

ASSESSMENT OF PROGRESS IN IMPLEMENTING GLOBAL STRATEGY AND PLAN OF
ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY FOR
SOUTH-EAST ASIA REGION

Bangkok, Thailand, December 16-18, 2014

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Acronyms

ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
AISA	International Affairs Office
ACHR	Australasian Compensation Health Research Forum
AMC	Advance Market Commitment
AMR	Antimicrobial Resistance
APIs	Active Pharmaceutical Ingredients
ARVs	Antiretroviral
ASEAN-NDI	ASEAN Network for Drugs, Diagnostics, Vaccines and Traditional Medicines Innovation
BCSIR	Bangladesh Council of Scientific and Industrial Research
BIPP	Biotechnology Industry Partnership Programme
BIRAC	Biotechnology Industry Research Advisory Council
BISR	Bangladesh Institute of Social Research
BMRC	Bangladesh Medical Research Council
BRICS	Brazil, Russia, India, China and South Africa
CCS	Country Cooperation Strategy
CDDA	Cosmetic Devices and Drugs Regulatory Authority
CIHR	Canadian Institute of Health Research
CEWG	Consultative Expert Working Group
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
COPD	Chronic Obstructive Pulmonary Disease
COSTI	Coordinating Secretariat of Science, Technology for Science, Technology and Innovation
CSIR	Council of Scientific & Industrial Research
DBT	Department of Biotechnology
DDA	Department of Drug Administration
DND <i>i</i>	Drugs for Neglected Diseases initiative
DoH	Department of Health
DoMSHI	Department of Medical Supplies & Health Infrastructure
DoP	Disease of Poverty
DTL	Drug Testing Lab
DTMS	Department of Traditional Medicine Services
EDP	External Development Partners
EML	Essential Medicines List
EU	European Union
GAVI	Global Alliance for Vaccines and Immunization
GCC	Grand Challenges Canada
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
GFHR	Global Forum for Health Research
GHIT	Global Health Innovative Technology Fund
GHP	Good Hygiene Practice
GPIA	Global Platform on Innovation and access
GSPA	Global Strategy and Plan of Action
GSPA-PHI	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HRH	Human resources for health
HSR	Health Services Research
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
ICMR	Indian Council of Medical Research
IHR	International Health Regulations
IMI	Innovative Medicines Initiative
IoM	Institute of Medicine
IP	Intellectual Property
IRB	Institutional Review Board
ISRO	Indian Space and Research Organisation
IVR	Initiative for Vaccine Research
LDCs	Least Developed Countries
LICs	Lower Income Countries
M&E	Monitoring and Evaluation
MICs	Middle-Income Countries
MDG	Millennium Development Goals
MDR TB	Multidrug-resistant tuberculosis
MIS	Management Information
MMV	Medicine for Malaria Venture
MoF	Ministry of Finance
MoH	Ministry of Health
MoST	Ministry of Science and Technology
MPP	Medicines Patent Pool
MSME	Micro, Small & Medium Enterprises
MSF	Médecins sans frontières
NARC	Nepal Agricultural Research Council
NAST	Nepal Academy of Science and Technology
NASTEC	National Science and Technology Commission
NAT	National Assessment Tool
NBC	National Biodiversity Centre
NCDs	Non communicable Diseases
NCL	National Control Labs
NDs	Neglected Diseases
NDRS	National Drug Resistance Survey
NeHA	National e-health Initiative
NGOs	Nongovernmental Organizations
NHP	National Health Policy
NHRC	National Health Research Council
NHRP	National Health Research Policy
NHRS	National Health
NIDs	Neglected Infectious Diseases
NIHRD	National Institute of Health Research and Development
NIPORT	National Institute of Population Research and Training
NIH-SBIR	NIH Small Business Innovation Research

NIPSOM	National Institute of Preventive and Social Medicine
NMITLI	New Millennium Indian Technology Initiative
NRC	Nuclear Regulatory Commission
NRCT	National Research Council of Thailand
NRA	National Risk Assessment
NSF	National Science Foundation
NSR&D	National System for Research and Development
NSTDA	National Science and Technology Development Agency
OSDD	Open Source Drug Discovery
PCP	Pharmaceutical Sector Country Profile
PDP	Product Development Partnerships
PEPFAR	President's Emergency Plan For AIDS Relief
PFHI	Public Health Foundation of India
PHC	Primary Health Care
PMI	Project Management Institute
PPP	Public Private Partnerships
PQ	Prequalification
RC	Regional Committee
REM	Risk Evaluation and Mitigation
SARS	Severe Acute Respiratory Syndrome
SBIRI	Small Business Innovation Research Initiative
SEA	South-East Asia
SEAR	South-East Asia Region
SEARO	South-East Asian Regional Office
SEC	Single Exposure Chemoprotection
SERCaP	Single Exposure Radical Cure and Prophylaxis
SMEs	Small and Medium Enterprises
SMTA	Standard Material Transfer Agreement
SRA	Social Risk Assessment
TDR	Special Programme for Research and Training in Tropical Diseases
TRF	Thailand Research Fund
WHA	World Health Assembly
WHO	World Health Organization
WHO TDR	WHO Special Programme for Research and Training in Tropical Diseases
WIPO	World Intellectual Property Rights Organization
WTO	World Trade Organization
R&D	Research and Development
TB	Tuberculosis
TRIPS	Trade Related Intellectual Property Rights
UGC	University Grant Commission
UHC	Universal health Coverage
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV and AIDS
UNASUR	The Union of South American Nations
UNICEF	United Nations Children's Fund
VBDR	Vijaya Development Resource Centre
XDR TB	Drug-resistant

EXECUTIVE SUMMARY

Introduction

A regional meeting was organized from 16–18 December 2014 in Bangkok, Thailand, for assessment of progress in implementation of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property for South-East Asia.

General objective

The general objective of this meeting was to assess the implementation status and develop a regional perspective on GSPA on public health, innovation and intellectual property.

Specific objectives

The meeting was inaugurated with an address by Dr Poonam Khetrpal Singh, Regional Director WHO-SEARO, read out by Dr Manisha Shridhar Regional Advisor, WHO, followed by an inaugural address by Dr Pathom Sawanpanyalert, Deputy Secretary-General, Food and Drug Administration, Ministry of Public Health Ministry, Royal Thai Government, who was also appointed as the chair for the session.

The following technical presentations were made:

- ◆ The Global Platform on Innovation and Access to medical products and technologies.
- ◆ R&D for Neglected Patients: Changes over the Past Decade and Future Challenges.
- ◆ Principles for developing collaborating networks, academia and public-private partnership engagement for research and innovation – the Africa, Asia and South America context.
- ◆ Developing a multidisciplinary approach for global health – clinical, epidemiological and basic research: A personal perspective.
- ◆ Canada’s Contribution to Global Health Research and Innovation.

Nine Member States from the Region participated in the meeting, giving elaborate presentations on the status on implementation of GSPA-PHI in their respective countries. The discussion was followed by a group work, which lead to consensus on recommendations for Member States and WHO as well.

Recommendations

The following recommendations were made:

Recommendation for Member States

It was agreed that Member States:

1. agree to provide a self-assessment, as established by WHA resolution 62.16,¹ of GSPA (Annex I) and also develop a priority mapping for the GSPA next steps on the matrix agreed to (Annex II) in the consultation.

¹ http://apps.who.int/gb/ebwha/pdf_files/A62/A62_R16-en.pdf

2. Stress upon the need for concerted action on the GSPA on the following:
 - strengthen their information systems and capacity (human and infrastructure) on R&D in a collaborative and transparent manner to support evidence-based policy-making and prioritization – for example, a national health R&D observatory.
 - develop and/or review the policy on promoting R&D, encouraging national and regional networks, as well as south-south cooperation between networks – for example, developing a mentorship process to improve quality of R&D proposal development and implementation.
 - strengthen the capacity of the regulatory authority of Member States to promote research innovation and product development.
 - develop technology transfer mechanisms.
 - enact/adapt national patent laws that incorporate the usage of TRIPS flexibilities and waivers as well as strengthen the expertise in IP management in a public health perspective.
 - strengthen their regulation and enforcement of ethical review of research.
 - invest in adequate and sustainable resources for R&D and improve its coordination, monitoring and evaluation.
 - develop processes that formally encourage cooperation and collaboration among various R&D institutions in academia, commercial, public and private sectors.
 - strengthen the regulation and enforcement of evaluation of quality, safety and efficacy of health products and medical devices.
 - work towards establishing innovative trade mechanisms such as pooled procurement of common health products including precursors (e.g. APIs) and reference standards for Member States.
 - promote exchange of information and R&D on traditional medicine.

Recommendation for WHO

It was recommended that WHO:

1. summarize and consolidate the self-assessment of GSPA for the Member States and forward the assessment from SEARO to WHA.
2. support Member States by carrying out the following recommendations:
 - develop guidelines and technical framework for prioritizing R&D needs.
 - support collaboration among Member States including lessons learned on best practices in promoting R&D and encourage multicountry funding proposal development.

- take appropriate measures to strengthen capacity in R&D in LDCs in the Region.
- provide a coordination mechanism for technology transfer among countries and regions as well as develop public health-oriented guidelines and capacity on technology transfer among Member States and regions.
- provide technical support to promote TRIPS flexibilities and strengthen the expertise in IP management to foster access to medicine and in particular to continue to support Member States to attend WHO/WIPO/WTO training on IP and public health.
- empower LDCs to use TRIPS waivers.
- provide technical support on developing capacity in ethical review of research.
- provide technical support on developing regulation and standards on quality, safety and efficacy of health products and medical devices.
- facilitate the maximum use of financing mechanisms, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices.
- develop a regional ME framework for R&D and its guidelines to be used by Member States.
- develop a new classification of diseases relevant to public health needs to replace the current type I, II and III terminology that reflects changes in the recognition of NCDs, drug resistance, one health, urban and rural populations, new disease epidemiology and genomics.

1. Introduction

A regional meeting was organized from 16–18 December 2014 in Bangkok, Thailand, as per WHA 62.16 resolution to conduct an overall programme review of the Global Strategy and Plan of Action in 2014 on its achievement, remaining challenges and recommendations on the way forward to the Assembly in 2015 through the Executive Board.

The Sixty-first World Health Assembly adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA61.21) and identified a number of deliverables with an aim to promote new thinking on innovation, transfer of technology and access to medicines.

This GSPA assessment is unique as the Member State self-assessment of their progress, success stories and lagging sectors enables concerted action for improvement. This meeting is an exercise that would enable Member States to identify and reprioritize for next steps; create a platform for sharing knowledge, collaboration and learning, and develop regional solidarity through experience sharing.

2. Objectives

2.1 General Objective

The general objective of the meeting was to assess the implementation status and develop a regional perspective on GSPA on public health innovation and intellectual property.

2.2 Specific Objectives

The specific objectives of the meeting were to:

- ◆ identify the implementation status of innovations, transfer of technology and access to medicines in light of the provisions of the GSPA in developing countries;
- ◆ share experiences and identify the opportunities and challenges in operationalizing the GSPA; and
- ◆ prepare a regional perspective/ position to inform the revision and updating of GSPA .

3. Opening Session

3.1 Opening Address

The regional meeting began with an address by Dr Poonam K. Singh, Regional Director, WHO South-East Asia Region, readout by Dr Manisha Shridhar, Regional Advisor.

The resolution WHA61.21 on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) is one of the most well-crafted and expansive resolutions adopted by the World Health Assembly in 2008. SEAR has taken a lead role in this global endeavour through several proactive steps. In fact, two of the three drafting groups at the Sixty-first World Health Assembly, for the intergovernmental working group leading to GSPA, were chaired by Mr Naresh Dayal (India) and Dr Viroj Tangcharoensathien (Thailand) from this Region.

The active involvement of Member States of the South-East Asia Region resulted in a regional resolution on the subject, and the Sixty-fifth Session of the Regional Committee for South-East Asia in Yogyakarta, Indonesia, was the first of all WHO regional committees to adopt SEA/RC65/R3² on Consultative Expert Working Group on Research and Development: Financing and Coordination. The SEAR resolution SEA/RC65/R3 on CEWG was also discussed at all other regional committee meetings of WHO and, more importantly, formed the basis for arriving at a consensus for the draft resolution for the Sixty-fifth World Health Assembly at the open-ended meeting of all WHO Member States in November 2012.

