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Effective management of medicines

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Acronyms

ADR	adverse drug reaction
AMR	antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization programme
APEC	Asia-Pacific Economic Cooperation
API	Active pharmaceutical ingredient
APL	above poverty-line
ASEAN	Association of South-East Asian Nations
AUSAID	Australian Agency for International Development
BDNF	Bangladesh National Formulary
BPL	below poverty-line
CBIA	Cara Belajar Ibu Aktif or Mother's Active Learning Method
CHAI	Clinton Health Access Initiative
CHC	Community health centre
CMSD	central medical store depot
CPD	Continuing Professional Development
CSMBS	civil servant medical benefit scheme
DGHS	Director-General Health Services
DHO	district health offices
DHS	Department of Health Services

DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committees
DTL	drug testing laboratories
EML	Essential Medicines List
EU	European Union
FDA	Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunization
GDP	gross domestic product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLP	good laboratory practice
GMP	good manufacturing practice
GMRH	Global Medicines Regulatory Harmonization Trust Fund
GPO	Government Pharmaceutical Organization
GPP	good pharmaceutical practice
GTZ	German Technical Cooperation
HC	Health centres
HTA	health technology assessment
ICDRA	International conference of drug regulatory authorities
IEC	information, education and communication
IHPP	International Health Policy Programme
JICA	Japan International Cooperation Agency

KDLWS	Karnataka State Drugs Logistics and Warehousing Society
LMD	Logistics Management Division
LMIS	logistics management information system
MDG	Millennium Development Goal
MFDA	Maldives Food and Drug Administration
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare
MOPH	Ministry of Public Health
MOQ	minimum order quantities
MOU	memorandum of understanding
MSD	Medical Supplies Division
MSH	Management Sciences for Health
NADFC	National Agency of Drug and Food Control
NCL	national drug control laboratory
NDP	national drug policy
NEML	National Essential Medicines List
NGO	nongovernmental organization
NHSO	National Health Security Office
NRA	national (drug) regulation authority
OECD	Organization for Economic Co-operation and Development
OGP	one-gate policy

OTC	over-the-counter
PADNRH	Pan-American Network for Drug Regulatory Harmonization
PHC	primary health care
PSM	Procurement and supply management
PTB	Physikalisch-Technische Bundesanstalt
PtD	People that Deliver (group of international agencies focusing on supply chain management)
QA	quality assurance
RMSCL	Rajasthan Medical Services Corporation Limited
SAMES	Service Autonomo de Medicamentos e Equipamentos de Saude (Timor-Leste)
SOP	standard operating procedures
SSFFC	substandard, spurious, falsely-labelled, falsified, counterfeit medical products
STG	standard treatment guidelines
SWOT	strengths, weaknesses, opportunities and threats (analysis)
TB	tuberculosis
TFDA	Thai Food and Drug Administration
TRIPS	Agreement on Trade Related aspects of Intellectual Property rights
UHC	universal health coverage
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNOPS	United Nations Office for Project Services

USAID	United States Agency for International Development
VHW	village health workers
WB	The World Bank
WCO	World Health Organization country office
WHO	World Health Organization
WHOCC	World Health Organization Collaborating Centre
WR	WHO Representative
WTO	World Trade Organization

1. Inaugural session

1.1 Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Regional Office

Dr Monir Islam, Director of Health Systems Development, WHO South-East Asia Regional Office and Acting WHO Representative Thailand opened the regional consultation on behalf of Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Regional Office and read out the speech of the Regional Director.

The Regional Director welcomed the delegates and said that in many countries, large parts of the population do not have access to essential medicines, and that medicines are often inappropriately used. In 2011, many South-East Asian countries requested WHO support to overcome these problems. Drug shortages are often due to poor drug management, procurement difficulties or inadequate budget. Long-term solutions for drug supply, involving other ministries such as finance, industry and the drug regulatory authority as well as the ministry of health (MOH), will be needed. There have been many calls to strengthen national drug regulatory authorities, which are often under-resourced and weak. Increased investment in national regulatory authorities will be needed in order to ensure adequate quality of drugs in the market. Irrational use of medicines is rampant and this can only be improved by a coordinated health systems approach involving all levels of the health care system and many stakeholders.

In South-East Asia, Member States adopted resolution SEA/RC64/R5 *on National Essential Drug Policy including the rational use of medicines* which asked WHO to help Member States conduct a situational analysis of medicines in health care delivery in order to identify and prioritize problems and to develop a package of practical and feasible recommendations for action. The WHO Regional office for South-East Asia developed a protocol to undertake a rapid analysis over a two-week period. Such analyses involved visits to all relevant stakeholders and a variety of

health facilities and ended up with a national workshop where findings were discussed and recommendations made. This was done in all 11 countries. Recommendations are only useful if they are acted upon. This regional consultation is being held so that the situational analyses, and progress made since, may be discussed and recommendations made for future regional action. The output of the consultation will be discussed at the next Sixty-sixth Regional Committee meeting to be held in September 2013. (The full text of the speech is in Annex 1).

1.2 Dr Chanvit Tharathep, Deputy Permanent Secretary for Public Health, Ministry of Public Health, Thailand

Dr Chanvit welcomed the delegates to Thailand and said that medicines are an essential component of health care delivery and universal health coverage. In Thailand the 30 Baht scheme was started 10 years ago and now universal health coverage has been achieved.

Thailand has a national drug policy with four elements – access to medicines, rational use of medicines, development of domestic pharmaceutical industry, and strengthening the regulatory system to assure quality, efficacy and safety of registered medicines. In Thailand, most drugs in the public sector are procured using funds allocated by the National Health Security Office (NHSO) which covers 74 percent of the population. Funds are allocated to health facilities which purchase drugs according to government rules. These rules include purchasing from the Government Pharmaceutical Organization (GPO) where possible and ensuring that the majority of drugs purchased belong to the national essential drug list. Government monitors procurement to ensure that facilities comply with the rules but we find that facilities find difficulty to stay within the limits of the Essential Medicines List (EML) and do purchase more non-EML drugs than they should. We are considering measures to ensure better compliance with the EML (such as co-payments for non-EML drugs, limiting budget allocations, improved monitoring and feedback to hospitals and doctors).

We have also found that there is irrational use of drugs, particularly antibiotics and we have formed a very high-level committee to look into this problem. Doctors are often not following standard treatment guidelines. We are considering various measures to improve use, such as strengthening hospital drug and therapeutic committees to undertake prescription audit

and feedback. We have instituted electronic patient databases in all facilities and we may ask facilities to use these to report on selected drug use indicators to MOPH. Also we are considering strengthening continuing medical education, teaching of clinical pharmacology and clinical pharmacy and undertaking public education programs on the prudent and safe use of medicines.

Drug regulation is extremely important to ensure the quality of medicines available in the market. Regulation of drug outlets and drug promotion also impact on how drugs are used. We are also aware of the dangers of having excessive number of products on the market—with multiple brands of the same chemical entity and are considering the introduction of 5-yearly re-registration of drugs and de-registering of all drugs not currently in the market.

We are very aware of the complexity of effective management of medicines. In Thailand we have five semi-autonomous bodies undertaking various aspects of drug management. In addition to the high-level committee on rational use of medicines, we have a number of working groups on various aspects of medicines management that report to the Prime Minister's Office. Thus, Thailand has been taking a multi-disciplinary approach to improving medicines management and we supported the Regional Committee resolution SEA/RC64/R5 on Essential National Drug Policy including the rational use of medicines in 2011.

Therefore I am very pleased that WHO is organizing this regional consultation on Effective Management of Medicines and that experts on drug supply, selection, use, regulation and policy from each country have been invited. Coordinated action between all these disciplines is needed to ensure effective management of medicines. I wish you all the best for the coming deliberations and look forward to the output and also wish you a very pleasant stay in Bangkok.

1.3 Dr Toomas Palu, Sector Manager, Health, Nutrition and Population, East Asia and Pacific Region, World Bank

Dr Toomas Palu stated that they share the same health concerns as WHO – namely how to deal with the increased health burden due to aging populations and the increase in non-communicable diseases. Risk factors

for disease burden had changed greatly in the last 20 years. Two particular health concerns are universal health coverage and the unfinished MDG agenda with regard to access, affordability and availability of essential drugs. Medicines already comprise 24.9% of total health expenditure globally¹ and this is likely to increase further in Asian low and middle-income countries. Areas that need to be considered include efficiency gains in health systems through pharmacological preventive therapy e.g. statins, aspirin, anti-hypertensives and pharmaceuticals as an industry with regard to manufacturing, research and development and intra- and inter-regional trade (and the case for greater regulatory harmonization to promote access to and affordability of pharmaceuticals). Poor drug quality and irrational antimicrobial consumption pose risks for the Region. Artemesin-resistant malaria is emerging in Indo-China and there are increased health costs from increased length of hospital stays, morbidity and mortality.

Since medicines comprise the largest share of direct payments at both public and private facilities, there is an imperative for cost control for the sustainability and equity of publically-funded medicines. The World Bank is involved both regionally and nationally in strengthening health systems. In individual countries, technical support is provided for financing access to essential medicines under universal health coverage schemes. There is a Global Medicines Regulatory Harmonization Trust Fund (GMRH) to promote harmonization of medicines regulation as a means to improve access to essential and quality medicines by strengthening governance and regulatory systems of the pharmaceutical sector. Funding under GMRH is available to many countries in the Region. In Africa, World Bank collaborates with WHO in the African Medicine Regulatory Harmonization (AMRH) project.

1.4 Dr Kathleen Holloway, Regional Adviser, Essential Drugs and Other Medicines, World Health Organization, South-East Asia Regional Office

Dr Kathleen Holloway concluded the inaugural session by introducing all the participants and explaining the background to the consultation, the objectives and expected outcomes.

¹ World Health Organization. World Medicines Situation 2011. WHO Geneva 2011.

2. Introduction

2.1 General goal

To improve the availability and safe use of good quality essential medicines.

2.2 Specific objectives

- To review the process of the situational analyses done in countries, and progress made, in order to identify the usefulness of the approach to inform planning and to monitor and evaluate progress.
- To share experiences in developing/strengthening/coordinating national drug policies and regulations to ensure appropriate availability and use of good quality essential medicines.
- To discuss constraints and opportunities and identify actions by Member States, WHO, donors and partners for strengthening national drug policies and regulation with specific reference to drug supply, procurement and distribution, rational drug selection and use.
- To agree on a plan for developing a format to allow countries to undertake situational analyses and monitoring of progress themselves.

2.3 Expected outputs

- Recommendations on the way forward for the Region with regard to drug supply, drug selection and use, drug regulation and drug policy and coordination, situational analyses.
- Recommendations for government, WHO and partners in achieving the way forward.

3. Global and regional perspectives

3.1 International evidence for a coordinated approach to effective management of medicines and experiences from South-East Asia Region.

Dr Kathleen Holloway, WHO Regional Adviser in Essential Drugs and Other Medicines, South-East Asia Region, began her talk by stating that the need for a coordinated health systems approach to effective management of medicines has been mentioned in many high-level international fora, including the International Conferences for Improving the Use of Medicines in 2004 and 2011, World Health Assemblies (resolutions WHA58.27 and WHA60.16) and WHO Regional Committees (resolutions SEA/RC55/R4, SEA/RC62/R6 and SEA/RC64/R5).

The second part of the talk focused on data on medicines use and medicines policy from the WHO database on medicines use in primary care in developing countries and the country pharmaceutical profile databases, respectively. Compliance with standard treatment guidelines is less than 40% in the public sector and less than 30% in the private-for-profit sector. Results are similar in all regions and are not improving. Implementation of policies to promote rational use of medicines is suboptimal globally and, likewise, it is not improving. Data on drug use and drug policy have recently been extracted from the respective databases and merged to form a new dataset and analysis shows that countries implementing certain policies have significantly better drug use. These policies include undergraduate education of health professionals on the essential medicines concept, a MOH department dedicated to promoting rational use of medicines, drug and therapeutic committees (DTCs), drugs free at the point of delivery, national drug information centre, national strategy to contain antimicrobial resistance, non-availability of prescription-only drugs without prescription, no health worker revenue from the sales of medicines; prescribing restricted to qualified personnel; doctors prescribing at primary care level and public education on prudent use of medicines. The more of these policies are implemented, the better is medicines use.

The third part of the talk focused on the situational analyses of pharmaceuticals in health care delivery that have been carried out in

South-East Asian countries. The process involved visits to all the major MOH departments and agencies responsible for drug supply, selection, use, regulation, drug policy, insurance and the training of health professionals in drug management, particularly clinical pharmacology and pharmacy. In addition, visits were made to at least one tertiary referral hospital and health facilities in two districts (one hospital, two primary care centres and two private pharmacies per district). At the end of the visit, a national workshop was held where the findings were discussed and validated and recommendations for action agreed by consensus in four areas – drug supply, drug selection and use, drug regulation and drug policy and coordination. A report was drafted by WHO and only finalized after the input and agreement of MOH.

It was found that the situational analyses were very useful in assessing country situations with regard to medicines in health care delivery. All areas of medicine management are under-resourced in most countries and the achievements made in some countries in the face of such resource shortages are amazing. Partner support is generally limited and fragmented. Most countries rely on manual drug management information systems, leading to poor forecasting, quantification and stock management. Few countries monitor drug use, but ad hoc examinations show suboptimal compliance with essential drug lists and rampant irrational use. All drug regulatory authorities were under-resourced to fulfil all their functions and drug policy was uncoordinated and sub-optimally implemented.

