

# Drug testing laboratories

*Report of the South-East Asia Regional Meeting  
Bangkok, Thailand, 27 April 2013*



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# Contents

	<b>Page</b>
Abbreviations.....	v
1. Introduction .....	1
1.1 Overall goal .....	2
1.2 Specific objectives.....	2
1.3 Expected outcomes.....	2
2. Laboratories with international/regional capacity .....	3
2.1. National Agency of Drug and Food Control (NADFC), Badanpom, Indonesia .....	3
2.2. WHO Collaborating Centre for Quality Assurance of Essential Drugs, Thailand.....	6
2.3. WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, Malaysia .....	8
2.4 WHO Collaborating Centre for Drug Quality Assurance, Singapore.....	10
3. Country reports .....	12
3.1 Bangladesh .....	12
3.2 Bhutan .....	13
3.3 Democratic People’s Republic of Korea .....	15
3.4 India .....	16
3.5 Indonesia .....	18
3.6 Maldives .....	20
3.7 Myanmar .....	21
3.8 Nepal.....	22
3.9 Sri Lanka.....	24
3.10 Thailand.....	25
3.11 Timor-Leste.....	28

4.	Group work .....	29
4.1	Introduction .....	29
4.2	Group A .....	30
4.3	Group B .....	31
5.	Recommendations .....	34

### **Annexes**

1.	List of participants .....	35
2.	Agenda .....	38

## Abbreviations

AAS	atomic absorption spectrometer
ACLCL	ASEAN Cosmetic Laboratory Committee
ADR	adverse drug reaction
API	active pharmaceutical ingredients
ARS	ASEAN reference standard
ASEAN	Association of Southeast Asian Nations
ASG	Applied Sciences Group
AWGPD	ASEAN Working Group on Pharmaceutical Development
BDN	Bureau of Drug and Narcotic
BE	bioequivalence
BMB	Bhutan Medicines Board
CDDA	Cosmetics, Devices and Drugs Act
CDL	Chittagong Drug Testing Laboratory
CDSCO	Central Drugs Standard Control Organization
DDA	Department of Drug Administration
DGHS	Director-General of Health Services
DHS	Department of Health Services
DRA	Drug Regulatory Authority
DTAC	Drug Technical Advisory Committee

DTL	drug testing laboratories
EDQM	European Directorate for the Quality Medicines and Healthcare
EQAAS	external quality assurance assessment scheme
FDA	food and drug authority
FTIR	Fourier transform infrared (spectroscopy)
GC	gas chromatography
GLP	good laboratory practice
GMP	good manufacturing practice
HPLC	high performance liquid chromatography
HSA	Health Sciences Authority
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICPMS	inductively coupled plasma mass spectrometry
IR	infrared
JICA	Japan International Cooperation Agency
LAL	limulus amebocyte lysate
LMD	Logistics Management Division
MFDA	Maldives Food and Drug Authority
MOHFW	Ministry of Health and Family Welfare
MOHP	Ministry of Health and Population
MRDTL	Malaysian Regulatory Drug Testing Laboratory
MS	meet the specification

MTG	Medicine and Therapeutic Goods
NCL	National Control Laboratory
NDQAL	National Drug Quality Assurance Laboratory
NHL	National Health Laboratory
NML	National Medicines Laboratory
NMR	nuclear magnetic resonance
NOMCOL	Network of Official Medicines Control Laboratories of the Asia - Pacific
NPCB	National Pharmaceutical Control Bureau
NQCL	National Quality Control Laboratory
NQCLDF	National Quality Control Laboratory of Drug and Food
OECD	Organisation for Economic Co-operation and Development
PDA	photodiode array
PHL	public health laboratory
PQM	Promoting the Quality of Medicines
PT	proficiency test
QC	quality control
SAARC	South Asian Association for Regional Cooperation
SOP	standard operating procedures
SSFFC	substandard/spurious/falsified/falsely-labelled/counterfeit
STC	short-term consultants
TLC	thin-layer chromatography

TOR	terms of reference
UPCL	ultra-performance liquid chromatography
USAID	United States Agency for International Development
USP	US Pharmacopeial Convention
UV	ultraviolet
WFI	water for injection
WHO	World Health Organization

## 1. Introduction

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

Dr Kathleen Holloway opened the regional meeting by giving a background to the meeting, describing the overall goal, specific objectives and expected outcomes of the meeting and then inviting all the participants to introduce themselves.

Quality assurance is critical to ensuring the quality of medicines. Lack of quality assurance may lead to substandard/spurious/falsely-labelled/falsified/counterfeit medical products, which, in turn, may have serious consequences in terms of therapeutic failure, adverse drug events which may be fatal and antimicrobial resistance. Quality assurance consists of all the processes taken to ensure that only drugs of adequate quality are provided to patients. Quality control is the process of testing that drugs are of adequate quality and is a critical part of quality assurance. Drug testing laboratories are thus critically important in drug quality control and quality assurance. Not only does drug testing help to ensure that drugs are of adequate quality, but it also sends signals to manufacturers concerning the quality of their products. There is a complexity of problems involved in drug testing so not all laboratories can perform all tests. Thus there is a need for collaboration between large and small laboratories and large and small countries.

WHO develops norms, standards and guidelines for international quality assurance and quality control for use by Member States. These include production of the International Pharmacopoeia (collection of quality specifications for pharmaceutical substances and dosage forms together with supporting general methods and analysis) and development of chemical reference standards; guidelines on good manufacturing practice, good distribution practice, good laboratory practice, stability testing, performing bioequivalence studies, registration requirements to establish the inter-changeability of multi-source generic pharmaceutical

products; international non-proprietary names; prequalification of drug suppliers and products; prequalification of laboratories; and an external quality assurance assessment scheme (EQAAS).

WHO produces standards through expert committees which review global evidence. These expert committees include experts from all regions, are strictly governed by rules and procedures and must report to WHO's governing bodies – the Member States. WHO Collaborating Centres produce the chemical reference standards and help to run the EQAAS. It is important that Member States make use of these standards, tools and services for quality assurance in their own settings. Of particular importance to drug testing laboratories are the International Pharmacopoeia, the chemical reference standards, guidelines on good laboratory practice, prequalification of laboratories, and the EQAAS. These services can all be used to build capacity in drug testing laboratories and drug quality control. WHO collaborating centres from both the South-East Asia and Western Pacific Regions are here to help us.

## **1.1 Overall goal**

To strengthen regional capacity for testing of essential medicines to assure their quality

## **1.2 Specific objectives**

- To review the current status of medicines testing services/facilities in Member countries;
- To identify mechanisms for augmenting national capacity for assuring quality of medicines;
- To forge a regional network of medicines testing laboratories;
- To draft/develop a roadmap for augmenting regional and national capacity for assuring the quality of medicines;

## **1.3 Expected outcomes**

- Recommendations on the way forward for the Region with regard to building capacity of drug testing laboratories.
- Recommendations for government, WHO and partners in achieving the way forward.

## **2. Laboratories with international/regional capacity**

### **2.1. National Agency of Drug and Food Control (NADFC), Badanpom, Indonesia**

Dra Anny Sulistiowati, Apt Head of Centre of Food and Drug Research,  
NADFC, Indonesia

The NADFC is independent of the Ministry of Health. Under the Head of the NADFC, there are three main divisions covering: therapeutic products and controlled substances; traditional medicines and cosmetics and food safety and hazardous substances. In addition, there is also an Inspectorate and a Permanent Secretary (with Bureaus of Planning and Finance, General Affairs, Foreign Affairs and Law and Public Relations) under which is the National Quality Control Laboratory (NQCL), the Research Centre, the Investigation Centre and the Information Centre.