It is imperative that the core issue that the GSPA seeks to address needs to be kept in mind: market mechanisms coupled with strong intellectual property rights have led to lack of investment for research and development (R&D) to generate health products to tackle diseases of relevance to developing countries. Further, the mandate of the CEWG was essentially to explore and, where appropriate, promote a range of incentive schemes for R&D, including encouraging de-linking of the costs of R&D from the price of health products.

This strategy for new models of health R&D can help the GSPA address the innovation and access gap in developing countries. This meeting was held in the backdrop of world attention being focused on public health in light of the significant threat from the Ebola epidemic. There is a need to gear ourselves for a regional assessment that will stand us in good stead in the next few years and also take into account the wide spectrum of issues relating to emerging infectious diseases, communicable and noncommunicable diseases. She hoped that the consultative process would lead to a regional consensus that would augur well for GSPA to reflect the regional aspirations and needs.

Dr Singh thanked the Ministry of Public Health, Royal Thai Government, for hosting this meeting as well as participants from the SEAR countries, and invited experts for sparing their valuable time to attend the meeting.

² <https://extranet.who.int/iris/restricted/bitstream/10665/128335/1/SEA-RC65-R3.pdf>

Finally the Regional Director encouraged Member States to ensure that the regional consultation recommendations are feasible and practical and to give necessary direction to the discussions of the GSPA process at the Sixty-eighth World Health Assembly.

3.2 Inaugural address

The inaugural address was given by Dr Pathom Sawanpanyalert, Deputy Secretary-General, Food and Drug Administration, Ministry of Public Health Ministry, Royal Thai Government.

Dr Sawanpanyalert explained the complexities of the three key terms of GSPA viz., Public Health, Innovation and Intellectual Property and the related intricacies. He said that it is very important to address these issues by all Member States for achieving their common goal of access to health products for the people of SEAR.

After discussion by Member States, it was unanimously decided that the Session Chair will be Dr Pathom Sawanpanyalert, Deputy Secretary-General, Food and Drug Administration, Ministry of Public Health Ministry, Royal Thai Government, while Dr Tjandra Yoga Aditama, Chairman, National Institute of Health Research and Development, Ministry of Health, Jakarta, Indonesia, would be the Co-Chair. Dr B.V.S.H. Benaragama, Director (Family Health Bureau), Ministry of Health, Colombo, was appointed Rapporteur.

4. Proceedings

4.1 An Overview

An overview of Assessment of Progress in Implementing Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property for South-East Asia – Dr Manisha Shridhar, WHO-SEARO.

In the first session after the inaugural, Dr Manisha Shridhar, Regional Advisor, WHO-SEAR, gave a brief history on access to medicines for public health. In this context, it is important to note the legal battle in South Africa to use TRIPS provisions of WTO in 1995 and for accessing HIV drugs, which culminated with the 2001 Doha Declaration. In 2003, the World Health Assembly through WHA56.27³ set up the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). The CIPIH gave its report in 2005. The CIPIH recommendations were eventually adopted as a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPH-PIH). The GSPA was endorsed by consensus in 2008 and WHA61.21 outlined a Global Strategy and plan of action (GSPA) on public health, innovation and intellectual property with 108 specific actions across 25 sub-elements and 8 main elements. These main elements are:

1. Prioritizing research and development needs;
2. Promoting research and development;
3. Building and improving innovative capacity;
4. Transfer of technology;
5. Application and management of intellectual property to contribute to innovation and promote public health;
6. Improving delivery and access;
7. Promoting sustainable financing mechanisms (Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG); and
8. Establishing and monitoring reporting systems.

Dr Shridhar then gave a brief overview of Types I, II and III diseases and the progress in the SEAR in respect of GSPA since 2011. There were meetings of all the relevant stakeholders in the SEAR on the CEWG report that led to the adoption of SEA/RC65/R3. Recommendations and action points arrived at aimed to: promote and strengthen R&D capacities, promote coordination of R&D, establish or strengthen health R&D observatories, promote partnerships and explore funding for health R&D.

The proposed Global health R&D Observatory would perform the functions to monitor and report on financial flows, integrate information, provide information, support capacity-building, benchmark activities and monitor and evaluate for R&D. The issue of coordination and priority setting in R&D to meet health needs in developing countries and potential actions that could be taken to strengthen the coordination of health R&D in light of the CEWG report were discussed.

The three approaches were outlined:

³ http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf?ua=1

- ◆ a passive approach through the improved sharing of information;
- ◆ an active approach such as networks of researchers agreeing on priorities and collaboration through a global health R&D week or conference, and
- ◆ managed coordination where there are formal structures to manage the research undertaken and the allocation of resources to support them through major targets for R&D at a global level for disease reduction.

Several Public–Private Partnerships such as i) Programme for Appropriate Technology in Health (PATH); ii) International AIDS Vaccine Initiative (IAVI); iii) Medicines for Malaria Venture (MMV); iv) Malaria Vaccine Initiative (MVI); v) Global Alliance for TB Drug Development (TB Alliance); vi) Aeras Global TB Vaccine Foundation (Aeras); vii) International Partnership for Microbicides (IPM); viii) Pediatric Dengue Vaccine Initiative (PDVI); ix) Foundation for Innovative New Diagnostics (FIND); x) Institute for One World Health (IOWH); and xi) Drugs for Neglected Diseases Initiative (DNDi) are active in the area of R&D.

Certain recent WHA resolutions are relevant to GSPA discussion viz., WHA67.20 (2014) Regulatory system strengthening for medical products; WHA67.22 (2014) Access to essential medicines; WHA67.25 (2014) Antimicrobial resistance; WHA67.21 (2014) Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy. She brought attention to the new concerns emerging with respect of access to treatment due to the global IP regimes, such as with the breast cancer diagnostic in the United States and Hepatitis C drugs and how lessons can be learned from the South African battle to access HIV/AIDS drugs.

The detailed assessment carried out by Sri Lanka on the GSPA would provide valuable insight for the regional assessment. Dr Shridhar concluded that the presence of several renowned international experts invited for the meeting could help Member State representatives to define global, regional and national strategies for taking forward the GSPA initiative.

Technical Presentations

The Global Platform on Innovation and Access to medical products and technologies

Ms Claudia Nannei, Technical Officer, WHO headquarters, gave a brief overview of the Global Platform on Innovation and Access to medical products and technologies. Ms Nannei described the new mapping tool developed – *National assessment tool for public health, innovation and intellectual property* for GSPA.

The tool is based on the country-specific items of the strategy. This tool will help in mapping health R&D policies, system, infrastructure, human resources and financing; access to know how and technology transfer, local production capacity for pharmaceuticals; intellectual property management; regulation and procurement of medical products and technologies, incentives for health innovation, health delivery infrastructures, trade agreements and information monitoring systems. The tool will help in identifying areas of improvement, contradictory policies, policies that are complimentary to each other, benchmarking areas of strength and further help in creating coordination among agencies. All this will eventually ensure policy coherence.

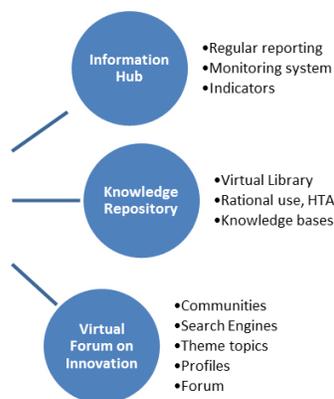
The GSPA clearly mandates in its Element 8, specifically action 8.1, for WHO and Member States to establish systems to monitor performance and progress of the implementation of each element of the GSPA.

The Global Platform on Innovation and Access (GPIA) is a unique web-based information bank for governments, intergovernmental organizations, public health researchers, NGOs and other stakeholders. It provides user-friendly, reliable and regularly updated information on innovation and access to medical products and technologies and the GSPA-PHI implementation. All the information collected via the tool would be deposited with GPIA, making it a repository and a virtual networking tool on innovation.

GPIA's expected outcome will be policy coherence as it will ensure a better design and management of regional and national health research and innovation systems; more efficient innovation based on combined expertise that has been traditionally working in isolation; more effective and targeted capacity-building programmes that will be tailored to identify national gaps and needs; and creation of visible and responsible community working together to facilitate innovation for and access to medical products and technologies.

The NAT has three components:

- ◆ Information hub
- ◆ Knowledge repository
- ◆ Virtual Forum on Innovation



The NAT currently depends on two sources for data and information –

- ◆ Pharmaceutical Sector Country Profile (PCP); and
- ◆ Regional Platform on Access and Innovation for Health Technologies.

To make NAT and GPIA a more expansive source of information and data, NAT will depend upon:

- ◆ The Global Health R&D Observatory
- ◆ New Pharmaceutical Sector Country Profile (PCP), Other External links (WIPO Re:Search?).

The GPIA platform would go through a development process where from the nascent stage of being an information hub it will eventually evolve into a final version of innovative information forum that will require a timely maintenance.

The evaluation of GSPA-PHI, requested by Member States, is going to be a comprehensive evaluation exercise that will highlight the remaining challenges and recommendations for the way forward. Ms Nannie then went on to give a brief demonstration of the operation of NAT. Finally, she mentioned that the proposed evaluation timelines have been shifted from January 2015 to January–May 2017, done in consultation with the regional offices of WHO.

R&D for Neglected Patients: Changes over the Past Decade and Future Challenges

By Dr Bernard Pecoul, Executive Director, DNDi (Drugs for Neglected Diseases initiative), Geneva. Dr Pecoul's presentation was on the global landscape in respect of R&D on neglected diseases over the past 10–15 years, future challenges and recommendations.

DNDi,⁴ is a not-for-profit model, driven by the public sector, where a variety of players collaborate to raise awareness of the need to research and develop drugs for those neglected diseases that fall outside the scope of market-driven R&D. They also build public responsibility and leadership in addressing the needs of these patients. The mission of DNDi is to improve the quality of life and the health of people suffering from neglected diseases by using an alternative model to develop drugs for these diseases and thereby ensuring equitable access to new and field-relevant health tools.

DNDi has four core objectives:

- ◆ deliver 11 to 13 new treatments by 2018;
- ◆ establish a robust pipeline;
- ◆ use and strengthen existing capacity in disease-endemic countries; and
- ◆ raise awareness and advocate for increased public leadership.

Because of economic growth, the world is rapidly undergoing several changes; there are nearly twice as many poor people living in emerging economies than those living in LDCs.⁵ Although there is a shift in the landscape from communicable to noncommunicable diseases, communicable diseases remain a major burden in MICs and LICs.⁶ Despite the shift, communicable diseases continue to remain a major burden for both MICs and LICs.

⁴DNDi is a not-for-profit patient's needs driven & innovative R&D model founded in 2003. The initiative was found in light of a fatal imbalance in Health R&D from 1975–1999, when only 16 of the 1393 total approved new products were for neglected tropical diseases, a mere 10% of R&D dedicated to 90% of global disease burden. It was founded by Indian Council for Medical Research (ICMR); Kenya Medical Research Institute (KEMRI); Malaysian MOH; Oswaldo Cruz Foundation, Brazil; Médecins Sans Frontières; Institut Pasteur France; TDR (permanent observer).