Common solutions across countries included:

- Establishing an electronic drug inventory system from central to peripheral levels and analysing the data for better stock management;
- Investing in drug regulatory authorities to ensure adequate human and financial resources to undertake all functions;
- Establishing a dedicated ministry of health unit to promote rational drug use;
- Promoting rational use of medicines through: monitoring of drug use and consumption; establishing drug and therapeutic committees and monitoring their activities; including the essential medicine concept in undergraduate and continuing

medical education; ensuring stricter adherence to essential medicines lists; and using existing MOH structures to deliver core messages on safe and prudent medicines use to communities.

3.2 Access to essential medicines and universal health coverage

Dr Kees de Joncheere, Director of Essential Medicines and Health Products, World Health Organization, Geneva, explained that his talk would cover the importance of access to essential medicines in achieving universal health coverage. Universal health coverage is more than just health financing, it also depends on quality of service delivery, human resources, medical education, availability of medicines, technologies and information – all of which impact on utilization of services. There is no standard package of universal health coverage, which needs to be tailored to the country context and for which country level analytic capacity is essential. Choices have to be made with regard to the population covered; the services covered; and to what extent people have to pay out of pocket.

Evidence was shown that, on average, globally, in 2010, 35% total health spending was out-of-pocket, but 50–80% in many poor Asian countries, contrary to the objectives of universal health coverage. Most Asian countries have small public sectors relative to the size of their economies and give low priority to health. Thus, on average, globally, in 2010, government spending was 35% GDP, but only 15–20% in many poor Asian countries. While 11% of government spending was dedicated to health globally in 2010, it was less than 8% in many Asian countries. Nevertheless, there is clear global evidence that increased government spending on health is linked to lower dependence on out-of-pocket expenditure by patients in countries with populations of more than 600 000.

In order to provide good financial protection, levels of public spending matter and governments may choose the share of the budget allocated to health even though spending may be limited by levels of public revenue which is harder in countries with a large informal sector. However, the way health systems are organized is also very important and a framework for coordinated action is needed to ensure access to medicines. Such a framework must include:

- rational selection of medicines, which requires the development of evidence-based treatment guidelines, essential medicines lists based on treatment guidelines, both regularly updated and used for drug supply, reimbursement and in training;
- affordable drug prices, which require drug price information, generic policies, reduction of duties, taxes and mark-ups, reimbursement lists and rates, reference price systems, differential pricing of new medicines and application of WTO/TRIPS safeguards as appropriate. (Low public sector availability leads patients to the private sector where medicines are unaffordable);
- adequate and sustainable financing, which often requires increased public spending, expansion of coverage/health insurance and targeted external funding such as grants, loans and donations;
- reliable drug supply systems, which require integration of medicines into health sector development, creation of efficient public-private-NGO mixes, assured medicines quality and promotion of the rational use of medicines. However, competitive parallel drug supply systems funded by different agencies, as happens in many countries, results in huge consumption of government resources to manage. An example from Tanzania with dozens of supply systems was shown.

A regulatory system is needed to ensure the quality, efficacy and safety of medicines. Such a system must include many functions including: norms and standards; licensing of manufacturers, wholesalers and pharmacies; regular inspection of all drug outlets and of GMP for all manufacturers; registration of drug products, regulation and control of medicines promotion; and pharmacovigilance. Regulatory collaboration can ease the burden for individual drug regulatory authorities. Such collaboration may be at global and regional levels such as ASEAN, EU, AMRH, PANDRH, ICDRA and may cover issues such as common standards, mutual recognition and fast-track procedures; pharmacovigilance (such as Uppsala WHOCC global monitoring programme); Substandard/Spurious/Falsified/False-labelled/Counterfeit (SSFFC) medical products (new Member State Mechanism); and information exchange.

Access to essential medicines is only worthwhile if the medicines are used properly. However, there is much evidence that they are used inappropriately. Many factors influence the use of medicines including knowledge and habits; social, cultural, economic and legal factors; availability of information including the pharmaceutical industry; issues of authority and supervision and peer-groups; and workload and staffing. Education will only address the problem of knowledge. However, sustained improvement in the use of medicines will only be achieved if all the other underlying factors are considered. For example, in many countries there is a strong financial incentive to sell more drugs and more expensive ones if one is getting revenue from drug sales. Thus, separation of prescribing and dispensing functions has been found to improve use.

Many policy options exist and it is important to be clear about their underpinning values such as equity, solidarity, access, quality, and participation, to balance them against industrial policy objectives and to ensure that they do not conflict with each other. A national medicines policy document and fully resourced plan of action can help to achieve this.

3.3 Perspectives on capacity building for effective management of medicines in the Western Pacific

Dr Klara Tisocki WHO Team Leader in Pharmaceuticals, Western Pacific Region, explained that her talk would cover the key challenges in the Western Pacific Region, capacity development issues and priority questions. Challenges in many countries include: lack of political commitment and financial support for implementation of national medicines policies; a changing health financing landscape, since many more countries have become middle-income ones; a lack of qualified human resources to work in pharmaceutical systems; under-resourced regulatory systems that limit capacity to ensure drug safety; high out-of-pocket expenditure; and low capacity for evidence-based informed decision-making.

Data was presented that showed that per capita pharmaceutical expenditure in Asia in 2012 was US \$136 on average, but only 12% of this in the poorest countries but more than four times this in the richest Asian and OECD countries. Per capita pharmaceutical expenditure as a percentage of total health expenditure in Asia in 2012 was 29.7% on average, but 40–50% in some countries as compared to 15.6% in OECD countries. To achieve universal health coverage, choices have to be made

with regard to the population covered; the services covered; and to what extent people have to pay out of pocket. An example was given of a Cambodian patient who stated that he wished he had HIV/AIDs rather than diabetes, because if he had the former he would receive free medicine and food, but with diabetes he had to pay US \$1.5 monthly for medicines.

There are many sources of inefficiencies including underuse of lower-priced generic medicines; use of substandard medicines; inappropriate and ineffective use with many medical errors; overuse of products and services; inappropriate hospital admission and length of stay and low use of peripheral health centres; inappropriate or costly mix of health workers who are often unmotivated; and health system leakages. Health systems must be strengthened to address such inefficiencies and areas that must be covered include: governance; health information; financing; service delivery; human resources; and medicines and technologies. To address inefficiencies to improve access, it is important to engage all stakeholders including ministries of health, policy-makers; regulatory agency; finance and insurance agencies; procurement and supply chain managers; civil society, pharmaceutical industry and end-users (health workers and patients). A pyramidal schematic was shown summarizing capacity development issues. At the top of the pyramid are individual issues covering performance and personal capacity, which are influenced by skills and tools. At the bottom of the pyramid are the much larger institutional issues covering staff and infrastructure (workload, supervision, facility and support service capacity) and structures, systems and roles.

Priority questions include: the impact of WHO and partners' development efforts; main barriers to effective and sustainable capacity development and country, WHO and partner capacity levels; gaps in capacity; and resources needed to change current practices and achieve better pharmaceutical systems.

To go forward, it is necessary to strengthen information and evidence on what works so that our resources and expertise can be targeted accordingly. In addition, regional and global networks as well as informational platforms need to be developed to enable information sharing to strengthen pharmaceutical systems, particularly with regard to regulation, evidence-based selection, health technology assessment (selection, use and financing) and monitoring and evaluation of the performance of national pharmaceutical systems.

4. Situational analysis and progress in countries with active national medicines policies

4.1 Sri Lanka

Dr BVSH Benaragama, Director Medical Technology and Supplies Division, described the findings of the situational analysis in 2010 which had revealed weaknesses in many areas of drug management.

Regarding drug supply, there were stock-outs at public facilities and a manual drug inventory control system. The Medical Supplies Division (MSD) was in the process of computing the drug consumption in the country in 2012 and a report is likely to be ready in May 2013. Efforts are ongoing to harmonize the inventory systems between the Medical Supplies Depot (distribution) and the State Pharmaceutical Corporation (procurement) through regular meetings and a new electronic medical supplies management information system that will be launched in 2013 and will be used by both agencies.

Regarding drug selection, there were out-of-EML purchases. However, there is now evidence about stricter adherence to medicine purchase from the EML list. In 2012, only 15% of the drug purchases were of drugs not on the EML (as compared to almost one third of purchases some years earlier). The EML was last updated in 2009 and is being updated during 2013.

Regarding drug use, there was irrational use of drugs, polypharmacy including high use of antibiotics and vitamins and prescribing by brand names. Antimicrobial treatment guidelines (2013) have been developed and a manual on management of drugs (2008) was distributed to all facilities. A national body is going to be set up to monitor drug use and coordinate policies and actions to promote rational use of medicines. Numerous activities have been undertaken to raise public awareness, including 820 workshops for school children and general public, 34 media seminars on prescription drug abuse, 622 discussions with prescribers and pharmacists and public education through a website. A national level drug and therapeutic committee has been established and similar committees are being established at institutional level. Action towards continuous

professional development includes formulation of guidelines for proper prescription and rational use of drugs; 75 workshops on technical support for strengthening the drug management system in provincial levels; 12 workshops for prescribers at district level; 8 training programmes for prescribers and 438 training programmes for pharmacists.

Regarding drug regulation, there was insufficient enforcement of regulation, inadequate numbers of pharmacists and inspectors, insufficient laboratory testing facilities and availability of too many brands of the same drug. The drug regulatory authority (DRA) is now being strengthened. There is a significant increase in the number of pharmacists and inspectors and various databases are being updated. A fourth amendment to the Cosmetics, Devices and Drugs Act has been enacted. Drug registration has been strengthened by requiring approval for all products by the Drug Evaluation Committee, computerization of drug registration (currently underway), development of SOPs for all registration and licensing activities, requiring GMP audits for all foreign manufacturers, standardization of the market authorization holder and a new recall procedure. WHO supported training on GMP inspection and dossier evaluation for drug registration. Guidelines on advertisements of cosmetics have been developed and a system of prequalification of suppliers instituted. An accreditation programme for pharmacies using good pharmaceutical practices (GPP) has been instituted.

Regarding drug policy and coordination, there was inadequate implementation of drug policy. The composition of the Technical Advisory Committee that guides the MOH in drug-related issues has been amended and is broad-based. The National Medicines Policy has been revised to be more specific and the final draft is ready. Unfortunately, no progress has been reported in establishing a unit dedicated exclusively to rational use of drugs.

Partner activities include the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the Global Alliance for Vaccine and Immunization (GAVI) support for HIV, TB, malaria and vaccines respectively. WHO supported development of the national DRA website, revision of the national EML and training programmes for rational use of medicines.

The situational analysis exercise was very useful as it provided an opportunity for conducting a SWOT (strengths, weaknesses, opportunities and threats) analysis and assistance in developing specific objectives and a concrete roadmap for achieving them. In future, similar exercises should involve more stakeholders and have more time allocated.

4.2 Bangladesh

Major General Md. Jahangir Hossain Mollik, Director General, Directorate General of Drug Administration, presented the country situation and progress.

Regarding drug supply, the situational analysis had revealed that an electronic drug management information system in all government health facilities was not yet established, storage facilities and conditions at all levels of government medical stores had deficiencies and that drug manufacturers and physicians were not sensitized to the production and utilization of drugs from the EML. For better estimation and forecasting of drugs and stock management the central portal of an electronic control system for the CMSD had been established and the system would be extended to all hospitals and district-level government medical stores by December 2013 with the support of USAID. It is anticipated that 712 staff will be needed and recruitment of staff is underway.

Regarding drug selection, an updated essential medicine list has been prepared by the expert committee along with the reviewed national drug policy which is awaiting approval by the Ministry of Health and Family Welfare (MOHFW). A larger share of the government drug budget will be apportioned to EML drugs and local manufacturers are being encouraged to produce more EML drugs.

Regarding drug use, DTCs are not yet formed in medical college hospitals, standard treatment guidelines (STGs) are still not adhered to and monitoring of drug use and consumption is not done. The core committee for rational use of drugs is yet to be established. However, the MOHFW has developed STGs for acute respiratory infection, arsenic poisoning management, malaria, dengue, leprosy, tuberculosis, acute watery diarrhoea, filariasis, leishmaniasis, helminthiasis, burn injuries and drug addictions. A committee has been formed to update and publish the fourth

edition of the Bangladesh National Formulary (BDNF) by December 2013. The BDNF will be made available in all medical colleges and uploaded on the DRA website. Regular action for continuing professional development is ongoing and included 100 workshops on rational use of antimicrobials in 2012, in each batch of which 40 medical officers were trained. In addition, training on ADR monitoring was undertaken in three medical colleges for 150 professional staff. Workshops for the public have been organized on arsenicosis, snake poisoning, drowning and the health consequences of smoking.

Regarding drug regulation, recruitment and training for DRA personnel is not yet completed and revision and updating of SOPs and other documents is not yet done. However, the DRA is being strengthened with the recent recruitment of 42 new officers including 16 pharmacists, biochemists, veterinary doctors, chemists and microbiologists. Hardware for automation has been installed within the office of the Director General of Drug Administration to facilitate online application for four different type activities—initially drug registration, project evaluation, retail licensing and “No Objection Certificates”. Software development is being supported by a USAID-funded NGO. A quality manual, quality policy and SOPs have been prepared and are under implementation for marketing authorization, GMP inspection, QA and lot release functions of vaccines. The National Drug Control Laboratory (NCL) for drugs and vaccines has been renovated and modernized and the number of technical staff has been increased. An OTC list has been prepared and included in the final copy of the National Drug Policy which is now awaiting requisite approvals. A notice has been issued to drug manufacturers to refrain from unethical drug promotion, but no monitoring mechanism has been developed. The number of products on the market continues to increase. Training is organized with the help of WHO. Recently, training on cGMP was conducted for 210 qualified staff of the pharmaceutical industry.

