Bangladesh

Pharmaceuticals in Health Care Delivery

Draft Mission Report
24 October - 3 November 2010

30th November 2010

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World Health Organization, Regional Office for South East Asia, New Delhi
Programme Agenda

Monday, October 25th
Morning: Secretary and Joint Secretary, Ministry of Health and Family Welfare, Directorate General of Drug Administration (DGDA)
Afternoon: Central Medical Store and Depot (CMSD), Essential Drug Company Limited (EDCL).

Tuesday, October 26th
Morning: Directorate General of Health Services
Dhaka Medical College Hospital (Tertiary Referral Hospital)
Afternoon: Bangladesh Medical and Dental Council

Wednesday, October 27th
Morning: Civil Surgeon Office, Narayanganj
Narayanganj District (Victoria) Hospital
Afternoon: Durpath Community Clinic
Sonargaon Upazilla Health Complex

Thursday, October 28th
Morning: DG, Directorate General of Health Services
Director, Hospital and Clinic
Director, Centre for Medical Education
Afternoon: Private pharmacies x 2

Friday, October 29th
Free

Saturday, October 30th
Morning: Dr. Zafrullah Chowdhury, Gonoshasthaya Trust
Dhaka Medical College, Clinical Pharmacology Dept.
Seminar on promoting antibiotic use by K.A.Holloway
Bangabandhu Sheikh Mujib Medical University, Pharmacology Department
Afternoon: Free

Sunday, October 31st
Morning: Secretary, Ministry of Health and Family Welfare (with Drug Testing Lab Consultant)
Directorate General of Drug Administration (DGDA)
Afternoon: Drug Testing Laboratory
Monday, November 1st
Visit to Manikganj District planned but cancelled due to consultant's illness

Tuesday, November 2nd
Morning: WHO Country Office
Afternoon: Debriefing with Ministry of Health and Family Welfare and stakeholders
<table>
<thead>
<tr>
<th>Acronyms</th>
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<tr>
<td>ABC</td>
<td>ABC analysis – method for measuring drug consumption</td>
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<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<td>ARI</td>
<td>Acute Respiratory Infection</td>
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<td>BDNF</td>
<td>Bangladesh National Formulary</td>
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<td>BMA</td>
<td>Bangladesh Medical Association</td>
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<td>BMDA</td>
<td>Bangladesh Medical and Dental Council</td>
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<tr>
<td>CPD</td>
<td>Continuing professional development</td>
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<td>Continuing medical education</td>
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<td>Central Medical Supplies Dept</td>
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<td>Directorate General of Drug Administration</td>
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<td>DIC</td>
<td>Drug Information Centre</td>
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<td>Drug Regulatory Authority</td>
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<td>DTC</td>
<td>Drug and Therapeutic Committees</td>
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<td>DTL</td>
<td>Drug Testing Laboratory</td>
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<td>EDCL</td>
<td>Essential Drug Corporation Limited</td>
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<td>EDL</td>
<td>Essential Drug List</td>
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<td>EML</td>
<td>Essential Medicines List</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>GTZ</td>
<td>German Aid Agency</td>
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<td>HQ</td>
<td>Headquarters</td>
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<td>INRUD</td>
<td>International Network of the Rational Use of Drugs</td>
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<td>IPD</td>
<td>Inpatient department</td>
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<td>MIC</td>
<td>Medicine Information Centre</td>
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<td>MIS</td>
<td>Management Information System</td>
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<td>Medicines Regulatory Authority</td>
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<td>Medicines and Therapeutic Committee</td>
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<td>NGO</td>
<td>Non-governmental organization</td>
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<td>NDP</td>
<td>National Drug Policy</td>
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<td>NMP</td>
<td>National Medicines Policy</td>
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<td>NOL</td>
<td>No objection letter</td>
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<td>OPD</td>
<td>Outpatient department</td>
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<td>OTC</td>
<td>Over-the-counter</td>
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<td>PHC</td>
<td>Primary Health Care</td>
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<td>Px</td>
<td>Prescription</td>
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<td>RUM</td>
<td>Rational use of medicines</td>
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<td>SOP</td>
<td>Standard Operating Procedures</td>
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<td>STG</td>
<td>Standard Treatment Guidelines</td>
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<td>TOR</td>
<td>Terms of Reference</td>
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<td>USAID</td>
<td>United States Aid Agency</td>
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<td>VEN</td>
<td>Vital Essential Non-Essential – method for classifying drug importance</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive Summary

A visit was made to Bangladesh during October 24 - November 3, 2010. The programme was arranged in agreement with the Ministry of Health and Family Welfare (MoHFW) with the terms of reference to: undertake a situational analysis of the pharmaceutical situation with a focus on health care delivery; to facilitate a second consultant's visit to advise on upgrading the Drug Testing Laboratory; to give a half-day debriefing to MoHFW officials on the findings; and to develop recommendations for national action. Visits were made to public health facilities and private pharmacies in Dhaka and Narayanganj district, the major MoHFW departments, the clinical pharmacology departments of one medical college, one medical university and the Bangladesh Medical and Dental Council. It was found that Bangladesh has an extensive health care system, with substantial infrastructure and trained health care personnel, 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 many local resources, expertise and capacity that could be used to address the problems.

Drug Supply and selection

Drugs are supplied by government to all public facilities by the Essential Drugs Company Limited, EDCL, (70%) and the Central Medical Store Depot, CMSD, (25%) according to a formula used by the Directorate General of Health Services (DGHS), based on the number of hospital beds and consumption of the previous year. Since there are often two patients to a bed and the supply of the previous year was already insufficient, there is a large shortfall of drugs with many complaints about stock-outs from all public facilities. Half of or more of patients must buy their drugs from private pharmacies, paying for them out-of-pocket. Good quantification and forecasting of drugs is needed but currently not possible due to poor inventory control and forecasting of need, there being no electronic inventory control system in public health facilities. There is a national Essential Drug List (EDL) 2008, which focuses mainly on drugs from primary care and which the public facilities must follow for 70% of their drug supply which must be purchased from the EDCL. For the other 30% (95% of which districts must purchase through the CMSD) they are allowed to choose non-EDL drugs subject to approval by the DGHS. There is no specific list covering these non-EDL drug purchases which vary between hospitals and districts. In addition, many hospital doctors prescribe non-EDL drugs for outside purchase. Analysis of data provided by the EDCL and CMSD shows that nearly half the drug budget may be consumed by antibiotics and one-third by non-EDL drugs.

Recommendations include (1) establishing an electronic medicines inventory system within the DGHS and all public hospitals and districts to better estimate need and to monitor adherence to the EDL and (2) revising the EDL in a process that includes wide representation from the medical profession to include the essential drugs needed in both hospitals and primary care.
Drug use
There was a dearth of official published information on medicine use, but much information from publications from the pharmacology departments of local universities. This local information and the survey conducted by the consultant showed that there is much polypharmacy, high vitamin use and high use of antibiotics, particularly in hospitals, where there is very low prescribing by generic name for drugs to be purchased in private pharmacies. There are no comprehensive national standard treatment guidelines, but there is a Bangladesh National Formulary. Unfortunately few prescribers were using the National Formulary or any clinical guidelines or other source of independent drug information. However, most prescribers were receiving pharmaceutical representatives on a daily basis when working in their private clinics after finishing work in the public sector. 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 admissions.

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

Drug Regulation
There was a severe manpower shortage in the drug regulatory authority, the Directorate General of Drug Administration (DGDA) so making it extremely difficult for all regulatory functions to be adequately undertaken. This is extremely serious in a country with a very large pharmaceutical sector, there being more than 250 allopathic medicine manufacturers, 90 000 registered pharmacy shops and 18 000 allopathic products (including many brands for the same active pharmaceutical ingredient) on the market. Thus, adequate inspection and supervision of manufacturers and drug outlets is not possible due to a lack of inspectors. As a consequence it was reported that pharmacists were often not available in shops to supervise dispensing. There is no drug schedule distinguishing between those drugs that should be sold only with a prescription and those drugs that can be sold without a prescription and thus all drugs (with the exception of narcotics) were available over-the-counter (OTC). There was no adequate monitoring of drug promotional activities or vetting of adverts aimed at prescribers or the public. There were insufficient laboratory testing facilities to ensure medicine quality. Some activities such as drug evaluation for registration (which was manual) were criticized for being biased by over-representation of the pharmaceutical industry in the Drug Control Committee. The pharmacovigilance activities were so little that the concerned committee had not met once. The Standard Operating Procedures had not been updated for a long time and were often not being followed. Furthermore, many of the same people sat on the various different committees such as the EDL Committee, Drug Control Committee for drug registration, Pricing committee, Standing Committee for Imports and the Project
It is recommended: that the manpower shortage be rectified as a matter of urgency; that Standard Operating Procedures (SOPs) be revised for the various committees; that an OTC list be developed; and that a system and committee to monitor drug promotion be established.

Coordination
Many functions such as monitoring of medicines use and adherence to the EDL, coordinating CPD, supporting DTCs, developing and updating clinical guidelines and ensuring their distribution and incorporation into CPD and undergraduate curricula, and public education on medicines use, are not undertaken by any MoHFW department. Furthermore, it was found that while there is a National Drug Policy document, there were many aspects of it that are not implemented, particularly with regard to use of medicines. This problem had already been recognized in 2008 when there was a consultation on establishing a "Core Committee for Rational Use of Drugs" that was never instituted.

It is recommended that (1) the "Core Committee for Rational Use of Drugs" be revived and endorsed by government as a multidisciplinary statutory committee, and (2) that a fully resourced executive unit dedicated to monitoring medicines use and coordinating implementation of strategies to improve use as recommended by the Core Committee, be set up in the DGHS/MoHFW.
Terms of Reference

The objectives were:
(1) to gain an introduction to the pharmaceutical sector in Bangladesh;
(2) to undertake an informal internal review of the pharmaceutical sector, focusing on health care delivery and medicines use, in collaboration with a national counterpart assigned by the MoHFW, in order to plan for WHO technical support;
(3) to facilitate the visit of a consultant, Mr Somsak Sunthornphanich, Senior Pharmacist from the Bureau of Drugs and Narcotics, Department of Medical Sciences, Thailand, to provide technical support concerning the setting up of the Drug Testing Laboratory within the Drug Regulatory Authority;
(4) to discuss any other pharmaceutical issues as requested by MoHFW and WHO country office;
(5) to conduct a half-day debriefing session with senior MoHFW officials.