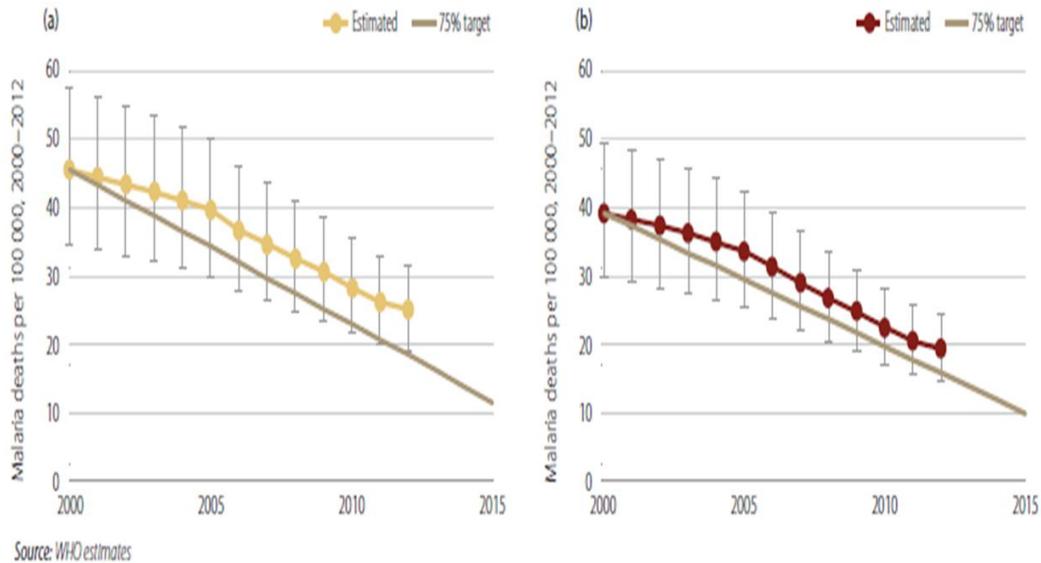
⁵ Source: Michel Kazatchkine, DNDi-Institut Pasteur meeting, Dec 2013.

⁶ Source: Healthdata.org, Global Disease Burden. 20 May 2014.

With these changes, there is an increased investment on the Global Health investment front by new key actors such as The Global Fund, GAVI Alliance, Bill & Melinda Gates Foundation, PMI, UNITAID, The President’s Emergency Plan For AIDS Relief (PEPFAR/Emergency Plan) and others.

As an example of the impact, Dr Pecoul presented a slide on the overall Malaria Mortality Rates, which have fallen by more than 25% since 2000.⁷

Figure 2: Estimated malaria mortality rates, 200-2012 in (a) all age groups and (b) Children <5 years of age.



There is an ongoing debate between strengthening of intellectual property vs open innovation. A TRIPS agreement has already been implemented in all major countries and we have witnessed the use of TRIPS flexibility clauses such as compulsory licensing in India, Indonesia and Thailand and voluntary licensing in the creation of the Medicines Patent Pool (MPP) for HIV and bilateral agreements between innovators and endemic countries. We have also witnessed open innovation to support drug discovery via open source lab, WIPRO Re:Search and Pathogen Box.

In 2012, an updated report, the Fatal Imbalance: the crisis in research and development for drugs for neglected diseases, by DNDi /MSF, concluded that limited progress has been made in the form of an increased PDP model; use of incentive mechanisms such as priority vouchers, prizes, AMC; new R&D projects, alliances/partnerships; more donors; open source/data sharing; friendly licensing agreements with industry; commitment from pharma biotech and regulatory harmonization and coordination. However, the future challenges of TRIPS; regulatory issues; very few R&D initiatives launched in LMICs; lack of political leadership from WHO for Global R&D framework; progress not covering the full spectrum of Type II and III diseases and the

⁷ Source: World Malaria Report 2013.

specific R&D need of developing countries in relation to Type I diseases and instability of partnerships (e.g. London declaration)⁸ outweigh the progress.

Dr Pecoul discussed the context of R&D and innovation/access environment as three fundamental challenges in the future environment for medical innovation:

- ♦ R&D priorities do not sufficiently originate from low- and middle-income countries; patients' needs are not prioritized;
- ♦ Scientific innovation is not linked to equitable access when there is profit incentive to drive innovation in both rich and poor countries, products are too often priced out of reach; and
- ♦ Market incentives aligned with Intellectual Property Rights do not adequately address health needs in developing countries.

The above-mentioned three challenges are well illustrated by the current three crises: HCV, Ebola and Antimicrobial resistance (AMR).

He said that while the overall global disease burden for neglected diseases is reducing, there still remains, however, an unmet need. Deaths due to neglected diseases (NDs) are projected to decrease over the next 15 years but NDs will not be eliminated.⁹ Thus despite a decade of global efforts and progress, the fatal imbalance continues as only mere 3.8% of new products for neglected diseases (reformulations, combinations), 1.2% of NCEs¹⁰ for neglected diseases have been discovered. Only 1.4%¹¹ clinical trials (of nearly 150 000 trials) focused on neglected diseases. The global health investment for neglected diseases is a scant 1%. He called attention to the fact that:

- ♦ there is still a major R&D deficit for anti-infective;
- ♦ the global TB drug pipeline is not poorly populated;
- ♦ antibiotic resistance is becoming an alarming reality in countries like India;
- ♦ broader challenges exist in discovery of multiresistant bacteria;
- ♦ Global Hepatitis C distribution new treatments will not be available to a large majority of patients; and
- ♦ children are still neglected in R&D pediatric HIV: the right formulation, dose and taste.

Notably, there is a continued lack of sustainable funding for neglected diseases with the “big three” (TB, Malaria and HIV/AIDS) accounting for 58% of overall R&D allocation. The philanthropic donors Bill & Melinda Gates Foundation and the Wellcome Trust together contribute to over 85% of all R&D funding by philanthropic donors for neglected diseases R&D.¹² There is still insufficient investment in R&D from emerging economies. As per G-Finder report, the only emerging economy in the top 12 Neglected Diseases Public Funders is India. Any new

⁸ http://www.who.int/neglected_diseases/London_Declaration_NTDs.pdf

⁹ WHO Global Burden of Disease 2013; WHO Global Estimates 2005: 2015–2030 Projection.

¹⁰ ‘The drug and vaccine landscape for neglected diseases (2000-2011): a systematic assessment’ Pedrique B et al. *Lancet*, Oct 2013.

¹¹ ‘Mapping of available health research and development data: what’s there, what’s missing, and what role is there for a global observatory?’ Rottingen et al. *Lancet*, May 2013.

¹² http://www.policycures.org/downloads/GF_report13_all_web.pdf

funding mechanisms such as pooled funding, transaction tax, etc. are yet to be fully developed and exploited.

Dr Pecoul advocated for a Global Framework for sustainable R&D for neglected diseases that will enable coordination of efforts; prioritize needs-driven R&D; encourage leadership from endemic countries; give WHO a central role; and overcome regulatory and Intellectual property rights barriers. He proposed following recommendations:

- ◆ put the specific needs of patients upfront, at the start of the innovation process;
- ◆ break the link between the cost of R&D and the price of products;
- ◆ ensure that the fruits of innovation are accessible and affordable;
- ◆ integrate global health R&D monitoring, coordination and financing; and
- ◆ strengthen and harmonize regulatory capacities in endemic regions to facilitate implementation of new health technologies.

Dr Pecoul ended with the plea that the SEAR along with the rest of the world should hear the voice of the neglected patients. It is the patients who should be at the core of the mission.

Principles for developing collaborating networks, academia and public-private partnership engagement for research and innovation – the Africa, Asia and South America context

The talk by Professor Simon L. Croft from London School of Hygiene & Tropical Medicine was on principles for collaborations, networks, partnerships for research and innovation for promoting R&D and access to health products.

Dr Croft said that for most diseases of poverty (DoP) and neglected infectious diseases (NIDs), the status of availability of health products is quite mixed. Some drugs are available but may be inadequate, and/or toxic with limitations in respect of administration, some may require for long duration of treatments and finally the recent emergence of drug resistance patterns for several neglected diseases. When it comes to diagnostics, the situation is that they are often invasive, non-predictive, complex and are poor biomarkers. The availability of vaccines is equally poor with vaccine development being a complex and stage-dependent process. In brief, the picture in respect of availability and access is quite grim with a highly variable implementation status.

Dr Croft outlined the factors that affect the development of collaborating networks, academia and public-private partnership engagement for research and innovation:

- ◆ The process of R&D is bi-directional and complex;
- ◆ the very landscape of players/participants;
- ◆ the varying needs of innovation;
- ◆ system of incentivization for health products for neglected diseases;
- ◆ difficulty in implementation/operational research;
- ◆ need to build and sustain partnerships; and
- ◆ need for education, training and experience.

The bi-directional and complex process of R&D

From discovery to the patients the whole gamut of the R&D process is bi-directional. It is a dynamic process driven by discovery and endpoint. When we look into the target product profile, it defines drug(s), treatments and decisions points but also the complexities of the process and relationships.

The very landscape of players/participants

Also, collaborators and partners need to understand the complexities of this R&D landscape. He stressed that at the global health level, the need for trust and clarity around the substance of a partnership at the country level and with international and national public authorities is important. When tracing the arena of R&D for DoP and NIDs, we see an advent of new players; in the last two decades up to the 1980s, some pharma such as Wellcome and Roche were the sole players; the 1990s were the empty years when the flame was kept alive by WHO TDR. The period from 2000 to 2005 witnessed an introduction and development of PPPs/PDPs; and funding from Bill & Melinda Gates Foundation, MMV (1999 to 2014) is an example of the work of a PPP or PDP. In 2005–2009, translational centres at universities came up with biotech/pharma sector engagement. And from 2010 onwards, new pharma models came into the picture. The GHIT Fund, a PPP in Asia, is the first public-private partnership to involve a national government, a UN agency, a consortium of pharmaceutical companies and an international philanthropic foundation.

The need of innovation

The key to it is understanding “innovation”; because of the multitude of players, there exist multiple combinations of potential collaborations, and each actor has different needs. The academics need to have a multidisciplinary approach, papers should focus on nature as well as impact, understanding different cultures and different standards must also have project management skills and improve decision-making. For researchers in pharma/biotech, when working with academics, it is important to have peer group respect and maintain it.

Implementation/operational research

Operational research is required to support implementation because of the bidirectional nature of R&D. What is also missing is a more open innovation. A recent review cites several reasons to enhance global collaborations through (McCloskey et al 2014):

- ◆ greater equity in access to technology and expertise and need for specific capacity strengthening activities;
- ◆ reduce barriers based around differences in commercial and academic drivers, including sharing of data; and
- ◆ the need for bodies to develop and share protocols, standards and arrangements and support resolution of conflicts of interest should they arise.

Education, training and experience

One way of attracting academics and the private sector to innovation and R&D is to incentivize the opportunities available. Funding is one crucial way of doing it; some examples are Wellcome Trust –Seeding Drug Discovery, DBT-MRC initiative for AMR centres, DST-OSDD, Gates Grand Challenges, EU-Horizon 2020 (with essential role of SMEs), EU-IMI, and NIH-SBIR grants. Career opportunities is another way to incentivize human resources such as fellowships for young scientists (PhDs and post-docs) to work in biotech/pharma, introduce sabbatical concept to encourage established academics to work in biotech/pharma, encourage biotech/pharma experts to lead ‘translational’ innovation and enterprise workshops in universities.

Dr Croft concluded that it is important for stakeholders to be true owners of programmes, how behavioural change and communication is important to promote innovation and access and finally the importance of engagement of communities for successful partnerships.

Developing a multidisciplinary approach for global health – clinical, epidemiological and basic research: A personal perspective

Professor Dr Gerald T. Keusch, Professor of Medicine and International Health from Boston University School of Medicine, Boston, spoke on the need for developing a multidisciplinary approach for global health – clinical, epidemiological and basic research. He said that the seven Ps are the essential elements that determine the outcome: Plan, People, Place, Partners, Parts, Politics, Persistence – and aligning all the Ps.

Referring to a paper by Clark E et al,¹³ Dr Keusch touched on the fact that the global health system is undergoing a period of rapid transition, with upsurge of funds and greater political recognition, a broader range of health challenges, many new actors and the rules, norms and expectations that govern them are in flux. The traditional actors such as WHO and notable health ministries are no more alone, but being joined by new actors such as civil society, NGOs, private firms and philanthropists, and the increasing number of low- and middle-income countries such as Brazil, China, India, Kenya, Mexico, Thailand and South Africa.