Regarding drug policy and coordination, a core group on antimicrobial resistance (AMR) has been established to develop national guidelines on antibiotic use, an institutional baseline for antibiotic use and an analysis of the situation with regard to AMR. Four core group meetings were held and AMR committees established in eight pioneer medical colleges, including experts in medicine, microbiology and pharmacology.

Partner activities include World Bank and WHO support to the national DRA to renovate and modernize the NCL. WHO is supporting the training of DRA and NCL staff and USAID is supporting the development of the electronic drug management information system.

The situational analysis helped stakeholders to learn a lot about drug management problems, which helped in preparing an action plan. It would be good to involve more government people in the process so that they could do such an analysis themselves.

4.3 Thailand

Ms. Worasuda Yoongthong from the Food and Drug Administration, Ministry of Public Health (MOPH), described the progress in Thailand.

Regarding drug supply, harmonization of the many electronic management information systems will be eased by the Thai Medicines Terminology Development Project which has been under development since October 2012. This project includes the development of a single national drug identity code and coding will be completed by 2015. A pilot implementation of the coding will be launched for nine priority medicines in the Civil Servant Medical Benefit Scheme (CSMBS) in April 2013. Monitoring of compliance by public providers with procurement regulations and prices is already done, all hospitals being required to send three-monthly summary reports to the MOPH, but will be strengthened by the launch of the Medicines Inventory Project.

Regarding drug selection, a guideline for non-EML drug use has been developed to try and control high expenditure due to non-EML drugs in the government insurance scheme. In addition, there is a policy proposal to cabinet to require all hospitals to reduce their procurement of non-EML drug by 10% of their baseline. MOPH infrastructure has been developed to monitor drug consumption more efficiently and a national survey for top twenty high cost drug values in MOPH hospitals was conducted in 2012.

Regarding drug use, prescription audits and drug use monitoring have been instituted in the public health care delivery system. Standard treatment guidelines for cancers and other important diseases have been developed. Public hospitals have their own DTC, which is a requirement

for hospital accreditation, and the national action plan includes strengthening of DTC function in promoting rational use of medicines. Continuing Professional Development (CPD) is implemented by professional councils and CPD on promotion of rational drug use and clinical pharmacology and pharmacy has been included in national drug strategies and action plan. Public education to promote rational drug use is also included in national drug strategies and action plan.

Regarding drug regulation, the Thai FDA (TFDA) is considering outsourcing functions to inspect pharmacies, monitor drug promotion and conduct post-marketing surveillance to local government officers, since there is strong government policy to restrict the growth of government offices. A single window on drug testing results and problem reporting has been established by the Department of Medical Sciences and information on non-EML drug consumption, pricing and drug quality for prescribers will be available in 2013. In order to reduce the large number of products on the market, a new drug bill has been proposed which will include the concept of re-registration of drugs after a specified interval. Registered drugs without importation or production for two consecutive years are automatically cancelled under the Drug Act. National ethical criteria for drug promotion are under development and will be piloted in select hospitals during 2013.

Regarding drug policy and coordination, it was mentioned that the National Drug Systems Development Committee serves to develop national drug policy (NDP) and evaluation and that it coordinates closely with other committees responsible for implementation of various aspects of the NDP and strategies. The TFDA works closely with the Office of the Permanent Secretary.

Partner activities should support external evaluation of the global situation comparing key indicators on medicines to generate recommendations; provide technical support at Member State request; and support coordination and evaluation of the progress on AMR within ASEAN countries.

The situational analysis was helpful as an input for developing policy and an action plan. However, there is a need to involve policy-makers in the exercise and more time needs to be devoted to doing it.

5. Situational analysis and progress in small countries

5.1 Maldives

Ms Aishath Mohamed, Director Maldives Food and Drug Administration (MFDA), stated that Maldives' major issues were a lack of an appropriate public sector medicines supply system, absence of a mechanism to monitor and promote the rational use of medicines, need to strengthen the regulatory mechanisms in the MFDA and the non-implementation of the national drug policy.

Regarding drug supply, most drugs are supplied through the private sector and annual import data and disposal data have been generated for planning. A medical procurement unit has been established in the MOH and is functioning in collaboration with UNOPS. Unfortunately, there is no available direct consumption data except for controlled drugs. Monitoring of the import, distribution and use of all hospital items and an annual requirement quantification exercise is in process.

Regarding drug selection, the national EML has been reviewed in consultation with specialists from different areas and the new medical procurement unit in MOH will ensure availability of all EML items in hospitals. Random inspections are conducted to monitor the availability of EML items in private pharmacies.

Regarding drug use, prescription audits have started and medicines import data is available. No progress has been made in implementing STGs. Awareness programmes on rational use of medicines for the public have started and such programs for pharmacists have been ongoing since 2010. Action against pharmacists for irrational dispensing is being taken by the Maldives Board of Health Sciences. Unfortunately, no progress has been made on establishing DTCs in all hospitals, continuing professional development for doctors, and a national drug information centre. The MFDA is working to establish a "hotline" for providing drug information to consumers.

Regarding drug regulation, a new medicine regulation, under the Common Regulations Act was passed by Parliament but the medicine bill is still awaiting finalization from the Auditor General's office. In respect of stricter adherence to the registration process, all products are endorsed by the Board of Pharmaceuticals for import, a time line is given to register all unregistered medicine and minimum criteria for product registration have been established to facilitate product registration. There is also close monitoring by the MFDA of medical prescription established at the ports. The MFDA is being strengthened in terms of more personnel and staff training and the introduction of a medicine registration fee in the new regulation. SOPs are in place for all the regulatory and enforcement activities and meetings have been held with prescribers to improve ADR reporting. There are a large number of private pharmacies in Malé and some islands and the need for these numbers should be assessed by the relevant agencies.

Regarding drug policy and coordination, the Pharmaceutical Board provides technical advice to the Minister of Health and Director-General Health Services (DGHS) while the MFDA is responsible for rational use of medicines. Regulatory harmonization is an area of interest and concern for the country. The recently established regional health corporations have been dissolved and the National Drug Policy of 2007 is being reviewed. However, generation of income for the MOH and MFDA through raising license fees has not been achieved.

Partner activities include WHO technical support for drug supply and regulation. There is a need for donor support to establish a networking mechanism for drug regulatory authorities of the region.

The situational analysis identified what areas of medicines management need to be strengthened and helped to motivate staff. It could be improved by close monitoring of progress, annual assessment visits and provision of budget.

5.2 Bhutan

Mr Sonam Dorji, Drug Controller of Bhutan, stated that the most serious recent problem in Bhutan had been stock-outs of some essential medicines and difficulties in procurement. In 2011 the number of drugs out of stock

had been 77 at the national referral hospital, 10–12 at the regional referral hospitals, 4–7 at the district hospitals and 1–3 at basic health units. A situational analysis was done by WHO in 2011 and, following some recommendations, drug availability at all facilities had increased to more than 98% in 2012.

Regarding drug supply, the procurement system had been reviewed and regulatory amendments made. New supplier registration and performance rating is now done by a Committee and product registration by the DRA increased. The annual tendering system has been revived to replace the new three-year tendering system and local suppliers are encouraged to quote even unregistered drugs but they must meet performance criteria of more than 90% to have their bids considered. In this way, difficulties in procurement have been overcome and drug availability improved. Also, updating of the electronic management system (DIGBY) is being explored. A new medical supply depot (MSD) is being constructed and one extra staff has been assigned to the MSD.

Regarding drug selection, the referral committee at the national referral hospital judges all requests for non-EML drugs. A national guideline for named patients to receive non-EML drugs has been revised and a substitution mechanism instituted. All prescribers are provided with the national EML and antibiotic guidelines. A revised national formulary is now being printed.

Regarding drug use, MOH already monitors drug use, but facilities are now being encouraged to monitor themselves and provide feedback to prescribers. MOH has initiated an awareness programme on the costs of drugs to prescribers and policy-makers. Dummy bills are being used to sensitize patients on the cost of medicines. Medicines available and registered with the DRA are updated regularly on the DRA web site and are available to providers. Drug and therapeutic committees are already established in major hospitals, but funding is being sought to sensitize DTC members on DTC functions. The Bhutan Medical Council credit system is to include prescription audit and feedback into continuing professional development and into the orientation course for new doctors. The national drug information centre is to be reviewed and strengthened.

Regarding drug regulation, drug companies are encouraged to register directly with DRA and wholesalers are encouraged to register products with the DRA, but this requires that only the supplier registering the product be allowed to import it. Regulations have been revised to include abridged registration for UN-prequalified drugs and drugs registered with other stringent drug regulatory authorities.

Regarding drug policy and coordination, seven new pharmacists are awaiting appointment, but so far, the Division of Essential Drugs and Vaccines and the Essential Drug Programme have not received any new staff. A new coordination mechanism is proposed for the next five-year plan and some coordination meetings have been convened between MOH departments and the DRA, but budgetary support is required.

Partner activities include WHO support for various aspects of drug management. Bhutan expressed a need for donor support for regulatory harmonization among South-East Asia Region Member States and regional forums for pooled procurement for essential drugs in the non-production Member States. Support is also needed for the prevention and control of SSFFC medicines, capacity development for evaluation of biologicals and vaccines and regular regional consultation on intellectual property, innovation, trade in public health for a common understanding for global negotiations.

The situational analysis provided an independent review and sensitization of policy-makers. It covered wide aspects of the medicine supply chain and was good for identifying problems and taking fast remedial actions and hence in improving the recent problems with regard to availability of essential medicines. The data collection tool should be institutionalized, guidelines and training on use of the tool developed and a regional forum instituted to share experiences.

5.3 Timor-Leste

Mr Narciso Fernandes , Director of Quality Control in SAMES, MOH, stated that there were a number of serious problems with regard to the pharmaceutical sector in Timor-Leste but that they were able to address some of these problems.

Regarding drug supply, one form for collecting medicine consumption information at the time of requisition is ready for implementation in the capital city. Although update of an electronic inventory management system has been slow and using it to analyse consumption is still not done, more training will be delivered in 2013 and there will also be training for pharmacy technicians and assistants in all district health offices and hospitals on drug management and supervision. SOPs for drug procurement and distribution (SAMES) have been drafted. World Bank and EU support SAMES, the semi-independent government agency for procurement and distribution of drugs.

Regarding drug selection, a recent decision has been made to revert the function of reviewing all orders prior to distribution to the Department of Pharmacy, in order to ensure better adherence to the EML, although the department has insufficient qualified staff.

Regarding drug use, there is donor support to revise the STGs and establish a DTC in the national hospital in 2013. WHO supported prescription audits in 5 districts and the training of MOH staff to do such audits in future. The GFATM regularly supports training on the use of STGs for HIV, TB and Malaria. Discussions are ongoing with MOH health promotion to undertake public education on medicines use.

Regarding drug regulation, a draft drug act is still under review and a DRA has still not been established, nor a technical drug registration process initiated. There has been no progress with regard to monitoring adverse drug reactions, starting a system for pre-approval of advertisements and package inserts or publishing drug schedules. A permanent statutory committee to advise the Minister of Health on pharmaceutical has not yet been formed.

Partner activities include World Bank and EU support for drug procurement and distribution and WHO support for development of EML, STGs and prescription audit. There is donor willingness to support development of the regulatory authority.

The situational analysis process resulted in a comprehensive analysis of the pharmaceutical sector. The workshop was well attended and the report was translated into two local languages and was presented at the Council of Directors, chaired by the Minister of Health. Practical solutions to problems were identified and some progress made with regard to the recommendations.

6. Situational analysis and progress in medium-sized countries

6.1 Nepal

Mr Gajendra Bahadur Bhuju, Senior Pharmacist of the Department of Drug Administration, MOHP mentioned that there were deficiencies in drug inventory management with dumping of short-dated medicines, high usage of antibiotics for upper respiratory tract infection and drugs not on the EML, lack of prescription audit and DTCs in hospitals, ad hoc CPD, sale of prescription-drugs over-the-counter, and too high a number of registered drug outlets ($>15\ 000$) and registered products (10 316) for the DRA to manage properly. The National Medical Laboratory cannot cope with the high workload of drug testing.

Regarding drug supply, the Logistics Management Division (LMD) undertakes procurement, quantification and distribution. Although there has been dumping of short-dated drugs in some facilities, the percentage of drugs out of stock decreased from 36% of drugs in 2007–2008 to 21% in 2010–11 through the timely use of its electronic logistics management information system (LMIS) and quarterly reporting by all health facilities. However, the LMIS has yet to be extended to district level and pharmacists are yet to be employed in all district and referral hospitals, as posts have not yet been sanctioned.

Regarding drug selection, the Department of Health Services (DHS) is undertaking a categorization of the revised EML by level of facility and attempting consistency between the national EML and the primary health care revitalization list. Once categorization by facility level has been done, districts should not purchase non-EML drugs.