Background

This mission was undertaken to (1) conduct a national situational analysis of the pharmaceutical sector in order to aid MOHFW in planning future action and to plan for future WHO technical support and (2) to facilitate the visit of Mr Somsak Sunthornphanich to provide technical support to upgrade the Drug Testing Laboratory. This report will only cover point (1) above as there is a separate report covering point (2).

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 24th October -3rd November, 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 half-day debriefing with senior members of the MOHFW, Drug Regulatory Authority and Directorate General of Health Services that was held at the end of the mission to discuss and validate the findings and to form a road map for action for the pharmaceutical sector in general. The participants of the debriefing can be seen in annex 2. The presentation made by consultant can be seen annex 3.

Bangladesh has a well developed health care delivery system with trained staff. 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.
Drug Supply

Public sector facilities get 25% of their medicines from the Central Medical Supplies Depot (CMSD) using a budget allocated to them by the government, 70% of their medicines from the Essential Drug Company Limited (EDCL) using a pre-determined allotment for them agreed by the government and 5% from local purchase. Patients must pay a small registration fee of about 5 Taka in most facilities but then get their medicines free of charge.

The CMSD supplies 25% of the drug requirement of the public sector using a national bidding process or an international bidding process if the cost of any single item or package (122/year) is more than 300 000 USD. While they supply mostly essential drugs, they do stock other items. They have extensive written SOPs, following the Public Procurement Act of 2006 and the Drug Procurement Regulation of 2008, which does not have any separate requirement for drugs. A procurement primer 1998-2003 is used. In fact they are mainly an equipment supplier and only started providing drugs to districts in the last one year after an order of the government. DGHS mentioned that this order was made because of expensive poor quality drugs purchased by independent tender in all the hospitals. Since CMSD started purchases, the quality has improved and the price has reduced by up to half for some items. Prices came down because the middle man was cut out and quality improved because districts were no longer obliged to buy the cheapest bid which was often of poor quality. The DGHS has given written criteria to the CMSD to ensure drug quality. The CMSD stated that they sent five samples from each batch to the Drug Testing Laboratory for testing and that they found no quality problems in general. They also mentioned that drug purchases by government were cheaper since the CMSD had started purchasing for government. Tertiary hospitals are not obliged to buy from the CMSD but from next year they will be obliged to buy from manufacturers prequalified by the CMSD. Some are unhappy about this (probably due to pressure from industry).

Unfortunately the CMSD were not able to provide an ABC analysis of their annual sales which, in any case, do not cover the majority of the drugs bought by the public sector. Public secondary hospitals and districts purchase drugs from them after the order is approved by MOHFW and with funds allotted to the budget of that facility but kept within the MOHFW and directly provided by MOHFW to CMSD. The annual supply of drugs was 58 Crore to the government and a further 30 Crore to other agencies from pooled funding (e.g. national control programs, emergency orders, supplies to NGOs which in fact distribute such drugs on behalf of government i.e. CMSD only purchases for govt). The CMSD arranges transport of drugs to the facilities. They have extensive storage facilities for drugs and equipment. Many drugs were stored in their cartons piled one on top of the other which may result in some damage though little damage was observed. The main problem they face is the long lead time for purchase - 14-18 months.

The EDCL supply 70% of the drugs for the public sector. They manufacture according to agreed annual amounts and only supply those drugs on the essential drug list. Their annual sales last year were about 193 Crore, of which 70% was sold to the
government and the rest sold, through participating in tender with the CMSD, to other purchasers such as the Army, Family Planning Services, etc. Antibiotics were the biggest therapeutic class manufactured and sold - but they were unable to break down the amount of this that was sold to government versus other sources. The prices they are allowed to charge to government are fixed by a pricing committee run within the DGDA. There are two types of price - a controlled price allowing a very narrow profit margin (15%) for certain essential drugs (which other manufacturers do not make in quantity) and an "indicated" price where they are allowed more of a profit margin (30-100%). Hospitals and districts collect their drug consignments from the EDCL which does not have to arrange any transport. They need one month for production time and their main problem is poor quality raw materials from China. However, they have become used to finding this problem in advance and they do not accept such poor quality consignments, insisting on adequate quality consignments which do arrive later, so it just causes a delay in manufacturing time. On mentioning a recent TB program evaluation complaint about poor quality drugs in insufficient supply, they mentioned that the national TB program is no longer purchasing drugs from them. The EDCL has its own laboratory for drug testing.

Both the CMSD and EDCL were satisfied with the quality of drugs and were paid promptly by government. One respondent mentioned that the quality of drugs from the top 10 manufacturers in Bangladesh was better than that of EDCL. Neither CMSD nor EDCL were involved in drug quantification, which is the responsibility of the Director General Health Services, Hospital Medical Superintendents and the Civil Surgeons in each district. Both CMSD and EDCL sit on the EDL committee with the DGDA. For drug quantification, the DGHS allocates a budget according to a formula based on the number of beds per facility, multiplying by a factor of 2000, 3000 or 3500 for Upazilla health complexes, district hospitals and tertiary hospitals, respectively. It was admitted that since bed occupancy is 150% or even 200% the drug allocation is insufficient. An agreement has now been reached with the pharmaceutical industry that all drugs produced for government will be colour coded in red and green and marked with "for use only in government facilities" in order to cut down on pilferage. However, one respondent mentioned that if one really wanted to stop all pilferage one would need to mark the actual tablets.

Dhaka Medical College Hospital mentioned that they generally had all the medicines they needed. The chief pharmacist mentioned that they get 60% of their drugs from EDCL and the rest locally, none coming from CMSD. He mentioned that they had an allocation of 12 crore worth of drugs per year and were short only of intravenous fluids - they could get only 10% of needed amounts. They were not able to produce an ABC analysis or a list of drug consumption availability. All stock inventories were manual. The chief pharmacist mentioned that the biggest budgetary item was antibiotics which accounted for approximately one third of the budget. He further mentioned that they do not supply specialist drugs such as streptokinase or oncology drugs as patients could get these from the national institute.

Narayanganj district mentioned that all their facilities were short of medicine. The Civil Surgeon stated that government supply covered 40% of their needs. Supply was
automatic from the DGHS according to a formula. Last year they received 90 Lakh worth of drugs - 1 lakh/year/health centre, 5.5 Lakhs/year/Upazilla Health Complex, 25 Lakhs/year/100 bedded district hospital. Each health complex or centre requests drugs monthly and they supply according to the allocation set by MOHFW. Durpath community clinic mentioned that they receive a kit once every 3 months and that the drugs lasted 3 weeks. Patients come when there are drugs and not when there are not.

The DGHS accepted that there was a shortage of drugs and that they did not have sufficient information to make good decisions on quantification etc. For this reason he has just started a project, which is due to finish in 2013, to develop an electronic Management Information System (MIS) concerning drug stock within his department and eventually reaching down to hospital and district level. USAID and GTZ are funding this.

A study on drug availability conducted in 2009 by the Centre for Medical Education found that availability of key essential drugs was only 39% at Upazilla health complex, and 17% at community health centres. They found from interviewing patients that only 28% of patients received all their drugs at the government facility, that 58% patients received some of their medicines and that 14% received no drugs at the facility. Of those not receiving some or all of their drugs, half said that they would not buy them due to non-affordability. It was mentioned by one respondent that the EDCL needs to promote its drugs more as some doctors are deliberately not prescribing EDCL drugs but giving prescriptions for outside purchase. However, others mentioned that all EDCL drugs were used up and did not expire unused.

Two private pharmacies were visited and mentioned that many of their clients came from two nearby teaching hospitals with prescriptions for drugs not available in those institutions. They do their drug ordering everyday and at least weekly for each item. It was generally reported that drug availability was much better in the private than the public sector. Even so, one pharmacy (80% of whose clients came with prescriptions from a nearby university teaching hospital) stated that Ceftriaxone injection, Cephradine capsules, Metformin tabs, Ketorolac tabs, Metronidazole tabs, Valsarten and Gliclazide were all temporarily out of stock. Another pharmacy mentioned that Thyroxine tabs were currently out of stock.

Possible solutions
1. Establish an electronic drug inventory management system, with extension to the level of hospitals and district stores that would allow monitoring of consumption in the public sector.

2. Train staff in the management of the electronic system that the DGHS is now starting to set up and in how to extract and use drug consumption data.
Drug Selection and Consumption

There is a national EDL, which has only has 209 chemical entities, including vaccines, and is missing many of the drugs needed in hospitals e.g. Cephalosporins. It was explained that the EDL is only for primary health care although this is not mentioned in the EDL booklet itself. The DGHS mentioned that focus was on drugs for acute care because government could not afford to pay for chronic care. However, the EDL does contain some medicines for chronic diseases such as diabetes mellitus (Glibenclamide, Gliclazide, Metformin, Soluble Insulin) and hypertension (Amlodipine, Atenolol, Hydrochlorthiazide, Methyldopa, Nifedipine, Enalapril). If the focus of the EDL is only on acute disease, then the rationale for exclusion of all Cephalosporins, yet the inclusion of Methotrexate and Cyclophosphamide, is unclear. There are also some surprising inconsistencies. For example, while there is no 5% dextrose for intravenous infusion, there is human immunoglobulin and peritoneal dialysis solution.

It was noted that the drug list for procurement from the CMSD (which presently supplies the district level and below and which consumes 25% of the allocated budget), contains more than 300 extra drugs so that, in fact, the practical public sector purchase list for district level is well over 400 drugs and nearer to 500 drugs. It was not possible to find overall country data to break down the amount of essential drugs purchased compared to “non-essential” ones.

The EDL was produced by 11 persons, mainly pharmacists. Since there was so little representation from the medical profession, neither specialists nor generalists, it is quite likely that many of them feel that it does not contain the drugs they need. Certainly at hospital level, they are purchasing a many drugs that are not on the list, some of which may not be the optimal, most cost-effective drugs.

The Bangladesh National Formulary (BDNF) 2006, produced by the DGDA, is a comprehensive formulary with all the drugs on the market listed and each drug described in the style of the British National Formulary. For this book, there were 74 contributors representing all disciplines plus an editorial board of 14. With this degree of representation in the development process, there is much more chance of acceptance and use by the medical profession and prescribers. However, it appears to have been poorly promoted as few doctors in facilities had a copy or had heard of it. Even a representative of the Bangladesh Medical and Dental Council had not heard of the BDNF.