The functions of the National Quality Control Laboratory consist of:

- annual planning and programming of drug and food testing;
- as a laboratory testing service;
- calibration of instruments and glassware for the national laboratory and provincial laboratories (accredited to ISO/IEC 17025:2005);
- as the national referral laboratory on drug and food control;
- as a training centre and to provide technical guidance on drug and food testing;
- establishing laboratory guidelines [QMS, GLP (good laboratory practice)];
- establishing national reference substances;
- developing methods of analysis (including non-compendia method development);
- provision of proficiency testing for provincial laboratories and the national accreditation committee for quality laboratories;
- evaluation and reporting of drug and food testing results (from provincial laboratories).

There are 17 laboratories in NQDL-DF, which test products based on chemistry, physicochemistry, biology (in vivo and in vitro), biotechnology (DNA and genetically modified organisms) and microbiology methods. The laboratories are well equipped, though some additional sophisticated instruments are needed to enlarge the scope of work and accreditation based on ISO/IEC 17025. NQCLDF (National Quality Control Laboratory of Drug and Food) has 170 staff and 116 staff are graduates and postgraduates in pharmacy, biology, chemistry, veterinary science, food technology and statistics, while 54 are non-graduates who hold certificates (as Bachelor D3) as pharmacist, technology pharmacist, food chemist, chemist, electricians and pharmacy assistants (technical grades equivalent to high school and junior high school). The Division of Therapeutic Products and Hazardous Substances is the division, besides the other four divisions in the NQCLDF, which holds the responsibility to test medicines (incl. essential medicines), narcotic and psychotropic (licit and illicit) substances, non-electromedic medical devices, household chemicals for hygiene and sanitary purposes as well as cigarettes.

In 2011, the NQCLDF received US\$ 900 000 from the Global Fund to enhance capacity for testing the quality of AIDS/TB/malaria medicines. The scope of accreditation is based on ISO/IEC 17025:2005 - verification of testing methods for 150 drug items is used as the baseline of the laboratory's performance. It is hoped that in five years the laboratory capability will be increased to be 479 drug items (>300%), including most drugs in the National Essential Drugs List and several items from WHO Essential Drug List and from specific programme lists such as antituberculosis drugs, antiretrovirals and antimalarial drugs.

The Reference Substances Laboratory was established in 1985. The scope of work includes firstly analysis of raw material compared to primary reference substances. Secondly it includes reporting, packaging and distribution of secondary reference substances for qualitative and quantitative analysis (US Pharmacopeia reference standards (USP-RS); International Pharmacopeia reference standards (IC-RS) or The National Institute for Biological Standards and Control reference standards (NIBSC-RS), etc) and use as National Reference Substances or Indonesian Pharmacopoeia Reference Substances (now 235 items including drug, food and cosmetic additives but excluding vaccine working standard and reference bacteria in culture) and ASEAN Reference Substances (150 items).

In 2012, the laboratory distributed 3677 vials to provincial labs (31 labs), 887 vials to universities, institutes and pharmaceutical manufacturing laboratories and 797 vials were used internally.

In addition to the central NADFC, there are provincial offices of drug and food control. Each such office has five divisions covering investigation and product control, certification and information services, drug testing laboratory, food testing laboratory and a microbiology laboratory. In addition, there are sections for administration and a quality control manager. The reporting system consists of samples being taken by the Province Office's Inspector from the market (direct buy, or undercover buy) and sent to the laboratories. A report of the laboratory testing results is sent electronically to the Central Laboratory (NQCLDF) and related deputy to be evaluated. The reports are sent monthly if the samples meet the specification (MS) and two days after the test, when defective. The defective samples are evaluated or re-tested (if needed) by the central laboratories before action is taken (such as re-call of the drugs) and a report sent to the Deputy Head of NADFC as well as to the laboratory of origin as feedback. In 2011 - 2012, of 35 235 samples tested by provincial laboratories, 276 were found to be defective and sent to the central laboratories for evaluation. Of these, 135 were confirmed defective without retesting and 88 confirmed defective after retesting.

Variation in different testing results from different labs sometimes occurs and investigations should be made for laboratory improvements. These include: misinterpretation of analytical results or methods by the laboratory staff; miscalculation (halogenated or alkali salts form, water content, RS used, labels etc.); or differentiation on instrumentation or methods used.

To control variation in different testing results between laboratories, a number of actions are taken including:

- establishment of national laboratory standard operating procedures (SOPs) and work instruction for laboratories staff;
- provision of regular training and on-the-job training programmes;
- technical assistance for intended laboratories;

- regular establishment of proficiency tests;
- regular internal audits (ISO/IEC 17025:2005);
- re-test of random sampling to the samples that have been tested, regularly.

## **2.2. WHO Collaborating Centre for Quality Assurance of Essential Drugs, Thailand**

Dr Wiyada Akarawut, Deputy Director, Bureau of Drug and Narcotic, Department of Medical Sciences, Ministry of Public Health, Thailand

The Bureau of Drug and Narcotics (BDN) was established in 1974 as an official medicines quality control laboratory of Thailand. BDN is an organization within the Department of Medical Sciences, under Ministry of Public Health. In 1986, BDN was designated as WHO Collaborating Centre for Quality Assurance of Essential Drugs and has been re-designated every four years. The Terms of Reference (TOR) for WHO-CC activities, during 1986 to 2008, consisted of the following six objectives:

- (1) to develop or verify basic tests for use especially when a fully equipped laboratory or analytical expertise are not available. These basic tests should be simple and readily applicable for verifying the identity of active ingredients;
- (2) to coordinate the production of ASEAN reference substances for utilization within ASEAN member countries;
- (3) to perform the analysis of antimalarial drugs in supporting the Roll Back Malaria project;
- (4) to contribute in the development and review of drug monographs in the International Pharmacopoeia;
- (5) to conduct training on pharmaceutical analysis for staff of national regulatory authorities from WHO Member Countries;
- (6) to perform appropriate tests of drug products as requested by other national regulatory authorities.

However, since 2009, the TOR has been redefined to reflect current collaboration with WHO. Activities regarding basic tests, production of reference substances and the roll back malaria project (TOR # 1-3) are no

longer in the current TOR. But BDN continues these activities under different support. Therefore, the current TORs are as follows.

- (1) to verify new test methods in the development and review of specification of drug monographs with the focus on essential medicines in the International Pharmacopoeia and other working documents;
- (2) to perform drug quality control testing of medicines from Member countries of the South-East Asia Region and other countries in Mekong Region;
- (3) to train through WHO training programmes, the staff from national drug regulatory authorities in the South-East Asia Region as well as outside the Region.

For drug quality testing, BDN received samples mostly from Bhutan but has tested samples in past years from Maldives, Nepal and Nigeria. As for the training, BDN has organized training courses upon request for WHO fellows from South-East Asian countries almost every year. Participants have come from Bangladesh, Bhutan, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Cambodia, Lao People's Democratic Republic. The most requested training programme is on aspects of quality assurance/quality control of pharmaceuticals which is suitable for laboratory staff. Occasionally, BDN provides training on regulatory aspects, such as dossier evaluation and drug inspection. In addition to the TOR mentioned above, BDN has also participated in other WHO activities. These include: participation in studies on the establishment of international standards in collaboration with European Directorate for the Quality Medicines and Healthcare (EDQM); provision of a temporary adviser in the WHO consultation meetings on specifications for medicines and quality control laboratory issues, provision of a WHO consultant in WHO missions on improving drug testing laboratory in Bangladesh and on performing a situational analysis for establishing a drug testing laboratory in Bhutan. Finally, BDN appreciates the WHO-SEARO effort in organizing the first regional meeting of drug testing laboratories and hopes that the network initiative will move forward.