Dr Keusch mentioned that the ‘Acting in Time’ initiative launched in 2007 at the Harvard Kennedy School grew from the observation that virtually all of the world’s most pressing problems, from climate change to health care to natural disasters to disease outbreaks to demographic change to terrorist threats, were relatively easy to see coming and would be far easier to deal with if people acted sooner rather than later. Yet in virtually every case, nations and institutions seemed unable or unwilling to act in time.

Dr Keusch says that an effective global health system has five components:

- ◆ agenda-setting;
- ◆ financing and resource allocation;
- ◆ research and development;
- ◆ implementation and delivery; and

¹³ <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000183>

- ♦ monitoring, evaluation and learning.

An analysis of these components resulted in seven central conclusions:

- ♦ No single actor can or should set the agenda for action. It must be broad-based, participatory, having a transparent processes of agenda setting, anchored by WHO's global political legitimacy and adhering to widely accepted procedural principles, must be required to define priorities, avoid unnecessary duplication and share knowledge.
- ♦ Sustainability depends on strengthening national health systems. Donors should allow greater flexibility for recipient countries to direct a portion of received funds beyond narrow programmatic interventions to strengthening national health systems.
- ♦ Ironically, the proliferation of global actors threatens to weaken health systems by placing additional reporting burdens on already thinly stretched health ministries. The global health system should identify and adopt analogous ways to streamline reporting and, more generally, to minimize the additional transaction costs put on countries.
- ♦ Basic and translational research and research capacity-building involving strong and long-term collaboration between technically advanced research institutions and emerging centres of excellence in disease-endemic countries are essential.
- ♦ Systematic investment in new and improving existing M&E programmes. Over time, this investment – if adequately financed – will contribute to building robust M&E systems and generate reliable, comparable data to inform action.
- ♦ Prioritize additional investments in long-term, multidisciplinary education and training.
- ♦ Support research that provides the evidence and knowledge bases for prioritization, resource allocation, the development and evaluation of new tools and interventions, and understanding variation in the performance of different national health systems to identify critical features to adapt to local conditions.

Hence, there is a great need for 'Acting in Time' in the health sector to prevent complexities after the event has occurred. There should be:

- ♦ a broad-based agenda setting.
- ♦ investing in national health (research) system.
- ♦ minimizing transaction costs.
- ♦ ensuring long-term collaboration.
- ♦ promoting systematic M&E programmes.
- ♦ encouraging multidisciplinary education and training.
- ♦ creating and supporting evidence base for policy decisions.

Commenting on the GSPA-PHI concept note, the individual component reflected that they require not only scientific training but mentoring from successful role models; no one works in isolation any longer; there is a need for colleagues and a supportive environment, attitude, infrastructure; a greater number of physicians–scientists working with PhD/DSc/MS/MPH; biomedical engineering, computational and systems biology linked to health-care environment; more career opportunities in full-time research with sufficient salary to make it lucrative in

order to avoid diversion of efforts; there must be opportunities for scientists to use their technical skills – otherwise they look for other avenues.

With respect to institutional component, there is a need for labs, equipment, maintenance, logistics for reagents and supplies; library, internet access to databases, international connections (communications, conferences, courses); scientific ambiance-presentations, lab meetings, critical reviews, pilot funds, enlightened charismatic leadership at the top and openness to inputs and ideas from below; grant preparation, management, financial auditing; autonomy to investigators, junior faculty that includes control of grant resources; ethics review system for human and animal research and functional system of grant support, review and decision-making.

It will be more effective to define individual scientist's needs first and build the supportive infrastructure needed around it. For this information, analysis, external evaluation and flexibility to change will be important. A co-mingling of disciplines beyond health care will create a scientific pipeline of human resource and the most appropriate centre for this is the university. Any steps to connect academia and the private sector will augur good results. Dr Keush also brought to notice the dangerous trends of corruption (falsification of data, plagiarism and skimming financial resources) that must be addressed. Regional cooperation is very valuable, and to avail the benefits, there is a need to overcome inertia of political and cultural conflicts.

When it comes to technology transfer and intellectual property rights expertise, betting correctly on what will be valuable is of importance. A clearly defined policy for royalty and licensing fees between institutions and investigators is an incentive that can be innovated upon. However, when it comes to innovation, there also arises the question of risk and failure and hence a requirement for management of innovation risk.

Dr Kesuch mentioned that capacity-building and its evaluation remains fragmented. He raised questions on how to assess the functionality of the relationship between funders, investigators, the multiple personalities involved and institutional staff as there exists a dichotomy where some may be interested in level of corruption and some on the other hand ignore it and focus on the output.

There is a need for assessment by local universities for an international basic science training grant as the existing training opportunities are rarely for basic science. What is required is a sandwich model with options for post-doc training, ongoing mentoring and a re-entry support system. The aim must be to set up high caliber labs to provide opportunities for well-trained scientists to return and build quality programmes; and to optimally train and equip independent researchers with grants so that they go on to build the infrastructure.

Dr Kesuch stressed the point that governments have a legitimate duty to invest in health R&D, and how vision is important and implementation critical. Finally, one cannot overemphasize the need for quick and proactive steps for action.

Canada's Contribution to Global Health Research and Innovation

The presentation by Dr Halla Thorsteinsdóttir, University of Toronto, focused on Canada's emphasis on global health research and innovation, its key research areas, efforts made by Canada's main funders and characteristics of these efforts.

Global health is a multidisciplinary discipline with focus on both health systems and policies and development of new products/services. In the early 2000s, the Canadian Institute of Health Research (CIHR) announced that global health was one of its five major pillars, which led to the establishment of the Global Health Research Initiative. Early on, from 1999–2009, funding allocated to the study of neglected tropical diseases was limited to around C\$29.8 million; however, with Grand Challenge Canada's¹⁴ agreement of about C\$150 million, there was a stronger focus on global health.

A look into the key research areas of Canada's global health research shows that most publications on neglected tropical diseases by authors from Canada, between 1950 and 2010, have been in leishmaniasis followed by African Sleeping Sickness and Leprosy.¹⁵ However, compared with other nations such as Brazil and India, it is much less.

The key funders from Canada for both within Canada and developing countries are Grand Challenges, Global Health Research Initiative and International Development Research Centre. Canadian Institutes of Health Research dealing in fundamental research mostly funds Canadian projects.

A look into the prioritized areas highlights Canada's emphasis on maternal, newborn and child health contribution reflected in the Muskoka Initiative under which Canada has committed to allocate C\$2.85 billion;¹⁶ research programmes such as Innovating for Maternal and Child Health in Africa¹⁷ (GHRI), Saving Lives at Birth¹⁸ and Saving Brains¹⁹ (GCC).

Capacity-building is another area where Canada has shown interest by building R&D capacity with the help of the International Development Research Centre and Global Health Research initiative, there are other organizations such as the Canadian Coalition for Global Health Research, which are contributing as well. Efforts are also being made towards building capacity to support global health innovation with innovation in Intellectual Property Laws such as the law faculty of University of Ottawa organizing training courses in intellectual property management aimed at African countries, drug regulation and bioethics such as the Joint Centre for Bioethics at the University of Toronto, which provides graduate bioethics training to health personnel from many developing countries. There is an emphasis on technology transfer as well with 37%²⁰ of Canadian biotechnology firms in cooperation agreements with developing countries. Most organizations pay emphasis to cooperation and networking with formation of network chains with the private sector as well as government and nongovernment funders such as the Bill & Melinda Gates Foundation.

Canadian Grand Challenge promotes an integrated innovation approach that incorporates science and technology with social and business innovation.

¹⁴ <http://www.grandchallenges.ca/who-we-are/>

¹⁵ Phillips et al, 2012.

¹⁶ http://www.who.int/pmnch/topics/part_publications/Web_Annex_1_-_29_09_2011.pdf

¹⁷ <https://www.idrc.ca/en/initiative/innovating-maternal-and-child-health-africa>

¹⁸ <http://www.grandchallenges.ca/grand-challenges/saving-lives-at-birth/>

¹⁹ <http://www.grandchallenges.ca/saving-brains/>

²⁰ Globetrotting firms: Canada's health biotechnology collaborations with developing countries.

Some of the impacts summarized by Dr Thorsteindottir are impacts on health practices and policies such as in HIV prevention; impact on capacity-building; applicability shown by GCC in several projects such as toilets that produce compost in Haiti, sanitary pads for girls and women in Kenya, neonatal kits in Pakistan, phone-based diagnosis of preeclampsia during pregnancy, hand-held diagnosis device for infectious diseases such as HIV, leverage to private investments and partnerships with an emphasis on social enterprises. However, GCC has been criticized for overemphasis on commercialization and corporatization. However, Dr Thorsteinsdóttir acknowledged that Canada needs a stronger innovation focus. She gave the example of the Ebola virus vaccine for which Canada had developed a vaccine candidate four years ago and was licensed to NewLink, a small US biotech firm which lacked experience and no production capabilities. This eventually had to be licensed to Merck, leading to a delay and reflecting on Canada's lack of innovation focus.

There exists a requirement for a more systematic approach that includes formal organizations and institutions of social norms; where learning is a central theme and incorporates science-based and experience-based learning; knowledge flows and interactions are critical and there is an emphasis on alignments of actors and coherence of policies.

Overall Canada is pursuing global health research in a very innovative manner by experimenting with different types of models. Its emphasis on capacity-building and networking has led to increased potential for both North-South and trilateral cooperation.

Dr Thorsteindottir mentioned that Canada needs to pay more attention to integration of the efforts into the innovation system in Canada as well as in participating developing countries. With more coherent and concerted efforts, the potential for impacts and innovation can be significantly enhanced in the area of global health.

Mr Francisco Viegas Neves da Silva from the International Affairs Office – AISA, Minister's Cabinet, Brazilian Ministry of Health, Brasília, spoke about the experiences of Brazil in the GSPA-CEWG negotiations.

Mr da Silva emphasized the need for full implementation of the Global Strategy on Public Health, Innovation and Intellectual Property, which was soon to be reviewed in the World Health Assembly. He also reiterated the need to implement the demonstration projects selected under the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) of the World Health Organization (WHO), taking into consideration that four of the eight projects selected involved BRICS countries. The importance of coordinating initiatives involving the research and development of vaccine for dengue in affected countries and the strengthening of the exchange of good practices to prevent and treat malaria and other neglected diseases was stressed. He informed that in response to decision WHA67(15),²¹ the secretariat organized a technical workshop in coordination with Oswaldo Cruz Foundation, Brazil (Fiocruz) in Rio de Janeiro, Brazil, from 26–27 August 2014, bringing together project proponents for the 7+1 demonstration projects, identified by the Global Technical Consultative Meeting, with technical experts. This workshop gave participants an opportunity to ask

²¹ http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_30Add1-en.pdf

questions, make clarifications, discuss, debate and provide recommendations on proposal and project plans.

4.2 National Presentations

BANGLADESH

The country profile of Bangladesh was presented by Professor Harun-Ar-Rashid, School of Health Sciences, State University of Bangladesh, Dhaka, Bangladesh, Ms Praveen Akter, Joint Secretary, Government of Bangladesh and Ms Salima Jahan, Deputy Secretary, Government of Bangladesh.

Bangladesh has triple burden of Types I, II and III diseases but there is a rise in the prevalence of Type I diseases. No reliable statistical data about cancer are available for developing countries such as Bangladesh. Based on the statistics provided by the World Health Organization, the numbers for cancer incidence, prevalence and mortality are an estimated at 2 00 000, 8 00 000 and 1 50 000 respectively for the 130 million people of Bangladesh. WHO estimates 167 new cases per 1 00 000 population.

In Type II disease category, AIDs is prevalent. Ever since the first case of HIV/AIDS reported in Bangladesh 1989, over 1495 cases of HIV/AIDS have been reported until December 2008. However, UNAIDS estimates that the number of people living with HIV in the country may be as high as 12,000, which is also within the range of the low estimate by UNICEF's State of the World's Children Report (2009). The overall prevalence of HIV in Bangladesh is less than 1%; however, high levels of HIV infection have been found among injecting drug users (7% in one part of the capital city, Dhaka). TB is prevalent, but is on the decline. Case detection stands at 94%. Cases of MDR TB are falling in number.

