Sri Lanka

Pharmaceuticals in Health Care Delivery

Mission Report 23-30 July 2010

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Programme Agenda

Friday, July 23rd
Morning: Director General Health Services, MOH
        DDG Laboratory Services, MOH
Afternoon: WHO country office and travel to Kandy

Saturday, July 24th
Morning: Kandy Teaching hospital
Afternoon: Raajya Osu Sala pharmacy

Sunday, July 25th
Morning: Royal Mall private pharmacy
Afternoon: Kadugannawa district hospital and return to Colombo

Monday, July 26th
Morning: DDG Laboratory Services, MOH
        Clinical pharmacology dept in Colombo University
        (pharmacovigilance, drug information)
Afternoon: MOH Medicines Supply Division (MSD),
          Osu Sala Colombo

Tuesday, July 27th
Morning: Clinical Pharmacology dept in Jayewardeneura University
         (Sri Lanka Medical Association)
         South Colombo Teaching hospital
Afternoon: State Pharmaceutical Corporation (SPC)
          Health Guard Private (chain) Pharmacy, Colombo

Wednesday, July 28th
Morning: Thalangama peripheral unit
         MOH central dispensary at Rajagiriya
         Municipal Dispensary at Narahenpita
Afternoon: Drug Regulatory Authority
          Unichemist private (non-chain) pharmacy

Thursday, July 29th
Morning: MOH
Afternoon: Sri Lankan Medical Council
          Secretary Health, Additional Secretary Health, Director DRA

Friday, July 30th
Workshop for national stakeholders
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
Acronyms

ABC  ABC analysis – method for measuring drug consumption
ADR  Adverse Drug Reaction
CPD  Continuing professional development
CME  Continuing medical education
DDG  Department of Directorate General
DIC  Drug Information Centre
DRA  Drug Regulatory Authority
DTC  Drug and Therapeutic Committees
EDL  Essential Drug List
EML  Essential Medicines List
HAI  Health Action International
HQ  Headquarters
IPD  Inpatient department
MIC  Medicine Information Centre
MOH  Ministry of Health
MRA  Medicines Regulatory Authority
MSD  Medicines Supply Division
MTC  Medicines and Therapeutic Committee
NGO  Non-governmental organization
NDP  National Drug Policy
NMP  National Medicines Policy
NOL  No objection letter
OPD  Outpatient department
OTC  Over-the-counter
RUM  Rational use of medicines
SOP  Standard Operating Procedures
SLMA  Sri Lanka Medical Association
SLMC  Sri Lanka Medical Council
SPC  State Pharmaceutical Corporation
STG  Standard Treatment Guidelines
TOR  Terms of Reference
VEN  Vital Essential Non-Essential – method for classifying drug importance
WHO  World Health Organization
Executive summary

A visit was made to Sri Lanka during July 23-30, 2010. The programme was arranged in agreement with the MOH with the TOR to undertake a situational analysis of the pharmaceutical situation with a focus on health care delivery and to conduct a 1-day workshop with stakeholders to discuss the findings and develop a roadmap for national action. Visits were made to public health facilities and private pharmacies in Kandy and Colombo districts, the major MOH departments, the clinical pharmacology departments of 2 universities and the Sri Lanka Medical Council. It was found that Sri Lanka has an extensive health care system, with substantial infrastructure, trained health care personnel and good health indicators, but that 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 that there are sufficient resources and capacity to address the problems.

Drug Supply and selection

Drugs are supplied by government to all public facilities but there was a shortfall with demand outstripping supply by about 25-30%. Thus there were complaints about stock-outs from all public facilities. Good quantification of drugs is needed but currently not possible due to a poor inventory control in public sector, there being no electronic inventory control systems in health facilities. In addition, requirements were underestimated in all facilities due to forecasting on last year’s consumption (which was insufficient) and fear of expiry (for which the pharmacist must pay) so resulting in frequency emergency orders. Unfortunately, the Medical Supplies Division (MSD) and the State Pharmaceuticals Corporation (SPC) of Sri Lanka cannot respond due to 6-12 month lead times and government financial regulations. There is a national Essential Medicines List (EML) 2009, which MSD follows but medical consultants are able to request out-of-list drugs and the MSD will buy them although these drugs are often purchased locally at much greater expense. Sometimes they come too late to be used by the requesting consultant who has moved to a different hospital. It was found that 29% of medicines supplied by MSD in 2006 were not on 2004 EML and that 29% of medicines in highest expenditure A-category items are not on the 2009 EML. The top 10 medicines by cost included rabies vaccine and immunoglobulin whereas the top disease category was infectious disease.

It was recommended that an electronic medicines inventory system be set up involving MSD, SPC and all public health facilities to better estimate need and to monitor adherence to the EML.

Drug use

There was a dearth of published information on medicine use. The consultant found polypharmacy, high use of antibiotics and vitamins in primary care facilities, with only 63% of medicines written by generic name. Although World Bank has sponsored the development of a number of new standard treatment guidelines, few prescribers were using any such guidelines or any other source of independent drug information. However, most 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 not followed by many prescribers and does not include much on rational use of medicines. Huge overcrowding in public clinics
results in 1 minute consultations leading to polypharmacy and unnecessary in-patient admission.

It was recommended that a unit dedicated to regular monitoring of medicines use and implementing strategies to improve use be created within the MOH. Other interventions recommended include strengthening Drug and Therapeutic Committees (DTCs) in all hospitals, distributing updated guidelines and incorporating them into Continuing Professional Development (CPD) curricula, and developing public education programs on medicines use to be delivered through the existing MOH health promotion units.

**Drug Regulation**

There was a severe manpower shortage in the drug regulatory authority (DRA) plus there were many brands for the same active pharmaceutical ingredient available on the market so making inspection and supervision more difficult. Thus, there was a lack of inspectors for drug outlets and a lack of pharmacists in shops to supervise dispensing and availability of many prescription-only medicines over-the-counter (OTC). While there was monitoring of adverts aimed at the public for OTC drugs, there was no monitoring of adverts aimed at prescribers. There were insufficient lab testing facilities to ensure medicine quality. Some activities such as drug evaluation for registration (which was manual) and pharmacovigilance relied on the outside expertise of clinical pharmacologists from Colombo University. In addition, the DRA was responsible for many activities that were not strictly regulatory ones such as developing and updating the EML and clinical guidelines. Furthermore, many of the same people sat on the various different committees such as the EML committee, technical advisory committee, drug evaluation committee, procurement committees, recall committee, advertisements sub-committee, clinical trials sub-committee, etc., which could result in conflicts of interest impacting decision-making.

It was recommended that the manpower shortage be rectified as a matter of urgency, that Standard Operating Procedures (SOPs) be revised for the various committees, that the OTC list be revised and that an electronic drug registration system be instituted.

**Coordination**

Many functions such as monitoring of medicines use, coordinating CPD, supporting DTCs, updating EML and ensuring adherence to the EML, updating guidelines and ensuring their distribution and incorporation into CPD and undergraduate curricula, public education on medicines use are not undertaken by any MOH department. Furthermore, it was found that while there is a National Drug Policy document, it was not specific with regard to many aspects of the pharmaceutical sector and much of it was not implemented. Much discussion was had about updating the National Drug Policy and which MOH department should do it but no agreement on this matter could be reached.

It was recommended that a unit dedicated to monitoring medicines use and coordinating the implementation of strategies to improve use be set up in the MOH. Such a unit should be guided by a multidisciplinary statutory committee.
Terms of Reference

The objectives were:

(1) to gain an introduction to the pharmaceutical sector in Sri Lanka;

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

(3) to conduct a 1-day workshop with national stakeholders to validate the findings of the situational analysis and to develop recommendations for future use by MOH, WHO and stakeholders in planning

(4) to pilot test a pharmaceutical sector assessment tool (developed by HQ) in undertaking the situational analysis and conducting the workshop

(5) To help with any other problems and planning issues

Background

This mission was undertaken to conduct a national situational analysis with regard to the pharmaceutical sector 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. This mission was undertaken during 23-30 July, 2010, 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 29 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.

Sri Lanka has a well developed health care delivery system with trained staff and very good health statistics. Part of this health delivery system includes delivery of medicines, free to the patient, in the public sector. However, government has noticed in the last few years that the demand is outstripping the budget resulting in frequent stock-outs and emergency orders. In addition there have been concerns about the quality of medicines and irrational use of medicines. For this reason, 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 by the State Pharmaceuticals Corporation (SPC) of Sri Lanka State and distributed by the Medicines Supply Division (MSD) of the Department of Health within the MOH. It is the policy that medicines are dispensed free of charge to patients in the public sector. Teaching hospitals have 10% of their budget to make discretionary purchases but all other facilities get all their medicines from the MSD. Medicines are distributed quarterly.