### **2.3. WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, Malaysia**

Dr Noraida Mohammed Zainoor, Senior Principal Assistant Director, Centre for Quality Control, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia

The Malaysian Regulatory Drug Testing Laboratory (MRDTL) is recognized as the National Pharmaceutical Control Bureau (NPCB) under the Ministry of Health, Malaysia and was set up in October 1978. Nowadays, NPCB executes laws and regulations such as the Sale of Drugs Act 1952, Dangerous Drugs Act 1952, Poisons Act 1952, Medicines (Advertisement & Sale) Act 1956 and Control of Drugs and Cosmetics Regulations 1984 to regulate pharmaceutical and natural or traditional products as well as to notify cosmetic products marketed in Malaysia.

In 1996, NPCB was given international recognition by the World Health Organization (WHO) as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals. Since then Malaysia has provided training to WHO fellowships for example from Sri Lanka, Bangladesh, Myanmar, Mongolia and Vietnam. NPCB is one of the participating authorities in Pharmaceutical Inspection Cooperation Scheme (PIC/S) since 2002. The scheme aims to lead the international development, implementation and maintenance of harmonized good manufacturing practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. NPCB Malaysia has been recently accepted as a member of the Organisation for Economic Co-operation and Development (OECD) for GLP (good laboratory practice) Compliance Monitoring Programme.

The two main activities of MRDTL are the evaluation of analytical data for pre-registration of pharmaceutical products and sample (products) testing for the pre-registration process (natural or traditional products only), and managing the surveillance programme (for pharmaceutical, traditional and cosmetics products) and enforcement programme (screening for pharmaceutical adulterants in traditional and cosmetics products). The main reference to evaluate dossier analytical data is the ICH (The International Conference on Harmonisation of Technical Requirements for

Registration of Pharmaceuticals for Human Use) guideline while the British and United States Pharmacopoeias are the main references to test samples.

Activities of MRDTL are classified into six sections namely, Pharmaceutical Chemistry Section, Biopharmaceutical Section, Natural Product Testing Section, Laboratory Coordination Section, R&D Section and Standardization and Quality Section. The MRDTL has about 43 pharmacists and 75 assistant pharmacists to do the activities. In January 2010, the MRDTL received an Accreditation of MS ISO/IEC 17025: 2005 by the Department of Standards, Malaysia on the scope of the microbial contamination test, heavy metal test (arsenic, plumbum, cadmium and mercury), disintegration test and uniformity of weight for traditional products. NPCB is also actively involved in proficiency testing schemes that are organized by the ASEAN, WHO, European Directorate for the Quality Medicines and Healthcare (EDQM) and other regulatory agencies to maintain and strengthen the skill and competency of MRDTL personnel. Besides that, at the ASEAN level, MRDTL continuously cooperates and collaborates with the ASEAN reference standard (ARS) production, ASEAN Working Group on Pharmaceutical Development (AWGPD) focusing on the ASEAN Non-Pharmacopoeial Analytical Method project and ASEAN Cosmetic Laboratory Committee (ACLC).

Statistical data between 2006 and 2012 shows that MRDTL performed tests on an average of 2000 samples per year and evaluated dossier analytical data for about 1500 products per year. About 800 samples under the enforcement programme were received per year and about 20% of these samples were found to be adulterated with pharmaceutical substances or drugs. The main challenge that MRDTL faces is screening and detection of pharmaceutical adulterants and authentication using chemical markers in natural or traditional products, since it requires extensive knowledge and skills, as well as technical expertise.

The MRDTL is willing to give support and training on quality control systems and GMP inspection to South-East Asian Member Countries.

## **2.4 WHO Collaborating Centre for Drug Quality Assurance, Singapore**

Dr Xiaowei Ge, Senior Analytical Scientist, Pharmaceutical Lab, Pharmaceutical Division, Applied Sciences Group, Health Sciences Authority (HSA), Singapore

The Pharmaceutical Laboratory in the Pharmaceutical Division, under the Applied Sciences Group (ASG) of Health Sciences Authority (HSA), Singapore, is the national laboratory which provides analytical investigation services on western medicines and complementary health products for the nation's regulator, Health Products Regulation Group (HPRG), HSA, Singapore and other regulatory agencies like the Police Department under the Ministry of Home Affairs. Thus, the Laboratory analyses a wide variety of health products in Singapore, ranging from western medicines to traditional medicines using liquid and gas chromatography, mass spectrometry, ultraviolet, FIAS-atomic absorption spectroscopy, inductively coupled plasma mass spectrometry (ICPMS) and various liquid and gas chromatography coupled with mass spectrometry.

The Laboratory has a staff strength of 24, with 9 Scientists and 15 laboratory officers. The Laboratory has been accredited under the Singapore Accreditation Council - Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) since 14 July 1997. The Laboratory is inspected annually by SAC-SINGLAS to ensure that it meets the international standards required under ISO/IEC 17025:2005.

The Pharmaceutical Laboratory was designated as the World Health Organization (WHO) Collaborating Centre for Drug Quality Assurance since 1993. The Laboratory provides on-going support to WHO in the development of draft monographs for WHO International Pharmacopoeia and the training of WHO fellows in pharmaceutical analysis. With HSA granted observer status to the European Pharmacopoeia Commission in February 2012, the Laboratory will be able to participate in other activities of the European Directorate for the Quality Medicines and Healthcare (EDQM). This will further enable the Laboratory to stay informed of public health matters and also share expertise on issues pertinent to pharmaceutical analysis. The laboratory will continue to support INTERPOL

in strengthening training in the investigations and testing of substandard/spurious/falsely-labelled/falsified/counterfeit medical products for law enforcement officers. As an ASEAN Member Country, the Laboratory will also continue to support ASEAN initiatives and programmes.

The scope of work includes ensuring the quality and safety of all medicines (Western, Chinese, health supplements), providing investigative services to hospitals, advising the pharmaceutical industry on products quality control, and conducting research and development projects related to regulatory science, as well as participating in regional and international activities. A number of examples of SSFFC (substandard/spurious/falsified/falsely-labelled/counterfeit) products investigated were shared. From 1998 to 2009, a total of 16 696 adverse drug reaction (ADR) cases were reported to the HSA. Of these ADRs, 627 (3.8%) were due to herbal products, mostly on account of adulteration with western medicines. Products implicated in ADRs were mostly those used for sexual performance (46.4%), joint pain relief (5.9%) and weight loss (4.3%). There is an emerging trend of adulteration with analogues, which are unregistered active pharmaceutical ingredients – designer drugs – which can only be detected using advanced equipment and highly trained staff. Such analogues have been detected in illegal health products, candy/sweets and coffee powder.

The Pharmaceutical Laboratory, HSA, is willing to help build capacity in the Region, including participation in a network, provision of training and provision of consultants to provide technical support.

### 3. Country reports

#### 3.1 Bangladesh

***Drug Testing Laboratory, Directorate General of Drug Administration,  
Ministry of Health and Family Welfare, Dhaka, Bangladesh***

*Mr A A Salim Barami, Director CC, Directorate General of Drug Administration, Dhaka, Bangladesh*

**The legislative framework** is the Drug Control Ordinance 1982, the Drug Acts 1940, the Drug Rules 1945 and 1946, amendments of these Acts and Ordinances, the National Drug Policy 1982 and 2005 and directives of the Ministry of Health and Family Welfare. The government, health and pharmaceutical sectors are committed to provide good quality medicines at an affordable cost.