In respect of Types III diseases, Bangladesh is considered as one of the malaria endemic countries in South Asia. Bangladesh has 34 Anopheles mosquito species and a total of 13.2 million people are at risk of malaria, with 13 of 64 districts being endemic. Dengue, filariasis are also found in a few districts of Bangladesh. Kala-azar is spread in 34 districts. The disease burden stands at 1900 cases in 2012. There is a decline in dengue cases with only 474 cases in 2012, with no deaths reported. Leprosy is nearing elimination with prevalence at 0.24 per 10 000 population.

Bangladesh possesses excellent pharmaceutical manufacturing capabilities and fulfills most of the domestic demand of health products for Type I, II and III diseases. Docetaxel (Taxotere), Oxaliplatin (Eloxatin), Lenograstin (Granocyte), Jevtana (Cabazitaxel) by Baxter are some of the Type I disease drugs produced in Bangladesh.

About 96% of drugs for domestic consumption are produced and marketed locally. The diagnostic services in the public sector and the private sector serve the entire population in town and city levels. Only a few drugs are imported such as cancer-related drugs. Vaccines are mostly made locally. Traditional medical systems (Unani, homeopathy and Ayurveda) are widely accepted and popular.

Manufacturing capabilities of the pharmaceutical sector are very strong. It generated US\$ 1.7 billion in sales in 2012, with export to 87 countries. About 10 of 253 enlisted firms have been following the GMP standards. At present, 20 companies are listed on the stock exchange. The National Drug Testing Lab (DTL) and the National Control Labs (NCL) are expected to start functioning from mid-2015, after staff recruitment stands done.

There is, however, a dearth of skilled nurses, and diagnostic labs and lab technicians in rural areas. There is a need for more equity in access to care. The private sector's services are not regulated and are not affordable by many.

The National System for Research and Development (NSR&D) of Bangladesh has public and private sector. While the R&D in the private sector stands at less than 2.5% of total generated revenue, the R&D in pharmaceuticals is nearly absent in the public sector. The Science & Technology Ministry has developed some processes in the pharma area with some R&D on herbs and plants ongoing in the traditional medicine area. Funding for R&D is not well-documented. Some private companies are doing limited research for active ingredients.

About 10 private companies have allocated funds for R&D, mostly for vaccine quality and for producing generic versions of patented medicines. There has been very little research on the status of traditional medicines and their pricing mechanisms. Research of the current status of pharmaceutical production has been done to some extent. There is ongoing data collection on sales, growth of the sector, annual revenue, profits, and taxes paid to the Government by the industry. Patented drugs are imported and are sold at very high prices. The TRIPS Doha round flexibilities have not been applied rigorously. Compulsory licensing has not been practiced and is not needed due to the exemption from TRIPS for Bangladesh, although production of "generics" of patented drugs has been encouraged under "public health interest" of the Doha Round flexibility allowed for Bangladesh (as an LDC). Some R&D experts are now teaching at universities and are working for the Council of Scientific and Industrial Research (BCSIR). The private sector has only a handful of R&D experts.

Gaps in R&D investments for Types I, II and III diseases has been growing in Bangladesh. Some donors have been supporting the containment of malaria and TB (Global funds and GAVI), through procurement of insecticide-treated bed nets and special medicines for Type-II and Type-III illnesses.

The government's SADP allocations have been increasing for Type-III illnesses mainly for treatment and for hospital infrastructure. Disease control and management for TB (XDR and MDR) and malaria and the Type III diseases has been strong. As for NCDs, behaviour-change communication and preventive support through health promotion have been spearheaded by the government. Universal health coverage (UHC), in terms of equity and access to care, is planned to be achieved by the year 2032, through a PHC essential package and through limited risk-pooling through community health insurance schemes. The government has begun to promote research through the BMRC supporting quantitative and qualitative research courses and formulating ethics and research guidelines. Clinical trials are being regulated by the government. There is an urgent need to start technology transfer for production of ARVs and APIs in Bangladesh. The NCL and DTL labs have to be started right away to test the quality of vaccines and medicines. Training is required for nurses and technicians (diagnostics).

Details on the infrastructure for drug development/testing were also presented. The NCL and DTL have been fully set up, with WHO support. They have also been given legal standing. Testing may begin from mid-2015. The ICDDR,B has been doing an average of 3-6 new clinical trials each year on diarrhea and cholera-related treatments. The IRB process is strong in Bangladesh. The public universities, ICDDR,B, and NIPSOM have their own IRBs, which are functioning in a very transparent and efficient manner. There is a plan to bring all invasive health research under the purview of the MOH and the BMRC, through new ethical guidelines. The DRICM has added testing lab facilities with its existing ones.

In respect of national coordinating systems in the health sector for R&D, the BMRC coordinates and keeps record of all the health-related research and work done in hospitals/institutes engaged in disease control and R&D in health systems work. The BMRC, the BCSIR, ICDDR,B, NIPSOM and NIPORT are dedicated to health research work. Coordination and collaboration among institutions are yet to be made robust and well structured.

In the area of priority setting for health research, drug-related data are scarce in Bangladesh. Systematically, a firm named IMS collects manufacturing and sales data for every pharmaceutical company in Bangladesh. The MIS department of MOH collects prevalence and incidence data. The Bureau of Statistics collects generalized health information. Disease burden studies have been done for only a few diseases, per episode, such as malaria, HIV-AIDS and dengue. Training for nurses is going on, but there is conspicuous shortfall. There is a critical need for qualified nurses and skilled birth attendants although the recruitment is a continuous process.

Some areas for potential collaboration were identified. These include HRH, an area that needs immediate attention. Staff retention in rural hospitals stands as a big challenge. The number of doctors is higher than the number of trained nurses (2:1). Bangladesh is interested in establishing partnerships for R&D with other developing countries. South-South collaboration (mainly with China, India, Malaysia and Thailand) may also be useful, for API technology transfer. Pre-qualification is a major barrier to further growth of the industry.

In the area of R&D, there is a need for more research funds. The government rarely allocates funds for true research. Much more needs to be done to train researchers and to develop R&D capacity of the private sector. Capability for technology transfer/absorption for research is important: The private sector in Bangladesh however has the capability to absorb research results and use them effectively. More rewards and incentives for R&D work have to be given out. The area of disease surveillance needs to be further strengthened.

India

Country presentation from India was made by Professor N.K. Ganguly, National Institute of Immunology, New Delhi.

Dr Ganguly gave a detailed overview on the health and socioeconomic indicators of India. Data on health status and disease burden show that Types I, II and III disease are widely prevalent in India. India has the highest burden of communicable diseases in the world; however there is a definite shift towards noncommunicable diseases, with India set to become the diabetes capital

of the world. There are higher rate of cardiovascular diseases & COPD and increase in incidence of cancer. This reflects an epidemiological transition of diseases burden with steady rise in NDCs.

About 20 diseases contribute to an estimated 80% of disease burden in India and these include both communicable and noncommunicable diseases. In Urban India, mortality is majorly because on noncommunicable diseases while in rural India it is the communicable, maternal, perinatal and nutritional conditions. The diseases burden is an important criterion for health research prioritization and over the next 25 years, many developing countries such as India are likely to be exposed to noncommunicable diseases for disability and premature death.

India has a strong health research policy framework such as the National Health Research Policy (NHRP). The NHRP formulated in 2011 aims to:

- ◆ identify priorities for effective and ethical health research in accordance with national health agendas and global commitments such as MDG and IHR, emphasizing that the results of health research are translated into action;
- ◆ foster intersectoral coordination to promote innovation leading to effective translation to indigenous production of diagnostics, vaccines, therapeutics, and medical devices, etc.;
- ◆ focus on the vulnerable, the disadvantaged and marginalized sections of society;
- ◆ strengthen national network;
- ◆ set strategies and mechanisms to assess the cost effectiveness and cost benefits of health interventions; and
- ◆ create, nurture human resources and infrastructure, encourage international collaborative research, which contributes to national health.

Several proposals for legislation to enable the achievement of the above-mentioned aims are pending such as Food Safety and Standard (Amendment) Bill 2014 (now withdrawn); The Indian Medical Council (Amendment) Bill 2013 (still pending); The Drug and Cosmetics (Amendment) Bill 2013 (now withdrawn), The National Commission for Human Resources for Health Bill, 2011 (still pending) and Biotech Authority Bill 2013 (lapsed).

There have been attempts towards priority-setting exercises for health research in India such as using matrices like the Global Forum for Health Research (GFHR), ACHR framework, WHO SEARO-Regional Priorities, the WHO-India Country Cooperation Strategy (CCS) 2012–2017, the National Institute of Health, etc. Priority settings in research are based on certain criteria:

- ◆ Answerability – the research question can be ethically answered.
- ◆ Effectiveness – the new knowledge is likely to result in an effective intervention or programme.
- ◆ Deliverability – the intervention or programme will be deliverable, acceptable and affordable.
- ◆ Potential Impact – the intervention or programme has the potential to substantially reduce maternal and perinatal mortality, morbidity and long-term disabilities.
- ◆ Equity – the intervention or programme will reach the most vulnerable groups.

India has a national data collection systems, some of them are disease-specific surveillance networks, integrated disease surveillance programme, registries for cancer and clinical trials, NCD framework for monitoring. The national e-health initiative (NeHA) has nation-wide implementation. In India, currently, there are more than 400 platforms for implementing Telemedicine projects. The main agencies implementing e-health initiatives are ISRO, department Of Information Technology, Ministry of Communication &IT, Ministry of Health &Family Welfare, State Governments and Medical Institutions.

Dr Ganguly gave an overview of the numerous institutions contributing to R&D such as the National System for Research and Development and the various Departments of Government of India viz., Department of Health Research, Department of Biotechnology, Department of Science & Technology, Union Ministry of Micro, Small & Medium Enterprises (MSME) Department of Scientific & Industrial Research, Indian Council of Medical Research (ICMR), and Council of Scientific & Industrial Research, etc.

ICMR has 6 medical research centres, 21 theme based National Institutes and more than 100 filed stations. Its strengths are in the area of disease biology, epidemiology, and clinical trials. CSIR has more than 12 institutes engaged in medical research and innovation, its area of strength being drug discovery, implants and devices, diagnostics, innovation in process technologies, open source drug discovery, PPPs and IT. MSME contribute nearly 8% to India's GDP with 45% contribution to the manufacturing output, of this 40% is exported; these enterprises are the launching ground for innovation.

There are 398 medical colleges registered with the Council of India, from 1998-2007, 3298 PhDs issued were in Medical sciences, 603 in general sciences and 3921 in engineering and technology. India has published total 2 lakh papers in last 10 years; most of them for communicable diseases with 100 medical journals. The Public Health Foundation of India (PFHI) is a public-private initiative to redress the limited institutional capacity in India for strengthening training, research and policy development in the area of public health.

Some of the major outbreaks which India tackled with its own resources are Dengue, JR, Cholera, Typhoid, CCHF fever (2010-2013), H1N1 (2009), H5N1 (2003-2004), SARS (2003) NIPAH (2001), Plague (1994).

One of India's success stories is their innovative financing mechanism called Biotechnology Industry Research Advisory Council (BIRAC) under the DBT that supports product development under the public-private mode. Till date the BIRAC has supported 240 companies for 360 projects with a funding support of about US\$ 100 million with the private sector contributing about US\$ 120 million. Of these, 77 projects involved Industry-Academia collaborations which have delivered 17 affordable products and 11 new technologies creating 24 intellectual property and 3 bioindustrial facilities.

Similarly BIPP (Biotechnology Industry Partnership Programme) and SBIRI (Small Business Innovation Research Initiative) are industry led with or without academic partners, CRSS is public-sector driven with industry partnership restricted to contract research; BISR is public-sector driven and industry supported, RAPID is a consortia with both public and private sector working for a common goal.

The Technology Development Board of the department of science and technology since inception in 1996 offered a total funding of Rs 1052.02 crore of which the assistance to health and medical sector accounted for 62 projects with a total cost of Rs 852.08 crore. Some major products included vaccines like Shanvac-B; Revac-B; LARV; FMD Vaccine, drugs like INF alfa; Indikinase, Cefixine, Betacarotene; human growth factor and some anti-infective. Support under another programme called the New Millennium Indian Technology Initiative (NMITLI) of the CSIR, New Delhi, has also resulted in several products for the health sector. There are also several interagency joint initiatives with the government, private sector, voluntary agencies from abroad for health product development, several clusters created by the DBT for product development, Translational Research Units created by the ICMR, biodesign initiatives steered by the DBT, etc.

