drug distribution system.
- Central Epidemiological Unit.
- Health Education Bureau;
 - Deals with IEC materials.
- Nursing.

It can be seen from the above list that many divisions and units are involved in implementing national drug policy. Many units, including the EDP, CMSD, MFDA are grossly understaffed and under-funded. The EDP unit responsible for developing STGs and EML only has 1 technical and 1 clerical staff. The basic district/township and tertiary hospital structures has

few pharmacists. This issue needs discussion with the Planning Division in the Department of Health in MOH and also with the Civil Service Commission (to create posts). Provision of adequate funds for drug procurement needs discussion with the Ministry of Finance.

Development of clinical pharmacy and clinical pharmacology specialties needs discussion with the Department of Medical Science under the MOH and also with the Myanmar Medical Council. Public education on drugs needs discussion with the Health Education Bureau in the Department of Health. Including safe use of medicines in school curricula would need discussion with the Ministry of Education. Implementation of drug pricing policies needs discussion with the Ministry of Commerce. Development of a drug manufacturing capacity needs discussion with the Ministry of Industry. Currently, there is no platform to hold such discussions or coordinate policy.

One way to overcome the problem of drug policy coordination would be to: (1) establish a Permanent Statutory Committee to advise the Minister of Health or Secretary of State on pharmaceuticals and (2) establish an Executive Body in the MOH to carry out the statutory recommendations of the Permanent Statutory Committee. Many people felt that such a Permanent Statutory Committee is needed and that the existing Food and Drug Board of Authority (which is currently not active) should be reformed to be such a Permanent Statutory Committee to advise the Secretary of State on all aspects of pharmaceuticals, not just regulation. A wide membership would be needed including laypersons, professional bodies and representation from all the concerned ministries. With regard to an executive body in the MOH, many people felt that the Essential Drug Program should be strengthened to become the executive division within the MOH.

Such an executive division should not only carry out the recommendations of the Statutory Committee but should also (1) update the National Medicines Policy to be more specific and to include an implementation plan and time line, (2) coordinate action between all MOH divisions and different Ministries, and (3) be responsible for promoting rational use of drugs (including NEML, STGs, DTCs, monitoring drug use, CME, Drug Information Centre and public education). It was mentioned that universities could provide students to collect information needed by the MOH as part of their research studies. Reforming the Food and Drug Board of Authority (FDBA), reviewing the NMP and developing a plan of action for the NMP could only be done in stages and would require working groups to undertake preparatory work and propose courses of action. It was estimated that reform of the FDBA

and review of the NMP would take one year and that building sufficient capacity to implement any new NMP would take at least 5 years.

The Myanmar Academy of Medical Sciences (MAMS) was created 10 years ago to be a “Think-Tank” to advise the Head of State of health issues. However, they have no administrative power and consist mostly of government retirees. Nevertheless they work with the MMA and MMC and do run workshops on health policies. The MAMS, MMC and MMA felt that a new structure was needed to coordinate drug policy. They could participate in the working groups to reform the Food and Drug Board of Authority, review the NMP and develop a plan of action for the NMP. It was agreed that any revised NMP should include a section on monitoring and evaluation for all components.

Possible Solutions

1. Establish a permanent, independent, national statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOH), under the chairmanship of the Minister of Health, to advise the Secretary of State on Pharmaceuticals.
 - Could be done by reforming the currently inactive Food and Drug Board of Authority but would require establishment of a working group.
2. Establish an Executive Division in the MOH to carry out the statutory committee recommendations – a strengthened Essential Drug Program Division?
 - To coordinate action between all MOH divisions and different Ministries;
 - To be responsible for rational use of drugs: NEML, STGs, DTCs, monitoring drug use, CME, Drug Information Centre, public education;
 - Could liaise with universities to provide students to collect information needed by the MOH as part of their research studies;
 - To update the National Medicines Policy to be more specific and to include an implementation plan and time line.
3. Update the National Medicines Policy so as to be more specific and with provision for implementation. This would require:
 - A sub-committee of the statutory committee to draft it;
 - An implementation plan and time line to be included;
 - Incorporation into the national health plan and regulations.