Regarding drug use, budget allocations were made in 2011–2012 for a peer-review program involving prescription audit in 23 districts but only 9 districts accomplished it. Significant improvement in prescribing habits for diarrhoea, ARI and worm infestation as a benefit of the peer-review programme is observed wherever it is implemented. The PHC Revitalization Division revised the Standard Treatment Protocol for Primary Health Care Facilities in 2012. The DHS developed, updated, distributed,

trained, and monitored adherence to different protocols on malaria, AIDS, Acute respiratory infections, and diarrhoeas. The Nepal National Formulary was published in 2010. National antibiotic treatment guidelines for the different level of health care will be finalized by 2013 and training of prescribers of all 75 districts is planned. An NGO conducted training on medicines awareness for journalists, school teachers and housewives. More hospitals have DTCs but few of them monitor drug use. Prescription audit and ethics have not been incorporated into CPD, which remains ad hoc for many prescribers. Guidelines for the establishment of an independent pharmacy in each hospital have been developed.

Regarding drug regulation, a proposal for additional pharmacists and inspectors has been submitted to the government. Training on GMP/GLP for inspectors and pharmacists was continued. Regulation of drug production is in process and SOPs and guidelines for drug registration, recall and pharmacy inspection, herbal GMP guidelines, and drug donation guidelines have been developed. GTZ is supporting an initiation to amend the current Drug Act and regulations, particularly with regard to drug categorization and schedules. A departmental technical committee and sub-committee under the Drug Advisory Committee were formed for the registration of non-pharmacopoeial products. Computerization of drug registration has been initiated, but no recent training on dossier evaluation for registration has been conducted. Drafting codes on drug advertisements have been initiated.

Regarding drug policy and coordination, a Drug Consultative Council under the chairmanship of the Minister of Health and including the secretary from different ministries has been formed to advise the government on pharmaceuticals. The MOH is currently being restructured and an executive division in MOH for the Drug Consultative Council has yet to be identified.

Partner activities include GFATM support for TB, HIV/AIDS and malaria; GAVI support for vaccines; JICA support for nutritional supplements, and WB support for procurement activities. GTZ and Physikalisch-Technische Bundesanstalt (PTB) are supporting strengthening of drug regulation and the national medicines laboratories. WHO is supporting development of guidelines, standard treatment schedules, the national formulary and training on GMP/GLP.

The situational analysis enabled the identification of gaps and problems in the pharmaceutical sector and appropriate solutions. It should be done regularly.

6.2 **Myanmar**

Dr Theingi Zin, Deputy Director of Drug Control, stated that a number of serious problems were identified in the situational analysis and that 27 recommendations were made.

Regarding drug supply, the CMSD procures according to the national EML, but cannot distribute medicines to meet the demand of health facilities, as the allotment of funds is insufficient. An electronic management information system is not established due to lack of human resources, inadequate hardware and software errors. A report on drug distribution could be done, but the data could not be analysed due to lack of budget.

Regarding drug selection, a proposal has been submitted to revise the existing EML (2010) to include categorization by health facility level. Some tertiary hospitals still need to develop formularies. After development of hospital formularies, all use of non-EML drugs should be justified.

Regarding drug use, training on monitoring prescribing and drug consumption (ABC analysis) has been done in 30 townships. STGs for basic health staff (2013) are ready for distribution to health care providers and training on using these STGs will be conducted in all states and regions. DTCs are not yet established, though medicines procurement committees exist in all tertiary hospitals, states and regions. A credit system is being developed by the Myanmar Medical Association and the Internal Medicines Society organized a workshop on ethical issues in clinical medicine. Some public education on rational use of medicines has been done through the media, basic health staff and non-service health care providers (medical officers, nurses, pharmacists) with the aid of international partners.

Regarding human resources, for 73 referral hospitals, 45 posts for pharmacists and 222 posts for pharmacy technicians have been sanctioned, but only 5 pharmacists and 125 pharmacy technicians have been appointed. In 43 district hospitals, there are 29 sanctioned posts for pharmacists, but only 7 have been filled. There are plans to revise the

pharmacy undergraduate curricula to include clinical pharmacy and to start a PhD programme in clinical pharmacy. Therapeutic lectures are given to undergraduate medical students, but a clinical pharmacology department is yet to be established at the tertiary referral teaching hospitals. Antibiotic usage patterns have been studied by two Masters students at Yangon Children's hospital.

Regarding drug regulation, there are plans to expand the Food and Drug Administration (FDA) to state and regional levels but more staff and training are required. The FDA is currently reviewing and setting up SOPs for existing procedures. Currently 1500–1800 drug samples are tested every year and two new medical officers have been appointed in the national drug testing laboratory to test more pre- and post- market drug samples. WHO is supporting laboratory training through the fellowship programme. Drug registration is being strengthened by training on dossier evaluation and starting to computerize the process. The FDA raised the registration fee and the Drug Advisory Committee is reviewing all me-too products within a therapeutic class in order to try to reduce the number of products on the market. There is also a fast-track registration system to increase access to essential medicines. The directive for selling new antimicrobial drugs is being reviewed and the licensing activities of states, regions, districts and townships are being monitored. The FDA reviews package inserts of products during renewal of registration, but has yet to set up a special inspection section to monitor drug promotional activities.

Regarding drug policy and coordination, there is no permanent statutory committee to advise the Minister of Health on pharmaceuticals.

Partner activities should include financial and technical assistance to develop a logistic management information system for medicines from the central to township level.

The situational analysis enabled the real situation of the pharmaceutical sector to be seen and possible solutions identified. The process needs to be done step by step and be more integrated with related ministries and stakeholders during implementation.

6.3 Democratic People's Republic of Korea

Dr So Yong Sun, interpreter Ministry of Public Health (MOPH), made the presentation on behalf of the Democratic Republic of Korea delegation. The situational analysis revealed a shortage of drugs. The National Essential Medicines List (NEML) had errors and was not widely used. Inappropriate drug usage was observed. Many technical functions of the national DRA, including monitoring of adverse drug reactions, were weak. There was a need to strengthen coordination between departments within MOPH and between MOPH and other ministries, including Ministry of Education.

Regarding drug supply, the national health budget has been increased by 105.4 % to address the shortage of drugs. There is a plan to expand the LMIS to county level during 2013–2017 with the support of UNFPA. National training on the LMIS was conducted in 2013 for drug managers at central and provincial levels. SOPs for establishment of LMIS were developed and a manual on principles of drug management developed, published and distributed. An annual report on drug procurement, distribution and consumption for 2011 was prepared and submitted to MOPH. A meeting was held in January 2013 on drug procurement and distribution during 2012 and was attended by directors of provincial medicines warehouses and drug managers in the presence of the health minister and vice-ministers.

Regarding drug selection, the NEML was reviewed and updated by the Clinical Pharmacology Committee members and approved by the MOPH in 2012 and will be printed with WHO support during 2013. The criteria for selection of traditional Koryo medicines in the NEML are set up differently from those for allopathic medicines and a list for Koryo medicines is now under development.

Regarding drug use, a prescription audit will be done by MOPH in selected facilities and training on how to do prescription audit and ABC analysis of consumption will be organized in 2013. Rational use of medicines was added into curricula for refresher training course for household doctors so that they could use it in their medical care services and public education. A proposal to establish postgraduate studies on clinical pharmacology and clinical pharmacy was submitted to MOPH and *How to prescribe antibiotics* was incorporated into the curricula of all

refresher medical schools. The National Institute of Public Health Administration has commenced development and updating of STGs. A central hospital is currently piloting a DTC. Protocols on quality control and disposal of outdated medicines were developed. Training on drug management and rational use of drugs was conducted.

Regarding drug regulation, the laws on people's health, law on medicines management, law on narcotics control, national strategic plan for improvement of access to essential drugs and national protocols on drug were translated into English for review by WHO. Guidelines on registration for imported drugs were updated and are now under review. The law on narcotics control is being partially amended by MOPH and some extra drugs will be added to the drug schedule for narcotics. Unfortunately, a pharmacovigilance system has not yet been started. Drug testing laboratories are being strengthened through increased government budget and support of GFATM to purchase equipment. Overseas training in GLP was organized by WHO and a local training conducted in March 2013.

Regarding drug policy and coordination, The Medicines Management Department (MMD), MOPH analysed the problems addressed last year in drug supply and distribution and submitted a proposal to solve them urgently to the Cabinet via the Minister of Health.

Partner activities include supply of drugs to primary care units by UNICEF and the International Federation of the Red Cross, support of LMIS by UNFPA, support of development of guidelines and training for TB and malaria by GFATM. WHO is supporting supply of emergency drugs, the updating of the national EML and training for DRA staff, while drug testing laboratories are supported by a number of these partners.

The situational analysis enabled a rapid, detailed, comprehensive and objective assessment as a result of which excellent recommendations were made to improve the pharmaceutical sector in Democratic People's Republic of Korea. The Government accepted them as the appropriate way to protect and to promote the people's health by scaling up the pharmaceuticals and took immediate measures based on most of the recommendations.

7. Situational analysis and progress in large decentralized countries

7.1 Indonesia

Dr Bayu Teja, Director of Public Medicine and Medical Supply, MOH, reported on the findings of the situational analysis and progress made since the situational analysis done in 10–23 July 2011.

Regarding drug supply, there are currently no electronic management inventory systems and economies of scale are lacking due to decentralized procurement, which is small in scale even though government procurement rules are followed. An e-logistic software has been introduced for drug inventory control at district and provincial facilities to facilitate quantification and comparison between provinces and districts and also an e-catalogue software is being established for use in electronic purchasing. Since 2010, MOH has been implementing a one-gate policy (OGP) in drugs procurement and supply at the central level and is promoting it more locally by giving rewards to provinces and districts that have implemented it. USAID/PtD and WHO are supporting the OGP strengthening drug supply at district level. In order to give pharmacists a lead role in district drug supply and selection, there is a regulation mandating that pharmacists should be responsible for any jobs related to drugs (including supply and selection). By 2012, about 71% of all district warehouses were managed by pharmacists. USAID and WHO are supporting a study to strengthen drug supply by developing SOPs, implementing them in studied districts, with pharmacist interns working at the district health offices (DHOs) and health centres (HCs), for guidance and mentoring. Pharmacist internship is one way to address the lack of pharmacists at DHO/ HC levels. Every year, MOH conducts a national workshop on drug supply and encourages local governments to undertake pooled procurement to achieve economies of scale, but no significant progress has occurred as local governments wish to remain autonomous. Annual reports are developed every three months by hospitals, districts and provinces and sent to MOH, but the local information needs improvement for analysis in planning, quantification and forecasting to improve stock management.

Regarding drug selection, an NEML has been established and regularly updated since 1980, but is only partially followed by districts, hospitals and insurance systems which have their own lists with many non-EML drugs. The NEML was revised in January 2013 and will be distributed in July 2013 to all public health facilities through provincial and district health offices. Harmonization and compliance to the NEML is also being encouraged by drafting a national formulary for universal health coverage and undertaking advocacy to professional organizations, hospitals, health centres and district health offices in five provinces.

Regarding drug use, there is high use of antibiotics, vitamins, steroids and *poyer* (powder of mixed drugs) and prescriptions poorly follow STGs. Health centres report prescribing indicators, compiled at district level to the sub-directorate on rational use of medicines within the MOH. Data from 21 provinces in 2012 showed that 51% of cases of upper respiratory tract infection and 44% of acute diarrhoea cases received antibiotics and that the average number of drugs per patient was 3.5. In 2014, MOH plans to provide guidelines for hospitals to undertake drug use evaluation. STGs were revised in 2011 and have been promoted to doctors and pharmacists through workshops. CPD is under the responsibility of the professional organizations, but MOH gives full support by providing resource people. A programme for joint training of pharmacists and medical doctors has been developed to encourage CPD and a module in clinical pharmacy for pharmacists provided. MOH is also advocating rational use of medicines to be included in undergraduate curricula. Training on rational use of medicines is regularly given by MOH to the provincial health officers, pharmacists and medical officers in health centres and 250 students have been trained in pharmaceutical care. Public education programmes on self-medication, antibiotic use and medicines in chronic disease using the CBIA (Cara Belajar Ibu Aktif or Mother's Active Learning Method) have continued. There has been a poster/leaflet campaign on using generic medicines and an audiovisual campaign on rational use of antibiotics but no programme on *puya* (practice of grinding tablets of many different medicines together).

Regarding drug regulation, there are many brands (12 552) on the market which makes regulation, selection and use more difficult. The task of the NADFC (National Agency of Drug and Food Control) is to monitor, but it can only recommend to MOH/local government whether to issue or

revoke licenses of wholesalers and retailers. There is monitoring of drug advertisements but not drug promotional activities. An attempt to reduce the number of products on the market is being made by reviewing all inappropriate fixed-dose-combination products in preparation for universal health coverage (UHC) in 2014, developing a programme for re-registration without which a product will automatically be deleted and re-registration only for products that have been produced/imported/distributed within the last two years. The existing law related to freezing the licenses of manufacturers, wholesalers, and retailers has been revised to give authority for such decisions to the high-level regulator, not local bodies. With regard to drug promotion, the focus is on monitoring of information content in labelling and promotional material of OTC products, while other ethical aspects of drug promotion are left to health care professionals. However, the MOH and NADFC have a plan to form a board in 2013 to address the issue of business ethics in the pharmaceutical sector. In order to inform prescribers about drug safety issues, it is planned to publish all product recalls on the web by 2014.