Dr Ganguly also gave a brief glimpse of the publication profiles, patent filings and technologies transferred to industries by the major health research agencies of India. He mentioned that the funding for the health sector as a percentage of GDP is about 3.9%, which is well below many developed countries or even China. There are various schemes for capacity-building in the health sector by various agencies. Dr Ganguly mentioned about the gaps in investments for health research and development and the need for newer models to promote innovation in health research.

India has identified some areas of potential collaboration. These are:

- ◆ common health problems of the Region such as leishmaniasis, polio (India and neighbours); melioidosis (Indonesia, Thailand); arsenic problem (Bangladesh); snakebite (Myanmar, Nepal);
- ◆ clinical research and ethics;
- ◆ cross-border material transfer agreements, pooling of patents and IP sharing;
- ◆ harmonization in regulatory guidelines across the Region;
- ◆ the creation of common manufacturing and testing facilities especially for devices; and
- ◆ creation of genome databases from the Region.

INDONESIA

The presentation on progress for implementation of GSPA-PHI for Indonesia was made by Dr Selma Siahaan and Dr Basundari Sri Utami of National Institute of Health Research and Development, MoHRI.

Incidents of type I and II diseases are more prevalent in Indonesia. Availability of health products (diagnostics, vaccines and drugs) is managed under the National Medicines Policy and is well designed to take care of the population's medicinal needs.

The national policy has three pronged objectives of availability, affordability, sustainability of medical products (e-catalog, fully controlled prices for generics); safety, efficacy and quality of medicines (NDRA); and rational use of medicines (EML, national formulary). Several medicines are provided by the central government such as vaccination for children under 5 and pregnant women; medicines for specific diseases such as TB, HIV-AIDS, Malaria are mostly locally made

generic medicines. The Indonesian government also has made use of the compulsory license provision to ensure availability of HIV and Hep-B drugs like Efavirenz, Abacavir, Didanosin, combination of Lopanavir&Ritonavir, Tenofovir and combination of Tenofovir and Emtristabin & combination of Tenofovir, Emtristabin and Evafirenz (Law No. 14 of 2001 on Patent Government Regulation No. 27 of 2004 on Procedures for the Implementation of Compulsory License by the Government).Indonesia plans to launch a Law of National Social Insurance system by 2014.

The domestic manufacturing capacity is however hindered by dependence on imported raw materials; limited R&D for raw materials and new medicines; and limited funding for R&D. Indonesia has the capability to produce and export vaccines to many countries (BIOFARMA) as it has the skilled human resource and knowhow but lacks infrastructure, funds and synergies among related R&D stakeholders, which stops the sector from achieving its full capacity.

Indonesia has a well spread-out national system for R&D with existence of R&D institutes such as NIHRD-MoH, universities and the Indonesian Institute of Science and National Research Council. There are active R&D collaborations between government sectors, government and private research consortiums, international collaborations (WHO) and INA Respond (Indonesia research partnership on Infectious Diseases). Funding sources are the government, private funders and international agencies such as the Global Fund, JICA, USAID and AUSAID. When it comes to R&D resource sharing, Indonesia produces both national and international journals with a system of INA response in place. Most of the patents have been filed in the field of diagnostics, vaccines, traditional medicines and medicines.

There are many gaps in R&D investments. Investment for type I, II and III diseases are spread out with the exception of traditional medicines. Links between disease control and management programmes have not been integrated; there is a need to strengthen top referral laboratories. Innovation in research is limited, and special attention must be given to specific requirements such as transfer of knowledge, capacity-building with a focus on medicines diagnostics and medical devices.

Indonesia has a National Research Agenda 2010–2014 in place for development of vaccines, drugs of raw materials, traditional medicines, health and medical devices. There are active clinical trials under various phases, which are monitored by the National Ethics Committee, NIHRD and universities.

A national coordination system in health sector R&D has been established, with MoH (as per decree no.791/1999) as the coordinator. Hospitals engaged in disease control and NIHRD carry out surveillance and clinical studies. Institutes like the Indonesia Institute of Science, Universities, Ministry of Research & Technology and NIHRD are engaged in medical research.

To prioritize health research, Indonesia has in place a national data collection system with an online library and management data library in NIHRD. A National Research Agenda 2015–2019 on the health sector is to be finalized based on burden of diseases for medicines, traditional medicines, vaccine and diagnostics. For allocation of resources, government, private and donor agencies support is being promoted.

Indonesia has identified several areas of collaboration. These are:

- ◆ Human resource development: on-the-job training; exchange studies, fellowship, internship; further studies; and conference, seminars, etc.;
- ◆ Research gaps, partnership prospects: strengthen research network, harmonize research agenda and interest, strengthen capacity for negotiation (MoU, LoA, etc.);
- ◆ Research needs for types I, II and III diseases: collaboration in transfer knowledge in research for self-supportive raw materials for medicines; medical innovation;
- ◆ Capability for technology transfer/absorption; and
- ◆ Systems of translation of leads to support and promote the development of indigenous herb medicines genetic resources to be innovative products.

Sri Lanka

The presentation of Sri Lanka was given by Dr B.V.S.H. Beneragama, Director (Family Health Bureau), Ministry of Health, Colombo, and Prof. Vajira H. W. Dissanayake, Professor in Anatomy, Human Genetics Unit, Faculty of Medicines, University of Colombo, Colombo.

Sri Lanka is a lower-middle-income country with strong health-care facilities available within 3.8 km of every household; working towards elimination of diseases such as polio, malaria, congenital syphilis, lymphatic filariasis, measles, leprosy and rabies; with free outdoor and indoor care to everyone; and expanded programme of immunization with greater than 95% coverage. Sri Lanka's private and public sector share almost equally in health-care financing. Sri Lanka is undergoing a demographic and epidemiological transition towards an increased burden of noncommunicable diseases.

The presentation discussed the GSPA national consultation process and presents the data from Sri Lanka on National Assessment Report commissioned by SEAR. For this consultation process, six meetings were organized over the span of eight months, a modified GSPA assessment tool was used Sri Lanka conducted workshop on "Promoting innovation and access to health products in Sri Lanka by National Assessment Tool" on 28-29 April 2014, Colombo utilizing the assessment tool developed for GSPA. A "Second National Consultation on Promoting innovation and access to health implementation GSPA" took place in Colombo on 26 September 2014, and the report has been launched and formally accepted on 13 March 2015.

Regulatory system for pharmaceuticals and clinical trials are managed via CDDA Act of 1980, eight ethics review committees recognized by CDDA and National Medicinal Drug Policy (2006). A separate draft for division for clinical trial regulation already prepared and an online registration system is under development as well. Various steps taken by the CDDA to improve the quality, safety and efficacy of pharmaceuticals include:

- ◆ Good Manufacturing Practices (GMP) inspections;
- ◆ making inclusion of bioequivalence data in product dossiers compulsory;
- ◆ evaluation of biosimilar products according to WHO guidelines;
- ◆ regulation of Active Pharmaceutical Ingredients (APIs);
- ◆ strengthening of Post Marketing Surveillance;
- ◆ strengthening of Pharmaco-vigilance; and
- ◆ prequalification of suppliers

Sri Lanka imports all its vaccines, biosimilars, injectable and 85% of its drugs. It has ten major local manufactures (including government owned pharmaceutical manufacturing corporation) producing generic medicines and one government owned national laboratory with limited facilities. Now steps are being taken to improve local production such as giving tax incentives for investment in production and buyback guarantee schemes by the state.

National system of Research & Development in Sri Lanka is limited despite having multiple stakeholders. The policy guidance is coming from NASTEC²² with coordination efforts from COST.I²³. Funding is sourced from government bodies like NRC, NSF, NHRC and UGC, which together propose total grants for approximately US\$ 5 million. Other sources of funding are international organizations like The Global Fund, Bill & Melinda Gates Foundation, private sector funding and venture capital are available but they are limited. Priority setting for health research is done by the National Health Research Council (NHRC).

When it comes to medical journals, Sri Lanka has an open and accessible online forum with average annual publication growth rate of 9.1%. Most of the journals originated from universities and are a product of international collaborations.²⁴ With respect to research institution framework, Sri Lanka has thirteen public and one private university, one western medicine research institute, one traditional medicine research institute and three private sector R&D institutes. In order to incentivize research work, there are provisions like research allowance, annual President's Awards for scientific publication, various awards by NSF and UGC. Clinical trials are few and commercial scale drug development is minimal. Sri Lanka must increase its focus in innovation, product development, there is a National Intellectual Property Office²⁵ and IP help desk at NSF²⁶ but the IP law needs to be strengthened.

THAILAND

Thailand's burden of disease classification is done on the basis of ICD-10 classification and health risk factors. Report on Burden of Disease for year 2009 shows an epidemiological shift for Thailand from infectious, maternal, perinatal and nutritional diseases to NCDs. Health Products (pharmaceuticals, vaccine, diagnostics, traditional medicines, medical devices) are both manufactured domestically as well as imported; 36.2% is manufactured domestically.²⁷

Looking at the R&D expenditure, from 1995–2009, total expenditure experienced an annual increase as a percentage of GDP but for the last decade it became stagnant between 0.21% and 0.26%.²⁸ From total expenditure, only 40% is by the private sector; the remaining 60% is

²² <http://www.nastec.lk/>

²³ <http://www.costi.gov.lk/index.php/en/>

²⁴ Sri Lanka in global medical research: a scientific analysis of the Sri Lankan research output during 2000-2009. BMC Research Notes 2012, 5:121.

²⁵ <http://www.nipo.gov.lk>

²⁶ <http://www.nsf.ac.lk/index.php/industry-partners-/intellectual-property>

²⁷ Source: TFDA.

²⁸ Source: R&D survey on expenditure and human resource and UNESCO Institute for Statistics. In: TDRI (2012). Evaluation system on R&D: From framework to implementation.

contributed by government, state enterprises, higher education, private non-profit and foreign sources. This however is likely to be increased to about 2.0% by 2012–2021. Human resource in R&D also witnessed an increase from 1995–2009, with health and medical science accounting for 13–15% of the increase. When it comes to technology transfer, Thailand remains a net importer as reflected in its balance of payments for royalty, patent license fees and consultant fees.

Coordination and collaboration between different sectors are managed through agencies such as MoST (NSTDA) and science parks for public and private sector, funding and research institutes for public to public and target-based budget allocation for science and technology to medical science.

Thailand has a strong indigenous base for R&D for medical devices with multisector and international participation. Thailand acknowledges the low level of investment by private sector and to stimulate some short- and medium-term financial as well as non-financial incentives have been adopted. For individual researchers there are incentives such as an annual prize, awards by TRF, NRCT, NSTDA, etc.; for students, there are scholarship and cofunding. For private sector financial incentives such as tax exemptions and non-financial incentives in the form of buddy/mentor system, etc. have been introduced.

Thailand's National plan and strategy on innovation (2012-2021) has a focus on green innovation with:

- ◆ increasing human resource in R&D to 25 per 10 000; 60% is working in the private sector;
- ◆ R&D investment \geq 2% GDP; private \geq 70%; and
- ◆ the main target in health being preventable diseases and emerging diseases with domestic science, technology and innovation in order to reduce dependence on imported technology.

Some main constraints in the Thailand R&D system include weak coordination, less than optimal human resources and suboptimal funding for R&D. R&D projects in pipeline which take priority are vaccines research & development for flu, dengue; development of HIV/AIDS medicines; diagnostics for melioidosis; and medical devices.

The area for R&D gap and prioritization include:²⁹

- ◆ self-care technologies, e.g. diagnostic tool kit for food safety, health risk;
- ◆ advanced health biotechnologies, e.g. genetic screening for ADR prevention, personalized medicines, stem cell therapy, gene therapy;
- ◆ sustainable health system, e.g. herbal medicines, substitution of imported technologies; and
- ◆ orphan medicines.