Workshop

At the end of the mission, a 1-day workshop was held on October 26th with over 80 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 in the context of national drug policy
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems

- Develop plan to:
 - implement recommendations, and
 - incorporate recommendations into the national health plan for sustained implementation and follow up

Agenda

Morning

- Introduction to National Medicines Policy and regional experience
- Presentation of the findings by the WHO consultant and discussion of the findings with identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations for implementation
 - include practical steps and the human and financial resources needed

Afternoon

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

Group work instructions

- Each group to draft recommendations with practical steps including:
 - Who will do it?
 - How many staff?
 - Budget?

- 4 groups, each one to discuss one topic as specified below:
 - Drug supply and selection
 - Promoting rational drug use
 - Drug regulation
 - National structure and drug Policy

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. Strengthen the CMSD:
 - to produce annual report on consumption with analysis;
 - To establish an electronic inventory management system to allow (1) better estimation / forecasting of drug need and stock control, and (2) ABC analysis of consumption for feedback to prescribers.
2. Employ at least 1 pharmacist per district & per referral hospital:
 - to be in charge of drug storage, distribution, procurement & quantification and to monitor consumption – all of which are all technical functions.
3. Increase the budget for general drugs from less than 0.2 USD/capita/year to at least 2.0 USD/capita/year.

B. Drug Selection

4. Ensure consistency between the NEML, other lists such as that used by CMSD and National Standard Treatment Guidelines.

5. Require stricter adherence to the NEML by tertiary referral hospitals:
 - Referral hospitals should develop their own formularies from within the NEML, monitor adherence and justify the quantity of non-EML drugs used (which should not normally be more than 10-20% of the budget);
 - Drug and Therapeutic Committees or specialist boards, established by specialist associations, could provide guidance on what specialist non-EML drugs are reasonable to purchase.
6. Continue to regularly update the NEML and increase the transparency and inclusiveness of the process to improve acceptability to prescribers by:
 - Publishing the selection criteria and the list of experts involved in the selection process;
 - Categorizing drugs by level of facility and/or level of prescriber to ensure that drugs are prescribed by prescribers who are trained to use such medicines.
7. Improve use of the NEML by:
 - Widely disseminating the NEML to all facilities and including it in pre-service and in-service training curricula in order to further sensitize doctors to the utility of following the NEML.

C. Promoting rational drug use

8. Monitor drug use including:
 - ABC analysis of consumption data both centrally and in each referral hospital and district/township to identify high consumption drugs and to make comparisons between districts/townships and between primary and hospital care;
 - adherence to the NEML;
 - Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above);
 - Use of clinical pharmacology and clinical pharmacy students to undertake drug use studies (see recommendation 16)
9. Annual publication (ideally as a statutory requirement) in all major hospitals and districts/townships of drug consumption analysis and prescription audit, with analysis of all publications in the MOH/EDP.

10. Establish functional DTCs in all major hospitals with an obligation to:
 - monitor drug use;
 - develop their own formulary from within the NEML, monitor compliance and justify non-EML use;
 - coordinate CPD in their institutions;
 - report annually to MOH on their activities so enabling MOH to know what is and is not going on and what needs to be done (requires MOH capacity to review these reports).
11. Develop an accreditation system for hospitals which includes a functional DTC as one of the criteria.
12. Develop and regularly update national STGs, for both primary care and hospitals, disseminate them to all doctors, and incorporate them into both undergraduate and postgraduate CPD curricula.
13. Include prescription audit into the MMA CME program being conducted in Yangon, Mandalay and 28 branches of MMA.
14. Encourage the MMA and MMC to develop a credit system to encourage voluntary CPD and to incorporate prescription audit and feedback and ethics into CPD.
15. Disseminate to the public of core pharmaceutical messages through the RHC and sub-centre health workers, community midwives and the media, e.g. does my child need more than one drug?
16. Strengthen pharmaceutical disciplines in the university system:
 - clinical pharmacology (to teach general prescribing at undergraduate and post-graduate levels) in all university hospitals teaching medical students;
 - clinical pharmacy (which includes the skills of drug monitoring, prescription audit DTC management, drug evaluation) into all pharmacy courses.
17. Establish a National Drug Information Centre
18. Employ more pharmacists such that every township and referral hospital has a pharmacist who can undertake monitoring of drug use, prescription audit and act as the secretary of a DTC.