In Dhaka Medical College hospital, they can use 40% of their budget allocation to purchase drugs locally of their own choosing. The other 60% must be purchased from the EDCL which supplies only EML drugs. Each head of department makes up a list by asking his colleagues and then all department head sit in a "Drugs and Therapeutic Committee (DTC)" and decide the list. However, clinical pharmacologists, who are likely to know a great deal about the safety and efficacy of drugs, are excluded. Mostly, the consultants get the drugs they want, although sometimes the committee refuses a drug if it is too expensive. Despite this, it was reported that many patients have to go outside to purchase their medicines. The committee meets quarterly to discuss drug purchase but
does not undertake any other function of a DTC e.g. training, monitoring. The committee needs no approval from the DGHS for local purchases. Recently, the Hospital Director mentioned that he had instituted a new system for monitoring the prescription of very expensive drugs for inpatients. Such drugs required a special system of signature in the pharmacy and, for some very expensive items, justification by the prescribing physician.

In Narayanganj district, they must spend 70% of their allocation on drugs from the EDCL which supplies only EDL drugs, 25% on drugs from the CMSD which supplies EDL and some non-EDL drugs and 5% on drugs purchased locally. It was stated that the 5% local purchase was all reserved for non-EDL drugs – particularly for diseases like hypertension, diabetes mellitus, etc. All the chiefs of each facility meet once a year to discuss what is needed and they reach consensus decisions. There are no written criteria for selection. The pharmacies in Dhaka Medical College and Narayanganj did not have an electronic management inventory system and were thus not able to monitor consumption or undertake an ABC analysis. All purchases from the CMSD and locally must be approved by DGHS but in practice this is a rubber stamping procedure because the DGHS does not have the capacity to judge whether purchases are appropriate or not.

Since the CMSD and EDCL, between them, are supplying 95% of all the drugs at district level and below, it should be possible to determine drug consumption (including ABC analysis overall and by district, % adherence to the EDL, etc) using the databases of sales kept at the CMSD and EDCL respectively. The DGHS officially requested that such information be supplied from the CMSD and the EDCL for four districts for the past one year. Unfortunately it was not possible to get all this information so a comparison of annual consumption by district, including adherence to the EDL was not possible. Nevertheless some data was supplied from which, after extensive manual calculation, some useful conclusions may be drawn. The fact that it was not possible to get the requested information from the EDCL and CMSD, both of whom have electronic inventory management systems, indicates that not only is an electronic inventory system needed at all levels, from district to hospital to suppliers, but also that training is needed on how to use this information.

EDCL supplied annual data aggregated for the whole country and for one district (Bogra) for the year July 2009-June 2010 and also for four individual districts (Manikganj, Narayanganj, Cox’s Bazaar and Satkhira) for four months (July –October 2010). The CMSD supplied annual data for four districts, (three districts the same as for the data supplied by EDCL and one different - Dhaka, Narayanganj, Cox’s Bazaar and Satkhira), but as three 4-monthly order sheets which had no date on them. Both EDCL and CMSD supplied the information for each drug separately by dosage form. Thus, even to estimate annual expenditure at district level for one drug for one year (assuming that EDCL supplied annual district-wise data) would require extensive manual calculation. Expenditures for all the different formulations from both the ECDL and the CMSD data (which in itself required adding up data from three separate 4-monthly consumption sheets) would have to be added up for each drug. This would have to be repeated for each district if one wanted to compare consumption district-wise. This should be easily possible now with the electronic inventory systems in the two organizations.
From the data supplied by EDCL, annual country-wide data showed that 10% of sales were for non-EDL drugs and that 47% of the sales were for antibiotics. The data from 4 districts for 4 months showed that 5-13% of the expenditure for drugs purchased from EDCL were for non-EDL drugs and that the percentage of expenditure on antibiotics ranged from 33 to 66%. Thus, contrary to stated policy, EDCL is supplying districts with a small quantity of non-EDL drugs – consisting mostly of diclofenac (tabs and injection), ranitidine (tabs and injection) and cephalosporins but also including indomethacin in one district and a multivitamin in another. Antibiotics consume a large part of the budget allocation and this varies widely from district to district. From the annual data supplied by CMSD for 4 districts, it was found that the percentage of drug items purchased by districts not belonging to the EDL ranged from 35% to 57% and that the percentage of expenditure on non-EDL drugs ranged from 49% to 66%. The percentage of expenditure on antibiotics ranged from 19% to 38%. Most of the antibiotic expenditure from the CMSD was for cephalosporins which consumed 10-24% of the budget allocation for purchase from the CMSD and none of which are on the EDL. Table 1 shows a breakdown of costs for medicines purchased from the CMSD and EDCL in individual districts in 2009.

### Table 1: Drug purchase in four districts in 2009-2010

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<td></td>
<td>% costs on non-EDL drugs</td>
<td>% costs on antibiotics</td>
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<td>Dhaka</td>
<td>54%</td>
<td>33%</td>
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<td>Narayanganj</td>
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<td>30%</td>
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<td>Cox’s Bazaar</td>
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Thus, the available data clearly shows that in all districts, antibiotics consume a large part of the budget allocation and also that a substantial amount of the drugs consumed are non-EDL. It was not possible to do such estimations for the large hospitals and tertiary referral centres since they do not purchase from the CMSD and have no electronic inventory control system. However, their consumption of non-EDL drugs is likely to be much larger than at district level – with good reason since the EDL is designed only for primary care. It is very likely that a substantial part of their expenditure is on antibiotics. The pharmacist at Dhaka Medical College Hospital estimated that a third of their budget allocation is spent on antibiotics.
**Possible Solutions**

1. Revise the EDL to include drugs suitable for hospital as well as PHC use so that hospital drug selection is more consistent and cost-effective.

2. Regularly update the EDL - with publicly available selection criteria, broad representation of the medical profession, 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 EDL.

3. Monitor adherence to the EDL and publish the results annually.
Use of medicines

There was no official information concerning the use of medicines. However, the consultant found more than 35 studies published by local authors on medicines use. Many of these publications describe medicine use surveys that took place more than 10 years ago in children less than 5 years with acute diarrhoea or ARI. Table 2 lists all the studies published that describe surveys done since the year 2000, together with the main results.

Table 2: Drug use surveys done in Bangladesh since the year 2000

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study type</th>
<th>Survey year</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larson et al 2006</td>
<td>Private informal providers</td>
<td>2003</td>
<td>% childhood diarrhoea cases treated with ORS 56% &amp; AB 35%</td>
</tr>
<tr>
<td>Hoque et al 2007 Arifeen et al 2004 Arifeen et al 2005</td>
<td>Public PHC; IMCI intervention</td>
<td>2000 baseline 2005 post-intervention</td>
<td>STGPX 11% ; INAPPAB 48-72% STGPX 78% ; INAPPAB 9% Reduced IMR</td>
</tr>
<tr>
<td>Mamun et al 2006</td>
<td>Private drug sellers</td>
<td>?</td>
<td>60% patients received ABs, half without prescription, &amp; all sold in inappropriate doses &amp; duration,</td>
</tr>
<tr>
<td>Rahman MS 2009</td>
<td>Community self-medication; Public education campaign intervention</td>
<td>2009 control group 2009 interv group</td>
<td>No change in control group and no change in prescribing by doctors. 13% reduction in no drugs/patient 10% reduction in patients getting ABs 25% reduction in patients getting VIT</td>
</tr>
<tr>
<td>Rahman Z, Nazeen R &amp; Begum M, 2009</td>
<td>Private doctors</td>
<td>2005</td>
<td>Average of 3.81 drugs/patient, 72% patients received ABs, 50% drugs from EML, 58% patients received proper instructions.</td>
</tr>
<tr>
<td>Shapna Sultana et al 2010</td>
<td>Public tertiary hospitals outpatient</td>
<td>2009</td>
<td>Prescribing for hypertension – polypharmacy, only brand name prescribing, most prescriptions without patient instructions</td>
</tr>
<tr>
<td>Rahman MS et al 2007</td>
<td>Public &amp; private hospital outpatients</td>
<td>2003</td>
<td>Private hosp used NSAIDs that are more potent, expensive and have more side effects than public hospitals</td>
</tr>
<tr>
<td>Rahman Z et al 2005</td>
<td>Public &amp; private hospital inpatients</td>
<td>2004</td>
<td>8-84 days AB prophylaxis for hysterectomy, all contrary to STGs</td>
</tr>
<tr>
<td>Islam et al 2007</td>
<td>Hospital inpatients; Prescription audit &amp; feedback interv</td>
<td>2003</td>
<td>AB prophylaxis for Caesarian Section reduced from 8 to 7 days and AB costs reduced by 2/3.</td>
</tr>
<tr>
<td>Akter et al 2005</td>
<td>Public &amp; private hospital pediatric inpatients</td>
<td>2002</td>
<td>Unnecessary multi-AB practice, more in private than public hospitals</td>
</tr>
</tbody>
</table>

STGPX = % cases treated in compliance with standard treatment guidelines
INAPPAB = % cases treated unnecessarily with antibiotics;
NSAID = Non Steroidal Anti-Inflammatory Drugs; interv = intervention
IMCI = Integrated Management of Childhood Illness; ORS = Oral Rehydration Solution
AB = Antibiotic; STG = Standard Treatment Guidelines; VIT = Vitamins
It can be seen from the various studies listed that there is widespread irrational use of medicines at all levels of the healthcare sector, from private informal providers in the community, through primary care providers to tertiary level providers in outpatients and inpatients. It can also be seen that a public education campaign did improve patient self-medication in the community (Rahman et al 2009), that the IMCI intervention improved treatment of childhood illness in primary care facilities (Arifeen et al 2004 and 2005; Hoque et al 2007) and that audit and feedback did reduce the duration of antibiotic prophylaxis for caesarian section, although the duration was still not in accordance with international or local guidelines even after the intervention.

**Consultant visits to the health facilities**

The consultant visited a number of health facilities during her visit as described below. In all public health facilities patients pay a 5 Taka registration fee and then all treatment and drugs were free. In patients were provided food paid for directly by government at 75 Taka per meal. In private pharmacies patients had to pay the full cost of the drugs. There was very little insurance coverage.