**Drug testing laboratories** comprise two – the National Control Laboratory (NCL) and a regional laboratory in Chittagong (CDL). The NCL has recently been renovated and modernized with support from WHO and World Bank. It now has a water for injection (WFI) system, electricity and other utility services. The NCL includes chemical, microbiology and pharmacology departments and the CDL includes chemical and microbiology departments. The functions of the laboratories consist of quality control of locally produced and imported drugs, testing and reporting of pre-registration drug samples and post-market drug samples, and testing and reporting of samples on request.

**Staff** comprises 54 technical and 21 supporting staff. The technical staff includes medical doctors, pharmacists, chemists, biochemists, engineers, medical technologists and technical assistants. While 42 new personnel have been recruited to the Directorate General of Drug Administration, no extra personnel have yet been recruited for the drug testing laboratories (DTL). Approval by MOHFW for a new organogram proposal is awaited.

**Samples** analysed include allopathic medicines (using British and US pharmacopoeias) including raw materials and finished products, traditional medicines (Unani and Ayurveda), homeopathic and biochemic medicines, herbal medicines, medical devices, chemicals and reagents. During 2010 - 2012, in NCL 13 932 samples were received and 9973 tests were

performed and in CDL 2696 samples were received and 1536 tests performed. Approximately 17% of these samples were pre-registration samples and the rest were from the market and about 2 - 3% of samples were found to be substandard.

**Quality of laboratory practices** is guided by an NCL quality manual which is prepared for compliance to ISO 17025-2005 and also has to meet the standards of the National Metrology Laboratory. All personnel must be familiar with the quality documentation. WHO is providing technical support and training to the drug regulatory and NCL staff by providing short-term consultants (STC) in Bangladesh and through overseas fellowships.

**The equipment** of the NCL includes: ultraviolet-visible (UV-VIS) spectrophotometer, electronic balances, Fourier transform near infrared (FT-NIR) spectrophotometer, Karl Fisher titrator, HPLC (high performance liquid chromatography), electronic refractometer, liquid particle counter, Gas chromatography, ELISA microplate washer, ELISA microplate reader, cold room, dissolution test apparatus, ultrasonic cleaner, water purification system, incubators, atomic absorption spectrophotometer, memory thermometer, water distiller, magnetic stirrer with regulator, rotating viscometer, muffle furnace, centrifuges, microbiological ovens, hardness testers, disintegration testers, multiple sample starter, melting point determination apparatus, polarimeter, colony counter, thin-layer chromatography (TLC), biological safety cabinets, ice-lined refrigerators, autoclaves, fume hoods, eye face wash shower, pyrometer, reflux condenser, vortex meter, hot water bath, ultrasonic bath, kinetic LAL (limulus amebocyte lysate) test apparatus, filtration units, light microscope, pH testers, and steam sterilizer.

## 3.2 Bhutan

***Drug Testing Laboratory, Public Health Laboratory, Department of Public Health, Ministry of Health, Bhutan***

*Mr Sangpo Offtg. Chief Regulatory Officer of the Post-Market Control Division, Drug Regulatory Authority, Thimpu, Bhutan*

There are no pharmaceutical manufacturers in Bhutan, so all the medicines, for both human and veterinary use, are imported, except traditional

(pso-ba-rig-pa) medicines, which are manufactured locally by Menjong Sorig Pharmaceuticals.

**The legislative framework** is the Medicines Act 2003 which regulates the import, export, manufacture, distribution and sale of medicines. It aims to protect the health of both humans and animals from use of counterfeit and substandard medicines. It is government policy that every citizen gets access to free essential medicines. To transform the government's policy for free medicines and to enforce the provisions of the Act into practice, the Medicines Rules and Regulation was first drafted in 2005 with subsequent revisions in 2008 and 2012. As per the Act, Drug Regulatory Authority (DRA) was established in 2004. DRA is guided by the Bhutan Medicines Board (BMB) for policy decision and by the Drug Technical Advisory Committee (DTAC) for technical guidance which also acts as technical adviser to the board. The DRA is an independent autonomous government agency headed by the drug controller with three technical divisions viz., Registration, Inspection and Post-Marketing Control Divisions. The Post-Marketing Control Division is responsible for sampling of medicinal products to be sent for quality control (QC) test.

**A Drug Testing Laboratory (DTL)** headed by the government analyst is enshrined in the Medicines Act 2003. The mandate to establish a DTL was formally given to the Public Health Laboratory (PHL), Department of Public Health, Ministry of Health, following the board decision in 2010 in order to avoid any conflict of interest. Since then, the PHL has recruited one pharmacist to work on establishing the DTL and is now in the process of developing DTL human resource capacity and equipment with support from WHO. Currently, due to lack of analytical equipment, the DTL does not analyse any samples, but will start soon for selected quality parameters. The physical infrastructure for DTL is already under construction in the new the Public Health Laboratory building which is scheduled to be completed by September 2014. Once the physical infrastructure is ready, it will be some time before a fully functional DTL is operational as essential equipment, reagents, reference standards and qualified technical staff will all be needed.

**Staff** currently comprises one full-time pharmacist appointed in the Public Health Laboratory to look after the testing of medicinal products for the DRA and to develop a proposal to have a DTL. However, recruitment

of an additional pharmacist is under process and one lab technician is undergoing diploma training on drug testing.

**Samples** of medicines were sent initially, during 2008 - 2009, directly to the Bureau of Drugs and Narcotics, Department of Medical Sciences, Thailand, by the DRA. Following the Bhutan Medicines Board directive in 2010, samples were sent to the Public Health Laboratory, which, in turn, sent them to the Bureau of Drugs and Narcotics, Department of Medical Sciences, Thailand. However, due to the time taken for reports to come back from Thailand, PHL signed a Memorandum of Understanding with the Shriram Institute for Industrial Research, Delhi, India, in 2011 for sample testing and samples are now sent there. Medicinal product sample collection is generally done twice a year based on the receipt of supplies in the government health institutions and private pharmacies. Sampling of medicines is also done based on complaints received from health workers from government health facilities. During 2008 - 2013, a total of 170 samples were sent to reference laboratories for quality testing and around 12% failed quality tests.

**Future actions** are to establish a functional DTL in Bhutan. This is already under process with support from the WHO. Recently, the government has also recognized the importance of establishing a DTL and has committed to provide support.

### 3.3 Democratic People's Republic of Korea

***National Drug Inspection Institute, Ministry of Public Health, Pyongyang, Democratic People's Republic of Korea***

*Dr An Yong Hwa, Pharmacist, National Drug Inspection Institute, Ministry of Public Health, Pyongyang, Democratic People's Republic of Korea and Mrs So Yong Sun, Interpreter, MOPH, Pyongyang, Democratic People's Republic of Korea.*

**Drug Testing Laboratories** comprise the National Drug Inspection Institute and 12 branch offices, one in each province. The laboratories test the quality of both allopathic and traditional medicines. A risk-based approach is used starting with an assay.

**Staff** comprises about 100 staff at the central level and 40 staff in the provinces.

**Samples** are tested centrally (about 3000 - 4000 annually) and in the provinces. Provincial laboratories refer some samples (mostly allopathic medicines) to the centre for testing.

**Future actions** will focus on rectifying current problems which include a lack of references standards, reagents and equipment. However, the government has increased the budget to purchase reagents and to modernize the laboratories. The Global Fund is supporting the purchase of new laboratory equipment and WHO is supporting overseas training on good laboratory practice. A local training for drug regulatory staff on quality control was carried out in March 2013.

### 3.4 India

#### ***Central Drug Testing Laboratory and National Drug Testing Laboratories, India***

*Dr N Murugesan, Director, Central Drug Testing Laboratory, Chennai, India*

India has a very large industry worth US\$ 20 billion, with a domestic market of US\$ 11.6 billion and an export market of US\$ 10.3 billion. Imports amount to US\$ 3.2 billion. There are 172 US FDA approved manufacturing facilities and 153 EDQM certified facilities.