Regarding drug policy and coordination, there has been intensive discussion among director-generals in MOH, NADFC and ASKES (insurance system) with regard to rolling out UHC and discussion topics covered STGs, Indonesia case-based groupings (for insurance purposes), drug selection for the national formulary, referral system and evaluation of data collection methods for monitoring drug use at hospitals and health centres. The sub-directorate on rational use of medicines has continued to run a programme on rational use of medicines since 2002 and on public education since 2007. An AMR containment programme is being developed. There is ongoing advocacy to local governments to include pharmacists in human resource planning and an MOH regulation is proposed to give pharmacists greater prominence at the provincial level.

Partner activities include strengthening of drug supply management which is being supported by WHO, USAID, MSH, and CHAI. AUSAID is supporting development of guidelines in pharmaceutical services in readiness for UHC. GFATM is supporting development of drug warehouses in districts, acquisition of laboratory equipment in provinces and facilitation of prequalification for the pharmaceutical Industry. The ASEAN Working Group on Pharmaceutical Development is supporting activities to promote rational use of antibiotics, including a workshop on rational use of

antimicrobial agents in November 2012, which was also supported by WHO.

The situational analysis provided an opportunity for the real situation to be observed by Indonesia and related government institutions to come together to identify recommendations for government and cross-cutting programmes. A comprehensive survey would be needed to get representative data which would facilitate widespread implementation of recommendations. A workplan needs to be developed to strengthen intersectoral networking and cooperation.

7.2 India

Rajasthan

Dr Samit Sharma, Managing Director, Rajasthan Medical Services Corporation Limited (RMSCL), India, described – as an innovation in making good quality drugs available to people free of cost – the *Mukhyamantri Nishulk Dava Yojna* (Chief Minister's Free Medicines Programme) under implementation in Rajasthan state in India since October 2011.

As a background, the participants were informed that India spends 4.2 percent of its GDP on health. Of the total expenditure on health, the government contributes about 30 percent – the rest is borne by individuals as out-of-pocket expenditure on health. Almost 70 percent of the expenditure on health is related to drugs. Expenditure on health is responsible for 3% shift from above poverty-line (APL) to below poverty-line (BPL) every year. Studies reveal that over 23% of the sick do not seek treatment due to poverty.

Prior to the launch of the *Mukhyamantri Nishulk Dava Yojna*, a majority of the patients were prescribed medicines for purchase from the open market. Prescribed medicines were expensive and usually unaffordable. Irrational combinations and use of unnecessary and useless drugs was common. Unnecessary prescription and diagnostic tests contributed to high health care costs. All this happened in the scenario of an ever-increasing demand for health care services and limited financial resources.

The *Mukhyamantri Nishulk Dava Yojna* has resulted in almost 100% availability of drugs on the Essential Medicines List. Several factors have contributed to this, including almost universal prescription of drugs by generic names accompanied by a well-managed procurement and distribution system. A strong emphasis on quality control of generic drugs procured by the public health system has contributed on the one hand to physician confidence in prescribing them and on the other, ensured acceptance and compliance by patients. Economies of scale have been leveraged in procuring generic drugs at a fraction of the market rates. The specific interventions to make quality essential drugs available in all public health facilities include:

- establishment of a centralized procurement agency;
- an open and transparent tendering process;
- well-managed warehouses with requisite facilities in every district;
- regular and stringent electronic monitoring of supply status and inventory control;
- empanelled laboratories for drug quality testing;
- setting up drug distribution centres in all hospitals;
- sufficient funds and prompt payment of suppliers.

Actions were also initiated to effect a behaviour change in the prescribing habits of physicians. These included:

- sensitization and orientation of rational drug use;
- insistence on writing prescriptions on self-carbonated double slips—one of which is retained for prescription audit;
- insistence about diagnosis being mentioned on each prescription slip;
- only generic drugs from the Essential Drug List can be prescribed;
- constitution of drug and therapeutics committee and institutionalization of prescription audits;
- formulation of standard treatment guidelines.

Dr Sharma concluded his presentation by recounting the achievements of the Scheme. These include a doubling of the patients seeking care at the public health primary care facilities. The number of people seeking care from public health facilities has increased from an average of 4.2 to 6.2 million per month. Since the inception of the scheme, over a hundred million patients has been treated free of cost. The average cost per patient has been reduced to INR 15–30 as compared to the market cost of INR 300–500. These measures have contributed to reducing out-of-pocket expenditures on health and will help in reducing inequities in health.

A situational analysis was done in March 2013 where it was found that there was universal availability of all essential medicines and that all medicines were prescribed by generic name. Remaining challenges included the high patient workload (following increased patient numbers), irrational use of medicines, including polypharmacy and antibiotic overuse, and weak regulation due to lack of resources.

Regarding drug use, recommendations included:

- monitoring drug use through prescription audit using diagnosis, (which should be added to the electronic drug management inventory system) in order to identify specific inappropriate practices needing correction;
- analysing prescriber workload through the electronic drug management inventory system in order to lobby for better distribution of doctors;
- making the doctors your friends in improving use – “help us to make the free drug supply system sustainable by avoiding the use of unnecessary drugs”;
- establishing DTCs in every hospital and community health centre (CHC) and require them to monitor drug use and report annually on their activities to the MOH and RMSCL;
- incorporating prescription audit and ethics into continuing professional development;
- conducting public education campaigns with core pharmaceutical messages, for example, *does my child need more than one drug?* through Ashas and the media.

Regarding drug regulation, recommendations included:

- more inspectors and pharmacists to inspect all outlets regularly;
- modernization of the drug testing laboratory and filling of all posts so that more samples can be processed;
- starting up of a unit to monitor drug promotional activities;
- implementation of drug schedules more strictly.

It was mentioned that there will be greater government budget for all State regulatory authorities and the drug testing laboratories under the twelfth five-year plan.

Karnataka

Mr N Vadivelu, Deputy Drugs Controller, Karnataka, India, explained that a situational analysis is yet to be done in Karnataka and is currently planned for later in 2013. He then went on to describe the situation Karnataka. Drug regulation is managed by the Department of Drugs Control. The latter has three wings – enforcement, drug testing laboratory and education in pharmacy. In addition to the state drug testing laboratory, there are also two regional drug testing laboratories located in the State. The Drugs Control department must regulate as sector consisting of 237 drug manufacturing units, 306 drug manufacturing loan licensees, 28 100 drug sale outlets, 89 other manufacturing units, 17 laboratories, and 319 blood facilities. Currently, there are 709 sanctioned posts in the Drugs Control Department but 254 are unfilled. During the last three years, 12 982 samples were tested, of which about 3% failed quality testing, 75 519 inspections were made to drug sales outlets and 643 to drug manufacturing units. During this same time, 66 manufacturing units had their licenses cancelled and 4 suspended, while 2434 drug sales outlets had their licenses cancelled and 2956 suspended.

Drug supply is managed by the Karnataka State Drugs Logistics and Warehousing Society (KDLWS), established in 2002. An e-tendering system has been used since 2002 for all items of INR 1 lakh or more. There are 14 district warehouses and a further 13 are being constructed. There is not yet an electronic drug management inventory system extending throughout the drug distribution system – though this is planned. Of 486 drugs on the state EML, only 332 are purchased by KDLWS as determined by a needs assessment committee. The value of drug order placed during 2012–2013 is INR 125 crores.

8. Partner reflections on country presentations

Partners were invited reflect on the country presentations and some agreed to speak. The points raised are summarized below:

8.1 IDA Trading Foundation Pvt. Ltd: Darshana Shah

- The situational analyses allowed a SWOT analysis to be done.
- Assessment of QA is very important. There is a need to have an agreement between the supplier and procurement agent. One way to bring down costs is to have only one QA system with a supplier and use this for all procurements. There is a need to harmonize QA systems across countries to achieve more cost-efficient processes for quality assurance during procurement.

8.2 Management Sciences for Health (MSH): Michael Gabra

- We appreciate all the assessments for we all know how difficult this is, but it has provided very rich and useful information on current issues.
- It is important to also identify where do we go next—a monitoring plan is needed to measure progress.
- We need a simple tool at country and regional level, to measure what we do. This would impact national health strategies, because it could show the impact of your work and could help to mobilize support.
- There is a need to have more collaboration and situational analyses that identify the problems and indicate how these need to be managed.

8.3 United Nations Office for Project Services (UNOPS): Dr Faisal Mansoor

- There has been a wonderful response to the situational analyses and everyone has made progress since then, so the tool developed by WHO is robust and useful.
- The quality of representations from the countries was good.

- There are good lessons in some states, for example Rajasthan, where the results of a commitment at the highest levels can be seen.
- There are gaps – for example, the EML is not followed by the highest levels in health care and these are the ones that everyone is looking up to; information on drug consumption is also not available.
- Since we are all engaged in working towards universal health coverage, drug supply is very important. Various mechanisms are used by different countries. For example, Maldives has contracted out procurement to UNOPS. However, the supply chain also extends down to the most peripheral levels such as village health workers (VHW) whose stock needs monitoring.
- Support is needed to develop regulatory harmonization.

8.4 German Technical Cooperation (GTZ): Dr Markus Behrend

- There are very diverse countries in the Region and there is a lot of work to do.
- It is difficult to keep drugs at appropriate levels of attention in the government.
- Funds need to come from within countries.
- There is a need to think about regional cooperation with donor groups.
- Efficiency should be used as an argument in agreements for support with donors.
- The private sector could be used for some services such as using wholesalers for distribution or outsourcing outside of MOH procurement and other supply chain functions.
- There is no need for distinction between communicable and non-communicable diseases (antiretrovirals vs insulin)—what is important is that the health system can respond and make medicines available and affordable for both type of diseases.
- One should not think only of one issue – there is a need to examine the whole system with a health system perspective, and more emphasis should be given to health system strengthening.

- There has been some progress on reduction in out-of-pocket expenditure, but it is important to remember that there is no free health care. Someone has to pay, but we should try to get away from payment at the point of health care delivery.

8.5 World Bank: Dr Wei Aun Yap

- Congratulations are due to WHO on the situational analyses – as lots of progress has been made in a short time.
- Capacity strengthening is a key need from many country situational analyses and this requires resources. Many resources should be from domestic sources through country prioritization, but some external financing is needed to achieve sustainable changes and we need to consider the strong economic case for this, such as:
 - negative externalities such as antimicrobial resistance; SSFFCs entering other countries;
 - positive externalities–facilitating trade; improving access to drugs in other countries.
- Countries should think strategically on tapping donor agendas for vertical programmes (HIV/AIDS, TB, malaria) and Millennium Development Goal attainment, for overall health systems strengthening (in particular for medicines regulatory systems).
- We need to think beyond regional categories which often have artificial delineation of countries according to different regional definitions – WHO's South-East Asia and Western Pacific regions; World Bank's East Asian Pacific/South Asian regions; ASEAN/APEC.
- We need to think more ambitiously about regional collaboration which should be deeper than just information sharing – how can we share and divide tasks particularly with regard to regulatory convergence and harmonization.
- More awareness is needed of the links between drug registration and UHC insurance schemes and the role of HTAs should be better understood as coverage is expanded under public financing.
- More regional collaboration and harmonization concerning registration of drugs, and understanding about why so many

products are registered, underlying causes; price differentiation or other issues, are needed.

- World Bank is interested in regional engagement in pharmaceuticals—promoting harmonization of medicines regulation; improving access to essential and quality medicines; strengthening governance and regulatory systems; and regional harmonization for regulation.

8.6 Comments from Countries in response to partner reflections

Countries were invited to respond to partner reflections. Their comments are given below.

Bhutan

- Pharmaceutical financing is the least talked about and there is no comparison of various financing models to identify which model is the best.
- Gross domestic product as an indicator is useful, but not suitable to capture health parameters.
- Universal health coverage is not talked about and out-of-pocket expenditure is increasing in some countries.
- There is a need to avoid duplication, particularly for quality assessments for various agencies and donor requirements.
- More collaboration, both among national governments and at the regional levels, is needed.

Rajasthan, India

- We do not agree with the World Bank views as we see the pricing strategies of the pharmaceutical industry are barriers to access that can only be overcome by generic policies and pricing controls.
- Industry serves, but not with the interest of the patients in mind, the patients pay exorbitantly, so we need policies to control prices.
- **World Bank in response** clarified that they support generic policies and were very much concerned with the achievement of cost-efficiencies to improve access to essential medicines.

9. Group work

9.1 Briefing

Dr Kathleen Holloway briefed delegates on what to do during the group work. She mentioned that there would be 4 groups to work on one of the following four subjects – drug supply, drug selection and use, drug regulation and drug policy and coordination. Each group was instructed to choose a chairman and rapporteur and to prepare a 10-minute presentation. For each specific area of drug management each group was asked to identify:

- 3-5 major conclusions;
- 3-5 major recommendations for future action by Member States, including the what, how, who and when for each recommendation;
- 3-5 major recommendations for coordinated future action by WHO and partners and how one would ensure coordination.

In addition each group was asked to reflect on the national situational analyses done and identify major conclusions on the process and how governments, WHO and partners may work together to develop a format to allow countries to undertake national situational analyses themselves to inform planning and monitor progress.

9.2 Group 1: Drug supply

It was concluded that in the Region there is:

- lack of electronic inventory systems in countries leading to poor procurement and supply chain management;
- inadequate capacity (technical, financial and logistics which includes transportation, storage and infrastructure);
- issues related to economies of scale (MOQ–low interest for suppliers);

- in-country/international procedural constraints leading to long lead times as well as inability to procure in case of emergencies (sometimes even 1 year);
- quality issues leading to disruption of supply (batch fail, recall).