One tertiary referral centre was visited - Dhaka Medical College hospital. This is one of the biggest hospitals in Bangladesh having 1700 beds with 2400 inpatients in any one day and 3500 outpatients per day. The Director of the hospital mentioned that there was no shortage of doctors, there being 700, but that they had a shortfall of nurses. There are generally only 3 nurses and 3 assistants to look after 60 patients in any ward. It was mentioned that many patients from all over Bangladesh come to Dhaka to the big hospitals, having more trust in them than in their local services, and thus causing extreme crowding. In the outpatient department two junior doctors mentioned that they saw about 30 patients per day but in the general acute emergency department doctors mentioned that they saw more than 50 patients per day, admitting about 10% of them. In the pharmacy, the pharmacist-patient interaction was time was just a few seconds.

One district - Narayanganj district – was visited. Within the district, there are 5 Upazillas and within each Upazilla there are 5-12 Unions (47 total) and within a Union there are Wards. There is one health complex per Upazilla and one Community Clinic per Union. In Narayanganj they have 2.6 million people and this year they have had, so far in 9 months, a total patient attendance of 468 881. 90% of all posts are filled. One District hospital, one Upazilla health complex and one Community Clinic were visited. In the district hospital four dispensers generally saw about 700 patients per day, junior doctors saw about 100 patients per day and senior doctors about 30 referred patients per day. In the Upazilla health complex and community clinics, doctors and medical assistants (paramedics of 3 years training and allowed to prescribe) saw about 30-50 patients each per day. The crowding tended to be less in the lower level facilities. In the community clinic when the Health Assistant or Family Planning and Welfare Assistant (paramedics of 21 days training allowed to prescribe from a list of 24 drugs) is alone without any visiting doctor, he/she sees about 30 patients/day, prescribing and also dispensing. All facilities visited had a supervision book that was written in by visiting supervisors.
Two private pharmacies were visited accompanied by a staff member of the DGDA. Both pharmacies were near to two major hospitals so most of their customers came from these hospitals. They each saw about 400-500 patients a day. Assistants in the shop were of School Leaving Certificate level or plus 12. Pharmacists were present in each shop during the visit. Sometimes they gave the patient a receipt "cash memo" for which they kept a carbon copy in the shop, not for audit purposes but in case the patient returned with a problem. They said they kept these cash memo copies for 1 year but it was difficult to find a used pad in either shop. For many prescriptions, they dispense on a daily basis because the patient cannot afford the whole prescription. At the time of the visit most of the patients were those from the nearby teaching hospitals. However, it was mentioned that in the evening most of the prescriptions would come from private GPs. All medicines (with the exception of narcotics) were available-over-the-counter without prescription.

A prescription (Px) survey was done by the consultant at four public health facilities. In each facility, 30 prescriptions were examined in the pharmacy during the dispensing process. In Dhaka medical college hospital, the dispensing process involved several steps. Firstly, patients brought their prescription to a person who authorized it and gave them paper slips, one for each drug that was available, and then told the patient from which counters they might receive the drugs. Secondly, the patient queued at different counters according to what drugs had been prescribed and were available. If the patient was prescribed several drugs he/she might have had to queue at several counters. Thirdly, the drugs were dispensed at the various counters, where the pharmacist retained the paper slip for each drug dispensed but not the prescription where many more drugs may have been written for purchase outside the hospital. The only place to do a prescription analysis was by standing with the “Prescription authorizer” who was able to say what drugs were and were not available. Expensive drugs needed a special signature. A similar paper slip system operated at the district hospital and the Upazilla health complex except that there was only one counter dispensing all drugs, rather than different counters dispensing different drugs, so a prescription survey could be done by observing the prescriptions at the pharmacy counter. In the community centre, unlike in other facility types, the health worker did both prescribing and dispensing and here a prescription survey was done by observing what was written in the patient register.

A prescription survey was also done in two private pharmacies. For this survey, prescriptions were analysed as the patients came in for drug purchase. Cash memos could not be used as they were incomplete and tended to focus on the more expensive unusual items. The cost per prescription was based on the cost of all drug items prescribed not on what the patient actually paid – which was often less for fewer drugs.

Table 3 shows the results of the prescription survey.
Table 3: Primary care outpatient drug use in facilities visited during the mission

<table>
<thead>
<tr>
<th>Health facility</th>
<th>Av.no.drugs per Px</th>
<th>% P肟 with AB</th>
<th>% prescribed drugs dispensed</th>
<th>Av.cost per Px</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dhaka Medical College</td>
<td>3.4</td>
<td>74%</td>
<td>69%</td>
<td>-</td>
</tr>
<tr>
<td>Narayanganj District Zinal (Victoria) hospital</td>
<td>2.8</td>
<td>47%</td>
<td>70%</td>
<td>-</td>
</tr>
<tr>
<td>Sonargaon Upazilla Health Complex</td>
<td>2.5</td>
<td>34%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Durpath Community Centre</td>
<td>2.3</td>
<td>36%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dhaka Private pharmacies (n=2)</td>
<td>3.8</td>
<td>28%</td>
<td>-</td>
<td>712 BT</td>
</tr>
</tbody>
</table>

It should be remembered that the patients in the public sector facilities were mainly acute patients and those attending the pharmacies mainly chronic patients. For this reason, the % of patients receiving antibiotics in the private sector was less than in the public sector. Apart from this, it can be seen that more drugs per patient were prescribed in the private sector and that the number of drugs per patient increased with increasing levels of health care i.e. more in secondary hospitals than in primary health care facilities and more in tertiary hospitals in district hospitals. Also, the % of patients receiving antibiotics in acute outpatient care was much higher in the higher level facilities. Since the patients were general outpatients with acute problems similar to that in PHC, there is no reason why antibiotic use should have been so much higher. Thus, it is likely that there is much unnecessary overuse of antibiotics in the larger hospitals. In the only facility where the use of vitamins was measured, Upazilla health complex, 59% patients received a vitamin. All these results were similar to what had been previously reported in Bangladesh for primary care type patients:

- high use of vitamins (Rahman MS 2009),
- polypharmacy particularly in the private sector and by specialists (Rahman MS et al 1998; Rahman Z, Nazeen R & Begum M, 2009).

The average cost of prescriptions coming to private pharmacies was high and out of reach of many patients. There were many diabetic patients buying insulin from the pharmacies accounting perhaps for the high average cost per prescription and also for the fact that about one third of patients received an injection. Virtually all prescribing was in brand name which may also have contributed to the high costs. The pharmacist/shop owners mentioned that generic substitution could be done legally but that they did not want to do this for fear of falling out with the local doctors. Publications citing average drug cost per prescription in the private sector could not be found but a recent study estimated that the average cost per prescription in the public sector was much less - only 77 BT (Rahman MS 2009).
There are many reasons for inappropriate overuse of medicines. In the public health facilities, short consultation times of 1-2 minutes and very short dispensing times of sometimes a few seconds, particularly in the public hospitals, is likely to lead to irrational inappropriate use of medicines. In the private sector consultation times with patients may be longer. One private paediatrician mentioned that he saw 7 patients (plus 2 drug representatives) during an evening. Nevertheless this same doctor mentioned seeing 200 patients in 2 hours during a charity clinic! The lack of consultation time means that doctors do not have time to make the proper diagnoses required for good prescribing. The lack of patient-dispenser interaction time during the dispensing process means that dispensers do not have time to explain to patients how to take their medicines.

In addition, there are a number of other factors impacting on drug use as explained below.

**Standard treatment Guidelines**

Few prescribers were using any standard treatment guidelines or other sources of independent information. There are no national standard treatment guidelines, covering the majority of diseases and compiled into one book. There are guidelines on Malaria, TB, Leprosy, Filaria, acute watery diarrhoea, ARI, Dengue infection, drug addiction and burn injury in annex 1 of the Bangladesh National Formulary (2006). The Bangabandhu Sheikh Mujib Medical University, Dhaka, had its own Antibiotic Guidelines (2005) and had been conducting a number of drug use evaluation studies, some of which are published in local journals and which constitute the majority of publications found and referred to in this report. No other clinical guidelines were seen. The excellent Bangladesh National Formulary 2006 was not seen in any health facility.

**Education and Information**

The Centre Medical Education (CME) teaches methods of education and oversees curricula changes which must then be approved by the Bangladesh Medical Council. At present all undergraduate medical students receive 60 hours training in clinical pharmacology during the 3 and 4th years followed by examination. This 60 hours includes 4 hours on the Essential Medicines Concept and the Essential Medicines List (EML), but no real problem-based learning approaches. In Dhaka Medical College and also at Bangabandhu Sheikh Mujib Medical University, Dhaka, they even do INRUD type prescription audits as well as critiquing prescriptions. Some of these surveys done by students (undergraduate and postgraduate) produce useful information but very few of them are discussed more widely in the hospitals or published or indeed used in any way. Unfortunately the good prescribing practices learnt in pre-clinical years get eroded by the final clinical years and then clinical practice when clinical pharmacology is not properly taught. The CME is trying to rectify this by introducing 15 days training on clinical pharmacology during the general medicine the pre-registration time. The Director of the CME and a number of other clinical pharmacologists feel that knowledge is not the
problem underlying irrational prescribing, rather there are other factors such as excessive
drug promotion, profit-motives, lack of time, etc.

There is no regular Continuing Professional Development (CPD) and whatever
adhoc seminars there are do not include prescribing. None of the studies done by students
on prescription audit are published and it was agreed by clinical pharmacologists that it
would be good if some, particularly the postgraduate theses, were put into the public
domain and discussed in the hospital as a whole. In addition there are no Drug and
Therapeutic Committees in the tertiary referral hospitals or districts. While there are drug
review committees who meet to decide drug selection, these committees do not perform
any other function.

In Dhaka medical college it was mentioned that each department organizes
regular lectures and seminars and also “Grand Ward Rounds” but that internal
prescription audit was not done. Some senior physicians admitted that there was much
irrational use of antibiotics and that prescription audit should be done but that they were
too busy to organize it. Two junior doctors in the outpatient department of Dhaka medical
college hospital mentioned that they had not been to any CPD lectures or seminars during
the last month although they got regular supervision from their supervisor during their
work. Doctors in Narayanganj district mentioned that they are generally too busy to go to
Dhaka for CPD sessions but that occasionally there is a special training organised by the
DGHS e.g. anthrax the previous week. In addition, in Narayanganj district it was
mentioned that there was supervision at all levels, involving checklists. While
prescription audit had not been done, doctors regularly visited the Community Centre to
supervise prescribing and other activities.