D. Drug regulation

19. Strengthen the MFDA by:

- Appointing sufficient staff, particularly inspectors and graduate pharmacists, one per district, to deal with all the required activities;
- Training existing staff for certain specialist activities such as dossier evaluation for drug registration, Good Manufacturing Practices, Good Laboratory Practices, Pharmacovigilance in community and hospital pharmacies;
- Amending the current regulations to increase punitive action.

20. Revise and update the standing operating procedures (SOPs) so as to improve:

- the way in which many procedures are conducted;
- how various committee meetings are currently managed, particularly with regard to membership and possible conflict of interest in members who sit on many committees.

21. Improve the process of drug registration by:

- installing an electronic system for drug registration to ease the process;
- reviewing the criteria for drug registration so as to reduce the number of applications of me-too products;
- raising the registration fee so as to reduce the number of brands of the same active pharmaceutical ingredient being registered;
- publishing the number of products approved by the technical advisory committee and the number of products approved without review by the committee.

22. Strengthen the drug testing laboratory to test more samples per year and to include bio-equivalence testing.

23. Start a unit within the MFDA dedicated to monitoring drug promotional activities, starting with pre-approval of adverts and package inserts for all medicines (not just OTC ones) and gradually expanding the system to monitor all promotional activities – all of which would require establishing an adverts approval committee.

24. Review the drug schedules to consider whether there should be an extra drug schedule consisting of drugs that should be only available on prescription in specialist centres and not available even with prescription in ordinary pharmacies, e.g. oncological drugs, anti-TB drugs and very new antimicrobials. Such a schedule could prevent misuse in the private sector, particularly of newer antimicrobial drugs, where misuse will lead rapidly to antimicrobial resistance.

E. National Structure & Drug Policy

25. Establish a permanent, independent, national statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOH), under the chairmanship of the Minister of Health, to advise the Secretary of State on Pharmaceuticals.
- Could be done by reforming the currently inactive Food and Drug Board of Authority but would require establishment of a working group.
26. Establish an Executive Division in the MOH to carry out the statutory committee recommendations – a strengthened Essential Drug Program Division?
- To coordinate action between all MOH divisions and different Ministries;
 - To be responsible for rational use of drugs: NEML, STGs, DTCs, monitoring drug use, CME, Drug Information Centre, public education;
 - Could liaise with universities to provide students to collect information needed by the MOH as part of their research studies;
 - To update the National Medicines Policy to be more specific and to include an implementation plan and time line.
27. Update the National Medicines Policy so as to be more specific and with provision for implementation. This would require:
- A sub-committee of the statutory committee to draft it;
 - An implementation plan and time line to be included;
 - Incorporation into the national health plan and regulations.

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

	Name	Affiliation
1	Dr Thida Hla	Chief, EDP/MOH
2	Dr Myo Win	Director, Central Medical Stores Depot (CMSD)
3	Dr Ninihlaing	Assistant Director, CMSD
4	Sometai	Admin Officer UNICEF store
5	Khinmaung Moiad	Clearance Officer CMSD
6	Dr Tin Htun Lwin	Transit Officer CMSD
7	Dr Ye Win Htat	Store Control Officer CMSD
8	Dr Khin Thi Tar Aye	Asst Director Warehouse CMSD
9	Daw Myint Myint Yee	Procurement CMSD
10	Prof Naung Hla Hla Win	Head Pharmacology IOM I, Yangon
11	Prof Kyi Kyi Thinn	Chief Microbiology, IOM I, Yangon
12	Daw Khin Swe Aye	Head Dept Finance, IOM I, Yangon
13	Dr Daw Hla Kyin	Medical Superintendant New Yangon General Hospital (NYGH)
14	Dr Tintinyee	Senior Deputy Medical Superintendant NYGH
15	Dr Zaw Than Htun	Assoc. Prof Medicine, NYGH
16	Dr Nu Nu Tha	Medical Superintendant, Yangon General Hospital
17	Yee Mon Soe	Pharmacist, Private Pharmacy (Emergencies), Yangon General Hospital
18	Zaw Min Htiu	Manager, Private Pharmacy, YGH
19	Dr Kin Chit	Deputy Director Research (Pharmacology), National Poisons Centre, Dept Medical Research
20	Dr Samuel Kuawhla	Paediatrician MMA/MMC
21	Dr Soe Aung	MMA (ex DoH)
22	Prof Myaint Thaung	Gen.Sec. MMA
23	Prof Myo Myint	MAMS
24	Dr Khaing Soe Win	GP society of MMA
25	Prof Ne Win	MAMS
26	Prof Kyaw Myint Naing	MMA/MMC