Unfortunately in recent years, demand has outstripped supply by about 25-30% with frequent complaints of stock-outs and patients having to buy drugs from outside pharmacies. All hospitals complained of a lack of space for drugs storage. It was mentioned that the current budget is only 13.5 billion rupees whereas 22 billion is needed. While part of the reason for drug non-availability is lack of budget, several other factors, which could be rectified, are contributing to this problem.

Firstly, there is poor inventory control in public sector with no electronic drug inventory systems in health facilities. Thus it is very difficult to monitor what drugs are being used and thus make accurate forecasts of need. Even an ABC analysis was not possible except within the MSD. Secondly, there is always under-estimation of requirement since it is based on last year’s consumption which is already insufficient. Thirdly, some pharmacists feared drug expiry (for which they have to pay) so they deliberately under-order. Last year 75 million rupees worth of medicines expired. However, some district hospitals are managing to deal with drugs about to expire before they can be used by sending them to other districts where they can be used before expiry. Fourthly, the SPC cannot respond to the frequent emergency orders because normal lead times for drug purchase are over 1 year and even for emergency orders, lead times are over 6 months. The lead time cannot be cut down due to government administrative and financial regulations. Fifthly, teaching hospitals are not restricted to following the EML in their emergency orders and MSD estimated that 15% of the budget is spent on non-EML drugs. Kandy teaching hospital mentioned that they spend 30 lakh per month on emergency orders and make frequent visits to MSD.

It was mentioned that there is need for a harmonized electronic inventory system between MSD and SPC. The MSD stated that the infrastructure of the SPC was insufficient while the SPC stated that the government rules and regulations made it impossible to make timely purchases and also that emergency orders were more often association with poor quality drugs. The SPC stated that they try to buy at lowest price and best quality but that DRA registration system does not take quality sufficiently into account. Therefore they are now doing prequalification of suppliers - mostly on paper but sometimes with joint visits by DRA and SPC prior to allowing only qualified suppliers to tender.

An electronic drug inventory system installed in all hospitals would allow much more accurate forecasting and also a more detailed analysis of consumption e.g. ABC analysis, that could be fed back to prescribers. Only with such a system can monitoring of adherence to the EML be done. The MSD mentioned that a plan has just been initiated to install such as system.
In the private sector, drug availability is better but it is very costly for the patients. The SPC is a parastatal organization accountable to government. In addition to procuring for the public sector, SPC also runs 24 Osu Sala pharmacies (on a business footing), operates 84 franchises and supplies drugs to 43 Cargills supermarkets and 52 wholesale distributors, distributing 680 products in all. Since the SPC is accountable to government, they do try to keep prices as low as possible, selling at company retail prices – which is often much lower than in other private pharmacies. While they run the Osu Salas as a profitable business, they do use some of the profits to offset losses in public sector, which currently requires payment of 1 million SLR per day interest. Since Osu Sala pharmacies must make a profit they do not follow only the EML. The SPC does inspect their outlets with difficulty. The SPC also has a promotional unit and funds (45 million SLR per year) about 15-20 Continuing Professional Development (CPD) activities per year including a bulletin, the Sri Lanka Prescriber (through the Sri Lanka Medical Association), and school programs.

Poor people cannot buy all the drugs in the prescriptions at private pharmacies. It was mentioned in all facilities visited that some patients must buy drugs at outside facilities and that the cost often precluded them buying all the drugs and the complete quantity. Many private pharmacies mentioned that many patients could not buy all their drugs and one Osu Sala pharmacist estimated that 50 patients per day could not buy all their drugs. Unfortunately there is no pricing policy in Sri Lanka and pharmacy shops generally sell at the retail price set by the pharmaceutical companies.

Table 1 shows the drugs mentioned as non-available by staff during the consultant’s visits.

**Table 1: Drugs out of stock in facilities visited**

<table>
<thead>
<tr>
<th>Public Facility Name</th>
<th>Drug out of stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kandy district hospital</td>
<td>Metformin, Tolbutamide</td>
</tr>
<tr>
<td>Kandy teaching hospital</td>
<td>Salbutamol tabs, Gentamicin inj, Cloxacillin inj, Atovastatin, Metoprolol</td>
</tr>
<tr>
<td>Narahenpita municipal dispensary</td>
<td>Erythromycin syrup (but prior to recent delivery many items had been out of stock)</td>
</tr>
<tr>
<td>Colombo South Teaching hospital</td>
<td>Theophylline, Thyroxine, Vitamin B Complex, Paracetamol syrup, Omeprazole</td>
</tr>
<tr>
<td>Thalangama peripheral unit</td>
<td>Atenolol, Atovastatin, Metronidazole, Enalapril, Cloxacillin, Clopidopril, Losarten, Prazocin, Domperidone</td>
</tr>
<tr>
<td>MOH Central dispensary</td>
<td>Prednisolone, Domperidone, Omeprazoel, Brufen, Atenolol, Losarten, Enalapril</td>
</tr>
</tbody>
</table>

Private pharmacies also suffered stock-outs. Colombo 4 Osu Sala pharmacy mentioned that 100 items were out of stock and that they often had to purchase from sources other than the SPC. A Unichemist private pharmacy mentioned that they bought medicines from the SPC as well as other sources and that glyceryl trinitrate had been out of stock for 6 months.
Possible Solutions
1. Establishment of an electronic drug inventory management information system that would allow monitoring of drug consumption in the public sector.

2. Support of the electronic system MSD is now starting to set up such with extension to the level of hospitals and regional stores.

3. Harmonization of the inventory control systems in MSD and SPC so that procurement is well coordinated with distribution and demand.

Medicines Selection and Consumption

Sri Lanka has a revised National List of Essential Medicines (EML), 4th revision, 2009, containing 477 essential medicines and vaccines (including supplementary anti-neoplastic agents). It was prepared by an Expert committee of 64 resource personnel, including a Secretariat of 4 persons, a chair, convener and the Director, Medical Technology & Supplies, Ministry of Healthcare & Nutrition. All specialties were represented, including 12 persons from Medical Technology and Supplies Division, 2 consultant community physicians but excluding any primary care physicians. The selection criteria used are not publicly available. The development of the EML was coordinated by the DRA with WHO support.

The Medical Supplies Division (MSD) follows the 2009 EML, but consultants are able to request out-of-list drugs and MSD will buy them. However, it was mentioned by several respondents that either drugs come too late from the MSD for the consultant to use (the doctor having transferred to another hospital) or they will be purchased locally at much greater expense. Some doctors did not believe that the EML was useful. In Kandy Hospital, consultants request non-EML drugs on an individual patient basis and the drugs are purchased on a daily basis after authorization by the Director. Teaching hospitals in Colombo were similar. According the clinical pharmacologists in 2 universities and the MSD, there is no proper vetting system for these consultant requests and that such a system needs to be urgently established. A municipal dispensary mentioned that the EML was not useful because the municipal list was different. Some doctors said that had not even seen the EML. An Osu Sala private pharmacist mentioned that the EML was not useful for the private sector.

A study done by the MSD in collaboration with University of Colombo, with WHO support (Ranganathan S et al 2006) on drugs issued to the public sector during 2002-6 found that 29% of medicines supplied by MSD in 2006 were not on 2004 EML. Furthermore, 29% of medicines in highest expenditure A-category items were not on the 2009 EML. In addition it was found that the top 10 medicines include Rabies vaccine, human immunoglobulin, paracetamol, cefuroxime injection, desferrioxamine, insulin, Normal Saline, meropenem, ceftazidime, while the top 10 diseases are infectious diseases, neoplasms, blood disorders, endocrine/nutritional/metabolic diseases, mental disorders, eye disorders, ear disorders, circulatory disorders, respiratory diseases i.e. the top drug costs are for
drugs that are not used to treat the commonest health conditions. The 24 most expensive items are mostly antineoplastic and immunomodulating agents, medicines acting on blood forming organs, anti-infectives and medicines acting on musculoskeletal system. It would be worthwhile to review whether these expenses are justified.

**Possible solutions**
1. Stricter adherence to the EML so enabling existing drug supplies to go further in treating patients and reducing wastage.

2. Regular updating of the EML with publicly available selection criteria, wide dissemination to all facilities and inclusion into pre-service and in-service training curricula in order to further sensitize doctors to the utility of following the EML.

3. Establish a permanent sub-committee to judge all out-of-list requests. The medical colleges and specialists boards could provide guidance on “reasonable” specialist drugs for out-of-EML purchase. This sub-committee could judge for all teaching hospitals. Judgements for such drugs do not need to be made on an urgent hour by hour basis so a permanent sub-committee could manage such requests.

**Medicines Use**

There was a great dearth of information concerning medicines use. Clinical pharmacologists mentioned that while 70-80% of the budget may be spent on EML drugs, these drugs are not used correctly.