²⁹ Healthy research for healthy nation, HITAP 2013 (2) Thailand country study: R&D on Health. SEAMEO TROPMED Network 2013.

The important findings from the country study on Thailand³⁰ are:

- ♦ there is no single body that provides the policy direction for health research in the country;
- ♦ there is no single body that identifies the priority areas for health research for the entire country;
- ♦ priority areas of current research efforts are based on the policies and plans of specific institutions;
- ♦ availability of internal and external funding sources, opportunities for collaborative researches, as well as interests and expertise of the researchers influence decisions for the type and area of research conducted. However, it was also noted that several of the areas covered in the current research efforts are relevant to the health needs of the country.

Thailand is interested in collaboration for R&D in several areas.

TROPMED

A systematic review in the context of GSPA for *National Review of the current status of the elements and sub-elements of the global strategy and plan of action on public health, innovation and intellectual property* was carried out by SEAMEO-TROPMED Network and presented by Dr Ophelia M. Mendoza, University of the Philippines Campus, Quezon City, Philippines.

The Terms of Reference of this exercise were to:

- ♦ perform literature search on the 25 sub-elements and 8 elements of the GSPA;
- ♦ analyse and delineate the findings based on regional and global situation;
- ♦ identify a draft of suggested next steps for each of the 25 sub-elements; and
- ♦ come up with a survey questionnaire tool that can be used at the Regional Consultation Meeting to complete the picture of the regional situation analysis.

The data sources for the study included:

- ♦ WHO/HQ website and those of regional offices;
- ♦ programme on Public Health, Innovation, Intellectual Property and Trade or its equivalent;
- ♦ related programmes such as the Global Observatory; Immunization, Vaccines and Biologicals, etc.;
- ♦ WHO-based programmes related to GSPA such as TDR, COHRED, IVR, HINARI, etc.; and
- ♦ other organizations, programmes, initiatives involved in activities related to GSPA (PATH, BRICS, Gates Foundation, DNDi, ASEAN NDI, etc.).

³⁰ Thailand country study: R&D on Health. SEAMEO TROPMED Network 2013.

All GSPA-related materials written/published in 2008 onwards or which referred to activities implemented from 2008 onwards were included. Materials documenting activities which serve as foundation of succeeding initiatives (e.g., development of COHRED framework and tools for NHRS assessment) and documentation of “rare” activities related to GSPA (e.g., Conference on Human Resources for Health Research conducted in Africa in 2006) were excluded.

These data were analysed and the preliminary findings were presented in the regional meeting. A questionnaire developed for assessing the progress on GSPA was also circulated at the meeting. Dr Mendoza mentioned about the study limitations that included:

- ◆ very wide scope of project (25 sub-elements x 2 levels (regional and global) = 50 areas) makes it difficult to do real complete and comprehensive review of documents within 4.5 months project duration);
- ◆ fine differences between some of the sub-elements could have resulted in misclassification/misplacement of some materials reviewed and reported (e.g. element 2.3 – improving cooperation, participation, coordination of health R&D vs Element 2.5 – strengthening national and regional coordinating bodies;
- ◆ several number of materials retrieved covered overlapping topics possibly leading to omission in some sub-elements because they were already mention in a related area/topic; and
- ◆ at the regional level, bias towards India and Thailand (and some towards Indonesia) because these are the countries which are good in disseminating documentation of their activities. A matrix was presented indicating the progress in respect of each element as also a questionnaire prepared that could be used by countries to collect and sent data for final analysis.

BHUTAN

Presentation for Bhutan was made Ms Sonam Yangchen, Programme Officer, Planning and Policy Division, Ministry of Health, Thimphu, Bhutan.

The major health and morbidity indicators of Bhutan were presented. The health indicators for the country and disease show the prevalence of mostly Types I and II diseases.

Looking at the availability of health products, only traditional medicines are manufactured in Bhutan (95 products) all other medical products (allopathic medicines, diagnostic devices, reagents and medical devices) are imported. Major constraints that Bhutan faces relate to:

- ◆ Economies of scale
- ◆ Escalating cost
- ◆ Warehousing and transportation facilities
- ◆ Human resources at DoMSHI

Bhutan has no manufacturing capacity in allopathic medicines and medical devices. However for traditional medicines manufactured there is a testing lab available under DTMS. There is a

National Drug Testing lab setup under Public Health Laboratory but its capacity needs to be strengthened. Hence most of the medicines are imported.

There is a national system for R&D. Bhutan has R&D institutes such as Menjong Sorig Pharmaceuticals under DTMS, University of Medical Sciences of Bhutan, Royal University of Bhutan, and National Biodiversity Centre (NBC). There is little funding support for R&D in health. Bhutan has few PhDs and MScs in pharmaceuticals, biotechnology and medical sciences specialized in research. Bhutan has in place procedures and a regulatory framework for drug management and safety in form of Ethics Committee, pharmacovigilance, National Drug Testing Lab. There is no record of any clinical trial as Bhutan lacks the infrastructure.

On collaboration and networking front, R&D collaboration are almost non-existent with networking systems completely absent. However there are few new initiatives such as NBC collaborating with international companies in bioprospecting.

Bhutan's national data collection system includes Health Management Information System (HMIS), annual health surveys and national health surveys. When it comes to allocation of resources in year 2011 and 2012, 7.5% of all government expenditure was spent on health sector. As a percentage of GDP, the overall health expenditure stood at 3.6% and 3.8% respectively in 2011 and 2012. There was no allocation of funds for R&D in the 11th plan; however 15% of the total health budget was allocated to public health in 11th year plan. Areas for potential collaboration identified by Bhutan:

- ◆ human resources development;
- ◆ training and competency development collaboration with development partners;
- ◆ research gaps and partnership prospects;
- ◆ strengthening coordination among the stakeholders for conducting health research;
- ◆ train researchers to develop R&D capacity;
- ◆ research on biomedicines from medicinal plants;
- ◆ development of health technologies;
- ◆ partnership with other countries in R&D for Types I, II and III diseases; and
- ◆ capability for affordable transfer of health-care technology.

Maldives

The country report of Maldives was presented by Ms Aishath Mohamed, Director Pharmaceutical, Maldives Food and Drug Authority, Male and Ms Shareefa Adam Manik, Director-General Maldives Food and Drug Authority, Sosun, Magu Male'.

There is a national system for surveillance and classification of diseases. Data on disease burden show that Type I and Type II disease are more prevalent. While vaccines and medicines are available for all the diseases, Maldives imports all medical products (medicines, vaccines, diagnostics, and medical devices). Some major constraints include:

- ◆ zero manufacturing capacity for health products;
- ◆ unavailability of health products in emergencies; and
- ◆ lack of proper public procurement system.

The national health laboratory in Maldives has the capacity to test pharmaceuticals but there is lack of local capability of manufacturing/testing of health products.

The R&D system in Maldives is still growing with no major R&D institute. Small operational research on health is conducted in some health facilities and in the Maldives National University. There are no R&D funding agencies and there is little allocation for R&D in health. There are also no R&D collaborations nor a formal system of resource sharing/networking. Also, no research papers are published from Maldives. There are no patent laws as of now but an Industrial Property Act is being drafted.

Infrastructure for drug development is poorly lacking; however, it does have medicine regulations, consumer protection law and ethics committees under MoH, which includes academia. The burden of coordination falls solely on the shoulders of the Health Research Committee. A National Communicable disease surveillance system is in place for data collection but lacks a system for priority setting.

Maldives has expressed a strong potential and need for collaboration.

MYANMAR

Country presentation for Myanmar was made by Dr Myint Myint Wai, Deputy Director (Planning), Department of Health, Nay Pyi Taw.

Myanmar has prevalence of all three types of diseases Type I, II and III. Availability of health products for these diseases suffers from limited accessibility of costly drugs, there is a need to procure rapid diagnostic kits, design and introduce new vaccines (such as pentavalent, measles-rubella) to the national immunization programme. Local production of some essential medicine is carried out by Myanmar Pharmaceutical Factory, yet there is a limited capacity to produce vaccines and diagnostic facilities. Constraints faced by Myanmar are lack of human resources both in quality and quantity, transfer of technology, infrastructure, dependence of programmes on donors and weak public-private partnership.

There are gaps in R&D investment such as sustainable funding, human resource development and long-term investment such as infrastructure development. Myanmar's each and every department of Ministry of health has research programmes in various fields such as clinical, epidemiological, public health, HSR, etc. R&D funding from the government is limited and most of the funding is provided by UN agencies such as WHO, UNICEF, etc. The area of R&D collaboration needs to improve. Myanmar does not have patent laws as these are in the nascent stage of drafting.

For drug development and testing there are laws like Traditional Drug Law (1996), Traditional Medicine Council Law (2000), ethics committees at DMR and ethical review committee under DOH; however there is not much experience in the field of clinical trials, National Drug Law (1992).

When it comes to coordinating systems in the health sector R&D all central, district and township hospitals up to the station hospitals provide data on the disease incidence and

prevalence data, conduct research. Some medical universities and university on public health are engaged in medical research. All collaboration and coordination between departments and universities are under MoH.

As far as priority setting is concerned, there are national data collection systems such as the National Health Information System and National Disease Surveillance system. For allocation of resources the country majorly depends on donor grants/aids as government health expenditure is very small. But with the increasing GHP, allocation of funding is expected to increase. There is a need to increase resources for health R&D as well as on capacity-building and technology development.

Myanmar has identified human resource development; research gaps, partnership prospects; and research needs for types I, II and III diseases with respect to introducing new vaccines, drug resistant problems, social factors as potential collaboration areas.

NEPAL

Mr Bal Krishna Khakurel, Director-General, Department of Drug Administration, Ministry of Health and Population, Kathmandu, presented the country status of Nepal.

The Ministry of Health and Population in Nepal has 3 departments, 6 divisions and 4 centres. The main disease control programmes focus on NIP (10 antigens), TB (36 470 cases), HIV/AIDS (0.28%), malaria (61 risk districts 48% population live in endemic areas), kala-azar (12 districts), lymphatic filariasis (13% v. 61 districts and under 56 MDA), zoonotic diseases (6 zoonoses, 23 929 animal bites, 14 768 snake bites), dengue (183 cases in 2012), TB (36,470 cases in the year 2012-13), leprosy (0.82/10,000).

Nepal has designed a strategy to introduce new and underused vaccines (rubella, pneumococcal, typhoid, rota virus) based on disease burden and financial sustainability. The NCDs are on the agenda of new NHP 2014.

For Nepal. R&D is not a priority as yet. The existing R&D institutes include NHRC, public sector medical colleges, VBDRC, NAST, NARC, Ayurveda Res Centre. Funding agencies such as MoF, EDP's(I)/NGO exist but despite having an incentive of tax waiver are not given priority. Nepal has limited publication, no career researchers except few academicians and what exist has rampant plagiarism. Nepal does have a national patent system on herbal/TRM products in place. There are few R&D collaboration programmes such as BPKIHS, IoM. The system of resource sharing and networking is left with NHRC, UGC, etc.

R&D investment has many gaps. To fill up these gaps, Nepal must follow a research discipline, carry out operational research. Specific needs are communication and awareness on scientific and ethical support. One potential area for research is private academic institutions.

For drug development infrastructure Nepal has Drug Act 2078 (DDA&NML), which is basis for regulations. However Nepal has no innovation and developmental initiative, no separate rule for vaccines and biological. Now DDA is adopting WHO recommended procedures to approve vaccine like approval to public sector NIP vaccines if they are WHO prequalified.

Nepal's coordination system in health sector for R&D are limited, the service delivery undermines research in general. When it comes to funding, pooled funding from World Bank, UK's department for International Development, Government of Australia, KfW and GAVI Alliance have been providing pooled fund to support MoHP/GoN via SWAp. This pool funding supports governments five year NHSP2 (2010/2011-2014/2015).