27	Dr Sein Winn	Trad Medicine, ex EDP chief
28	Dr Soe Myat Tun	Former chief MFDA
29	Dr Tinaye	GP society of MMA
30	Khin Theingi Myint	Chairman of Township Supervisory Committee in Yangon (& medical superintendant)
31	Lwin Maung	Manager, AA Pharmacy Yangon
32	Hnin Yuyu Lwin	Cashier, AA Pharmacy
33	Pyi Sone Aung	Owner, AA Pharmacy
34	Dr Chaw Wut Yee	Manager, Select Pharmacy (Retail), Yangon
35	Dr Aye Aye Myo	Yangon Township Medical Officer
36	Mr Aung Kyaw Oo	Regulatory Affairs, Select Wholesaler, Yangon
37	Dr Myo Win Nyunt	Dentist & MO in charge of drug store/pharmacy, Tharawaddy District Hospital
38	Dr Khin Yuyu Zin	Obs & Gynae, Tharawaddy District Hospital
39	Dr Pe Win Aung	Surgeon, Tharawaddy District Hospital
40	Dr Ohnmar	Physician, Tharawaddy District Hospital
41	Dr San San Myint	Paediatrician, Tharawaddy District Hospital
42	Daa Aye Aye	HA, Tharawaddy District Hospital
43	Dr Chocho Lwin	District Health Officer, Tharawaddy District.
44	Dr Than Naing Lin	MO, Tharawaddy District Hospital
45	Mar Mar Aung	Midwife, Tha Phyu sub-centre, Tharawaddy Township
46	U Tun Lwin	HA, Ngaphyugalay RHC, Tharawaddy Township
47	Dr Saw Kalaya	MO, Kungyangon Township Hospital
48	Thanthan Htay	Midwife, Daidanaw sub-centre, Kungyangon Township
49	Dr Theingi Zin	Deputy Director, Food and Drug Authority (MFDA)
50	Dr Kyaw Lin	Director, Food and Drug Authority (MFDA)
51	Dawnyunt Shwe	HA, Nat Sin Gone RHC, Kaw Hnu Township
52	Dr Khaing Zin Latt	Asst MO Leiway Hospital
53	Dr Soe Soe Naing	MO, Leiway Township hospital
54	Ms Myat Myat	Pharmacist, Leiway Township hospital
55	Nant Shwe Htay	HA, Tha Byay Pin, RHC, Leiway Township
56	Dr Htun Naing Oo	Director General, DoH, MOH, Nay Pi Daw
57	Dr Min Than Nyunt	Deputy Director General, Medical Care, DoH, MOH
58	Dr Zaw Win	Director Public Health
59	Marinus Gotink	Chief , Young Child Survival and Development Section, UNICEF

Annex 2: Participants of Workshop on National Drug Policy and the Pharmaceutical Situation –Nay Pyi Taw, Myanmar, 25 October 2011

SN	Name	Organization
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Annex 3: Slide presentation given by consultant to stakeholders in the 1-day workshop

Medicines supply and use in Myanmar

WHO mission: 19-26 October 2011

Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Agenda of the workshop

- Presentation by WHO with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
 - include practical steps and the human and financial resources needed
- Presentation of group work with plenary discussion and finalization of recommendations
 - Road map for MOH, stakeholders and WHO to follow

Background

- **Irrational use of medicines in all countries of region**
 - Increasing demand for medicines but very limited government budget in Myanmar with frequent stock-outs
- **July 2010 SEAR regional meeting attended by 9 countries, including Myanmar**
 - Recognised the need for a comprehensive health system approach to promote rational use of medicines
 - Recommended doing national situational analysis to identify major problems and possible solutions to develop national action plan
- **Myanmar wish to revise/discuss its National Drug Policy 2001**
 - Non-implementation of many aspects of current policy
 - Requires a situational analysis to review the drug policy
- **Situational analysis**
 - WHO fact finding mission, 19-26 October, 2011
 - Workshop to develop recommendations for national drug policy

What is a National Drug Policy?