In the private sector there is no CPD for GPs. One staff member of the
Bangladesh Medical and Dental Council, who is also a paediatrician, had not been on any
CPD seminars recently because he was too busy. It was mentioned that the Bangladesh
Medical Council is planning accreditation for relicensing every 5 years and may
incorporate CPD into the criteria for accreditation. However, this would require an act of
parliament.

There are few sources of independent information on medicines available to
prescribers. There is no national drug information centre and there were very few sources
of independent drug information available to prescribers, particularly at district level or
below. Even the 2006 National Formulary is often not available to most prescribers. In
the medical colleges there are medical journals and in the clinical pharmacology
department a 2001 copy of a drug bulletin “Health” published by the Health Action
Forum was available. At district level there is a health promotion unit for community
education but they have not spread messages to the people on drug use e.g. no need for
drugs for coughs and colds, does my child need more than 2 medicines? etc.

While there is little independent information on medicines available there is a
great deal of information available from the pharmaceutical industry. All respondents
mentioned that there is a great deal of drug promotion. The Director General of Health
Services mentioned that there is a circular forbidding any drug representative to enter any public facility before 1 pm but that it was difficult to police this. The Civil Surgeon of Narayanganj district mentioned that they only allowed pharmaceutical representatives to be seen twice per week on the public premises after working hours. He mentioned that he was very strict about this and had even once called the police to remove a pharmaceutical representative from the premises. Nevertheless, everyone agreed that pharmaceutical representatives have great influence over prescribers as most doctors work in private clinics after public sector time.

**Core committee for rational use of medicines**

The MOHFW/DGHS has been well aware of the problem of irrational use of medicines. It was realised that it is difficult for any one department within the existing MOHFW/DGHS structure to coordinate all these functions. Therefore, it was suggested in 2008 to have “Core Committee for Rational Use of Drugs” under the chairmanship of the DGHS. Consultative meetings were held (sponsored by WHO) – one each with the professional bodies, the prescribers and health managers and civil society organizations. All meetings agreed with the need for a core committee on RUM. Following this a National Committee for Rational Use of Drugs/Medicines under the chairmanship of the Director General Health Services, with the Member Secretary being the Coordinator, Program to promote rational use of medicines, Department of Pharmacology, Bangabandhu Sheik Mujib Medical university.

The terms of reference for this committee were to:

- “facilitate cooperation among policy makers, regulators, prescribers, medical educators, medicine sellers, dispensers and consumers (patients and care givers) in initiating, developing, carrying out and monitoring measures directed towards ensuring rational use of medicines in Bangladesh
- Conduct a review of the following issues to explore the present situation and suggest the opportunity:
  - Course and curriculum of health related disciplines
  - Content of the continuing medical education;
- Establish sub-committees to provide advice or to assist in the performance of its functions, e.g.
  - Undergraduate and post graduate medical education
  - Continuing medical education.”

It was proposed that the committee meet every 3 months and a proposed membership list was drawn up. The document was due to be submitted to the MOHFW for endorsement but, unfortunately, due to changes in the administrative positions of different committee members, the process was halted.

**Possible Solutions**

1. An electronic drug inventory stock control system 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 level or between districts

2. Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above).

3. Annual publication in all major hospitals and districts of drug consumption analysis and prescription audit, as a statutory requirement, with analysis of their reports in the DGHS/MOHFW

4. Development and regular updating of Standard Treatment Guidelines, with dissemination to all doctors and incorporation into CPD curricula

5. Regular updating of the Bangladesh National Formulary, with dissemination to all doctors and incorporation into CPD curricula

6. Establish functional Drug and Therapeutic Committees in all referral and university hospitals and also in each district - with an obligation to monitor drug use, coordinate CPD in their institutions and report annually to MOHFW/DGHS. A reporting system that enables health facilities to report on quality of care issues and drug use will enable MOHFW/DGHS to know what is and what is not going on and what needs to be done. However, such a system does require capacity in the MOHFW/DGHS to review these reports.

7. Encourage the Bangladesh Medical and Dental Council and the Bangladesh Medical Association to develop a credit system for undertaking CPD and to incorporate prescription audit and feedback and ethics into the CPD

8. Disseminate to the public core pharmaceutical messages through the already existing MOHFW health education units and the media e.g. does my child need more than one drug?

9. Revive the "Core Committee for Rational Use of Drugs" and get endorsement from the government for a statutory committee and establish a dedicated unit within the DGHS to monitor medicines use, coordinate policies and carry out the policy suggestions of the Committee (see section on medicines policies and health systems).
Drug Regulation

The Directorate of Drug Administration (DDA) was upgraded to a Directorate General of Drug Administration (DGDA) directly under the MOHFW in Jan 2010. This upgrading will allow access to more resources in the future, although so far they have not received new resources. The DGDA works according to the Drug Act of 1940, the Drug Rules of 1945, the Drug (Control) Ordinances of 1982, Drug Policy 2005 and the Amendment Act of 2006. The functions of the Directorate General of Drug Administration (DGDA) were stated to include the following:

- Drug evaluation and registration
- Issue and renewal of manufacturing licence
- Pricing of medicines
- Inspection of manufacturers
- Inspection and licensing of outlets
- Pre-approval for drug advertisements
- ADR Monitoring, Post-marketing surveillance and pharmacovigilance
- No objection certificates
- Development of the NDP document of 2005
- Development of the national EDL of 2008
- Development of the national formulary of 2006

The pharmaceutical sector is very large in Bangladesh. According to the DGDA, 97% of the drugs are locally manufactured and there are 18 687 registered allopathic brands including 546 brands of amoxicillin in 35 different forms (dosage and combination), 400 brands of ciprofloxacin, 239 brands of omeprazole and 99 brands of ibuprofen. The DGDA further mentioned that there are 255 local allopathic medicine manufacturers and 90 000 registered medicine shops in the country – all of which need to be inspected to renew their licence once every 2 years. The most pressing urgent problem is one of manpower deficiency which is compromising their work. A large pharmaceutical industry requires a large DRA. They have estimated that they need 700 staff members to adequately carry out the necessary work and have requested this number of staff. However, as of now, they have only 370 approved posts, 135 filled and 235 vacant. There are no clinical pharmacologists employed. Thus, it is urgent to hire qualified staff for the DGDA. At the time of writing, an embargo on recruitment had been removed and two new officers of scientific background had been recruited.

There is a website but it is not regularly updated - [http://www.ddabd.org](http://www.ddabd.org). There are no updated written Standard Operating Procedures (SOPs) - for most procedures including product dossier evaluation, registration of medicines, inspection of manufacturing premises, inspection of retail premises, sampling for quality control testing, recall or withdrawal of medical product. Some checklists exist but need updating. There are a number of technical committees that advise the DGDA as follows:

- Project Evaluation Committee to advise on the establishment of new pharmaceutical industry and to prepare GMP guidelines
- Drug Control Committee to advise on drug registration

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- Project Evaluation Committee to advise on the establishment of new pharmaceutical industry and to prepare GMP guidelines
- Drug Control Committee to advise on drug registration
• Technical sub-committee to support to Drug Control Committee
• Technical Committee for Price Fixation of Medicines
• Standing Committee for the Import of Pharmaceuticals including raw materials and finished products

There is no committee to advise on drug promotion and it was mentioned by some that it is not monitored. However, others mentioned that there is one staff member who is supposed to review adverts. With regard to pharmacovigilance, only 11 ADRs were reported last year and there has been no activity for unexpected lack of efficacy, quality defects, medication errors or poisoning. There has been so little data on ADRs that the ADR committee has never met. There is a separate unit for narcotic regulation. Up until May 1994, all drugs were price-controlled but since then only 117 EDL drugs are strictly price-controlled and for the rest the manufacturers set the price.

Drug Registration

Drug registration is controlled by the Drug Control Committee (DCC) of 21 members who meet 2-3 times per year. When a new molecule, not already in the market, is put forward for registration, a technical sub-committee of 15 members will consider the dossier of papers. If the molecule is already registered in UK, USA, Australia, France, Germany, Switzerland or Japan, they will consider the molecule with regard to efficacy, safety, usefulness and quality (which involves checking the adequacy of manufacture) when considering registration. The Technical sub committee must report to the Drug Control Committee (main committee) which then takes a decision by consensus. This process is followed whether the product is to be imported or produced locally. New molecules, that are not already on the market and that are not registered in the UK, USA, Australia, France, Germany, Switzerland or Japan, will not be considered for registration. When a new product of a molecule that is already in the market (i.e. a me-too product for a molecule already approved by the DCC) is put forward for registration, whether for importation or local manufacture, then further approval from the DCC is not required and the applicant may apply to the licensing authority (DGDA) for registration. Provided the manufacturer can produce the product to a satisfactory standard, as determined by examination of a dossier of documents and an inspection of the premises by the DGDA, there is provision for getting registration i.e. there are no me-too restrictive criteria for registration. Thus there are 18687 brands on the market for about 1100 molecules, with hundreds of brands for some drugs such as amoxicillin, ranitidine, and paracetamol. While they only approve molecules already approved in the UK, USA, etc, they feel that, though they are a poor country, they do need all these drugs, including the combination drugs.

The Drug Control Committee only meets twice a year which a number of past and present committee members feel is not sufficient. Recently they approved 60 drugs in one meeting which one respondent felt was far too much. Several respondents mentioned that there is over-representation of the pharmaceutical industry in the committee which is a clear conflict of interest. One respondent mentioned that some government members (who constitute the Chair and Member Secretary of the Drug Control Committee and the
members of the Technical subcommittee) were often absent and that a number of other members, while officially representing certain organizations were, in fact, “industry plants”. He suggested having a Consumer representative on the committee. Although the Drug Control Committee must take decisions by consensus, some respondents mentioned that sometimes there is voting and that there is pressure to approve drugs because if one refuses them one is thought to be negative towards the Bangladesh industry. Most respondents strongly felt that all persons sitting on the Drug Control Committee should not only represent a certain organization but should also be technical qualified and should attend regularly.

The problem of regulating such a large market and how to cut down on the number of registered products was discussed. One respondent mentioned that increasing the registration fee to a minimum of 1000 USD and preferably 2000-5000 USD would cut down on the me-too drugs and that if this money was kept for the DGDA, instead of going to the treasury, the DGDA could be strengthened.