**The legislative framework** is the Drugs and Cosmetics Act of 1940 and Rules of 1945 and the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare is the responsible implementing agency. The objective of the Act is to ensure the safety, efficacy and quality of drugs and it covers regulation of the manufacture, sale, distribution and import of all drugs, cosmetics, biological, medical devices and other products including traditional medicines. Amendments to the Drugs and Cosmetics Acts in 2008 enhanced penal provisions and introduced new sections on the regulation and restricted manufacture of drugs in the case of an epidemic or natural calamity, the definition of adulterated cosmetics, compounding of offences

and special courts. A further Amendment Bill 2012 is still in the pipeline to incorporate more stringent penal provisions, register clinical research organizations and ethics committees, mandate clinical trial inspections and introduce guidelines for compensation, amongst other things.

**Drug regulation** is managed by the CDSCO which has its headquarters in Delhi and there are nine zone/subzone branches located in port and airports. The CDSCO is headed by the Drugs Controller of India and is responsible for making legislation; laying down standards for drugs, cosmetics, diagnostics and devices; updating the Indian Pharmacopoeia; registration and control on the quality of imported drugs; and clearance of new drugs and investigational new drugs. The CDSCO is also responsible for producing guidelines for promotional literature, promotion of the rational use of medicines, guidelines on self-medication, monitoring of clinical trials and bioequivalence studies, monitoring ADRs, interaction with consumers and handling of complaints, central nodal intelligence-cum-legal cell to coordinate interstate activities and training of regulatory and laboratory personnel.

State drug licensing authorities under the ministries of health of the state governments control the local manufacture and sale of drugs; licensing of manufacturers and sale outlets; monitoring compliance with the conditions of licenses by periodic inspection; post-marketing surveillance; and penal action against defaulters. Joint approval of both the central and state levels are needed for licenses for the manufacture of vaccine and sera, blood products, r-DNA products, large volume parenteral products and medical devices. The Mashelkar Committee recommends that one autonomous Central Drug Authority be created with a centralized licensing system but this has not been implemented.

**National drug testing laboratories** comprise eight national central government laboratories (six for drugs, one for vaccines and one for r-DNA and diagnostic kits), state laboratories and more than 500 private laboratories. National laboratories analyse drugs and cosmetics sent by CDSO branch offices at ports and airports and also by state drug regulatory authorities. State laboratories analyse samples sent by the State regulatory authorities.

**Samples** received during 2010 - 2013 from four national laboratories in Mumbai, Chennai, Kolkata and Chandigarh, were 28 157 samples of which 24 014 samples were tested. During 2007 - 2012 in all central and state government laboratories, 221 274 samples were tested of which 11 426 were not of standard quality and 579 were declared spurious or adulterated. Some 856 prosecutions were launched but only 96 decided and 641 people were arrested. The value of substandard/spurious/falsified/falsely-labelled/counterfeit (SSFFC) medicines was INR 383 621 721 and also 18 264 raids were conducted.

**Future actions** include a capacity-building project which is in process to: achieve uniform good manufacturing practice (GMP) and good laboratory practice (GLP) and better enforcement of the Drug and Cosmetics Act; enhance capacity of laboratories at central and state levels through infrastructure strengthening and training of personnel; strengthening ADR surveillance systems; and augmentation of the Indian Pharmacopoeia Commission for preparation, printing and distribution of the National Formulary of India. The project will cover state drug laboratories. Training will also cover drug regulatory staff and industry personnel.

### 3.5 Indonesia

***Drug Testing Laboratory of National Quality Control Laboratory of Drug and Food (NQCLDF), Jakarta, Indonesia.***

*Dra Ati Setiawati, Head of Therapeutic Products and Hazardous Substances Division, NQCLDF, National Agency of Drug and Food Control, Jakarta, Indonesia.*

**The legislative framework** consists of the Ministry of Health Decree No.145/MenKes/SK/IV/1978 which decreed the initiation of the National Drug Testing Laboratory in 1978.

**The National Drug Testing Laboratory** is the National Quality Control Laboratory of Drug and Food (NQCLDF) initiated in 1978. In 1984, development of a second laboratory, donated by Japan International Cooperation Agency (JICA), extended the scope of analysis to biological

tests (pharmacology, toxicology, vaccines, and potency). NQCLDF has five divisions; one of these divisions is the Therapeutic Products and Hazardous Substances. The Drug Testing Laboratory, Biopharmacy Laboratory and Narcotic Laboratory are under the Section of Physicochemical Drugs, Narcotics and Psychotropics; which is one of two sections in the Therapeutic Products and Hazardous Substances Division. The Section on physicochemical testing is located in first laboratory, equipped by electricity, generator and UPS. The main functions of NQCLDF are to act as reference laboratory for sample testing, establish methods of analysis and to provide a training centre for 31 provincial laboratory staff.

**Staff** in the physicochemical section comprises 20 persons - 16% with Master's degrees, 52% pharmacists, 16% chemists and 16% college graduates.

**Equipment** in the physicochemical section includes: autotitrator, Karl Fisher titrator, pH meter, micro and analytical balance, UV-VIS spectrophotometer, Fourier transform infrared (FTIR) spectrophotometer, densitometer, thin-layer chromatography (TLC) system; high performance liquid chromatography (HPLC), fluorescence and photodiode array (PDA); ultra-performance liquid chromatography (UPCL), atomic absorption spectrometer (AAS), dissolution tester, dissolution media preparation, disintegration tester, gas chromatography-mass spectrometry (GC-MS), and liquid chromatography-mass spectrometry (LC-MS/MS).

**Samples** are collected by 31 provincial laboratories, which then test them based on guidelines of sampling and testing. If there are any samples that do not meet requirements, they are sent to NQCLDF for confirmation tests. The Section of Physicochemical in NQCLDF tested 527 samples in 2011 and 566 samples in 2012.

**Quality of laboratory practices** is regularly assessed. In 1999, NQCLDF was accredited by KAN-BSN (National Accreditation Body member APLAC, ILAC) regarding ISO 25. In 2003, NQCLDF was reaccredited by KAN-BSN regarding ISO 17025; and finally in 2013, it will be reassessed by KAN-BSN regarding ISO 17025. NQCLDF participates in the Laboratory Network: FIP-LMCS Proficiency Programme, Laboratory of the Dutch Pharmacists – Netherlands.

**Future actions** are based on Strategic Plan 2010 – 2014. The Physicochemical section plans to improve drug testing capability, focusing on anti-tuberculosis medicine, antimalarials and antiretrovirals. Since 2010, 150 kinds of sample monograph have been accredited by the National Accreditation Body. In 2012, support from the Global Fund will enable training of the Section's staff, training of trainers for province staff and procurement of reagents, reference standards, accessories and instruments. In 2014, key performance indicators for improved testing capabilities will be 30 verified methods of analysis per year until 2016.

### 3.6 Maldives

***Pharmaceutical Testing Laboratory, National Health Laboratory (NHL), Maldives Food and Drug Authority (MFDA), Malé, Maldives***

*Ms Aishath Mohamed, Director, Maldives Food and Drug Authority, Malé, Maldives*

**The legislative framework** consists of the Medicines Act and Regulations under which the Maldives Food and Drug Authority (MFDA) operates.

**The National Drug Testing Laboratory** consists of the Pharmaceutical Testing Laboratory which is a unit established under the National Health Laboratory (NHL) of the MFDA. Pharmaceutical testing covers chemical and microbiological analysis. Microbiological analysis is done in the same facility where microbiological analysis of food is done but chemical analysis is done in a separate laboratory set up inside the NHL.