Each conclusion was discussed and recommendations made for Member States, WHO and partners, as in the table 1 below.

Table 1: Recommendations on Drug supply

	Issue	Recommendation	How	Who	When (time frame)
A	Lack of electronic inventory system leading to poor procurement and supply management (PSM).	Online electronic inventory management system should be adopted.	Establish a cost-effective and quality software system customized according to country needs.	By MOH with support from donor and technical partners.	End of 2015.
B	Inadequate capacity (technical, financial, logistics which includes transportation, storage and infrastructure).	Undertake capacity development for management of essential medicines and logistics.	Develop a standard national training package for PSM; ensure availability of optimal resources for management of essential medicines and logistics.	By MOH with support from donor and technical partners.	End of 2014.
C	Issues related to economies of scale (minimum order quantities, MOQ, – no interest for suppliers).	Create a mechanism for International pooled procurement, and also explore centralized procurement.	Have MOU between countries on procurement; harmonize regulations and drug registrations.	By Member States, regional donors and partners.	Mid-2015.

	Issue	Recommendation	How	Who	When (time frame)
D	In-country/ International procedural constraints leading to long lead times as well as inability to procure in case of emergencies (at times even 1 year).	Have simplified policies in place for procurement of pharmaceuticals.	Review in-country procurement procedure and policy for pharmaceuticals.	By Member States.	Mid-2014.
E	Quality issues leading to disruption of supply.	Strengthen the Quality Assurance system (develop prequalification for manufacturers and suppliers).	Have prequalification of suppliers and continuous quality assessment; strengthen the laboratory testing skills at national level.	By MOH, donors and technical partners.	End of 2014.
F	Lack of coordination and assistance to countries on pharmaceutical supply.	Have a full time staff at the WCO to look after pharmaceutical matters.	Strengthen the coordination and assistance to countries on pharmaceutical supply.	By WHO.	Within a year.
G	Securing funds and resources for web-based inventory management systems.	Facilitate communication between Member States and donors.	Facilitate securing funds and resources for web-based inventory management systems.	Partners (Financial), WHO (Technical).	Initiate within a year.

	Issue	Recommendation	How	Who	When (time frame)
H	Mobilizing resources for institutional and individual capacity building for supply chain management.	Facilitate communication between Member States and donors; develop a standard training package for PSM.	Facilitate mobilization of resources for institutional and individual capacity building for supply chain management.	Partners (Financial), WHO (Technical).	Initiate within a year.
I	Sharing procurement unit cost prices of essential medicines within countries.	Develop a common platform for sharing of information.	Share procured unit cost price of essential medicines within countries.	WHO to facilitate development of a website and member countries to fill in the information.	End of 2014.

With regard to the situational analysis tool, it was concluded that it is useful for gap analysis and regular monitoring. It was recommended that the tool should be refined and developed and adapted at country level for regular monitoring of progress at intervals of two years. Member States and WHO could arrange training programmes for implementation.

9.3 Group 2: Drug selection and use

It was concluded that in the Region there is:

- poor compliance to EMLs, STGs and national formulary in all countries of the Region;
- inadequate prescription monitoring systems in South-East Asia Region countries and lack of a regional database on drug use, including irrational prescribing and use;
- inadequate drugs and therapeutics committees at national and institutional / tertiary / referral hospital levels in countries;
- inadequate CPD schemes for health professionals and lack of focus on rational drug use in health professionals' education/curricula;

- lack of public education through appropriate IEC materials/media about rational drug use;
- inadequate national pharmacovigilance programmes in all countries to collect, monitor, analyse data on ADRs of pharmaceuticals/vaccines.

It was recommended that Member States implement and fund the following national policies:

- A. National list of essential medicines, standard treatment guidelines, and national formulary, should be updated periodically every 2–3 years by the ministries of health.
- B. A national drugs and therapeutic committee at MOH level, comprising policy-makers, regulatory authorities, pharmacologists, clinicians, pharmacists, civil society, economists, patients, and other stakeholders, should be established.
- C. Drugs and therapeutic committees should be established in all referral/tertiary care hospitals and medical colleges/teaching hospitals.
- D. Monitoring of drug use by drugs and therapeutics committees for compliance to standard treatment guidelines and formulary to ensure rational use of medicines should be done at regular intervals and include prescription audit and analysis of aggregate consumption such as ABC analysis.
- E. Continuous professional development for fostering rational use of medicines should be done periodically every five-year period by councils/authorities for possible renewal of the license of all healthcare professionals to practise.
- F. National pharmacovigilance programme should be established, expanded and sustained, and the data documented and analysed, for possible regulatory actions by the DRA.

It was recommended that WHO and partners should act in a coordinated and systematic manner and that:

- A. international organizations/partners and WHO country offices should have a dedicated focal point in countries to provide technical support and liaison with the country government authorities.

- B. WHO and other partners could play a convening role for horizontal collaboration or bi-lateral collaboration among countries in the Region. There should be technical support for capacity building and implementation aspects.
- C. there should be a harmonization of technical support (within partners) provided to countries with MOH leadership; any partner could play the facilitator role.

With regard to the situational analysis tool, it was concluded that it enables assessment of the real situation, identification of priority areas and possible solutions. It could be improved by development of some key performance indicators for inter and intracountry comparison and it needs to be more comprehensive. There could be more policy-level dialogues and awareness at higher levels in MOHs and WCOs. Also the results could be fed into more policy-level advice by the WHO at the World Health Assembly and other such forums for advocacy and commitment by countries. It was recommended that a tool should be developed for countries themselves to undertake such analyses in future with partners' support. This would mean having a simpler comprehensive tool, including knowledge performance indicators, prepared in the Region to monitor progress, which should be developed with the support of partners/WHO. This tool could be adapted or tailored to country-specific needs.

9.4 Group 3: Drug regulation

It was concluded that in the Region there is:

- lack of capacity and a need for capacity building of national drug regulatory authorities (NRA) and drug testing laboratories in all the Member States;
- need to establish a regulatory information sharing network amongst the NRAs in the Region;
- lack of coordination amongst the stakeholders within the Member States on a regular basis;
- lack of resources in all NRAs, which need more staff and skilled human resources;

- need to review and update laws and regulations and policies to meet the national requirement for increasing and enhancing availability, accessibility and affordability of essential medicines.

It was recommended that Member States:

- A. should work towards a harmonization process of regulatory procedures in the Region:
 - what: regulatory harmonization,
 - how: regional forum,
 - who: Member States, WHO and donors,
 - when: biennium 2014–2015.
- B. should (especially ministries of health) facilitate coordination amongst stakeholders on a regular basis to improve, selection, drug use, quality use of medicines and regulation:
 - what: coordination and policy frame work,
 - how: regular consultation amongst the stakeholders within the country,
 - who: Ministries of Health with technical support from WHO and Partners,
 - when: 2013–2014, till the next situational analysis.
- C. should mobilize adequate resources to strengthen NRA and drug testing laboratories (DTLs) to address the increasing and changing needs of the healthcare system:
 - what: mobilization of resources by strong political commitment,
 - how: increase budgetary support to NRAs and DTLs strengthening,
 - who: governments / WHO and partners with technical support,
 - when: 2014–2015.

- D. should develop and strengthen health technology assessment to improve the availability of cost-effective and need-based medicines and technology in the country by reducing and limiting the number of 'me-too' drugs and pharmacy retail outlets:
 - what: proper and prudent selection of medicines,
 - how: develop capacity of NRAs along with government medical supplies system with the support from WHO and donors,
 - who: technical committee member,
 - when: in the next five years.
- E. should strengthen inspection and monitoring of use of medicine with appropriate SOPs to reduce irrational use of medicines to prevent development of drug (antibiotic) resistance and for efficient use of limited resources.
 - What: Quality use of medicine,
 - How: strengthening the NRAs and DTCs,
 - Who: NRAs, other related government agencies with support from WHO, donors and NGOs,
 - When: 2014-2015.

It was recommended that WHO and partners:

- A. should collaborate to create a common platform for the MOH and NRA to address the availability and accessibility of quality medicine;
- B. should strengthen WHO technical capacities in the Member States and Regional Office to address the coordination and collaboration gaps amongst the Member States and the donors;
- C. should facilitate the networking of NRAs in the Region for exchanging regulatory information and support capacity building of NRAs for regulatory and enforcement activities especially for new drugs, biological and vaccines;

- D. should provide technical support to strengthen the health system, and to a regulatory and quality control system to address quality use of medicine and appropriate technological assessment;
- E. should support capacity building of the Member States in a collaborative manner to avoid duplication of resources and to achieve uniform standards and implementation.

With regard to the situational analysis tool, it was concluded that it was an eye-opening experience for Member States to understand some of the problems of the regulatory system. It was recommended that WHO and partners with Member States develop a uniform and harmonized format for future similar situational analyses and that countries should try to conduct them regularly. WHO should coordinate and monitor the data collection regionally and should disseminate the information to all Member States. In addition, countries need to appoint focal points to coordinate activities at the country level and, with WHO, donors and partners, establish a national task force, led by MOH and consisting of all stakeholders, WHO, partners and NGOs. A regular regional meeting needs to be convened to share progress and plan the way forward and this should be supported by technical partners like WHO and others.

9.5 Group 4: Drug policy and coordination

It was concluded that in the Region there is:

- lack of a comprehensive national medicines policy, implementation framework and coordination in countries;
- poor access to essential medicines in some countries;
- concerns about the quality, efficacy and safety of some medicines;
- lack of affordability of some medicines;
- irrational use of medicines;
- improper dispensing of medicines.

It was recommended that each Member State should develop a comprehensive national medicines policy document and implementation

framework. This may need a permanent statutory committee to draft and periodically review the policy document and implementation framework and should involve all stakeholders. WHO should provide technical support which should include drafting templates for formulation, implementation and evaluation.

It was further recommended that a collaborative mechanism be established among Member States of the Region. This should include: prioritization of a list of essential medicines in the Region and collaboration for better access; collaboration to ensure access to biological products, vaccines and intercountry supply; collaboration to assess the quality of biological products, vaccines through drug testing laboratories; intercountry inspections and capacity building.

Every aspect of national medicines policy was discussed and recommendations made as in the table 2 below, which is divided into several parts.

Table 2A: Recommendations to improve access to medicines

Recommendation	What?	How?	Who?
Rational selection and use	National list of essential medicines and standard treatment guidelines	Training and monitoring	Ministry of health (MOH)
Sustainable financing mechanism	Adequate government funding and price control, if necessary by finding other sources	Political commitment, advocacy	Government and UN Agencies
Reliable drug supply system	Provision of essential medicines	Strengthen supply chain management	MOH
Assured Availability	Equitable and continuous availability	Quantify needs	MOH, international partners

Recommendation	What?	How?	Who?
Promotion of local production	More manufacturing Units	Investment, concessional land, tax Incentives	Government or foreign
Use of generic/INN name	Procurement, supply and prescription by generic name	Policy formulation	Government
Facilitation of Imports/exports	Simplify processes		Government
Regional cooperation	Formulation of a regional body	Political commitment	WHO HQ and SEARO

Table 2B: Recommendations to ensure quality, efficacy and safety of medicines

Recommendation	What?	How?	Who?
Independent regulatory authorities	Effective regulatory system		MOH
GMP compliance for manufacturers			National drug regulatory authority
Collaboration and harmonization			WHO
Adequate DTL facilities including trained staff			
Pre-market and post-market sampling	Quality testing		National drug regulatory authority
Need, efficacy and safety based permission to 'me-too' molecules			National drug regulatory authority

Table 2C: Recommendations to make medicines affordable

Recommendation	What	How	Who
Price control	Pricing policy with ceiling prices	Administrative orders	Government
Provision of essential medicines in all public health institutions	Reasonable prices/free of cost	Declaration of rights to essential medicines	Government
Centralized pooled procurement	Generic medicines	Economies of scale	Government procurement agency
Price information and sharing of price data	Comparison of tender prices for procurement and for granting marketing permission to new medicines	Publication of prices on web site	Procurement agency

Table 2D: Recommendations to ensure proper dispensing

Recommendation	What	How	Who
Qualified pharmacists		On-the-job Training	Government and donors
Good dispensing practices			
Dispense only POM			
Management of medicines	Establish electronic inventory management systems	Training	Government and donors

Table 2E: Recommendations to promote rational use of medicines

Recommendation	What	How	Who
National formulary	Development and updating		Essential medicines focal point
National essential medicines list	Regular updating every two years	Technical experts	
Standard treatment guidelines	Printing and distribution among prescribers		
Drug and therapeutic committees	Formation		Medical superintendent
Prescription audit	Monitoring of drug use		Pharmacists
Dissemination of objective drug information	Establishment of a drug information centre	Leaflets, on website	MOH, WHO
Antibiotic policy			
Continuing medical education			
Implementation of code of medical ethics for doctors		Awareness, training	Medical council
Regulation of drug promotional activities	Code of ethics for pharmaceutical promotion		
Regulation of traditional medicines			

10. Conclusions and recommendations

10.1 Drug supply

Conclusions

- Most countries either rely on a paper-based inventory system or are not able to fully utilize the electronic inventory management systems, leading to poor forecasting, quantification and stock management.
- Small economies of scale adversely impact procurement.
- Countries often face difficulties in national/international procurement, especially during emergencies.
- Many countries experience problems in quality assurance of drugs and poor quality drugs lead to supply disruptions.
- Financial allocation for procurement of essential medicines in the national health budgets of some countries is inadequate.
- In some countries, there are too few products registered, leading to lack of availability and higher prices.