### Regulation of outlets and drug schedules

There is no OTC list yet formed although there have been recommendations to develop one for some years. Therefore all drugs (except narcotics) are available OTC. Apparently, generic substitution is allowed legally but little is done because doctors do not accept it – so leaving patients with unnecessarily high drug costs. This may be partly due to a lack of confidence on the part of doctors in the quality of many generic drugs in the private market.

In the 3 private pharmacies visited (prescription audit only done in two), all 3 stocked 15 brands of amoxicillin, 30 brands of paracetamol and 50-60 brands of ranitidine. They all stated that it was necessary to stock different brands of drug in order to accommodate different doctor preferences.

All pharmacies should have a pharmacist on the premises. However, this is often not followed and the DGDA mentioned that it was difficult to enforce this because they did not have the manpower or resources to do sufficient inspections. One respondent suggested training certificate-level pharmacists (6 months) to manage shops as there were too few diploma pharmacists to be present in all the shops. A number of persons mentioned that that in the rural areas, 95% of drug shop owners are unqualified and need to have training on the EML and good dispensing practices. It was further suggested that district staff, academicians and inspectors could train such drug shop owners and that district staff could be trained to inspect the shops – so saving the DGDA manpower.

### Drug Quality and Drug Testing Laboratory (DTL)

The EDCL and CMSD have adequate quality assurance systems and from next year, hospitals will be required to purchase from manufacturers pre-qualified by the CMSD. Thus the majority of drugs supplied to the public sector are of reasonable quality and most public sector health workers reported no problems with drug quality. The
DGHS does not think that EDCL is as good as the top 10 manufacturers in the country. They have 256 manufacturers of which only 30-35 produce quality products. However, most public sector drugs come from these few good manufacturers, so quality in the public sector is reasonable. It was suggested that any increase in the capacity of the drug testing laboratory should focus on the small manufacturers, with poor quality control.

Apparently 2% of drugs tested per year are substandard - which comes to 80 substandard molecules per year on the present testing capacity - but companies are not named and shamed. For this reason some respondents felt that any drug testing facility should be independent of DGDA, under a statutory body, in order for appropriate action to be taken. The National Drug Policy 2005 recommends publishing the names of companies found to have produced sub standard drugs. However, so far, no company name has ever been published with the exception some years previously of the one found to have produced paracetamol syrup with diethylene glycol which killed a child and where one person went to jail.

The EDCL and CMSD (or CMSD prequalified manufacturers), which supply most of the public sector drugs, already include precautions to ensure quality through pre-qualification of suppliers and sample quality testing using their own laboratory facilities. Foreign purchasers also take similar precautions. Thus, the main purpose of the upgraded DTL should be to test drug quality in the private domestic market.

It was mentioned that the DTL is currently testing 4000-5000 samples per year i.e. 15 drugs per days but that for such a large private sector they should be testing 20000 samples per year. While there is a shortage of staff in the DTL itself, it was mentioned that there is no shortage of technical staff in Bangladesh, rather it is just that the government does not employ them. It was recommended by senior DTL staff that the government should double the staff, do more staff training and double the number of samples tested per year. One respondent mentioned that the DTL could contract out testing to other laboratories.

Recently the DTL has been separated from the Institute of Public Health because of a potential conflict of interest resulting from the fact that the Institute manufactures vaccines and other products that the laboratory was testing. Therefore, in response to advice from WHO and other external parties, the DTL has been put under DGDA. However, some local Clinical Pharmacologists thought that the DTL should be a statutory body independent of government and not under DGDA as otherwise there could again be conflict of interest and no proper action on the results taken. Mr Somsak, the consultant from the Thai DTL mentioned that in Thailand the DTL is independent and not under the DRA.

There is a separate report from the Drug Testing consultant, Mr. Somsak Sunthornphanich, from Thailand. However, some general points from his visit are summarized here. The main objective of his visit was to advise on upgrading the DTL in terms of equipment, staff and training. It was agreed that the upgrading of the DTL would be to meet WHO, not ISO, standards. Mr Somsak mentioned that currently they are not
doing all tests on all drug samples. Thus, to achieve WHO standards, more tests and much more work needs to be done to process the same number of samples. Thus, even if the activities are doubled, the number of samples tested will not increase greatly if they are processed according to WHO standards. For increasing the number of samples, the number of staff actually undertaking the tests will need to be increased. The current premises, even when upgraded, may only allow a limited increase in staff and thus the number of samples tested. Furthermore, if the number of samples tested is increased, the DGDA will need to be strengthened and given more resources in order to take the appropriate action.

**Regulation of the Private Sector**

Bangladesh has a large private sector there being 2630 private hospitals and clinics, including 40 private medical colleges, as compared to 120 hospitals (secondary and tertiary) and 482 Upazilla health complexes in the public sector. The DGHS is responsible for regulating this sector and gives a license annually to each private facility dependent upon a successful inspection by an inspection team, which includes the divisional chief, the district civil surgeon and a clinical consultant. The team uses a checklist which requires collection of information on the physical facility, equipment and staffing, but does not require any information on drug use. The Hospital Director under the DGHS coordinates licensing of private facilities.

**Possible Solutions**

Strengthen the DGDA by:

1. **Urgently appointing sufficient staff, particularly inspectors and pharmacists, but also including clinical pharmacologists, 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:**
   - Reviewing the criteria for drug registration so as to the reduce the number of me-too products;
   - Raising the registration fee so as to reduce the number of brands of the same active pharmaceutical ingredient being registered;
   - Reviewing criteria for membership of the Drug Control Committee (DCC) to ensure that all members are suitably qualified, in addition to representing departments or organizations, and also to ensure that there is no more than 1-2 representatives of the pharmaceutical industry;
   - Requiring regular attendance at the meetings for all members of the DCC;
   - Publishing the number of products approved by the DCC and the number of products given no-objections certificates without review by the DCC.

4. **Revising and updating the standing operating procedures (SOPs) so as to improve:**
   - The way in which procedures are conducted;
• How various committees 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. Reviewing the drug schedules and developing an OTC list which should be widely disseminated so that pharmacists and retailers know which drugs can be dispensed without prescription and which ones need a prescription. Consideration should be given to having a category of drug that is only available in certain specialist institutions even with prescription e.g. the newer antibiotics.

7. Considering whether certain services could be contracted out e.g. ADR monitoring and pharmacovigilance, the development of a drug information centre and monitoring of drug advertisements to clinical pharmacology departments in universities in Dhaka - these institutions have the necessary expertise to undertake such activities if properly recompensed. This could overcome the acute lack of manpower and expertise in the DGDA. Nevertheless capacity must be built within the DGDA to be able to take action on the information that will come from the contractees on inappropriate adverts or ADRs.

8. Strengthening the DTL so as to reach WHO standards and be able to process more samples.

9. Seeking external technical support from WHO and other sources to develop an institutional plan for the DGDA and to advise on the how to address the above issues.
Medicine Policy and Health System Issues

Bangladesh has an extensive National Drug Policy Document that was revised in 2005. There are 18 objectives and policy areas covering laws and regulation, the Drug Regulatory Authority (DRA), Drug registration, drug production, drug procurement, drug distribution and storage, drug sales, drug pricing, drug quality assurance, manpower of manufacturing units, drug information and monitoring and Essential Drugs. While some objectives have been met e.g. increasing manufacturing capacity, others have not e.g. regulating drug promoting, improving access, improving price controls, ensuring rational use of medicines, proper monitoring of ADRs and strengthening the DRA. Table 4 summarises implementation of various medicine policies that may impact on drug use.

Table 4: Medicine Policies in place in Bangladesh

<table>
<thead>
<tr>
<th>Drug Policy</th>
<th>State of implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Drug Policy</td>
<td>Official document 2005, but many aspects of it not implemented</td>
</tr>
<tr>
<td>Monitoring the use of medicines</td>
<td>No official monitoring of use but some ad hoc surveys on actual prescribing done by students of clinical pharmacology</td>
</tr>
<tr>
<td>Essential Medicines List</td>
<td>National List 2008 used in public sector procurement, covering mainly PHC drugs</td>
</tr>
<tr>
<td>Standard Treatment Guidelines</td>
<td>No national STGs</td>
</tr>
<tr>
<td>Generic Policies</td>
<td>Generic substitution legal but not done by retailers as they do not want to upset the doctors</td>
</tr>
<tr>
<td>Regulation of promotion of medicines</td>
<td>DRA responsible but unable to do this – one person examines some adverts but no committee</td>
</tr>
<tr>
<td>Monitoring of ADRs</td>
<td>DRA responsible but unable to do this – only 11 ADRs reported last year, so committee has never met</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 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 DGHS runs some specific training programs in districts</td>
</tr>
<tr>
<td>Medicines Information Centre</td>
<td>No national medicines information centre</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>No functional DTCs in hospitals or districts (only drug review committees for drug purchase)</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 MOHFW structure. In particular the DRA needs strengthening. While the department has been upgraded from the Directorate of Drug Administration under DGHS to the Directorate General of Drug Administration under the MOHFW, no extra resources have so far been forthcoming. Virtually all respondents agreed that irrational use of medicines was a huge problem in Bangladesh. Many of the core policies, structures and functions needed to improve the use of medicines are not in place. Examples include:

- the EML does not cover many of the common drugs used by hospitals and many hospitals are not following it;
- there are no national standard treatment guidelines for the majority of illnesses and even the few guidelines that do exist are not being used;
- Drug and Therapeutic Committees to undertake basic monitoring and educational functions with regard to drugs do not exist, only drug review committees to decide on purchase exist;
- there is a lack of independent drug information and no drug information centre but an over-abundance of information from the industry which is not being adequately regulated;
- CPD is adhoc and does not include prescribing;
- There is no monitoring of consumption and no prescription audit.

It is not clear in the current structure which department is looking after some of these functions. Furthermore, it is difficult for any one department within the existing MOHFW/DGHS structure to coordinate all these functions. Therefore, it was suggested that the proposal in 2008 to have “Core Committee for Rational Use of Drugs” be revived. It was noted however, that without resources for implementation and monitoring that it would be difficult for such a committee to function. Therefore, it was suggested that an executive unit under the DGHS be established to carry out the recommendations of this committee. It was further mentioned that the National Drug Policy is to be updated and that a committee had met twice under the chairmanship of the DGDA for this purpose.