"An NDP is a commitment to a goal and a guide for action. It expresses and prioritizes the medium to long-term goals set by the government for the pharmaceutical sector and identified the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and private sectors and involves all the main actors in the pharmaceutical sector." WHO 2003

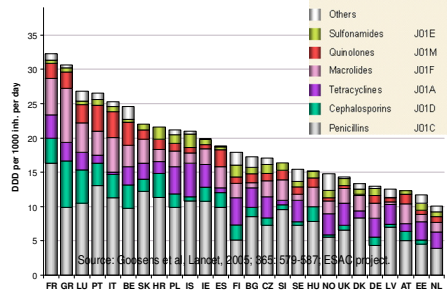
Objectives of the workshop

- Introduction to national drug policy (NDP) and Myanmar's NDP
- Review the WHO fact finding results
- Identify the main priority problems to be addressed in pharmaceutical sector
- Formulate recommendations for policies to resolve / address the problems
- Develop plan to:
 - implement recommendations, and
 - incorporate recommendations into the national health plan for sustained implementation and follow up

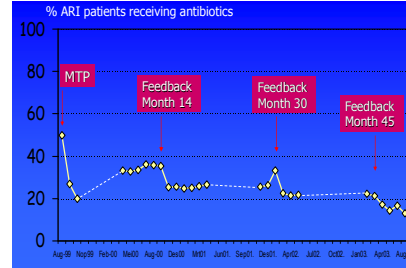
Key components of a NDP

- Selection of essential medicines
- Affordability
- Financing options
- Supply systems
- Regulation and Quality Assurance
- Rational Use
- Research
- Human Resources Development
- **Monitoring and Evaluation**

Variation in outpatient antibiotic use in 26 European countries in 2002



Sustained impact on antibiotic use through transferring MTP skills to health centre staff



Public education campaigns in industrialised nations

Huttner et al 2009, Lancet Infectious Diseases, 2009,10(1):17-31.

Country	Period	Campaign Type	Antibiotic (AB) reduction
France	2002 -	Yearly mass media targeting Providers & Consumers	27% AB prescriptions
Belgium	2000 -		36% reimbursed packages
UK	Yearly		Stable use
Australia	2000-8		14% AB consumption (DDDs)
USA	1995 -	Limited Seasonal	18-36% in ABs for ARI
Canada*	1996-2005	mass media	9% AB Prescriptions
Spain	2006-8	campaign targeting consumers	High use / No change
Portugal	2004-7		
Germany	2000 -		Low use / No change
Norway	2004		

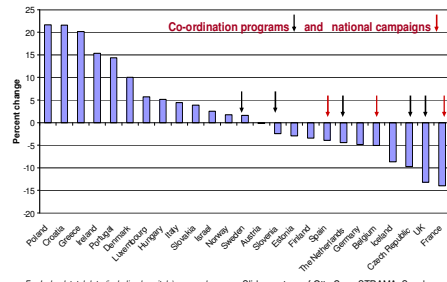
* Providers also targeted

Impact of user fees on prescribing quality, Nepal

Source: Holloway et al: HPP 2001 & SSM 2002

User Fees (complete drug courses)	control fee / Px N=12	1-band item fee N=10	2-band item fee N=11
Av. no. drugs per prescription (Px)	2.9 → 2.9 (+/- 0)	2.9 → 2.0 (-0.9 drugs)	2.8 → 2.2 (-0.6 drugs)
% prescriptions containing ABs	66.7 → 67.5 (+0.8%)	63.5 → 54.8 (-8.7%)	60.7 → 54.3 (-6.4%)
% prescriptions according to STGs	23.5 → 26.3 (+2.7%)	31.5 → 45.0 (+13.5%)	31.2 → 47.7 (+16.5%)
Average cost per prescription (Rs)	24.3 → 33.0 (+8.7 Rs)	27.7 → 28.0 (+0.3 Rs)	25.6 → 24.0 (-1.6 Rs)
Interviews with patients & providers	Both wanted the most drugs for least cost so the item fee resulted in many people opting for fewer drugs		