Recommendations

Member States should:

- invest in and implement online electronic inventory management systems;
- invest in and promote capacity development for management of essential medicines and logistics;
- establish prequalification systems for ensuring quality drugs;
- consider outsourcing the procurement and distribution of essential medicines to specialized agencies;
- create a mechanism for intercountry/multicountry pooled procurement which would require harmonization of certain drug regulatory processes and procurement procedures and simplify the procurement regulations for pharmaceuticals.

10.2 Drug selection and use

Conclusions

- Compliance with essential medicines lists and standard treatment guidelines is suboptimal in most countries.
- Most secondary and tertiary health facilities in the Region do not have drugs and therapeutics committees.
- Irrational use of medicines by providers and consumers is a major concern in the Region. This includes nutritional supplements, self-medication, use of antimicrobials for veterinary and agriculture as well as traditional medicines.
- Regular monitoring of drug consumption, and appropriate use including prescription audits are not done.
- Effective pharmacovigilance is not done.
- Undergraduate training and continuing professional development on essential medicines concept and rational prescribing is weak.
- Public education on safe and prudent use of medicines is often inadequate.

Recommendations

Member States should:

- establish and sustain a multi-stakeholder committee at the national level for:
 - formulating and monitoring policy guidelines;
 - preparing and/or periodically reviewing the national EML, formulary, and standard treatment guidelines;
 - allocating resources and identifying executive units in the MOH for implementation of its policies.
- establish drug and therapeutic committees and pharmacy services in all public and private hospitals to oversee

implementation of national policies, EMLs, generic prescribing, clinical guidelines and monitoring drug use;

- establish, implement and sustain pharmacovigilance programmes in countries;
- institutionalize continuous professional development on the essential medicines concept and rational use of medicines for all health care professionals;
- include the essential medicines concept and rational use of medicines in the undergraduate and postgraduate curricula of healthcare professionals;
- include safe and prudent use of medicines in public health education messages and consumer forums;
- appropriately regulate private retail pharmacy services and promote the implementation of good pharmacy practice;
- establish/strengthen capacity for health technology assessment to support evidence informed decision-making regarding selection, financing and supply.

10.3 Drug regulation

Conclusions

- Capacity of NRAs and DTLs in the Region is limited.
- Human and financial resources are insufficient to carry out all the functions including regular inspections.
- There is inadequate sharing of information and networking of NRAs of Member States.
- Drug-related laws and regulations are not regularly updated and enforced.
- There is inadequate regulation of drug promotion.
- In some countries, there are many 'me-too' products, inappropriate combination products and many brands with the same active pharmaceutical ingredient (API), leading to regulatory burden and compromising patient safety. In some

countries, there are too few products registered leading to lack of availability and higher prices.

- Poor regulation of traditional medicinal products, nutraceuticals and food supplements.

Recommendations

Member States should:

- set up a mechanism, such as regional forum, to share information and work towards convergence of regulatory systems and practices and regional harmonization of registration;
- allocate adequate human and financial resources to allow the NRAs to conduct all their responsibilities including inspections in an optimal manner;
- establish/strengthen capacity for evaluation/assessment of health technologies;
- regulate and monitor drug promotion to prevent irrational and unethical use of medicines;
- review and update existing drug regulation laws to ensure compliance with international standards;
- explore options to effectively regulate the market to address excessive multiplicity of products.

10.4 Drug policy and coordination

Conclusions

- Health coverage of the population in the Region is inadequate and many patients do not have access to essential medicines.
- There is a lack of comprehensive national medicines policy and an implementation framework in many countries of the Region and inadequate coordination with the overall health policy.
- Human and financial resource allocation for implementation of drug policy is inadequate.

- Human and financial resource allocation for drug supply, monitoring of drug use and other functions such as regulation and training are inadequate.
- There is a lack of coordination between ministries (commerce, education, finance) and other MOH departments (such as maternal and child health).
- Policy and regulatory frameworks for traditional medicines are weak.

Recommendations

Member States should:

- develop a comprehensive national medicines policy and implementation framework and secure resources for its implementation, to cover:
 - access to essential medicines,
 - quality, efficacy and safety of medicines,
 - affordability,
 - rational use of medicines,
 - sustainable financing,
 - regional collaboration,
 - operational research.
- ensure that the national medicines policy is coordinated with the national health policy and contributes to the aim of universal health coverage;
- establish a pharmaceutical policy department in the ministry of health to support a national coordination committee, involving all stakeholders, to draft, periodically review and monitor the national medicines policy and implementation framework;
- make appropriate financial allocations to meet the essential drug requirements.
- ensure that support to the medicines and health technology area is a part of the WHO country cooperation strategy.

10.5 WHO and partners

Conclusions

Partner technical capacity in countries is often limited and their technical support fragmented.

Recommendations

WHO and partners should:

- appoint full time essential drugs and other medicines personnel in WHO country and regional offices for a meaningful technical collaboration in the area of drugs;
- provide technical support and capacity building in a coordinated and collaborative manner, avoiding duplication, in the areas of drug supply, regulation, use and policy;
- facilitate the exchange of information and networking between countries and identify and share best practices;
- collaborate to create a common platform for the Ministries of Health (MOH) and NRA to address the availability and accessibility of quality medicine;
- explore options for the development of pooled procurement mechanisms between countries.

10.6 Situational analysis

Conclusions

Situational analysis was a useful tool for gap analysis, identifying priority areas and interventions, and for regular monitoring – an ‘eye opener’.

Recommendations

- The tool should be further refined and developed to be easy for countries to use and to include some key performance indicators for inter- and intra-country comparison.

- The tool should be adapted at country level for regular monitoring of progress every two years.
- Countries and WHO should monitor data collection and disseminate the information to countries.
- Countries should publish and share the situational analysis reports, and comparative analytical reports should be prepared.
- Member State focal persons/task force and WHO should arrange training programmes for implementation of the tool.
- Partners should support development and implementation of the tool.
- The results of the situation analyses should be used in more policy-level dialogues between countries, partners and WHO in various advocacy forums in order to gain commitment by all parties.
- A regular regional meeting should be convened to share the progress and to plan the way forward which should be supported by technical partners like WHO and other partners.

Annex 1

Message from Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia

Delivered by Dr Monir Islam, Acting WHO Representative Thailand
and Regional Director for Health Systems Development,
Regional Office for South-East Asia

Distinguished participants, honourable guests, ladies and gentlemen,

It gives me great pleasure to welcome you all to this important meeting and to convey greetings from the Regional Director. As Dr Samlee is unable to attend, I have the honour of delivering his message. I quote:

It is with great pleasure that I welcome you all to this regional consultation.

Medicines are one of the cornerstones of modern health care and critical to achieving universal health coverage. Unfortunately, in many countries, large sections of the population do not have access to good quality essential medicines. Even for those that do, the medicines are often inappropriately used. In 2011–12, many countries in the South-East Asia Region complained to us of the lack of availability of good quality essential medicines and irrational use and requested WHO support to overcome these problems.

Over the years, Member States have often complained of drug shortages and difficulties in procurement. In particular, small countries often have difficulty in procurement, although the problems of drug shortages are common in many large countries as well. Drug stock-outs may occur because of poor drug management, frequent emergency orders which cannot be dealt with quickly, slow government procurement due to administrative rules, or insufficient government drug budgets. There is a clear need for a long-term strategy to build capacity to improve the situation in countries. Furthermore, it is clear that multiple stakeholders are involved and that any solutions will need to involve not only the ministry of health but also other stakeholders including the Ministry of Finance (drug

budget and fiscal rules), the Ministry of Industry (drug prices), Ministry of Education (training pharmacists), Drug Regulatory Authority (licensing suppliers) and industry.

In recent years, there has been much concern globally about substandard and poor quality drugs available in the market. Strong, independent, national drug regulatory authorities that enforce comprehensive drug legislation and regulation are required to ensure that all drugs are of adequate quality. Calls to strengthen national drug regulatory authorities have been made in several resolutions adopted by the WHO Regional Committee for South-East Asia. Unfortunately, many national drug regulatory authorities in the Region are weak, under-resourced and not independent. Therefore, they experience problems with marketing authorization (drug registration), ensuring compliance with good manufacturing practices (GMP), inspecting all drug outlets and controlling unethical drug promotion. There is a clear need to strengthen this mechanism which can only be effective if sustained over many years.

Globally, less than half of all patients may be treated in compliance with clinical guidelines and over half of all patients may fail to take their medicines as prescribed or dispensed. Such inappropriate use wastes resources and causes patient harm in terms of lack of satisfactory outcome, serious adverse events and increased antimicrobial resistance. The causes of inappropriate use of medicines are multiple–inadequately trained prescribers, inadequate drug supply, poor regulation, absence of monitoring and supervision, pre-and in-service curricula that do not include prescribing skills, and uncontrolled drug promotion. Small-scale interventions or even national-scale training alone will not control these factors. A systemic change is needed. Since health systems are so varied and complex, no one package of interventions will fit all countries. Rather, different packages will be needed for different countries. In countries with multiple problems and limited resources, where does one start?

Global consensus is building on the need to invest in and strengthen health systems and to develop a coordinated national approach to promoting appropriate use of medicines. Recommendations for such an approach – which would need an executive body in the ministry of health to implement it–have been clearly stated in many high-level forums. The WHO Global Strategy for Containment of Antimicrobial Resistance 2001,

recommendations from the second and third International Conferences for Improving the Use of Medicines in 2004 and 2011, World Health Assembly Resolutions WHA58.27 in 2005 on antimicrobial resistance and WHA60.16 in 2007 on progress on the rational use of medicines. However, in many countries it is not clear how to develop a more coordinated national approach.

An intercountry meeting on rational use of medicines held in the WHO Regional Office in July 2010 recommended undertaking a national situational analysis of the pharmaceutical sector to identify and prioritize problems and to develop a package of solutions that are context specific. This approach was subsequently endorsed at the Sixty-fourth Session of the Regional Committee through adoption of resolution SEA/RC64/R5 on national essential drug policy including the rational use of medicines. This resolution urges Member States to conduct national situational analyses with WHO help and requests that WHO develop a methodology and tool for countries to use for monitoring and planning purposes and to pilot it. Progress made in this regard is to be reported to the Sixty-sixth Session of the Regional Committee in 2013.

In collaboration with national counterparts, the Regional Office carried out national situational analysis of the pharmaceutical sector in all countries of the Region during 2010–2013 as mandated by Regional Committee resolution SEA/RC64/R5. While the focus was on medicine use, the process also included a review of the drug supply systems, drug regulation and drug policy. There is no standard method for conducting such an analysis so the Regional Office developed a methodology and piloted it while at the same time providing technical support as requested by countries.

The methodology aims to provide a framework whereby information can be systematically collected from all the major stakeholders and analysed in an integrated, holistic manner to identify major problems and solutions. It involves visits, over a two-week period, to the major government departments concerned with pharmaceuticals and a selection of public and private health facilities. Data on drug availability and drug use are collected at facilities. At the end of the field work, a national workshop for stakeholders is held, the results presented and validated and

recommendations agreed. Finally, a report is drafted by WHO and finalized in collaboration with MOH.

All countries have now undertaken a situational analysis and found it useful. We are here now to discuss progress made in each country with regard to the recommendations made in the situational analyses. Also, how can we make the tool for undertaking a national situational analysis more suitable for use by countries for monitoring and planning purposes? A situational analysis to identify solutions will only be worthwhile if the solutions are acted upon. Therefore, it is important to know whether countries have acted upon recommendations and, if not, why not. In this way, areas for future investment and technical support may be identified. Therefore, you are all here to discuss what progress has been made and what future action is needed. The output of this consultation will form the basis of the progress report to be presented to the Sixty-sixth Session of the Regional Committee in September 2013.

With these words, I wish you all fruitful deliberations and an enjoyable stay in Bangkok.