**Staff** comprises only one person who is trained in pharmaceutical testing and has a background in chemistry. Technical assistance is provided to the laboratory by the Medicine and Therapeutic Goods Division (MTG) of the MFDA.

**Equipment** available includes UV/visible spectrophotometer, melting point apparatus, weighing balance, thin-layer chromatography (TLC) equipment, Fourier transform infrared spectroscopy (FTIR), high performance liquid chromatography (HPLC) and dissolution apparatus.

**Samples** of registered products are sent to the laboratory by the MTG/MFDA. Assay testing is mainly done according to British Pharmacopoeia standards. Indian, US and International pharmacopoeial standards are also followed. Identification tests follow WHO guidelines. In 2012, ten samples were tested.

**Future action** is to identify a reference laboratory in the Region to send emergency samples.

### 3.7 Myanmar

**The legislative framework** consists of the National Drug Law 1992 in which the fifth paragraph states the need for quality assurance in respect of manufacture and for laboratory analyses of all pharmaceutical products including raw materials and registered drugs.

**The National Drug Testing Laboratory**, known as the Drug Control Laboratory, is under the Myanmar Food and Drug Administration. It was originally established in Yangon in 1995 and a branch laboratory established in Mandalay in 2007 for post-marketing surveillance. In 2009 the Drug Control Laboratory was moved to Nay Pi Taw and it has four sections – pharmaceutical chemistry, drug microbiology, bio-standardization and pharmacology. The routine function of the Drug Quality Control Laboratory is quality testing of pre-market and post-market samples, including from the disease control programmes.

**Staff** comprises two assistant directors, four officers, nine pharmacists and nine lab technicians. On-the-job training is provided and some training is supported by US Pharmacopoeial Convention (USP) and WHO – but only eight staff have been exposed to external training.

**Equipment** consists of one HPLC, three UV spectrometers, two infrared (IR) spectrometers and one potentiometric titrator.

**Samples** received in 2011 - 2012 were 3868, on which 3230 tests were performed. About 13 - 15% of samples are collected as part of post-market surveillance. Thus, the Drug Control Laboratory (Myanmar) is overworked for its capacity. The Pharmaceutical Chemistry Laboratory tests

pharmaceuticals to see if they meet the specifications of various reference pharmacopoeias (British, US and European pharmacopoeias).

**Quality of laboratory practices** is not assessed externally but there are plans to participate in laboratory networks, specifically to join the USP technical assistance programme and to participate in the Network of Official Medicines Control Laboratories of the Asia–Pacific (NOMCOL) supported by USP. This will include support for reference standards, technical training and proficiency testing.

**Future actions** include plans to expand the setup of the Drug Control Laboratory but more skilful laboratory technicians, hardware and software facilities and a maintenance programme for major analytical equipment will be needed. Capacity-building of technical staff, sustainable development of the facilities and updating of knowledge on quality control will be needed to improve and expand QC activities and build up to the standard of good laboratory practice.

### 3.8 Nepal

***National Medicines Laboratory, Ministry of Health and Population, Kathmandu, Nepal***

*Gajendra Bahadur Bhujju, Senior Pharmacist, Department of Drug Administration (DDA) and Bade Babu Thapa, Senior Pharmacist, Logistics Management Division (LMD), Department of Health Services (DHS), Ministry of Health and Population (MOHP).*

**The legislative framework** consists of the Drug Act 1978 which stipulates that the National Medicines Laboratory is the principal organization for testing, analysis and scientific research of drugs.

**The National Drug Testing Laboratory** is called the National Medicines Laboratory (NML). It functions under the Department of Drug Administration, Ministry of Health and Population, Government of Nepal. This laboratory supports the Government of Nepal to provide safe medicines of adequate quality and efficacy to the people of the nation through pharmaceutical analysis.

**Staff** comprises one NML Chief, with more than 30 years' experience, under whom are three senior divisional chemists with more than 20 years' experience, covering the chemical laboratory, the instrument laboratory, and microbes. Under the divisional chemists are professional staff including chemists and pharmacists, some of whom have more than 10 years' experience. There is also a good laboratory practice (GLP) section. About 80% of the posts are filled.

**Equipment** includes four machines for high performance liquid chromatography (HPLC), three UV spectrophotometers, one infrared (IR) spectrometer, one flame photometer, and three dissolution testing machines.

**Samples** tested during 2011 - 2012 comprised 669 samples of which about 2% failed quality tests. Drug samples (111 in 2011 - 2012) are collected by the Department of Drug Administration routinely from different regions of the country during the process of inspection and investigation of drugs by drug inspectors. Drug samples (502 in 2011 - 2012) are also submitted by the Department of Health Services, embassies, Nepal Police, customs and courts for quality control purposes. Pre-market analysis of drugs from the domestic pharmaceutical industries and imported drugs from other countries is also done in the process of registration for issuing marketing licenses. Drug samples as part of post-market surveillance (56 in 2011 - 2012) are also tested.

**Quality of laboratory practices** has been monitored since 1998 through participation in proficiency testing programmes run by WHO, HSA Singapore, Wetenschappelijk Instituut Nederlandse Apotheker (Department of the Royal Dutch Association for the Advancement of Pharmacy) Netherlands, as well as Bureau of Standards in Nepal.

**Future activities** include: acquiring new equipment (atomic absorption spectroscopy, nuclear magnetic resonance (NMR) spectroscopy, infrared spectroscopy) and reference standards which are expensive; capacity-building – training, including higher education which is needed to update staff in the latest techniques in tests and analysis of medicines; human resource retention and motivation (e.g. promotion); provision of

regular electricity and water, and incentives against chemical hazards. There is a draft plan for strengthening the NML.

### 3.9 Sri Lanka

#### ***National Drug Quality Assurance Laboratory, Directorate General Health Services, Ministry of Health, Colombo, Sri Lanka***

*Mr A Ajith Priyadarshana, Director, National Drug Quality Assurance Laboratory, Colombo, Sri Lanka*

**The legislative framework** consists of the Cosmetics, Devices and Drugs Act (CDDA) No 27 of 1980 which is the legislative framework to control cosmetics, drugs and devices and is administered by the Drug Regulatory Authority under the Director-General of Health Services (DGHS), Ministry of Health.

**The National Drug Testing Laboratory**, known as the National Drug Quality Assurance Laboratory (NDQAL), is a fully equipped modern laboratory. It was established in 1990, following the prior establishment in 1971 of a drug quality control laboratory where only chemical analyses were done. The NDQAL is also under DGHS. There is an additional approved analyst. The NDQAL has three divisions – chemical, microbiological, biological as well as an administration office. The main function of the NDQAL is analysis of locally manufactured and imported pharmaceuticals, at the pre-marketing and post-marketing stages, in order to ascertain the quality of products and to issues recommendations on quality.

**Staff** comprises 46 technical staff positions with 36 staff in position and 28 non-technical staff positions with 26 staff in position. Technical staff includes graduates in chemistry, botany, zoology, pharmacy with postgraduate qualifications in pharmaceutical analysis, pharmaceutical technology, pharmaceutical services, analytical chemistry, experimental biotechnology, biochemistry, molecular biology, polymer chemistry and food technology. Most scientific officers have had training on pharmaceutical analysis, good laboratory practice and good manufacturing practice from national regulatory authorities of Australia, Malaysia,

Singapore, and Thailand, or from the National Institute of Pharmaceutical Educational Research in India.