Percent change in antibiotic consumption, out-patient care in 25 European countries 1997-2003
Data from ESAC

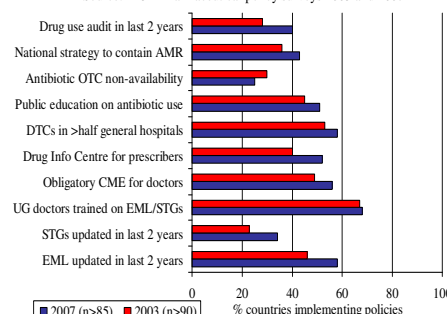


National Drug Policies (NDP) in SEAR

- Sri Lanka
 - NDP 2005 non-specific and not implemented leading to court action by patients
- Bangladesh
 - NDP 2005 comprehensive but manufacturing capacity only built and access to drugs not achieved
- Indonesia
 - NDP 2006 comprehensive but serious irrational use of medicines remains particularly after decentralisation
- Bhutan
 - NDP 2007 comprehensive and many aspects implemented - good access to and use of medicines - due to sustained government support and monitoring
- Nepal
 - NDP 1995 but many aspects not implemented
- Maldives
 - NDP 2007 but new constitution in 2008

What national policies do countries have to promote rational use?

Source: MOH Pharmaceutical policy surveys 2003 and 2007



Mission 19-26 October, 2011

- 19 Oct: Arrive Myanmar; visits to WHO country office; New Yangon General Hospital; Central Medical Store Depot.
- 20 Oct: visits to Myanmar Medical Association; Myanmar Medical Council; University of Medicines I (Pharmacology); Kungyangon Township Hosp, Sub-centre & RHC.
- 21 Oct: visits to Tharyarwaddy Township Hosp, Sub-centre & RHC.
- 22 Oct: visits to two private pharmacies; Yangon General Hospital.
- 23 Oct: Yangon to Nay Pyi Taw
- 24 Oct: Visits to Director General DOH/MOH; Myanmar Food and Drug Administration; Leiway Township hosp & RHC
- 25 Oct: workshop of National Drug Policy
- 26 Oct: workshop on National Drug Policy; Nay Pyi Taw to Yangon
- 27 Oct: Leave Myanmar

Mission findings

- Extensive health care system, with substantial infrastructure, many trained health care personnel, but...
- Serious problems in the pharmaceutical sector concerning:
 - Drug supply, selection, use, regulation, policy, information and coordination, but...
- Sufficient resources and capacity to address some of the problems

Drug selection

- **National EML 2010**
 - but CMSD supplies < half of the drugs on the NEML to townships
- **Categorisation of use by level of facility**
 - Drugs divided into those for tertiary level and others
 - No distinction between drugs for sub-centre, RHC & township hospital (although distinguished by level in previous edition 2002)
- **Township staff prescribe some non-EML drugs**
 - e.g. roxithromycin, tranexamic acid
- **Teaching hospitals – drug selection is based on the recommendation of clinical departments**
 - New Yangon General Hospital & Yangon General Hospital both have private pharmacies operating in their compounds, both of which stock 2000 products
 - No hospital formularies

National Drug Policy 2001

13 objectives covering:

- Drug supply, availability and affordability
- Rational use of drugs
- Manufacture of drugs
- Drug Regulation
- Human resources for drug management
- Adequate financial resources for drug management

Possible solutions for supply and selection

- **CMSD**
 - to produce annual report on consumption with analysis
 - To establish an electronic inventory mgt system to allow (1) better estimation / forecasting of drug need and stock control, and (2) ABC analysis of consumption for feedback to prescribers
- **Stricter adherence to the NEML**
 - Ensure consistency between lists – national EML and the CMSD lists
 - Categorise NEML by level of health facility and prescriber
 - Require all tertiary hospitals to develop formularies with justification for all non-EML drugs used.
- **Employ at least 1 pharmacist per district & per referral hosp**
 - 100 pharmacists trained per year in Myanmar but only 10% employed in government sector
 - to be in charge of drug storage, distribution, procurement and quantification – which are all technical functions