Only 3 published studies on drug use were found – all more than 10 years old (Angunawela et al 1991, De Silva AVKV 1990, Tomsom et al 1990). Two more recent unpublished studies done by masters students were found in the Clinical Pharmacology department of Colombo University (Nirmalie M.I 2003, Thevamoorthy C, 2005). Tomson et al undertook a survey in 1988 of paediatric prescribing in public sector out-patient acute primary care and found that 49% of patients received an antibiotic and that the average number of drugs per patient was 2.7. Nirmalie M.I 2003 undertook a survey of paediatric prescribing (mostly acute cases) in the private sector clinics and found that 72% of children received antibiotics, the average number of drugs per patient was 2.2, the % of drugs prescribed by generic name was 20% and that only 50% of all prescribed drugs belonged to the EML. Thevamoorthy C, 2005 found that in an Osu Sala pharmacy, where many patients were adults with chronic diseases, that 9% of patients received and antibiotic and 38% of drugs were prescribed by generic name.

The consultant undertook a rapid prescribing survey in the outpatient departments in 6 public facilities (serving mostly acute patients) and 5 private pharmacies (serving acute and chronic patients), examining 30 prescriptions per public facility and 30 patient bills or records per private pharmacy (total 330 patient episodes). The results are shown in table 2.
Table 2: Primary care drug use indicators in facilities visited during the mission

<table>
<thead>
<tr>
<th>Drug use indicator</th>
<th>Public (n=6)</th>
<th>Private (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number drugs per prescription</td>
<td>3.0</td>
<td>3.5</td>
</tr>
<tr>
<td>% prescriptions containing antibiotics</td>
<td>49</td>
<td>23</td>
</tr>
<tr>
<td>% prescriptions containing vitamins</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>% drugs prescribed by generic name</td>
<td>63</td>
<td>37</td>
</tr>
<tr>
<td>% prescribed drugs on EML</td>
<td>99</td>
<td>57</td>
</tr>
<tr>
<td>Average drug cost per prescription</td>
<td>-</td>
<td>SLR 685</td>
</tr>
</tbody>
</table>

It can be clearly seen that vitamin use is high in both sectors and that the private sector uses more drugs per patient, more non-EML drugs and fewer generic drugs than the public sector. The % of patients receiving antibiotics was lower in the private pharmacies compared to the public facilities due to the greater proportion of chronic patients included in the prescription sample. It was further noted that the percentage of patients receiving antibiotics in OPD was much higher in tertiary level hospitals (66% Kandy hospital and 59% Colombo teaching hospital) than in district hospitals and primary care centres (Kandy district hospital 36%, Thalangama peripheral unit 49%, MOH Central dispensary 22%). In the municipal facility 60% of patients received an antibiotic. The average drug cost per prescription in the private pharmacies was SLR 685 and it was mentioned that many patients could not buy all the drugs prescribed.

In one facility it was noticed that every child with cough and cold was prescribed panadol, piriton, salbutamol, vitamins and sometimes with an antibiotic and/or an antacid or H2 antagonist (e.g. ranitidine) also. Not only does this show serious polypharmacy, but also it was calculated that the overall annual cost to the public sector of paracetamol, chlorpheniramine, salbutamol, vitamin B Complex and multivitamins in 2009 was SLRs 355,806,110.

The results of the consultant’s rapid survey are similar to the few studies done previously. In addition, it was noted that hospitals wards and outpatients were very crowded. In most facilities, while medical chiefs may see 50 patients per day most doctors in the OPD were seeing 100 or more patients per day often with average consultation times of 1-2 minutes. Such short consultations are very likely lead to unnecessary over-prescribing and inpatient admissions simply because the doctors have no time to make sure diagnoses. A number of doctors said that they cannot make a proper diagnosis, give the treatment and educate the patient in 1 minute!

Pharmacy technologists may see more than 200 patients per day with an average patient-dispenser contact time of less than 30 seconds, so allowing no time to give patients proper instruction on how to take their medicines. Such rapid dispensing was achieved by having a conveyor belt system of dispensing pre-packaged drugs. Thus, in private pharmacies, it was observed that one staff member received the prescription, the next wrote the label, the next put the pills into the envelope with the paper label, the next calculated the bill and gave it to the patient, the next took the money and the final staff member gave the medicines. A similar system was observed in public facility pharmacies except that the stages of giving a bill and taking money were omitted.
Standard Treatment Guidelines (STG)
Few prescribers were using any Standard Treatment Guidelines (STGs) or other sources of independent drug information. There is no national formulary. The Sri Lanka Medical Association (SLMA) has developed some STGs from their own funds including ones on antibiotics, vaccination, diabetes mellitus, asthma and hypertension. In 2007, World Bank funded STG development for many conditions through the professional colleges. Conditions covered by the World Bank STGs included paediatrics, medicine, surgery and Obstetrics & Gynaecology. Although it was reported that the STG booklets had been sent to all hospitals, few printed copies were available anywhere and they were generally unavailable in the facilities visited. Only one facility mentioned having the STGs and they were locked in a cupboard, for which no key was available during the visit. It was mentioned by some clinical pharmacologists that there was inconsistency between STGs and EML, that an evidence-based process had not always been followed in developing the STGs and that not all interested parties had been involved. Only the committee developing the STG on paediatric conditions had invited a clinical pharmacologists to contribute and then only because she was also a paediatrician. As a result there is no consensus on the use of STGs by consultants – and some felt that it was better for big hospitals to develop their own STGs. Few doctors had seen either the STGs or the EML.

Education and Information
It was mentioned that prescribing principles are taught at undergraduate pre-clinical level in sufficient detail but that what they learn is undermined by their clinical studies and later work with senior consultants. Therefore, prescribing skills and clinical pharmacology teaching is needed during the clinical as well as the pre-clinical training. While some STGs are included in undergraduate training, these STGs are not followed in the clinical setting.

Continuing Professional Development (CDP) is adhoc and not followed by many prescribers, nor does it include much on prescribing or rational use of medicines. It was mentioned that most CPD consists only of pharmaceutical sponsored lectures. While the SLMA and SLMC do hold monthly meetings, these are not mandatory. The SLMA and SLMC are developing an accreditation points system for re-licensing but this has not yet started, nor is it certain that it will include any elements on rational use of medicines. All pharmacists (both government and private sector) have a 2-year diploma training and there is an ethical code of practice for them but no CPD although the Pharmaceutical Society of Sri Lanka and SPC do organize adhoc lectures and meetings which are often sponsored by pharmaceutical industry.

While CPD is adhoc or minimal for many prescribers, daily visits by pharmaceutical representatives are common, not only in the private sector but also in the public sector. It was even mentioned by one respondent that representatives bribe reception staff to direct them to doctors to prescribe their medicines. Almost all respondents mentioned that there is too much pressure and too many promotional activities from the pharmaceutical industry.

Sources of independent drug information are few. Very few doctors had seen any of the STGs developed. Some doctors were receiving the Sri Lanka Prescriber (produced by the SLMA and sponsored by the SPC) and some teaching hospitals were receiving the Australian Prescriber and 1-2 other journals. There is no Drug Information Centre
(DIC) run by MOH. However, there are DICs run by university hospitals. Thus there is a DIC run by Colombo University Teaching Hospital but it is open only in office hours and has no dedicated staff. The Kandy District Hospital Chief Medical officer mentioned that there was another DIC in Perandanuya University but that he had never used it.

All MOH facilities have a public education facility that is used to spread various public health messages in the community. The topics they teach are decided by MOH and so far these facilities have not been used to spread messages on the proper use of medicines to the community, although many people felt this would be good to do as patient demand for drugs is high. So far only NGOs such as HAI Asia-Pacific have undertaken any community education projects on medicine use. HAI/Pacific had actually conducted some school children education projects. 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”.

**Drug and Therapeutic Committees (DTC)**

There is no national DTC. Most hospitals and health facilities have a Drug Review Committee which only discusses drug shortages and does not undertake any other activities that a DTC should undertake such as monitoring drug use, supervision, drug use evaluation, coordinating training activities, monitoring adverse drug reactions and events or formulating local drug policy. While there is no formal DTC in health facilities, there are some local initiatives to improve quality of care and medicines use. For example, in Kandy district hospital (Kadugannawa) the Chief Medical Officer organizes monthly staff meetings for general issues such as attendance and cleanliness, a Medical Officers’ meeting to discuss clinical problems and drug availability and 5 ‘quality circles’ for each ward and OPD to discuss problems and solutions in their areas of jurisdiction. Like other facilities there was also a drug review committee which meets monthly to discuss drug availability and drug stock-outs.