**Sample** testing is random. All tests are performed as per the label claim using specifications of the British and US pharmacopoeias. If no standard specifications are indicated on the label then validated test procedures are required. During 2009–2012, 3067 samples were received and 2963 reports issued. Most samples were received through complaints, or for registration purposes, or from post-marketing surveillance.

**Quality of laboratory practices** is maintained by the regular participation of NDQAL in external quality assurance assessment (proficiency testing) schemes conducted by WHO/EDQM and FIP-LMCS Netherlands.

**Equipment** includes HPLC, dissolution apparatus, UV/visible spectrophotometer, FTIR spectrophotometer, atomic absorption spectrophotometer, disintegration apparatus, Karl Fisher titration unit, analytical balances, melting point apparatus, friability tester, pH meters, cooled incubators, polarimeter, potentiometric titrator, autoclave, sterilizing oven, freeze dryer, water distiller, hot air oven, drying cabinets, muffle furnace, laminar airflow cabinet, bio-safety cabinet, top loading balances, pyrogen processor, incubators, water baths, shaking water bath, vacuum ovens, microscope, magnetic stirrer/hot plates, vortex mixer, ultrasonic baths, refrigerators, freezers and centrifuges.

### 3.10 Thailand

***Bureau of Drug and Narcotic, Department of Medical Sciences, Ministry of Public Health, Thailand***

*Witinee Kongsuk, Assistant Head, Physico-Chemical Testing Section, Bureau of Drug and Narcotic, Bangkok, Thailand*

**The legislative framework** consists of the Drug Act 1967, which has been amended four times, the last time being in 1987.

**The National Drug Testing Laboratory** is the Bureau of Drug and Narcotic (BDN) which serves as Thailand's national quality control laboratory within the Department of Medical Sciences, Ministry of Public Health. Within BDN, there is an administrative office, and sections on quality and technical development, Thai pharmacopoeia, physicochemical testing, biological testing, narcotics, reference standards and bioequivalence testing. The roles and functions of BDN are (1) chemical and biological testing of pharmaceutical products, active pharmaceutical substances, and drug containers (pre-marketing assessment and post-marketing surveillance), (2) analysis of narcotics, illicit drugs and psychotropic substances in seized material and biological samples, (3) production of reference substances, (4) establishment of Thai Pharmacopoeia and Thai Herbal Pharmacopoeia, (5) research and development, (6) training centre and proficiency test (PT) provider.

**Staff** comprises 137 staff, including 68 pharmacists, 14 scientists, 12 laboratory assistants, 10 administrators and 33 other persons.

**Equipment** includes high performance liquid chromatography (HPLC), ultra-performance liquid chromatography (UPCL), gas chromatography (GC), gas chromatography-mass spectrometry (GC-MS), liquid chromatography- mass spectrometry (LC-MS/MS), capillary electrophoresis, dissolution tester, UV-vis spectrophotometer, FTIR spectrometer and atomic absorption spectrometer.

**Samples** analysed annually are approximately 2500 samples – of which about 14% are herbal products and 19% are illegal drugs. There is collaboration between BDN and hospitals all over the country for quality assurance under the universal health coverage scheme and 12 027 samples have been tested during 2002 - 2011. There is collaboration between BDN (which does drug testing) and the Thai FDA (which collects samples from manufacturing, import and other sites) to undertake post-marketing surveillance.

**Quality of laboratory practices** is maintained and improved by BDN's regular participation in proficiency testing (PT) programmes organized by competence providers such as EDQM, WHO, Laboratory and Medicines Control Section of the International Pharmaceutical Federation

(LMCS-FIP), Wetenschappelijk Instituut Nederlandse Apotheker (Department of the Royal Dutch Association for the Advancement of Pharmacy) Netherlands, IFM Quality Services Limited in Australia, and the United Nations of Drugs and Crime proficiency testing for narcotics. BDN has been ISO/IEC 17025 certified since 1994 and a WHO prequalified laboratory since 2012. In addition, BDN has been designated as a WHO Collaborating Centre for Quality Assurance of Essential Drugs since 1986.

**Collaborative** activities include:

- collaboration with the United States Agency for International Development (USAID) on the Promoting the Quality of Medicines (PQM) Programme by serving as a confirmatory testing laboratory and providing lecturers for screening test by Minilab® in the Roll Back Malaria Project;
- a quality control laboratory for the project “Partnership for containment of artemisinin resistance and moving forwards the elimination of plasmodium in Thailand” in collaboration with Department of Disease Control, Thailand;
- ASEAN Consultative Committee for Standards and Quality-Pharmaceutical Product Working Group (ACCSQ-PPWG);
- ASEAN Working Group on Pharmaceutical Development (AWGPD);
- ASEAN TMHS (Traditional Medicines and Health Supplement) Scientific Committee (ATSC);
- lead country and coordinator of ASEAN Reference Standards Project – for which it provides 150 substances;
- proficiency testing provider for pharmaceutical quality control laboratories in Thailand and ASEAN Member Countries.

### 3.11 Timor-Leste

***Warehouse Management and Drug Testing, SAMES, Ministry of Health, Dili, Timor-Leste***

*Mr Pedro A da Silva, Director of Warehouse Management and Drug Testing at the National Laboratory and Ms Saturlina Ximenes, Head of Section for Drug Testing and Warehouse Management, SAMES, Ministry of Health, Dili, Timor-Leste.*

**A Drug Testing Laboratory** (DTL) does not yet exist. A mini laboratory was established under the Warehouse of Drugs and Equipment under the Central Medical Store, SAMES, in 2011.

**Staff** comprises two persons in the mini laboratory, one with a pharmacy background trained in 2009 at Frankfurt University in Germany. The staff allocation is five, so more staff is needed.

**Equipment**, reagents and reference standards available are in line with that needed for a mini laboratory. Tests include physical inspection, degradation test, colour reaction test and thin-layer chromatography (TLC).

**Sample** testing is done according to the mini laboratory manual and depends on the goods that arrive in the warehouse. Physical inspection and the degradation test are done for all items (tablets). Colour reaction tests have been done for 25 tablet items and TLC test for 31 tablet items.

**Future action** is to acquire reference standards, pharmacopoeias, WHO technical guidelines, increase staff allocation, arrange training for staff, build capacity to participate in external quality assurance schemes for mini laboratories and to identify a regional reference laboratory to send emergency samples.

## **4. Group work**

### **4.1 Introduction**

Dr Aparna Shah briefed delegates on what to do during group work. She reminded participants that ensuring drug quality is a very important component of the health system and a topic of public concern. Quality of drug testing laboratories is affected by methodology, instruments and personnel as well by sampling, transport, storage and infrastructure. Quality testing of drugs (quality control) is only one part of quality assurance which also relies on drug policy, drug regulation, procurement procedures and the supply chain. Quality testing of drugs may be very complex and it is not possible for all laboratories to do everything. However, all countries can do something to ensure the quality of drugs even without sophisticated laboratories, and it is important that countries have drug testing laboratories that suit their context and needs.

It was explained that there would be two groups as follows:

- Group A: Facilitators – Dr Wiyada Akarawut and Dr Ge Xiaowei
  - Bhutan, Timor-Leste, Maldives, Democratic People’s Republic of Korea, Nepal, Myanmar
- Group B: Facilitators – Dra Anny Sulistiowati and Dr Noraida Mohammed Zainoor
  - India, Indonesia, Thailand, Bangladesh, Sri Lanka

Each group was to discuss:

- (1) Challenges and needs – which will be different in smaller and larger countries,
- (2) How to overcome the challenges,
- (3) Role of government, WHO and partners, and
- (4) Mechanism for forging networks.

After discussion each group was to make a presentation and then there would be plenary discussion to make recommendations.