Drug Policy Objectives 2001: Drug availability and supply

- To ensure that good quality effective and safe drugs can easily be purchased by the community
- To ensure that adequate quantities of essential drugs are provided at all times to the community, based on its needs, the prevailing disease pattern and national health programs
- To make drugs easily accessible to the community by establishing an effective procurement, storage and distribution system throughout the country
- To make essential drugs available to the community at a price they can afford by establishing an appropriate drug pricing system

Drug Policy Objectives 2001: Rational use of drugs

- To promote the development of a habit for rational and efficient use of drugs
- To develop mechanisms for protection of the individual and the community from abuse of drugs, including narcotics and psychotropic agents, which are known to be harmful
- To establish drug information system for availability of adequate information about drugs, especially newer preparations
- To promote and strengthen the use of Myanmar Traditional Medicine

Drug availability and supply

(1) Complaints about stock-outs from all public facilities

- **CMSD**
 - Supplies a limited list of 80 drugs or less to public facilities twice yearly, according to past procurement & distribution
 - Most supplies last 1 month or less & reserved for the poor
 - Budget very low - <0.2 USD/person/year for general drugs
- **Observation by consultant**
 - Most patients buying drugs from private pharmacies at prices set by manufacturers & Ministry Commerce with 5-10% mark-ups at each level in Yangon according to what the market will bear
 - Some health workers buying drugs from pharmacy shops to dispense to patients in facilities where there is no pharmacy

(2) Difficult manual drug inventory control system

- No electronic inventory system so stock control difficult
- System of quantification of drug need unclear
- No routine monitoring of consumption or use

Drug use

- No routine monitoring of drug use or prescription audit
- STGs available in most facilities but many doctors do not seem to use them and there are few other sources of independent drug information and no national Drug Information Centre
- Daily pharmaceutical representative visits reported by all private facilities and referral hospitals
- Prescribing taught at undergrad pre-clinical level but undermined by clinical studies and later work
- No nationwide public education on medicines use
 - Sub-centre midwives and RHC staff have undertaken some patient education not to demand injections
- CME regular for most government staff but does not include general prescribing
 - MOH program generally for government staff
 - MMA CME training courses for private GPs

Drug use indicator survey

Drug use indicator	Referral hosp n=2	Township hosp n=3	RHC / sub-centre n=5	Drug Retailer n=2
Av.no.drugs/patient	2.8	2.7	2.1	2.3
% patients with ABs	27%	56%	31%	9%
% patients with INJs	32%	25%	5%	1%
% patients with VITs	27%	25%	36%	38%
% generic drugs	4%	51%	75%	11%
% EML drugs	62%	94%	98%	59%
% URTI given ABs	-	100%	72%	-
Av.cost/Px (Kyats)	5665	1241*	-	4363

* One hospital operating a Revolving Drug Fund

Human Resources

- Adequate numbers of clinical doctors, nurses and paramedical health workers but:
 - insufficient numbers of pharmacists employed in public sector
 - Only 10% pharmacy graduates find a post in public sector
 - No clinical pharmacology or clinical pharmacy
- Pharmacists can improve drug supply and distribution, undertake drug use monitoring, drug use evaluation, and participate in DTCs
- Pharmacy curricula do not include very much on clinical pharmacy, drug use monitoring or DTCs

Possible solutions for improving use

- **Monitor drug use**
 - ABC consumption analysis, prescription audit
- **Standard Treatment Guidelines**
 - Continue to develop, update, disseminate to every doctor and incorporate into CME and UG education
- **Drug and Therapeutic Committees (DTC)**
 - To establish DTCs in all hospitals to monitor drug use, encourage CME, and report annually on activities to MOH
- **Continuing professional development (CME)**
 - MMA & MMC to develop credit system for CME,
 - incorporate prescription audit & feedback and ethics into CME
- **Public Education**
 - Core pharmaceutical messages e.g. *does my child need more than one drug?* through Community Midwives and media