**Private prescribers/dispensers**

It was mentioned and observed that all medicines were freely available over-the-counter (OTC). While prescribers in the public sector do not dispense, those in the private sector often do dispense. Many mentioned that the profit-motive leads to the prescribing and dispensing of many newer branded products which many patients cannot afford. One Osu Sala pharmacist mentioned that many doctors were using a prescription stamp that prohibited generic substitution for branded products and that if such stamps were prohibited they could do such substitution and save the patients a lot of money.

**Possible Solutions**

1. An electronic drug inventory stock control and management information system which will allow monitoring of drug use including:
   - ABC analysis in association with VEN analysis (are the drugs consuming the most budget vital and essential?);
   - adherence to the EML
   - comparison of consumption at primary care versus hospital or between districts could be done.
2. Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above).

3. Annual publication (ideally as a statutory requirement) in all major hospitals and districts of drug consumption analysis and prescription audit, with analysis of all publications in the MOH.

4. Development and regular updating, with dissemination to all doctors, of STGs with incorporation into the CPD curricula.

5. Upgrading the Drug review committees to full DTCs with an obligation to monitor drug use, coordinate CPD in their institutions and to report annually to MOH. A reporting system that enables health facilities to report on quality of care issues and drug use will enable MOH to know what is and is not going on and what needs to be done. However, such a system does require capacity in the MOH to review these reports.

6. Encouragement of the SLMA and SLMC to further develop a credit system and to incorporate prescription audit and feedback and ethics into CPD.

7. Dissemination to the public of core pharmaceutical messages through the already existing MOH health education units and media. e.g. does my child need more than one drug?

**Medicines Regulation**

There is a comprehensive Cosmetics, Devices and Drugs Act 1980 with several amendments from 1985. Since then it appears not to have been revised. While the Act is fairly comprehensive the Drug Regulatory Authority has difficulty to enforce all aspects of this act due to a shortage of human and financial resources. Currently there are only 9 pharmacists in post in the DRA which has no website and no annual report of activities. Furthermore there are no graduate pharmacists for drug evaluation in the permanent cadre of staff. There are 10 local drug manufacturers.

**Regulation of outlets and drug schedules**

Although by law a pharmacist should always be present on the pharmacy premises to supervise dispensing, often they are not. It is not possible to enforce this due to the shortage of human resources, particularly inspectors. All pharmacies are supposed to receive a visit once a year to renew their license. However, with the shortage of inspectors and lack of transport and funds together with the large number of pharmacies it is not possible to inspect annually all distributors and outlets. When inspections are made the lack of time means that anything more than a cursory look at the premises is not possible. Currently there are 3 Food and Drug inspectors per province and 4 centrally (soon another 4) to inspect 3000 pharmacies (500 in Colombo). It was estimated that 20 inspectors would be needed to properly inspect 500 pharmacies. Some pharmacists felt that there were too many pharmacies causing not only difficulties in inspection but also excessive competition resulting in
behaviours, some unethical, that do not always benefit the patient (e.g. selling of prescription-only drugs OTC).

There are OTC (schedule 1 and 2A) and prescription-only (schedule 2B) drug schedules but both types of drug are freely available without prescription. In addition, homeopaths and other practitioners are also prescribing antibiotics and other prescription-only medicines. One criticism was that the OTC list has not been updated for many years and is not available so that many pharmacists do not know what is on the OTC list. The DRA mentioned that it was not possible to take punitive action for the selling of schedule 2A drugs without prescription.

**Drug Promotion**

There is very little monitoring of drug promotional activities. While there is a committee to examine and approve (pre-use) adverts aimed at consumers, it does not review adverts aimed at prescribers, nor is there any other system to review such adverts. Some prescribers felt that the editor of medical journals could review these adverts before placing them in their journal. However, the clinical pharmacologists strongly disagreed with this and insisted that a committee be formed to examine these kinds of adverts also. Once an advert aimed at consumers had been approved there was an inadequate mechanism for monitoring whether the concerned company stuck to the letter of the agreed text for the advert. Last year there were 5-6 prosecutions for inappropriate advertising of schedule 1 (OTC) drugs to consumers.

**Drug registration, drug quality and pharmacovigilance**

The SPC and a number of pharmacists mentioned that there were drug quality problems because of a weak registration system and weak post-marketing surveillance and that there was a lack of laboratory facilities to monitor and ensure adequate quality. Some pharmacists mentioned that there was evidence of removal of expiry dates on some medicines but that this could be avoided if sealed packets were used.

DRA currently cannot manage post-marketing surveillance within its own department and has outsourced pharmacovigilance activities to the Clinical Pharmacology Department in Colombo University.

It was mentioned that there are many brands on the market (>8000) so it is difficult to monitor and control. For example, one pharmacist mentioned that there were 40-60 brands of amoxicillin, diclofenac and atorvastatin and 15-30 brands of paracetamol, omeprazole, losarten, clopidogrel and cephalexin on the market and that he had to stock at least half of all available brands for each chemical entity particularly because of the use of stamps by doctors not to do generic substitution.

A further criticism made was that products should only be registered for use after approval by the Technical Advisory Committee but that some unregistered products are used after issue of a no-objection certificate without recourse to the Technical Advisory Committee. However, the DRA Chief mentioned that this was not frequent now and that it only happened in relation to the importation of medicines by the SPC for use in the public sector. He did admit to the need for some restriction on the number of products registered as they as have limited capacity to monitor and control such a large market which has too many products available. One way to do this may be to increase the registration fee. Currently this fee is quite low so encouraging more
registrations which earn more money. A large increase in registration fee may help to cut down the number of registrations while still maintaining some income. The funds raised could be used to strengthen the DRA rather than just going to the treasury as at present.

The Chief of the DRA mentioned a number of very serious problems in drug registration and ensuring drug quality including:

- insufficient capacity of national drug testing laboratory which can only process 2 samples per inspector per month plus 20 samples for registration purposes per month, which is insufficient to ensure adequate quality
- a need to strengthen the drug registration process which relies on the minimally paid services of a clinical pharmacologist in Colombo University and 12 DRA pharmacists who have to do everything else also.
- Possible conflict on interest and lack of time for some of the Members who sit on all the various committees including the Technical Advisory Committee, Drug evaluation committee (for drug registration), EML Committee, Recall Committee and various other subcommittees for devices, clinical evaluation, Clinical Trials, advertising for OTC drugs (not prescription-only ones).

The registration process would be helped if it were computerized. The WHO country office has some software for this and could give support for setting this up. However, in addition other aspects need attention such as fully reimbursing the time given by external experts such as clinical pharmacologists.

**Other functions**

A number of other functions currently assigned to the DRA are outsourced. For example, pharmacovigilance and updating the national EML are outsourced to the Clinical Pharmacology Department in Colombo University. The DRA is supposedly responsible for STG development and compliance but they are not able to do very much about these issues and also it is questionable whether the regulatory body is the best body to do such activities. There is no pricing policy and all the pharmacists interviewed stated that they sell at the retail price which is set by the pharmaceutical companies. Some argued that a pricing policy was needed to encourage use of essential drugs and discourage use of non-essential ones.

**Possible Solutions**

Strengthen the DRA by:

1. Appointing sufficient staff, particularly inspectors and graduate pharmacists, to deal with all the required activities;

2. Training existing staff for certain specialist activities such as dossier evaluation for drug registration;

3. Improving 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;
   - ensuring that all products are approved by the technical advisory committee
• publishing the number of products approved by the technical advisory committee and the number of products given no-objection certificate without review by the committee.

4. Revising and updating 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;

5. Amending the current regulations to increase punitive action;

6. Expanding the system of pre-approval of adverts for OTC medicines to include pre-approval for adverts aimed at prescribers and a system to monitor all promotional activities;

7. Update and disseminate the OTC list so that pharmacists and retailers know which drugs can be dispensed without prescription and which ones need a prescription.

8. Reviewing 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 with regard to the newer antimicrobial drugs, where misuse will lead rapidly to antimicrobial resistance.

**Medicine Policies and Health system issues**

There is an extensive public health care system in which patients can receive free health care. However, many patients have to pay out of pocket due to medicine shortages. Very few patients have health insurance. There is no referral system and any patient can go to any hospital s/he likes. Many patients apparently like to come to city hospitals which are very crowded resulting in very short consultation times, probably unnecessary admissions and over-prescribing. A referral system might decrease patient density in hospitals. Most MOH officials felt that there was inadequate supervision of many medicine-related activities.

There is a national medicines policy (NMP) document published in 2005 which attempts to describe a full set of pharmaceutical polices. However, many respondents felt that the policy document lacked detail. Furthermore, no implementation of the NMP had started despite meetings of the Standing Committee for the past 2 years. Due to this non-implementation, there is now a court case being brought by the People’s movement against the government. While most stakeholders were involved in development of the NMP, there was apparently little representation from actual health facilities.