Possible Solutions

1. Revive the “Core Committee for Rational Use of Drugs”, making it a permanent committee.

2. Establish an executive unit/department on RUM within the DGHS to undertake activities concerning:
   - Monitoring of use;
   - Development, updating and dissemination of a national EML and STG
   - Coordination and monitoring of DTCs, CPD, Medicines Information Centre, public education;
   - Liaison with universities to provide students to collect information needed by MOHFW as part of their research studies - so helping overcome the lack of human resources and using locally available expertise.
3. Incorporate a responsibility of the Core Committee for RUM to monitor implementation of all policies relating to drug use as stated in the NDP and to ensure that implementation of such policies are included in national health plans and regulations.

**Debriefing with MOHFW Officials**

At the end of the mission, a half-day debriefing was held on November 2nd with about 20 MOHFW officials to discuss the consultant’s findings and to develop recommendations. The participants in the debriefing can be seen in annex 2. The consultant’s presentation at the workshop can be seen in annex 3.

There was a lively discussion and the MOHFW officials agreed with the many of the consultant’s findings and most of the consultant’s recommendations. During the debriefing, the major recommendations were agreed by consensus. Following the debriefing, this report with recommendations was drafted and then circulated to all MOHFW officials for comment. The final agreed recommendations are summarized below.
Recommendations

Drug Supply
1. Establish an electronic drug inventory management system, with extension to the level of hospitals and district stores that would allow monitoring of consumption in the public sector.

2. Train staff in the management of the electronic system that the DGHS is now starting to set up and in how to extract and use drug consumption data.

Drug Selection
3. Revise the EML to include drugs suitable for hospital as well as PHC use so that hospital drug selection is more consistent and cost-effective.

4. Regularly update the EML - with publicly available selection criteria, broad representation of the medical profession, 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.

5. Monitor adherence to the EML and publish the results annually.

Drug Use
6. An electronic drug inventory stock control system 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.

7. Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above).

8. Annual publication in all major hospitals and districts of drug consumption analysis and prescription audit, as a statutory requirement, with analysis in the DGHS/MOHFW.

9. Development and regular updating of Standard Treatment Guidelines, with dissemination to all doctors and incorporation into CPD curricula.

10. Regular updating of the Bangladesh National Formulary, with dissemination to all doctors and incorporation into CPD curricula.
11. Establish functional Drug and Therapeutic Committees in all referral and university hospitals and also in each district - with an obligation to monitor drug use, coordinate CPD in their institutions and report annually to MOHFW/DGHS. A reporting system that enables health facilities to report on quality of care issues and drug use will enable MOHFW/DGHS to know what is and what is not going on and what needs to be done. However, such a system does require capacity in the MOHFW/DGHS to review these reports.

12. Encourage the Bangladesh Medical and Dental Council and the Bangladesh Medical Association to develop a credit system for undertaking CPD and to incorporate prescription audit and feedback and ethics into the CPD.

13. Disseminate to the public core pharmaceutical messages through the already existing MOLH health education units and media e.g. does my child need more than one drug?

**Drug Regulation**

Strengthen the DGDA by:

14. Urgently appointing sufficient staff, particularly inspectors and pharmacists, but also including clinical pharmacologists, to deal with all the required activities.

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

16. Improving the process of drug registration by:
   - Reviewing criteria for drug registration so as to the reduce the number of me-too products;
   - Raising the registration fee so as to reduce the number of brands of the same active pharmaceutical ingredient being registered;
   - Reviewing criteria for membership of the Drug Control Committee (DCC) to ensure that all members are suitably qualified in addition to representing departments of organization and also to ensure that there is no more than 1-2 representatives of the pharmaceutical industry;
   - Requiring regular attendance at the meetings for all members of the DCC;
   - Publishing the number of products approved by the DCC and the number of products given no-objection certificates without review by the DCC;

17. Revising and updating the standing operating procedures (SOPs) so as to improve:
   - The way in which procedures are conducted,
   - How various committees are currently managed, particularly with regard to membership and possible conflict of interest in members who sit on many committees.

18. Amending the current regulations to increase punitive action.
19. Reviewing the drug schedules and developing an OTC list which should be widely disseminated so that pharmacists and retailers know which drugs can be dispensed without prescription and which ones need a prescription. Consideration should be given to having a category of drug that is only available in certain specialist institutions even with prescription e.g. the newer antibiotics.

20. Considering whether certain services could be contracted out e.g. ADR monitoring and pharmacovigilance, the development of a drug information centre and monitoring of drug advertisements to clinical pharmacology departments in universities in Dhaka - these institutions have the necessary expertise to undertake such activities if properly recompensed. This could overcome the acute lack of manpower and expertise in the DGDA. Nevertheless capacity must be built within the DGDA to be able to take action on the information that will come from the contractees on inappropriate adverts or ADRs.

21. Strengthen the DTL so as to reach WHO standards and be able to process more samples.

22. Seeking external technical support from WHO and other sources to develop an institutional plan for the DGDA and to advise on the how to address the above issues.

**Coordination and Management**

23. Revive the “Core Committee for Rational Use of Drugs”, making it a permanent statutory committee.

24. Establish an executive unit/department on RUM within the DGHS to undertake activities concerning:
   - Monitoring of use
   - Development, updating and dissemination of a national EML and STG
   - Coordination and monitoring of DTCs, CPD, Medicines Information Centre, public education
   - Liaison with universities to provide students to collect information needed by MOHFW as part of their research studies - so helping overcome the lack of human resources and using locally available expertise

25. Incorporate a responsibility of the Core Committee for RUM to monitor implementation of all policies relating to drug use as stated in the NDP and to ensure implementation of such policies are included in national health plans and regulations.
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Annex 1: Persons met during the situational analysis:

<table>
<thead>
<tr>
<th>S.N</th>
<th>Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>1</td>
<td>Prof A.F.M Ruhal Haque</td>
<td>Ministry of Health and Family Welfare</td>
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<tr>
<td>2</td>
<td>Mr Md. Humayun Kabir</td>
<td>Secretary, Ministry of Health and Family Welfare (MoHFW)</td>
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<td>3</td>
<td>Prof Shah Monir Hossain</td>
<td>Director General Health Services, MoHFW</td>
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<td>4</td>
<td>Major General Md Abdul Kalam Azad</td>
<td>Director General Directorate General of Drug Administration (DGDA), MoHFW</td>
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<tr>
<td>5</td>
<td>Mr Md Matiur Rahman</td>
<td>Deputy Director, DGDA, MoHFW</td>
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<td>6</td>
<td>Dr A. A. Salim Barami</td>
<td>Assistant Director, MoHFW</td>
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<td>7</td>
<td>Mr Ruhul Amin</td>
<td>Drug Superintendent, DGDA, MoHFW</td>
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<tr>
<td>8</td>
<td>Dr MD. A. B. Siddique</td>
<td>Bacteriologist and Govt Analyst, Drug testing Lab, DGDA</td>
</tr>
<tr>
<td>9</td>
<td>Dr Nasima Pervin</td>
<td>Bacteriologist, Drug testing Laboratory (NCL), DGDA</td>
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<tr>
<td>10</td>
<td>Dr Md. Abul Hasnat</td>
<td>Director Administration, DGHS, MoHFW</td>
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<tr>
<td>11</td>
<td>Dr. Md Mumtaz Uddin Bhuiyan</td>
<td>Director Hospital and Clinics, MoHFW</td>
</tr>
<tr>
<td>12</td>
<td>Mr Shafiqul Bari (Shipon)</td>
<td>Essential Drugs Company Limited (EDCL)</td>
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<td>13</td>
<td>Dr. M Kadrul Huda</td>
<td>Managing Director, EDCL</td>
</tr>
<tr>
<td>14</td>
<td>Mr Md. Ali Mukarram</td>
<td>Deputy Manager, EDCL</td>
</tr>
<tr>
<td>15</td>
<td>Mr Md. Feroze-Ul Alam</td>
<td>Director Operations, EDCL</td>
</tr>
<tr>
<td>16</td>
<td>Mr Pijush Kanti Debnath</td>
<td>Senior Manager QA, EDCL</td>
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<tr>
<td>17</td>
<td>Brigadier General Abdur Rab</td>
<td>Director, Central Medical Stores Depot (CMSD)</td>
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<tr>
<td>18</td>
<td>Dr Md. Lutfor Rahman</td>
<td>Deputy Director, CMSD</td>
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<td>19</td>
<td>Brigadier General Dr Mallik</td>
<td>Director, Dhaka Medical College Hospital</td>
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<tr>
<td>20</td>
<td>Prof Dr Quazi Tarikul Islam</td>
<td>Dhaka Medical College &amp; Hospital, Dept Medicine</td>
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<tr>
<td>21</td>
<td>Prof Dr Md. Ismail Khan</td>
<td>Dhaka Medical College: Head Pharmacology, Dean Faculty Medicine, President Teachers Assoc</td>
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<tr>
<td></td>
<td>Name</td>
<td>Organization</td>
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<tr>
<td>22</td>
<td>Prof Dr Khan Abul Kalam Azad</td>
<td>Dhaka Medical College &amp; Hospital</td>
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<td>23</td>
<td>Prof (Dr) Md. Enamul Karim</td>
<td>Dhaka Medical College &amp; Hospital</td>
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<td>24</td>
<td>Prof Dr H.A.M. Nazmul Ahsan</td>
<td>Dhaka Medical College, Dept. Medicine</td>
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<td>25</td>
<td>Dr Md. Motiar Rahman</td>
<td>Civil Surgeon, Naryanganj District</td>
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<td>26</td>
<td>Prof Dr AFM Saiful Islam</td>
<td>Centre for Medical Education (CME)</td>
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<td>27</td>
<td>Dr Ashraf Uddin Ahmed</td>
<td>Centre for Medical Education (CME)</td>
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<td>28</td>
<td>Dr Md. Zahedul Haque Basunia</td>
<td>Registrar, Bangladesh Medical and Dental Council</td>
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<td>29</td>
<td>Dr Md. Sayedur Rahman</td>
<td>Bangabandhu Sheikh Mujib Medical University, Dept Pharmacology</td>
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<td>30</td>
<td>Prof Mir Misbahuddin</td>
<td>Bangabandhu Sheikh Mujib Medical University, Dept Pharmacology</td>
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<td>31</td>
<td>Dr Zafrullah Chowdhury</td>
<td>Gonoshasthaya Public Charitable Trust</td>
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<td>32</td>
<td>Prof Dr Md Abul Faiz</td>
<td>Sir Salimulah Medical College</td>
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<td>33</td>
<td>Aftab Ahmed Babu</td>
<td>Suparana Drugland</td>
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<td>34</td>
<td>Mr Abdul Muktadir</td>
<td>Incepta Pharmaceuticals Ltd.</td>
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<tr>
<td>35</td>
<td>Mr Md. Mobhubur Rahman (Milon)</td>
<td>United Drug Stores</td>
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Annex 2: Participants at the debriefing meeting on Nov.2\textsuperscript{nd}, 2010