Possible solutions for human resources

- **Employ at least 1-2 pharmacists per district to:**
 - supervise drug management, distribution & quantification and undertake drug use monitoring
 - undertake regulatory functions of the FDA at district and township level
- **Employ one pharmacist per referral hospital to:**
 - Manage drug supply, monitor drug use and act as secretary to the DTC
- **Add clinical pharmacy to the pharmacy curricula**
 - Include prescription monitoring and DTCs
- **Develop the speciality of clinical pharmacology**
 - Include more on therapeutics in undergrad curricula
 - Develop a post grad speciality of clinical pharmacology with a department in every tertiary referral teaching hospital
 - Get post grad students to undertake research on prescription monitoring

Drug Policy Objectives 2001: Manufacture, human resources, regulation

- To promote the local production of drug formulations and availability of raw materials and to encourage integration of drug production, distribution and utilization in health programs with the national economic and industrial development
- To enable systematic assessment of the country's needs for technical manpower in the field of drugs and related activities, and to take effective steps for technical manpower development, including the development of pharmacy, pharmacology, clinical pharmacology, and the pharmaceutical sciences
- To promote research to identify priority areas in drug programs and supply management, and implement activities for development in these areas
- To ensure allocation of adequate financial and manpower resources for implementation of drug programs
- To take appropriate steps for identification of sub-standard and counterfeit drugs and their removal from the market

Drug regulation

- **Food & Drug Administration (FDA) under-resourced**
 - Has 42 technical staff to manage a sector consisting of 10,300 products, 10,000 registered retail shops and 4 manufacturers
 - F & D supervisory committees (including Township health officers) help FDA by inspecting drug outlets but mostly controlled drugs
 - Lacks pharmacists & FDA has asked for more staff, yet only 10% of trained pharmacists find employment with government
- **Prescription-only drugs available OTC**
 - often dispensed by unqualified shops assistants
- **Little monitoring of drug promotional activities**
 - Pre-approval of adverts for OTC medicines only
- **Many brands on the market so difficult to control**
 - About 30-50 brands of some medicines on the market e.g. amoxycillin, ciprofloxacin, paracetamol
- **Drug Prices**
 - Prices set by manufacturers in agreement with Ministry Commerce

Possible solutions for improving regulation

- **Strengthen the FDA**
 - More inspectors & pharmacists – 1 pharmacist per district
 - Standard operating procedures and guidelines for all procedures
 - Amend current regulations to allow more punitive actions
- **Strengthen the drug registration process**
 - Computerize drug registration & do training for dossier evaluation
 - Aim to have fewer drugs registered on the market as fewer brands of each chemical entity will make controlling the market easier
- **Extra drug schedule for drugs that should not be available on prescription in ordinary pharmacies**
 - E.g. oncological drugs, anti-TB drugs, very new antimicrobials
- **Start unit to monitor drug promotional activities**
 - Develop monitoring of promotional activities and start pre-approval of adverts for prescription-only as well as OTC drugs
- **Strengthen Drug Testing Laboratory**
 - To test more samples
 - To undertake bio-equivalence testing

Group work

- **Each group to draft recommendations with practical steps including:**
 - Prioritize the problems and choose the most important (max 3)
 - For the most important problems
 - What will we do
 - Who will do it
 - Resources needed – staff and funds
 - Time-line
- **Groups**
 - Drug supply and selection
 - Promoting rational drug use
 - Drug regulation and national drug law
 - National structure and Drug Policy

Coordination and management

- **MOH Structure:**
 - 10 divisions, including Medical Care & FDA
 - Essential Drug Program (EDP) is within the Medical Care & has only 1 medical and 1 clerical staff
- **Drug policy 2001 comprehensive but inadequately implemented**
 - implementation mainly done by EDP and FDA, both of which are very under-resourced
- **NDP implementation requires coordination of policy**
 - Which unit in MOH can coordinate between different divisions in MOH and different Ministries?
 - Min Educ (school curricula); Min Finance (CMSD budget); civil service commission (pharmacy posts); Min Commerce (prices of drug imports); Min Industry (Manufacturers)

Possible solutions for coordinating structure and national policy

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership incl. laypersons, professional bodies ...**
- **Strengthen the EDP to be the Executive Division in MOH to carry out the statutory committee recommendations**
 - To coordinate action between all MOH divisions and different Ministries
 - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, Drug Info Centre, public education
 - Could liaise with universities to provide students to collect information needed by the MOH as part of their research studies
 - To update the National Medicines Policy to be more specific and to include an implementation plan and time line