The various medicine policies that may impact on drug use and are in place, adapted from a report sent by MOH to WHO Geneva in 2007, are shown in table 3.
**Table 3: Medicine Policies in place in Sri Lanka according to the WHO Pharmaceutical Survey in 2007**

<table>
<thead>
<tr>
<th>Drug Policy</th>
<th>State of implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Medicines Policy</td>
<td>Official document &amp; implementation plan, but implementation not yet started</td>
</tr>
<tr>
<td>Monitoring the use of medicines</td>
<td>Consumption monitoring done centrally in terms of cost, recently published for the first time, but very little information available on actual prescribing</td>
</tr>
<tr>
<td>Essential Medicines List</td>
<td>National List used in public sector procurement</td>
</tr>
<tr>
<td>Standard Treatment Guidelines</td>
<td>No national STGs (although standard treatment guidelines have been produced for hospitals and PHC)</td>
</tr>
<tr>
<td>Formulary</td>
<td>National formulary published in 1994</td>
</tr>
<tr>
<td>Generic Policies</td>
<td>Generic substitution in the public sector</td>
</tr>
<tr>
<td>Regulation of promotion of medicines</td>
<td>Government regulation only with capacity only to undertake pre-approval for OTC drug adverts</td>
</tr>
<tr>
<td>Monitoring of ADRs</td>
<td>Done by the national centre for Pharmacovigilance contracted out to Colombo University</td>
</tr>
<tr>
<td>Payment for medicines</td>
<td>All medicines received free of cost in the public sector.</td>
</tr>
<tr>
<td>Health Insurance</td>
<td>Public health insurance does not cover a significant proportion of the population</td>
</tr>
<tr>
<td>Revenue from medicines</td>
<td>Never used to pay salaries in the public sector</td>
</tr>
<tr>
<td>Medicine Pricing policies</td>
<td>No strict pricing policies used in either the public or private sectors</td>
</tr>
<tr>
<td>Undergraduate medical training</td>
<td>National EML and STGs are not part of the curricula but training on prescribing and problem-based pharmacotherapy are included</td>
</tr>
<tr>
<td>Continuing medical education</td>
<td>No non-commercially funded CME, but SLMA developing a program of CME/CPD</td>
</tr>
<tr>
<td>Medicines Information Centre</td>
<td>No national medicines information centre but University of Colombo has a local unit</td>
</tr>
<tr>
<td>Public education on medicines use</td>
<td>No public education campaigns on medicines use done in the past 2 years</td>
</tr>
<tr>
<td>Drug and Therapeutic Committees (DTCs)</td>
<td>DTCs are mandated in the draft document on National Medicines Policy but few hospitals have functional DTCs</td>
</tr>
<tr>
<td>National Strategy for containing antimicrobial resistance</td>
<td>No national strategy and antibiotics frequently available over-the-counter with prescription</td>
</tr>
</tbody>
</table>

**Coordination and Management**

One of the possible reasons for non-implementation of the NMP may be the existing MOH structure. Currently the DDG Laboratory services is in charge of the health laboratories, the national blood transfusion service, the cancer control program, the medical research institute, and pharmaceuticals including the Drug Quality Assurance laboratory, the Medicines Supply Division and the DRA. Thus, pharmaceuticals are
managed by departments relatively low in the hierarchy of MOH and this, in turn, limits their ability to recruit staff and get resources.

While the DRA is nominally in charge of the EML, it is not clear what department or unit in the MOH is actively looking after such functions as the updating and implementation of STGs, monitoring of drug consumption and prescribing, implementation of DTCs, CPD and public education. In addition, the same experts are serving on various sub-committees e.g. EML selection, drug registration, technical advisory group, drug procurement. This leads to a lack of time and conflict of interest for these experts. Such a structure, where it is not clear which unit or department is carrying out some of the core functions specified in the NMP, may be one of the reasons for its non-implementation. Furthermore, there is disagreement within the national stakeholders concerning where the DRA should be in the organogram. Some people feel it should be elevated to an independent body directly under the MOH with wide responsibility for many functions in addition to the traditional regulatory ones e.g. pricing, drug information, drug monitoring etc. Others disagreed. However, all stakeholders felt that there should be a dedicated properly resourced unit somewhere within the MOH to monitor medicines use and coordinate policies to improve medicines use.

**Possible Solutions**

1. Two possible structures were suggested:
   - Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with a wide membership including laypersons and professional bodies and an Executive Body in the MOH to carry out statutory committee recommendations and distribute work to the existing departments, including the MSD, the DRA and a new extra unit in MOH responsible for rational use of drugs.
   - To continue with the existing structure but to add a dedicated unit/department responsible for promoting rational use of medicines within the MOH.

2. The dedicated unit on RUM should undertake activities concerning:
   - Monitoring of use,
   - Development, updating and dissemination of a National EML and STGs,
   - Coordination and monitoring DTCs, CPD, Medicines Information Centre, public education
   - Liaison with universities to provide students to collect the information needed by MOH as part of their research studies (so overcoming lack of human resources to carry out these functions in The MOH while at the same time developing and using locally available expertise)

3. The National Medicines Policy should be revised to be more specific, requiring:
   - 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 July 30th with 29 national stakeholders to discuss the consultant’s findings and to develop recommendations. The participants in the workshop can be seen in annex 2. The consultant’s presentation at the workshop can be seen in annex 3.

Objectives of workshop

• Review the WHO fact finding results
• Identify the main priority problems to be addressed
• Formulate recommendations to resolve / address the problems
• Develop plan to:
  – implement recommendations, and
  – incorporate recommendations into the national health plan for sustained implementation and follow up

Agenda

Morning
• Presentation of the findings by the WHO consultant with 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.
Conclusions and Recommendations

A. Drug Supply and Selection

Discussions concerning drug supply and selection concluded that:

- drug availability is lower than ideal with frequent stock-outs, emergency orders and a delay in drugs arriving after purchase due to long lead times;
- there is a shortfall between drug demand and the available budget of about 25%
- there is a lack of detailed information at facility level and in the public domain on past drug consumption, which makes drug estimation and efforts to control drug use difficult;
- the manual drug inventory control system operating in all public facilities is cumbersome and cannot provide the needed information in a timely manner;
- many out-of-list drugs (not on the EML) are being purchased at considerable cost, more than may be necessary.

Based on these findings it is recommended that:

1. The Medicines Supply Division produce an annual report on drug consumption:
   - The annual report should be published within the 1st quarter of the subsequent year, with an electronic copy posted on the MSD web site and sent through emails to all relevant MOH departments, regional health authorities and large hospitals with an allocation of budget for local purchase.
   - The content of the report should include:
     a) ABC Analysis – in full and by therapeutic category and VEN category,
     b) Out of stock situation – which drug items and the duration of stock-out,
     c) Unused stocks by hospitals – which drug items, the volume and value,
     d) List of locally purchased drugs in full and by institution - with the quantity & value and the % to allocation for individual institutions,
     e) Emergency orders for epidemics and other emergencies during the year,
     f) Reports on drug consumption and use produced by the DTCs of health facilities and submitted annually to MSD (see section B).
   - Activity can be incorporated within the existing MSD budget and staff.

2. An electronic inventory management system for all hospitals be established:
   - It will allow better estimation / forecasting of drug need and feedback on drug consumption (ABC analysis) and adherence to the EML to prescribers;
   - The Medical Supplies Management Information system (electronic) is being established:
     a) Cadre & financial requirements have been identified and approved. (40-50 staff already approved)
     b) The current scope is limited to line ministry hospitals and other major health institutions due to financial constraints but the system should be expanded to all hospitals under provincial council administration.
c) Funds are allocated to establish the system for the line ministry level but more funds are required to expand the system to hospitals under provincial council administration.