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<th>S.N</th>
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<td>Director General Drug Administration (DGDA), MoHFW</td>
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<td>5</td>
<td>Mr. A K M Amir Hossain</td>
<td>Additional Secretary, MOHFW</td>
</tr>
<tr>
<td>6</td>
<td>Mr. Md. Shafiqul Islam Laskar</td>
<td>Joint Secretary, Ministry of Health &amp; Family welfare</td>
</tr>
<tr>
<td>7</td>
<td>Mr. Md. Abdul Mannan</td>
<td>Joint Chief, MoHFW</td>
</tr>
<tr>
<td>8</td>
<td>Mr. Md. Kafil Uddin</td>
<td>Director, DGFP</td>
</tr>
<tr>
<td>9</td>
<td>Mr. Md. Iftekhar Uddin Khan</td>
<td>Deputy Secretary, MOHFW</td>
</tr>
<tr>
<td>10</td>
<td>Dr. Md. Musharraf Hossain</td>
<td>Deputy Director, Hospital-2, DGHS</td>
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<tr>
<td>11</td>
<td>Dr A. A. Salim Barami</td>
<td>Assistant Director, MoHFW</td>
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<tr>
<td>12</td>
<td>Mr. Abdul Muktadir</td>
<td>General Secretary, Bangladesh Association of Pharmaceutical Industries.</td>
</tr>
<tr>
<td>13</td>
<td>Dr. Frank Pollin</td>
<td>Ag. WR to Bangladesh</td>
</tr>
<tr>
<td>14</td>
<td>Dr Kathleen Holloway</td>
<td>Regional Advisor-EDM, WHO/SEARO</td>
</tr>
<tr>
<td>15</td>
<td>Mr. Somsak Sunthornpanich</td>
<td>Bureau of Drug &amp; Narcotic Thailand, Consultant -WHO</td>
</tr>
<tr>
<td>16</td>
<td>Dr. Selina Ahmed</td>
<td>NPO-VSQ, WHO/BAN</td>
</tr>
<tr>
<td>17</td>
<td>Mr Faridur Rahman</td>
<td>Programme Coordinator-EDM, WHO/BAN</td>
</tr>
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</table>
Annex 3: Slide presentation given by consultant to stakeholders in the debriefing to Ministry of Health Officials

Pharmaceutical sector in Bangladesh:
Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Terms of Reference
- to gain an introduction to the pharmaceutical sector in Bangladesh;
- to undertake an informal internal review of the pharmaceutical sector, focusing on health care delivery and medicines use, in collaboration with a national counterpart assigned by the MOH, in order to plan for WHO technical support;
- to facilitate the visit of a consultant, Mr Somsak Sunthornphanich, Senior Pharmacist from the Thai Drug Regulatory Authority, to provide technical support concerning the setting up of the Drug Testing Laboratory within the Drug Regulatory Authority.
- to discuss any other pharmaceutical issues as requested by MOH and WHO country office

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 availability, selection, use, regulation, policy, information and coordination, which ...
- Can be addressed if the lack human resources in DGDA and DGHS are corrected.

National Drug Policy 2005
- Manufacturing capacity developed and self sufficiency in drugs, but:
- No program to promote rational use
- Insufficient availability of drugs in the public sector
- Insufficient regulation
  - Insufficient post-marketing surveillance and no functional ADR monitoring program
  - Insufficient price control
  - No monitoring of drug promotional activities
  - No OTC list

- 25 Oct: MOH, DGDDA, CMSD, EDCL
- 26 Oct: DGHS, Dhaka Medical College, BMHD
- 27 Oct: visit to Narayanganj District – hospital, upazilla health complex and community centre
- 28 Oct: DGHS, Centre Medical Education, visit to 2 private pharmacies
- 29 Oct: free
- 30 Oct: visits to Dr. Zafirullah Chowdury, Clinical Pharmacology depts. at Dhaka Medical College and Bangabandhu Sheikh Mujib Medical University, Shalbag, Dhaka & gave a seminar at Dhaka Medical College hosp.
- 31 Oct: visit to MOH, DGDDA and drug testing laboratory;
- 1 Nov: visit to a district (but cancelled due to illness)
- 2 Nov: debriefing

Drug availability
(1) Complaints about stock-outs from all public facilities
- Study in 2009 by CME
  - Only 1/3 key drugs available in 2009
  - 72% of patients had to purchase drugs outside
  - Half of these patients said they would not purchase these drugs due to non-affordability
- Rapid survey by consultant
  - 70% drugs dispensed in OPD, rest needing purchase outside
  - Many patients in shops bought 1 days worth of drugs only
(2) Difficult manual drug inventory control system
- No electronic system so no information for quantification of drug need or monitoring of use
(3) Policy change to buy from CMSD
- Change of policy to restrict local purchase to CMSD has resulted in reduced prices and improved quality
Recommendations: drug supply

- Electronic management information system
  - Electronic drug inventory control system for all hospitals
  - already under construction in DGHS with help of USAID and GTZ, due for completion in 2013
  - Better estimation/forecasting of drug need
  - Better monitoring of drug use to detect inappropriate medicines use & analysis of out-of-list purchase e.g. ABC analysis
  - Annual report should be produced of drug consumption by district, facility type, therapeutic class, etc
- There is a CMSD-purchase list but is not clear that this is a hospital EML approved by wide consensus of doctors

Drug selection

- National EML 2008 aimed at PHC, which EDCL follows but...
- Hospitals and districts are able to request out-of-list drugs from CMSD or directly from manufacturer within budget allocation:
  - DGHS approves purchase but does not have information to judge whether all purchases are appropriate.
  - Districts can choose for 25% of allocation whatever drugs in whatever quantity they need
  - Nearly all CMSD purchases are drugs not on EML
- There is a CMSD purchase list but is not clear that this is a hospital EML approved by wide consensus of doctors

Recommendations: selection

- Develop an EML for use at hospital level
  - At least 25% of budget is spent on this and with a hospital EML one could optimize use of current non-EDL drugs purchased
  - WHO can provide technical support for development
- Develop national clinical guidelines
  - First step in improving use
  - WHO can provide technical support for development

Drug consumption and use

- 47% of EDCL sales was on antibiotics
- Most CMSD sales are for non-EDL drugs
- Much irrational use of medicines
  - Mamun et al 2006: 60% patients coming to rural medicine shops get antibiotics often for 1 day
- Rahman et al 2009: in community (Union's) awareness raising, program reduced % patients request ABs or vitamins from 50% & 30% to 30% and 25%, respectively
- Rahman et al 2006: Private GPs - 80% no drugs/patient 3.8, 25% of patients receive ABs
- Ariefin et al 2005: IMCI intervention reduced inappropriate use of ABs from 49.7% to 9%
- Aker et al 2005: 21 different ABs used to treat pneumonia in Dhaka hospitals
- Islam et al 2007: Px audit and feedback for AB prophylaxis in CS reduced inpatient infection rates and cost
- Sultana et al 2010: Hypertension inadequately treated in 4 teaching hospitals, all brands, polypharmacy, Px not well written

Drug use

- Few prescribers using any STGs or other sources of independent drug information
- Daily pharmaceutical representative visits reported by all private facilities but not public ones before 1pm
- 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 poly-pharmacy and maybe unnecessary IP admissions
- Some local initiatives have improved used & need support

Recommendations: drug use

- Monitor drug use
  - ABC analysis, prescription audit
  - Establish a unit under DGHS to monitor use and coordinate policies to improve use
- Standard Treatment Guidelines
  - Develop & disseminate to every doctor, incorporate into CPD
- Drug and Therapeutic Committees
  - To monitor drug use, encourage CPD and report annually on activities to MOH
- Continuing professional development (CPD)
  - BMA, BMDC, 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 promotion unit and media
- WHO can provide technical support to any of these

Drug regulation

- Big pharmaceutical industry requires a strong Drug Regulation Authority, but … regulation is weak
  - 256 manufacturers, 90 000 pharmacy shops and 22 000 brands on the market requires more than 135 staff
  - 64% of posts are unfilled
  - 370 officially sanctioned posts not enough – need 700 as previously asked
- OTC list not available – all drugs OTC
- Pharmacists often not on premises of shops
- Lack of lab facilities to monitor & ensure adequate quality
  - 4000 samples tested but need to test 20 000 per year
- No monitoring of drug promotional activities aimed at prescribers
- Many brands on the market so difficult to control
  - 30-50 brands of amoxycillin, ranitidine on the market

Consultant prescribing survey

<table>
<thead>
<tr>
<th>Facility</th>
<th>Av. no. Rx/Px</th>
<th>% patients receiving ABs</th>
<th>% drugs dispensed</th>
<th>Av. cost Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tertiary level hospital</td>
<td>3.4</td>
<td>74%</td>
<td>69%</td>
<td>732 BT</td>
</tr>
<tr>
<td>District hospital</td>
<td>2.8</td>
<td>47%</td>
<td>70%</td>
<td></td>
</tr>
<tr>
<td>Upazila health complex</td>
<td>2.3</td>
<td>34%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community centre</td>
<td>2.3</td>
<td>36%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private pharmacy</td>
<td>3.8</td>
<td>28%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Recommendations: Regulation

- Have fewer brands of same drug (active pharmaceutical ingredient) in the market
- Develop monitoring of promotional activities aimed at providers
- Develop and distribute OTC list
- Renovate and strengthen drug testing laboratory
- Strengthen the DRA
  - More inspectors, pharmacists
  - Computerized drug registration system and training for dossier evaluation
  - Standard operating procedures and guidelines for all procedures
- WHO can provide technical support

Wider issues

- Referral system to decrease patient density in hospitals
- Insurance system for financing drugs

Conclusion

- Focus of current government policy is on manufacturing, and …
- Drug Testing Laboratory will help to improve drug quality, but …
- Many other actions can be taken to improve drug supply, selection, regulation and use, which will help to achieve the aims of the National Drug Policy 2005.