## 4.2 Group A

It was concluded that the major challenges facing smaller and/or less developed countries of the Region include: limited infrastructure, shortage of human resources including competent and skilled personnel; lack of equipment, maintenance and validation of equipment, primary reference standards, reagents and chemicals; lack of budget; delay in receiving reports from external laboratories; and lack of information-sharing between Member States.

It was agreed that overcoming the challenges will require:

- Political commitment and government support to build permanent positions in the laboratory and adequate resource allocation;
- Identification of the basic minimum tests and equipment required for all countries – which are:
  - physical examination
  - mini laboratory
  - identification tests
  - assays (in accordance to the specification standards using titration, UV/Visible spectrometer)
  - dissolution apparatus, disintegration apparatus
  - weighing balance
  - HPLC
- Identification of the required staff allocation (qualifications, number) depending on workload and the tests done:
  - 3 - 5 staff in Bhutan, Timor-Leste and Maldives
  - 40 - 50 staff in Nepal, Myanmar and Democratic People's Republic of Korea
- Technical and financial support from government and donors;
- National and regional networking and identifying a focal person in each country for information-sharing and dissemination.

**Recommendations** were made as follows:

Governments should show commitment to supporting drug testing laboratories through allocation of human resources and development of a strategic plan for development of the Drug Testing Laboratory.

WHO/donors should provide:

- Technical support to develop the strategic plan (WHO)
- Technical and financial support in training:
  - In-country training by external experts (hands-on) – as identified by WHO and the collaborating centres
  - Training and study visits to the WHO collaborating centres
- Reference standards, pharmacopoeias, technical guidelines
- Capacity-building in external quality assurance systems

A regional drug testing laboratory network should be established in the Region, with links to ASEAN and SAARC networks and involving the WHO collaborating centres, and for which a country focal point must be identified.

### 4.3 Group B

It was concluded that the major challenges facing the larger and/or more developed countries of the Region and methods to overcome them are as in the table below:

	<b>Challenges</b>	<b>Methods to overcome challenges</b>
1	Retention of trained QC personnel	(a) Mobilization of staff based on priority/demand (b) Contractual appointment (c) Need-based criteria for recruitment
2	Insufficient infrastructure	
	• Building	(a) Appropriate internal and external funding

	<b>Challenges</b>	<b>Methods to overcome challenges</b>
	<ul style="list-style-type: none"> <li>Laboratory equipment</li> </ul>	(a) Appropriate internal and external funding (b) Acquiring appropriate analysis technology
	<ul style="list-style-type: none"> <li>Sustainable services and maintenance of analytical instrumentation</li> </ul>	(a) Appropriate internal and external funding (b) Support from international agencies especially WHO
	<ul style="list-style-type: none"> <li>Utilities</li> </ul>	Government support
3	Long-term and current financing	(a) Sufficient allocation for current laboratory needs (b) Certain percentage of testing fee should be used for laboratory development and current expenditure
4	Lack of expertise	(a) Training and training of trainers, on job training (b) Further education and fellowship
5	Procurement of reference standards for active pharmaceutical ingredients (API) and impurities	Collaboration, support and training from countries that have capability to produce reference standards
6	Testing method development for non-compendial pharmaceutical products	Development of harmonized testing method for non-compendial methods (ncm)
7	Laboratory accreditation	Technical assistance to achieve and sustain the laboratory accreditation
8	Proficiency tests	Networking with Proficiency Test (PT) providers and collaborating centres
9	Sampling plan	Survey of sample distribution & statistical evaluation
10	SOP for laboratory	Laboratory accreditation

	<b>Challenges</b>	<b>Methods to overcome challenges</b>
11	Testing of cytotoxic drugs	Collaboration with related laboratory and developed laboratory
12	QC laboratory inspection for GMP compliance	Collaboration with related laboratory and developed laboratory
13.	Testing of vaccine and biological products	Collaboration with related laboratory and developed laboratory
14.	Bioequivalence (BE) studies	Collaboration with related laboratory and developed laboratory

**Recommendations** were made as follows:

- (1) Government should show commitment to regulation and quality assurance through allocation of adequate budget and development of appropriate policies and planning.
- (2) There should be technical cooperation between Member States (networking).
- (3) The local government should work closely with the WHO country offices for developing work plans for drug testing labs.
- (4) WHO should provide technical support for trainings and facilitate acquiring reference standard substances.
- (5) Supporting funds from partners should be sought to sustain infrastructure, training, procurement of reference standards, instrument maintenance and sharing of method development.
- (6) A network should be forged by:
  - identifying focal points from WHO and countries;
  - establishing a task force for laboratory capacity development;
  - undertaking a situational analysis and recommendation for harmonization, implementation and sustainability of drug testing lab functions;
  - networking and sharing knowledge through regional conferences and meetings.

## 5. Recommendations

The groups presented their findings in plenary and recommendations were agreed.

Governments should show commitment to supporting drug testing laboratories through:

- allocation of human and financial resources;
- development of a strategic development plan.

WHO should provide:

- technical support to develop the strategic plan;
- technical and financial support in training:
  - in-country training by external experts (hands-on) – as identified by WHO and the collaborating centres,
  - training and study visits to the WHO collaborating centres.

Partners/donors should provide:

- financial support to sustain infrastructure, training, procurement of reference standards, pharmacopoeias, technical guidelines, instrument maintenance and sharing of method development;
- support to build capacity in external quality assurance systems.

A regional drug testing laboratory network should be established in the region:

- with links to ASEAN and SAARC networks;
- involving the WHOCCs;
- by identifying focal points in countries and WHO;
- by establishing a task force for laboratory capacity development;
- by undertaking a situational analysis and making recommendations for harmonization, implementation and sustainability of drug testing laboratory functions;
- by networking and sharing knowledge through regional conferences and meetings.

## Annex 1

### List of participants

#### **Bangladesh**

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Control  
Jl. Percetakan Negara No.23  
Jakarta  
Indonesia

**WHO Regional Office for South-East Asia  
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## Annex 2

### Agenda

Topic	Responsible person(s)
<b>Opening Session</b>	
Opening and welcome address, Agenda, Objectives, and expected outcome	Dr Kathleen A. Holloway
<b>Technical Session 1</b>	
Presentations by:  WHO Collaborating Centre, Thailand WHO Collaborating Centre, Malaysia WHO Collaborating Centre, Singapore WHO Collaborating Centre, Indonesia	Moderator: Dr K.A. Holloway Co-Moderator: Dr A Shah Rapporteur: Dra. Anny Sulistiowati Rapporteur: Dr Ge Xiaowei Rapporteur: Dr Noraida M. Zainoor Rapporteur: Dr Wiyada Akarawut
<b>Technical Session 2</b>	
Country presentations	Moderator: Dr Wiyada Akarawut Co-Moderator: Dr Noraida M. Zainoor Rapporteurs: Dr Ge Xiaowei and Dra. Anny Sulistiowati
Orientation on Group work	Dr Aparna Shah
Group work	
Plenary discussion on group work Finalization of recommendations and the way forward	Moderator: Dr Ge Xiaowei Co-Moderator: Dra. Anny Sulistiowati Rapporteurs: Dr Noraida M. Zainoor and Dr Wiyada Akarawut

This regional meeting on Drug Testing Laboratories was held on 27 April 2013 to strengthen regional capacity for testing of essential medicines to assure their quality. All 11 Member States of the Region participated and described their current status of medicines testing. Group work identified mechanisms for augmenting national capacity for assuring the quality of medicines and how to forge a regional network of drug testing laboratories. Recommendations for Member States, WHO and partners were developed on the way forward for the Region with regard to building capacity of drug testing laboratories.



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SEA-Drugs-162