3. The inventory management systems of the MSD and SPC be harmonized
   - An online connection between the MSD and SPC is being established under MSMIS project to obtain online data on status of procurement activities.
   - Would allow supplier performance history to be maintained so aiding procurement
   - SPC & MSD should dedicate a monitoring team (3 pharmacists from each side) with authority to coordinate the work

4. Adherence to the national EML be stricter
   - Colleges and specialists boards should provide guidance on “reasonable” specialist drugs for out-of-EML government purchase
   - A permanent committee should be established by the MOH to judge all out-of-list requests
   - The permanent committee should have a core membership (3-4 persons) with external specialists (consultants) from the relevant specialist colleges invited from time to time to:
     a) recommend on specific out-of-EML purchases used in their specialties
     b) recommend additions & deletions to the list of approved drug list for government sector (updating the national EML and urgent requests between national EML updates)

B. Promoting rational drug use

Discussions concerning drug use concluded that:

   • Irrational use of medicines and poly-pharmacy exist throughout the health sector
   • The highest costing drugs are not on those used to treat the majority of illnesses and a significant proportion of the budget is spent on non-EML drugs
   • There is no monitoring or medicines use
   • Few prescribers are using any clinical guidelines or other sources of independent unbiased information yet most prescribers are meeting pharmaceutical representatives daily
   • Continuing professional development is followed on an adhoc basis or not at all by most prescribers and that issues of prescribing are not incorporated into the curriculum
   • There are no functional Drug and Therapeutic Committees in hospitals to monitor use and CPD, merely Drug Review Committees that only discuss stock-outs
   • While pre-clinical medical undergraduates are taught prescribing skills, this is undermined by practices learnt in their clinical attachments with senior prescribers
   • There is huge overcrowding in public facility outpatients resulting in 1-minute consultations and subsequent irrational polypharmacy and unnecessary inpatient admissions.
Based on these findings it is recommended that:

1. **Drug use be monitored:**
   - ABC analysis and prescription audit with feedback should be done at the local level
     a) by Chief Pharmacist of the hospital or health centre,
     b) monitored by the DTC
     c) feedback given to the prescriber
     d) incorporated into an annual report to be sent to a national body to be set up
   - A national body should be set up to monitor medicines use and coordinate policies and actions to promote rational use of medicines. The body could be an independent such as National Institute of Clinical Excellence in the UK and/or it could be a fully resourced unit in the MOH (see section D)
   - Prescribers should be accountable to the DTC and the national body (see section D)

2. **Standard Treatment Guidelines be developed, updated and implemented**
   - Development and updating should be coordinated by the MOH and national body responsible for promoting rational use of medicines (see section D) with the Colleges and Specialist Boards taking a lead role
   - Should be disseminated by the MOH to every doctor in both the public and private sectors
   - Should be incorporated into CPD
   - Finances should be provided by MOH for updating and dissemination

3. **Functional Drug and Therapeutic Committees be established in all hospitals**
   - Should monitor drug use, encourage CPD, and report annually on activities to MOH
   - DTCs should be given clear operational guidelines by MoH and fully resourced from within hospital or MOH budgets
   - The MOH operational guidelines for DTCs should include how they should function, e.g. membership, regular meetings with minutes, expenditure and expected activities e.g. monitoring prescribing and encouraging CPD. Heads of Institutions should write annual reports on their activities and send to the MOH

4. **Continuing professional development (CPD) be strengthened**
   - Sri Lanka Medical Association and Sri Lanka Medical Council should be encouraged to further develop their CPD credit system
   - Prescription audit and feedback, ethics, ethical pharmaceutical promotion should be incorporated into CPD curricula of doctors
   - Good pharmaceutical practice, clinical pharmacy, ethics, ethical pharmaceutical promotion and drug regulations should be incorporated into CPD curricula of pharmacists
   - Teaching of prescribing skills and rational use of drugs use should be strengthened in undergraduate curricula by including more teaching into the clinical part of the course
   - MOH should encourage CPD by:
a) supporting programs financially in all areas including the peripheries (having a separate budget line for CPD),
b) by providing IT facilities, official study leave, etc.
c) by having a focal point in the MOH to coordinate & fund CPD of doctors, medical officers and pharmacists through the SLMC

5. Public education on medicines use be undertaken
- There should be public education campaigns addressing drug use by the consumer
- Core pharmaceutical messages to improve rational use of medicines should be included in these programmes to address specific problems such as poly-pharmacy e.g. encouraging mothers to ask doctors whether their children really need more than one medicine
- Messages can be delivered via TV, Radio, printed materials and posters, schools, within health facilities especially in the OPD,
- Public education can be coordinated by Health Education Bureau, MOH and using the health promotion units attached to many health facilities.

C. Drug regulation

Discussions concerning drug regulation concluded that:
- Drug regulation is insufficiently enforced, as indicated by prescription-only medicines being available without prescription, the absence sometimes of pharmacists from pharmacies, the occurrence of misleading drug promotional materials and inappropriate promotional activities targeting prescribers and concerns about some poor quality drugs;
- The Drug regulatory authority has insufficient human and financial resources, lacking inspectors and pharmacists;
- There are too many brands of the same active pharmaceutical ingredient on the market so making it difficult to monitor the market and also to manage the drug registration process which is manual not electronic and which relies also the free services of pharmacologists in Colombo University.

Based on these findings it is recommended that:

1. There be fewer brands of same active pharmaceutical ingredient on the market
- Measures to reduce the number of brands on the market to be undertaken include:
  - thorough evaluation and control at the point of registration
  - implementing exclusion criteria such as me-too drugs
  - black listing any manufacturers that provide false documents and undertake any other improper action according to criteria to be defined by the DRA on continuing basis
  - Increasing the registration fee
• Retaining registration fees (presently sent to Treasury) within the DRA in order to build it up (see the groupwork on structure)
• GMP inspection for new companies – which would require the establishment of a GMP team with proper training

2. There be stricter adherence to the registration process
• All products should be approved by the advisory committee – Currently it is functioning
• The number of products approved by the advisory committee and given no-objection letter (NOL) without review by the committee should be published
  ▪ Drug index for approved products updated regularly every 2 years);
  ▪ quarterly news letter from DRA (postage paid by MOH);
  ▪ DRA should continue not to encourage NOL, only issuing them by a sub-committee of the Drug Evaluation Committee and on the basis of accepted published criteria

3. The OTC List be updated and published
Schedule 1 and IIA drugs list should be updated and circulars sent to the regulatory council to distribute to the private pharmacies.
[It was not accepted to introduce extra scheduling categories]

4. The DRA be strengthened by having:
• More inspectors and pharmacists
  a) the number of dedicated pharmacists assigned to product evaluation should be increased from 10 to 30 staff for drugs, from 0 to 5 dedicated staff for devices, and from 0 to 2 dedicated staff for cosmetics.
  b) pharmacists should be authorised to inspect drug outlets and undertake joint inspections with the drug inspectors doing inspections as a team.
  c) pharmacists should be authorized to do GMP inspections and there should be a trained GMP inspection team.
• Improved drug registration system and dossier evaluation:
  a) Computerized system using special software for drug registration is needed. This could be developed specially or could be adapted from other systems to suit the needs of Sri Lanka. WHO already has software that could be used unchanged or adapted. This activity would require hiring external expertise
  b) Internet connectivity and electronic communication with key institutions doing voluntary work needed
  c) Training of pharmacists in drug registration and recognition for voluntary work done such as that done by local pharmacologists at Colombo University
  d) Strengthening the evaluation procedures for drug registration
• Improved technical capacity, procedures and regulations
  a) Develop Standard Operating Procedures (SOPs) and guidelines for all procedures using WHO guidelines
  b) Develop monitoring of promotional activities aimed at providers by expanding the advertisements committee to include the monitoring of adverts to prescribers in medical journals as well as adverts for OTC drugs
  c) Amend current regulations to improve the options for punitive action
  d) Amend regulation to include a documented procedure and criteria for the establishment of community pharmacies
e) Strengthen the system of drug quality assurance by improving the current laboratory facilities, having a separate budget for Reference standards + Instruments + Maintenance + Training

- **Improved staff development**
  a) Establish continuing professional educational programmes for pharmacists working in the DRA on drug evaluation, the registration process, regulations, GMP, inspections and raids, and for pharmacists working in the community on drug schedules and new regulations
  b) Establish schemes for retaining pharmacists trained in drug regulation, registration and drug evaluation within the DRA
  c) Appointing a clinical pharmacologist to the DRA – *there is an application in process*

**National Structure & Drug Policy**

**Discussions concerning national structure and drug policy concluded that:**

- There are a number of functions with regard to promoting rational use of medicines that are currently not undertaken in any department within the MOH such as coordinating and monitoring prescribing, CPD for health professionals, DTCs, development, updating and *implementation* of clinical guidelines and the EML, and public education.
- The skills needed for these activities are different from those needed in the current pharmaceutical departments concerned with procurement, supply and regulation.
- Pharmaceutical policies involve many different sectors and there is a need for coordination across sectors and departments
- The national Drug Policy document of 2005 is very non-specific in content.

**Based on these findings it is recommended that:**

1. **Consideration be given to the creation and legislation of a new Statutory body in the health infrastructure, the “National Medicinal Drug Regulatory Authority (NMDRA):**
   - in the MOH directly under the Secretary of Health,
   - With functions and responsibilities formulated and included in legislation.
   - With a board of Directors appointed by the Minister of Health on the basis of ex-officio appointments
   - With managerial and administrative staff who will report to the board of directors at regular intervals.
   - With appointed sub-committees for various functions e.g. Drug evaluation, Consumer education, etc
   - With responsibility to implement the recommendations of the sub-committees.
   - With responsibility to refine the National Drug Policy Document of 2005 to be more specific in content.
• With the following suggested directorates (covering individual departments related to pharmaceutical sector currently under the MOH although MSD could continue under the DGHS as at present) all with permanent staff:
  o Registration of Drugs
  o Drug Evaluation
  o Pharmacovigilance
  o Clinical trials / Research
  o Publications (SL Drug Index, Prescriber, EML, STGs)
  o Web-site providing data for healthcare professionals and public.
  o Pricing
  o Inspection and Licencing
  o Drug Information
  o NDQAL
  o Additional unit responsible for promoting rational use of drugs, particularly with regard to managing and coordinating national EML and STGs, DTCs in hospitals, monitoring of drug use, CPD, National Medicines Information Centre, public education

[Not all persons agreed with the structure so further discussion is needed]

2. The creation of a special unit within the MOH to promote rational use of medicines
• To oversee monitoring of drug use and prescribing, CPD, DTCs, EML, STGs, National Medicines Information Centre and public education.