Annex 2

List of participants

Bangladesh

Major Gen. Md. Jahangir Hossain Mollik
Director General
Directorate General of Drug Administration
Motijheel
Dhaka

Dr Md. Ismail Khan
Professor and Head
Department of Pharmacology
Dhaka Medical College
Dhaka

Mr Md Ejaz Ahmed Jaber
Deputy Secretary
Ministry of Health and Family Welfare
Dhaka

Mr A. A. Salim Barami
Director (CC)
Directorate General of Drug Administration
Dhaka

Bhutan

Mr Sonam Dorji
Drug Controller
Drug Regulatory Authority
Thimphu

Mr Kinga Jampel
Officiating Chief Programme Officer
Drugs, Vaccines & Equipment Division
Department of Medical Services
Ministry of Health, Thimphu

Mr Tandin
Senior Programme Officer
Equipment, Medicines and Technology
Division
Department of Medical Services
Ministry of Health
Thimphu

Mr Ugyen Dendup
Head, Menjongsoring Pharmaceuticals
Department of Medical Services
Ministry of Health
Thimphu

Democratic Republic of Korea

Dr Pak Song Chol
Deputy Director
Department of Drug Management
Ministry of Public Health
Pyongyang

Mr Sin Tong Chol
Section Chief
Section of Drug Information
Central Medical Warehouse
Ministry of Public Health
Pyongyang

Dr An Yon Hwa
Inspector of Quality, Inspection and
Information Management
National Drug Inspection Institute
Ministry of Public Health
Pyongyang

Mrs So Yong Sun
Interpreter
Ministry of Public Health
Pyongyang

India

Mr N. Vadivelu
Deputy Drugs Controller (HQ)
Department of Drugs Control
NO. 817, 27th Main, Sector – 1
HSR Layout
Bangalore

Dr Samit Sharma
Managing Director
Rajasthan Medical Services
Corporation Limited (RMSCL)
Government of Rajasthan
Jaipur

Mr Surendra Maheshwari
Executive Director (Q.C.)
Rajasthan Medical Services
Corporation Limited, Jaipur

Indonesia

Mr Bayu Teja Muliawan
Director
Directorate of Drugs and Medical Devices,
Ministry of Health
Jakarta

Mr Heru Sunaryo
Head
Sub-Directorate of Medicine Supply
Directorate of Public Drugs and Medical
Devices, Ministry of Health
Jakarta

Ms Sari Mutiarani
Head
Section of Standardization of
Pharmaceutical Services
Directorate of Pharmaceutical Services
Ministry of Health
Jakarta

Dra Anny Sulistiowati
Head of Research Centre for Drug and Food
National Agency of Drug and Food Control
Jakarta

Dra Yulia Purwarini
Head
Sub-Directorate of Drug Promotion and
Labeling Control
National Agency of Drug and Food Control
Jakarta

Maldives

Dr Jumailath Beygum
Chairperson
Board for Pharmaceutical
Malé

Mr Ubeydulla Thoufeeq
Public Health Programme Coordinator
Ministry of Health,
Malé

Ms Aishath Mohamed
Director, Pharmaceuticals
Maldives Food and Drug Authority
Ministry of Health
Malé

Myanmar

Dr Aung Gyi Maung
Deputy Director
Central Medical Store Depot
Ministry of Health
Yangon

Dr Thida Hla
Deputy Director (Medical Care)
Department of Health
Naypyitaw

Dr Zaw Than Htun
Sr Consultant Physician
Ministry of Health
Department of Medicine
Yangon

Dr Theingi Zin
Deputy Director (Drug Control)
Food and Drug Administration
Department of Health
Naypyitaw

Nepal

Mr Gajendra Bahadur Bhuju
Senior Drug Administrtror
Department Drug Administration
Ministry of Health and Population
Kathmandu

Mr Kusumakar Sharma Dhakal
Under Secretary
Ministry of Health and Population
Balkumari Lalitpur
Kathmandu

Dr Tanka Barakoti
Medical Superintendent
Mechi Zonal Hospital
Bhadarpur – 15, Jhapa

Mr Bade Babu Thapa
Senior Pharmacist
Department of Health Services
Ministry of Health and Population
Ramshah Path

Sri Lanka

Mr E. D. Weerarathne
Assistant Director
Medical Supplies Division
Ministry of Health, Colombo

Dr J. H. M. K. K. B. Jayasinghe
Director
Medical Supplies Division
Ministry of Health, Colombo

Mr A. Ajith Priyadarshana
Director
National Drug Quality Assurance
Laboratory
Norris Canal Road, Colombo

Dr B. V. S. H. Benaragama
Director – Cosmetic Devices and
Drug Regulatory Authority
Norris Canal Road
Colombo

Dr Vijith Gunasekara
Director
Laboratory Services
Ministry of Health
Colombo

Thailand

Ms Worasuda Yoongthong
Pharmacist, Senior Professional Level
Division of Policy and System
Development,
Bureau of Drug Control,
Food and Drug Administration,
Ministry of Public Health,
Bangkok

Dr Thankamol Chunpraphaph
Senior Pharmacist, Professional level
Division of Policy and System Development
Bureau of Drug Control,
Food and Drug Administration,
Ministry of Public Health,
Bangkok

Mr Nipat Suksaensamran
Pharmacist, Professional Level
Bureau of Drug Control,
Thai Food and Drug Administration
Ministry of Public Health,
Bangkok

Mrs Vanicha Chaisamran
Deputy Managing Director
Government Pharmaceutical Organization,
1868 Charunsani Twong,
75 Road, Bangkok-10700

Mrs Achara Eksaengsri
Director
Research & Development Institute,
Government Pharmaceutical Organization,
Bangkok

Timor-Leste

Mr Narciso Fernandes
Director of Quality Control in SAMES
Ministry of Health
Dili

Ms Rosa M. da Reissureicao
Officer of Pharmacy Department
Ministry of Health
Dili

Ms Saturlina Ximenes
Head of Section for Drug Testing &
Warehouse Management, SAMES
Ministry of Health,
Dili

Mr Inacio da Costa
Pharmacist
Department of Pharmacy,
National Hospital,
Guido Valadares,
Ministry of Health,
Dili

Temporary Advisers

Dr Gitanjali Batmanabane
Professor of Pharmacology
Jawaharlal Institute of Postgraduate
Medical Education & Research
Pondicherry, India

Professor Kumud Kumar Kafle
Former Head of Clinical Pharmacology
Institute of Medicine
Maharajgunj, Kathmandu, Nepal

Dr Phusit Prakongsai
Director
International Health Policy Programme (IHPP)
Ministry of Public Health
Nonthaburi, Thailand

Observers

Mrs Naphaphorn Purpanyavanich
Pharmacist
Food and Drug Administration
Ministry of Public Health
Bangkok, Thailand

Miss Wannisa Theantawee
Pharmacist, Professional Level
Division of Policy and System
Development
Bureau of Drug Control
Bangkok, Thailand

Dr Farsai Chanjaruporn
Pharmacist
Division of Policy and System
Development
Bureau of Drug Control
Food and Drug Administration
Ministry of Public Health
Bangkok, Thailand

Miss Chittapak Boonsorn
Pharmacist
Division of Policy and System
Development
Bureau of Drug Control
Food and Drug Administration
Ministry of Public Health
Bangkok, Thailand

Dr Chutima Akaleephant
Senior Researcher
International Health Policy Programme
(IHPP), Ministry of Public Health
Nonthaburi, Thailand

Ms Masvmol Pichaya
Pharmacist
Development, Bureau of Drug Control
Food and Drug Administration
Ministry of Public Health
Nonthaburi, Thailand

Donors/Partners

Mrs Darshana Shah
Manager—Quality Affairs India
IDA Trading Foundation Pvt. Ltd
Worli, Mumbai, India

Dr Faisal Mansoor
Head of Programme Unit
UNOPS
Yangon, Myanmar

Ms Bianca Auping-Kamps
Senior Portfolio Manager
UNOPS
Bangkok, Thailand

Mr Michael Gabra
Country Programme Director
Management Sciences for Health (MSH),
Philippine for Improved Access to
Pharmaceuticals Services (SIAPS)
ProgramLung Center of the Philippines
Quezon City, Philippines

Mrs Lang Siv
Consultant
Promoting the Quality of Medicines
(PQM) programme
United States Pharmacopeia
Phnom Penh, Cambodia

Dr Vinit Sharma
Regional Adviser – RH & RHCS
Asia and Pacific Regional Office
United Nation Population Fund
Bangkok, Thailand

Dr Markus Behrend
Programme Manager
German Development Cooperation (GIZ)
Health Sector Support Programme Deutsche
Gesellschaft fur
Internationale Zusammenarbeit (GIZ)
Kathmandu, Nepal

Mr Bhupendra Bahadur Thapa
GIZ – Consultant
C/O MoHP- GIZ Health Sector Support
Programme (HSSP)
Deutsche Gesellschaft für Internationale
Zusammenarbeit (GIZ)
Health Sector Support Programme,
Kathmandu, Nepal

Ms Sharlene Bagga-Taves
Health Development,
US Agency for International Development
Regional Development Mission Asia
Bangkok, Thailand

Ms Momoko Nitta
Deputy Director
Health Division 3, Health Group 2,
Human Development Department,
Japan International Cooperation Agency
Tokyo, Japan

Mr Royce Escobar
Regional Programme Manager
AusAID, Australian Embassy,
Bangkok, Thailand

Mr Toomas Palu
Sector Manager for Health, Nutrition and
Population
East Asia and Pacific Region
The World Bank
Bangkok, Thailand

Dr Wei Aun Yap
Health Specialist
World Bank
The World Bank Country Office
Vientiane
Vientiane, Lao People's Democratic Republic

Secretariat

WHO headquarters

Dr Kees de Joncheere
Director
Essential Medicines and Health Products

WHO Regional Office for South-East Asia

Dr Kathleen A. Holloway
Regional Adviser
Essential Drugs and Other Medicines

Dr Sudhansh Malhotra
Regional Adviser
Primary and Community Health Care

Dr Manisha Shridhar
Technical officer
Intellectual Property Rights and Trade
and Health

Mrs Sneh Talwar
Senior Administrative Secretary

Mrs Naina Sethi
Secretary

WHO Western Pacific Regional Office

Dr Klara Tisocki
Team Leader
PHA Pharmaceutical

WHO country offices

Dr Selina Ahmed
NPO-Vaccine Safety and Quality
Bangladesh

Dr Madhur Gupta
National Professional Officer
India

Dr Atul Dahal
National Professional Officer
(HIV Programme)
Nepal

Annex 3

Agenda

Topic	Responsible person(s)
Inaugural Session	
• Opening and Message from the Regional Director, WHO Regional Office for South-East Asia	Dr Monir Islam, Ag WR Thailand
• Welcome address by the Deputy Permanent Secretary for Public Health	Dr Chanvit Tharathep, Ministry of Public Health, Government of Thailand
• Address by World Bank	Dr Toomas Palu, World Bank
• Background to the consultation, objectives and expected outcomes	Dr Kathleen Holloway, WHO Regional Office for South-East Asia
• Introduction of participants	
Technical Session: global and regional perspectives	Moderator: Dr Phusit Prakongsai Rapporteur: Dr G.Batmanabane
International evidence for a coordinated health systems approach to managing and experience of doing situational analyses in countries	Dr Kathleen Holloway, SEARO
Global perspectives on capacity building for effective management of medicines	Dr Kees de Joncheere, Director EMP/HQ
WPR perspectives on capacity building for effective management of medicines	Dr Klara Tisocki, WPRO
Country Presentations of situational analysis and progress (1): Experience in countries with an active national medicines policy • Thailand	Moderator: Dr Klara Tisocki Co-moderator: Dr Kumud Kafle MOH Thailand

Topic	Responsible person(s)
<ul style="list-style-type: none"> • Sri Lanka • Bangladesh • Moderated discussion 	MOH Sri Lanka MOH Bangladesh Rapporteurs: Dr P. Prakongsai and Dr S. Malhotra
Country Presentations of situational analysis and progress (2): Experience in small countries <ul style="list-style-type: none"> • Bhutan • Maldives • Timor-Leste • Moderated discussion 	Moderator: Dr Gitanjali Batmanabane Co-moderator: Dr P Prakonsai MOH Bhutan MOH Maldives MOH Timor-Leste Rapporteurs: Dr K K Kafle and Dr M. Shridhar
Country Presentations of situational analysis and progress (3): Experience in medium-sized countries <ul style="list-style-type: none"> • Nepal • Myanmar • Democratic People's Republic of Korea • Moderated discussion 	Moderator: Klara Tisocki Co-Moderator: G. Batmanabane MOH Nepal MOH Myanmar MOH DPR Korea Rapporteurs: Dr P. Prakonsai and Dr S. Malhotra
Country Presentations of situational analysis and progress (4): Experience in large decentralized countries <ul style="list-style-type: none"> • Indonesia • India–Rajasthan • India – Karnataka Moderated discussion 	Moderator : Phusit Prakongsai Co-Moderator: Kumud Kafle MOH Indonesia MOH India – Rajasthan MOH India – Karnataka Rapporteurs: K. Tisocki and S. Malhotra

Topic	Responsible person(s)
The Way Forward: Group Work on Strategic Approaches <ul style="list-style-type: none"> Summary of common priority problems presented by countries Guidance for Group Work 	Dr Gitanjali Batmanabane Dr Kathleen Holloway
Group 1: Drug supply Group 2: Drug use and selection Group 3: Drug regulation Group 4: Drug policy & coordination	All secretariat and consultants
Partner/donor response to the country presentations on situational analysis	Moderator: Dr Kumud Kafle Co-moderator: Dr Gitanjali Batmanabane Rapporteurs: Dr K.Tisocki and Dr M.Sridhar
Group Work Presentations and discussion Group 1: Drug supply and selection Group 2: Drug use and monitoring of use	Moderator: Dr Klara Tisockie Co-moderator: Dr Kumud Kafle Rapporteurs: Dr G.Batmanabane and Dr M. Shridhar
Group 3: Drug regulation Group 4: Drug policy and coordination	Moderator: Dr Gitanjali Batmanabane Co-moderator: Dr Kumud Kafle Rapporteurs: Dr K. Tisocki and Dr S. Malhotra
Country discussions with partners	All secretariat and consultants
Plenary discussion of conclusions and recommendations arising from group work	Moderator: Dr Kees de Joncheere Rapporteur: Dr Gitanjali Batmanabane

Topic	Responsible person(s)
Concluding session	Secretariat
Closing comment by each Member State	Member State delegates
Closing comment by Director WHO/EMP	Dr Kees de Joncheere
Closing comment by Regional Adviser Medicines, WHO Regional Office for the Western Pacific	Dr Klara Tisocki
Closing comments and thanks by WHO Regional Office for South-East Asia	Dr Kathleen Holloway