[All persons agreed with this suggestion]
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Annex 1: Persons met and places visited during the situational analysis:

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Position/Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr. Ravi Ruberu</td>
<td>Secretary / Ministry of Health</td>
</tr>
<tr>
<td>2</td>
<td>Dr. Palitha Maheepala</td>
<td>Additional Secretary / Ministry of Health</td>
</tr>
<tr>
<td>3</td>
<td>Dr. Ajith Mendis</td>
<td>Director General of Health Services</td>
</tr>
<tr>
<td>4</td>
<td>Dr. H.R.U. Indrasiri</td>
<td>Deputy Director General (Laboratory services)</td>
</tr>
<tr>
<td>5</td>
<td>Dr. B.V.S.H. Beneragama</td>
<td>Director / Medical, Technology &amp; Supplies, MOH</td>
</tr>
<tr>
<td>6</td>
<td>Dr. K. Jayasinghe</td>
<td>Director / Medical Supplies Division, MOH</td>
</tr>
<tr>
<td>7</td>
<td>Mr. E.D. Weeraratne</td>
<td>Asst. Director / Medical Supplies Division, MOH</td>
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<tr>
<td>8</td>
<td>Prof. Rohini Fernandopulle</td>
<td>Senior Lecturer (Pharmacovigilance Centre), Dept. of Pharmacology.</td>
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<tr>
<td>9</td>
<td>Dr. S. Sri Ranganathan</td>
<td>Senior Lecturer, (Essential Medicines List), Dept. of Pharmacology, University of Colombo</td>
</tr>
<tr>
<td>10</td>
<td>Dr. Manuj Weerasinghe</td>
<td>Sri Lanka Medical Association</td>
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<tr>
<td>11</td>
<td>Prof. Gita Fernando</td>
<td>Professor of Pharmacology, Dept. of Pharmacology, University of Sri Jayawardenepura</td>
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<tr>
<td>12</td>
<td>Dr. V. N. Fernando</td>
<td>Senior Lecturer, Dept. of Pharmacology, University of Sri Jayawardenepura</td>
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<td>13</td>
<td>Dr. C. Wanigatunge</td>
<td>Senior Lecturer, Dept. of Pharmacology, University of Sri Jayawardenepura</td>
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<tr>
<td>14</td>
<td></td>
<td>Pharmacists, Outpatients Department, Teaching Hospital, Colombo South</td>
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<tr>
<td>15</td>
<td>Mr. Piyal De Silva</td>
<td>Senior Pharmacist / Healthguard Pharmacy, Colombo 3</td>
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<tr>
<td>16</td>
<td></td>
<td>Medical officers / Colombo Municipality Dispensary, Narahenpital</td>
</tr>
<tr>
<td>17</td>
<td>Mr. D.D. Abeyratne</td>
<td>Pharmacist / Colombo Municipality Dispensary, Narahenpita</td>
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<tr>
<td>18</td>
<td>Dr. Costa</td>
<td>Registered Medical Officer / Central Dispensary</td>
</tr>
<tr>
<td>19</td>
<td>Dr. Chandra Gunathilake</td>
<td>Director / Teaching Hospital, Kandy</td>
</tr>
<tr>
<td>20</td>
<td>Mr. Nalin Herath</td>
<td>Matron / Teaching Hospital, Kandy</td>
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<tr>
<td>21</td>
<td></td>
<td>Pharmacists / Teaching Hospital, Kandy</td>
</tr>
<tr>
<td>22</td>
<td>Mr. Rohitha Chandraratne</td>
<td>Manager / Raajya Osu Sala, Kandy</td>
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<tr>
<td>23</td>
<td></td>
<td>Pharmacist / Royal Mall Pharmacy, Kandy</td>
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<tr>
<td>24</td>
<td>Dr. S.N. Dayarathna</td>
<td>District Medical Officer / District Hospital, Kadugannawa</td>
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<td>25</td>
<td></td>
<td>Sister in-charge / District Hospital, Kadugannawa</td>
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<td>26</td>
<td></td>
<td>Medical Officers / Peripheral Unit, Koswatte, Thalangama</td>
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<td>27</td>
<td></td>
<td>Medical Officers / Peripheral Unit, Kowatte, Thalangama</td>
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<tr>
<td>28</td>
<td>Mrs. Sunethra Atapattu</td>
<td>Pharmacist / Peripheral Unit, Kowatte, Thalangama</td>
</tr>
</tbody>
</table>
# Annex 2: Participants of Workshop on Rational Use of Medicine - Colombo, Sri Lanka, 30 July 2010

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
</tr>
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<tbody>
<tr>
<td>1. Ms. Gayani Manchanayake</td>
<td>Sri Lanka Standards Institution</td>
</tr>
<tr>
<td>2. Ms. Suranganie Perera</td>
<td>State Pharmaceuticals Corporation</td>
</tr>
<tr>
<td>3. Prof. Colvin Goonaratna</td>
<td>Ceylon Medical College Council</td>
</tr>
<tr>
<td>4. Dr. M.C. Weerasinghe</td>
<td>Sri Lanka Medical Association</td>
</tr>
<tr>
<td>5. Mr. Chula Edirisinghe</td>
<td>MOH/ Drug Regulatory Authority</td>
</tr>
<tr>
<td>6. Mr. L.A. Warakagoda</td>
<td>MOH/ Drug Regulatory Authority</td>
</tr>
<tr>
<td>7. Mr. G. Karunapala</td>
<td>Sri Lanka Pharmaceutical Manufacturers Association</td>
</tr>
<tr>
<td>8. Dr. W.A.A. Tissera</td>
<td>MOH / ET&amp;R Unit</td>
</tr>
<tr>
<td>9. Dr. Pradeepa Jayawardana</td>
<td>Dept. of Pharmacology, University of Sri Jayewardenepura</td>
</tr>
<tr>
<td>10. Mrs. Ganga Senarathana</td>
<td>Dept. of Pharmacology, University of Sri Jayewardenepura</td>
</tr>
<tr>
<td>11. Mr. Parakrama Dharmadasa</td>
<td>MOH/ Drug Regulatory Authority</td>
</tr>
<tr>
<td>12. Ms. Chamila Samarasinghe</td>
<td>MOH/ Drug Regulatory Authority</td>
</tr>
<tr>
<td>13. Mr. K.P.H. Sandaruwan</td>
<td>MOH/ Drug Regulatory Authority</td>
</tr>
<tr>
<td>14. Ms. B.P.R. Cooray</td>
<td>MOH/ Drug Regulatory Authority</td>
</tr>
<tr>
<td>15. Mr. Ananda Samarasinghe</td>
<td>Sri Lanka Chamber of the Pharmaceutical Industry</td>
</tr>
<tr>
<td>16. Mrs. A.R. Ahamed</td>
<td>MOH / Legal Division</td>
</tr>
<tr>
<td>17. Dr. P. Chandrasiri</td>
<td>MOH / National Hospital</td>
</tr>
<tr>
<td>18. Dr. H.M.S.S.D. Herath</td>
<td>Sri Lanka Medical Association</td>
</tr>
<tr>
<td>19. Mr. A. Ajith Priyadarshana</td>
<td>MOH / National Drug Quality Assurance Laboratory</td>
</tr>
<tr>
<td>20. Dr. J. Munasinghe</td>
<td>MOH / Medical Research Institute</td>
</tr>
<tr>
<td>21. Mr. D.D. Abeyratne</td>
<td>Colombo Municipality Dispensary / Narahenpita</td>
</tr>
<tr>
<td>22. Mrs. S. Tennakoon</td>
<td>Government Analyst's Department</td>
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<tr>
<td>23. Dr. S. Sri Ranganathan</td>
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<td>25. Mr. E.D. Weeraratne</td>
<td>MOH / Medical Supplies Division</td>
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<tr>
<td>26. Dr. R.P.P. Karunapema</td>
<td>MOH / Non-communicable Diseases Unit</td>
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<tr>
<td>27. Dr. S. Dissanayake</td>
<td>MOH / Epidemiology Unit</td>
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<tr>
<td>30. Prof. R. Sheriff</td>
<td>Postgraduate Institute of Medicine</td>
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<tr>
<td>31. Dr. Dennis Aloysius</td>
<td>College of General Practitioners</td>
</tr>
<tr>
<td>32. Dr. R. Balasubramaniam</td>
<td>Dept. of Pharmacology, University of Colombo</td>
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<td>No.</td>
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<td>33</td>
<td>Ms. B.P.T. Warnasooriya</td>
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<td>34</td>
<td>Dr. Sarath Gamini De Silva</td>
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<td>Dr. Ananda Wijewickrama</td>
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<td>38</td>
<td>Dr. B.V.S.H. Beneragama</td>
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<tr>
<td>39</td>
<td>Prof. Rohini Fernandopulle</td>
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<tr>
<td>40</td>
<td>Dr. Palitha Abeykoon</td>
</tr>
<tr>
<td>41</td>
<td>Dr. Kathleen Holloway</td>
</tr>
<tr>
<td>42</td>
<td>Ms. Chinta Abayawardana</td>
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</tbody>
</table>
Annex 3: Slide presentation given by consultant to stakeholders in the 1-day workshop


Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Background
• Current problems in the pharmaceutical sector
  – Increasing demand for medicines but limited budget
  – Frequent stock-outs and emergency orders
  – Concerns about quality of medicines
  – Poly-pharmacy and irrational use of medicines
• Need for national action plan to address the problems
  – Workshop to develop recommendations for national plan of action, incorporated into national health plan

Objectives of the workshop
• Review the WHO fact finding results
• 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 of the workshop
AM
• 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
PM
• Presentation of group work with plenary discussion and finalization of recommendations
  – Road map for MOH, stakeholders and WHO to follow

Mission 23-29 July, 2010
• 23 July: Orientation in WHO country office
• 24 July: Visit to Kandy Hospital; private pharmacy; Osu Sala pharmacy
• 25 July: Visit to District Hospital Kadugannawa
• 26 July: Visit to DG/PH; MSD; Pharmacology dept, University of Colombo; Pharmacovigilance & drug information; private pharmacy
• 27 July: Visit to Pharmacology dept, University of Sri Jayewardenepura (medical education & SLMA); Teaching hospital Colombo South; SPC; DRA; Osu Sala pharmacy
• 28 July: Visit to MOH central dispensary; municipal primary care centre; Koswatte peripheral unit; private pharmacy
• 29 July: Visit to SLMC, Secretary/MOH
• 30 July: Workshop

Mission findings
• Extensive health care system, with substantial infrastructure, trained health care personnel and good health indicators, but...
• Serious problems in the pharmaceutical sector concerning:
  – Drug supply, selection, use, regulation, policy, information and coordination, but...
• Sufficient resources and capacity to address the problems
Drug supply

- Complaints about stock-outs from all public facilities
- Poor inventory control in public sector
  - no electronic systems in health facilities
  - under-estimation of requirement in all facilities due to forecasting on last year’s consumption, fear of expiry
  - frequent emergency orders
- 1 year lead time to procure drugs in order to get max amount of drugs for least budget
  - Cannot respond quickly to emergency orders
  - Cannot have shorter lead time due to administrative and financial regulations
  - SPC and MSD drug management systems different so forecasting difficult
- Funds from MOF approx. 25-30% less than demand

Possible solutions for supply and selection

- MSD annual report on consumption
- Electronic inventory management system for all hospitals
  - Better estimation/forecasting of drug need
  - ABC analysis for feedback to prescribers
- Harmonize inventory system between MSD and SPC
- Stricter adherence to EML
  - colleges and specialists boards to provide guidance on ‘reasonable’ specialist drugs for out-of-EML purchase
  - permanent sub-committee to judge all out-of-list requests

Drug selection

- National EML 2009, which MSD follows but...
- Consultants are able to request out-of-list drugs and MSD will buy them but:
  - Either drugs come too late for consultant to use or they will be purchased locally at much greater expense
- 29% of medicines supplied by MSD in 2006 were not on 2004 EML
- 29% of medicines in highest expenditure A-category items are not on the 2010 EML

Drug use

- No international publications on drug use found since 1990
- Few prescribers using any STGs or other sources of independent drug information
- Daily pharmaceutical representative visits reported by all facilities
- Prescribing principles taught at undergraduate pre-clinical level but undermined by clinical studies and later work
- CPD adhoc
  - not followed by many prescribers
  - does not include much on rational use of medicines
- Huge overcrowding in clinics resulting in 1 minute consultations leading to polypharmacy and unnecessary IP admission

Drug consumption

- Top 10 medicines include Rabies vaccine, human immunoglobulin, paracetamol, cefuroxime injection, desferrioxamine, insulin, NACL, meropenem, cefazidime
- Top 10 diseases are infectious diseases, neoplasms, blood disorders, endocrine/nutritional/metabolic diseases, mental disorders, eye disorders, ear disorders, circulatory disorders, respiratory diseases
- 24 most expensive items are mostly antineoplastic and immunomodulating agents, medicines acting on blood forming organs, anti-infectives and medicines acting on musculoskeletal system

Drug use indicator surveys

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<th>Drug Use Indicator</th>
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<th>Private n=5</th>
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<tbody>
<tr>
<td>Av. no. drugs per prescription (P)</td>
<td>3.0</td>
<td>3.5</td>
</tr>
<tr>
<td>% P containing Antibiotics</td>
<td>49%</td>
<td>23%</td>
</tr>
<tr>
<td>% P containing Vitamins</td>
<td>23%</td>
<td>22%</td>
</tr>
<tr>
<td>% drugs prescribed by generic name</td>
<td>63%</td>
<td>37%</td>
</tr>
<tr>
<td>% prescribed drugs on EML</td>
<td>99%</td>
<td>57%</td>
</tr>
<tr>
<td>Av. Cost per prescription</td>
<td>SLR 685</td>
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### Cost of irrational prescribing

- **Typical OPD child with cough and cold receives:**
  - Panadol, piriton, salbutamol, vitamin and sometimes an antibiotic
- **Cost of paracetamol, chlorpheniramine, salbutamol, vitamin B Co and multivitamins per year in 2009 was:**
  - SLRs 355,806,110

### Possible solutions for improving regulation

- **Have fewer brands of same drug (active pharmaceutical ingredient) in the market**
- **Strengthen the DRA**
  - More inspectors, pharmacists
  - Computerized drug registration system and training for dossier evaluation
  - Standard operating procedures and guidelines for all procedures
  - Develop monitoring of promotional activities aimed at providers
  - Amend current regulations e.g. punitive actions
- **Stricter adherence to the registration process**
  - All products should be approved by the advisory committee
  - The number of products approved by the advisory committee and given no-objection certificate without review by the committee should be published
- **Extra category in drug schedules for drugs that should not be available on prescription in ordinary pharmacies**
  - E.g. oncological drugs, anti-TB drugs, very new antimicrobials

### Possible solutions for improving use

- **Monitoring drug use**
  - ABC analysis, prescription audit
  - Standard Treatment Guidelines
    - Development, updating, dissemination to every doctor, incorporation into CPD
  - DTCs
    - To monitor drug use, encourage CPD, and report annually on activities to MOH
- **Continuing professional development (CPD)**
  - SLMA, SLMC, credit system, incorporation of prescription audit and feedback and ethics into CPD
- **Public Education**
  - Core pharmaceutical messages e.g. does my child need more than one drug? through MOH health education unit and media

### Drug regulation

- **Prescription-only drugs available OTC**
- **Pharmacists not on the premises often**
- **Lack of laboratory facilities to monitor and ensure adequate quality**
- **Lack of inspectors and pharmacists**
- **No monitoring of drug promotional activities aimed at prescribers**
- **Many brands on the market so difficult to control**
  - 30-50 brands of amoxycillin, diclofenac, panadol, omeprazole on the market
  - Products are registered for use after approval by the advisory committee but some unregistered products are used after issue of a no-objection certificate without recourse to the advisory committee

### Possible solutions for coordinating structure and national policy

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership including laypersons, professional bodies …**
- **Executive in MOH to carry out statutory committee recommendations – MSO, DRA and …**
- **Extra unit in MOH responsible for rational use of drugs:**
  - EML, STGs, DTCs, monitor use, CPD, MIC, public education
  - Liaison with universities to provide students to collect information needed by MOH as part of their research studies
- **Revise the National Medicines Policy to be more specific**
  - Sub-committee of statutory committee to draft it
  - Include implementation plan and time line
  - Incorporate into national health plan and regulations
Wider issues

• Referral system to decrease patient density in hospitals

• Insurance system for financing drugs

Group work

• Each group to draft recommendations with practical steps including
  – Who will do it
  – How many staff
  – Budget

• Groups
  – Drug supply and selection
  – Promoting rational drug use
  – Drug regulation
  – National structure and drug Policy