Nepal is open to and has identified for itself various potential areas of collaboration. These include:

- ◆ human resources development with research focus on priority diseases, funds allocation, employment / career / academic / IP opportunity;
- ◆ integration or institutionalization of R&D and TT;
- ◆ UG /PG research curricula in health disciplines;
- ◆ exploitation of IPR waiver for LDC and promotion of export of health products as incentive for research;
- ◆ research needs on Types I, III and III diseases; and vi) collaboration with VBDR, screening of TRM, PQ of local manufacturer, pool procurement/scale;
- ◆ WHO could play role in EDP orientation on research needs, PQ of health products, laboratory capacity, SRA NRA/LDCs collaboration for HTA, REMS of health products - drugs, biologicals and vaccines, diagnostics and devices; and regional collaborative initiatives on TRM;
- ◆ use of research output in fiscal planning or resource allocation;
- ◆ impact of 70 EMs for free distribution basic HC;
- ◆ research on access to health products, VfM; and
- ◆ help in price control / monitoring systems for reducing out of pocket expenditures on health products.

4.3 Group Work

The presentations were followed by group work where the nine countries discussed the progress of GSPA over 2008–2014 and formulated the proposed action plan for the Region. Several important recommendations were made for Member States as well as for WHO.

Background for Group Work

The Global Strategy and plan of action (GSPA), **WHA61.21**, on public health, innovation and intellectual property outlined 108 specific actions across 25 sub-elements and eight main elements. These main elements are:

- I. Prioritizing research and development needs;
- II. Promoting research and development;
- III. Building and improving innovative capacity;
- IV. Transfer of technology;
- V. Application and management of intellectual property to contribute to innovation and promote public health;
- VI. Improving delivery and access;
- VII. Promoting sustainable financing mechanisms; and
- VIII. Establishing and monitoring reporting systems.

WHA62.16 called upon the public health community “to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievement, remaining challenges and recommendations on the way forward and report to the Assembly in 2015 through the Executive Board” (WHA62.16 para 6).

In July 2014 during High-Level Preparatory Meeting for Regional Committee of SEARO on GSPA and the related regional resolution SEA/RC65/R3 on the subject, the Member States have requested to take up an assessment at regional level so as to inform the World Health Assembly in 2015.

The Member States “desired that outcomes should focus on R&D for health products related to developing country needs and those of Member States of the Region. This should include mechanisms to strengthen and build R&D capacity, promote innovation and improve access to medical products, including drugs, vaccines and diagnostics. These aspects need to be reflected in the assessment of the Global Strategy and Plan of Action”. The review period is 2008–2014.

Group Guidelines

- ◆ To review 25 sub-elements of GSPA for a regional position.
- ◆ To assess existing systems of coordination functions of global entities engaged in health R&D relevant to developing countries.

5. Recommendations

5.1 Action by Member States

1. Member States agree to provide a self-assessment, as established by WHA resolution 62.16, of GSPA (Annex II) and also develop a priority mapping for the GSPA next steps on the matrix agreed (Annex II) to in the consultation.

2. Member States stress the need for concerted action on the GSPA on the following:
 - ◆ strengthen their information systems and capacity (human and infrastructure) on R&D in a collaborative and transparent manner to support evidence-based policy-making and prioritization - for example a national health R&D observatory
 - ◆ develop and/or review the policy on promoting R&D, encouraging national and regional networks, as well as south-south cooperation between networks – for example, developing a mentorship process to improve quality of R&D proposal development and implementation
 - ◆ strengthen the capacity of the regulatory authority of Member States to promote research innovation and product development
 - ◆ develop technology transfer mechanisms
 - ◆ enact/adapt national patent laws that incorporate the usage of TRIPS flexibilities and waivers as well as strengthen the expertise in IP management in a public health perspective
 - ◆ strengthen their regulation and enforcement of ethical review of research
 - ◆ invest in adequate and sustainable resources for R&D and improve its coordination, monitoring and evaluation
 - ◆ develop processes that formally encourage cooperation and collaboration between various R&D institutions in academia, commercial, public and private sectors
 - ◆ strengthen the regulation and enforcement of evaluation of quality, safety and efficacy of health products and medical devices
 - ◆ work towards establishing innovative trade mechanisms such as pooled procurement of common health products including precursors (e.g. APIs) and reference standards for Member States
 - ◆ promote exchange of information and R&D on traditional medicine

5.2 Action by WHO

1. WHO to summarize and consolidate the self-assessment of GSPA for Member States and forward the assessment from SEARO to WHA.
2. WHO should support Member States by carrying out the following recommendations:
 - ◆ develop guidelines and technical framework for prioritizing R&D needs.
 - ◆ Support collaboration among Member States including lessons learned on best practices in promoting R&D and encourage multicountry funding proposal development.
 - ◆ take appropriate measures to strengthen capacity in R&D in LDCs in the Region.

- ◆ provide a coordination mechanism for technology transfer among countries and regions as well as develop public health oriented guidelines and capacity on technology transfer among Member States and regions.
- ◆ provide technical support to promote TRIPS flexibilities and strengthen the expertise in IP management to foster access to medicine and in particular to continue to support Member States to attend WHO/WIPO/WTO training on IP and public health.
- ◆ empower LDCs to use TRIPS waivers.
- ◆ provide technical support on developing capacity in ethical review of research.
- ◆ provide technical support on developing regulation and standards on quality, safety and efficacy of health products and medical devices.
- ◆ facilitate the maximum use of financing mechanisms, including that through public-private and product development partnerships, to develop and deliver safe, effective and affordable health products and medical devices.
- ◆ develop a regional ME framework for R&D and its guidelines to be used by Member States.
- ◆ develop a new classification of diseases relevant to public health needs to replace the current type I, II and III terminology, that reflects changes in the recognition of NCDs, drug resistance, one health, urban and rural populations, new disease epidemiology, and genomics.

ANNEX 1

Address by Dr Poonam Khetrpal Singh,

Regional Director, WHO South-East Asia

Dr Pathom Sawanpanyalert, Deputy Secretary-General, Food and Drug Administration

Ministry of Public Health, Ministry of Public Health, Royal Thai Government, Distinguished participants,

Ladies and gentlemen,

I warmly welcome you to this regional meeting for assessment of progress in implementing the Global strategy and plan of action on public health, innovation and intellectual property (GSPA). Resolution WHA61.21 on the Global strategy and plan of action on public health, innovation and intellectual property is one of the most well-crafted resolutions adopted by the Sixty-first World Health Assembly in 2008. This resolution, running into 48 pages, has eight elements, 25 sub-elements and 108 action points in an Annex, which is why an exercise for assessment of GSPA is no easy task.

Nevertheless, our Region is familiar with the work relating to the GSPA and has taken the lead in the global debate on many elements of the Global strategy. We recall that at the Sixty-first World Health Assembly, in the intergovernmental working group leading to GSPA, two of the three drafting groups were chaired by Mr Naresh Dayal (India) and Dr Viroj Tangcharoensathien (Thailand) – from countries in the South-East Asia Region. The third drafting group was chaired by Dr Gashut (Libyan Arab Jamahiriya) that reviewed the matrix containing the plan of action.

The active involvement of the Member States of our Region also resulted in a regional resolution on the subject and the Sixty-fifth Session of the Regional Committee for South-East Asia in Yogyakarta, Indonesia was the first of all WHO regional committees to adopt resolution SEA/RC65/R3 on Consultative Expert Working Group on Research and Development: Financing and Coordination, (CEWG) for element 7 of the GSPA. For this reason, our resolution was discussed at all other (five) regional committee meetings of WHO. Further, this resolution formed the basis for arriving at a consensus for the draft resolution for the Sixty-fifth World Health Assembly at the open-ended meeting of all WHO Member States in November 2012. In 2013, Thailand again chaired the drafting group in the Sixty-sixth World Health Assembly for element 7 of the GSPA for CEWG.

Distinguished participants, dear colleagues, ladies and gentlemen,

The key issue that GSPA seeks to address is that market mechanisms coupled with intellectual property rights lead to a lack of investment for research and development (R&D) to generate health products to tackle diseases of relevance to developing countries. Further, the mandate of the CEWG was to explore and where appropriate, promote a range of incentive schemes for R&D, including addressing and encouraging de-linking of the costs of R&D from the price of health products. We need innovative interventions in public health that result in better health-care models and better regimens of treatment, including more effective surveillance systems for better health outcomes for our populations.

The GSPA is an expansive instrument for action and encompasses many aspects and programmes. This is why the GSPA resolution WHA61.21 has spawned and is quoted in a number of WHA resolutions in diverse domains. For example in 2009, GSPA was referred to in WHA62.13 for promoting policies on innovation and standard settings to ensure quality, safety and efficacy of traditional medicine. Again, in 2010, GSPA was mentioned in WHA63.21 on WHO's role and responsibilities in health research. This year, at the Sixty-seventh World Health Assembly, GSPA was quoted in a number of resolutions, for example, WHA67.20 on Regulatory system strengthening for medical products WHA67.22 for Access to essential medicines and WHA67.25 on Antimicrobial resistance.

The issues of intellectual property also have particular significance in other resolutions such as the standard material transfer agreement (SMTA 2) in resolutions WHA62.10 on Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits of the Sixty-second World Health Assembly in 2009, and WHA67.21 on Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy of the Sixty-seventh World Health Assembly in 2014.

Distinguished participants, dear colleagues, ladies and gentlemen;

Resolution WHA62.16 on the Global strategy and plan of action on public health, innovation and intellectual property has called upon the public health community "to conduct an overall programme review of the GSPA in 2014 on its achievement, remaining challenges and recommend on the way forward and report to the Assembly in 2015 through the Executive Board". A number of Member States are proceeding with consultations. For instance, I understand that in December 2014, the Union of South American Nations, (UNASUR) in Latin America is also meeting to discuss issues related to intellectual property rights to follow up on the CEWG report.

During the years following the GSPA, a wealth of information is available. There is a need to examine global coordination, and mobilization of inputs and contributions from all stakeholders and partners. While we work through this assessment, we need to examine how a follow-up for the GSPA can result in

resolving some of the persistent public health challenges in our Member States. We need to revisit the issues relating to basic, clinical and health systems research for assurance of its safety, efficacy and quality. We also need to strengthen our health systems, developing clear national policies on health research and improving coordination of health activities at national and institutional levels to address various issues. Integration of the use of traditional systems of medicine into national health-care systems is also important for our Region.

The exchange of views and information during the course of this meeting should enable an assessment that leads to next steps in GSPA that are feasible and practical. For this reason, it is important to have a wide range of deliberations. I am happy to note the presence of international and national experts, senior public health officials from the ministries of health of our Member States, WHO national focal points, experts from government and academic institutions as well as representatives from international organizations dealing with GSPA and related issues.

This meeting is being held at a time when world attention is focused on public health. As you are aware, we are facing significant threats from the Ebola epidemic that continue to be worrisome. As we gear ourselves for an assessment which will stand us in good stead in the next few years, we need to take into account the wide spectrum of issues relating to emerging infectious diseases, communicable and noncommunicable diseases.

Distinguished participants,

I hope this consultative process would promote discussions and regional consensus in a global perspective. This would augur well for GSPA and reflect our regional aspirations and needs in this vast area. I encourage you to actively participate to make this consultation fruitful and give necessary direction to the GSPA process for the Member States in our Region and at the global level. I hope that this meeting will enable Member States to take this agenda forward in a coordinated and concerted manner at the Sixty-eighth World Health Assembly.

In conclusion, I thank the Ministry of Public Health, Royal Thai Government for hosting this meeting as well as all participants for sparing their valuable time to attend the meeting. I also wish you all the best for a productive consultation and for a pleasant stay in Bangkok.

Annex 2

IMPLEMENTATION OF THE GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (GSPA-PHI)

REGIONAL SITUATIONAL ANALYSIS

COUNTRY: _____

NAME OF PRINCIPAL RESPONDENT: _____

POSITION: _____

OFFICE _____

EMAIL ADDRESS _____

Objectives

- 1. To conduct self-assessment in a honest way the achievements of the implementation of GSPA-PHI 2008-2014, main challenges and future priorities by each of the 25 sub-elements of the plan**
- 2. To generate country-specific priority actions for the subsequent phase of the GSPA 2015-2020**
- 3. To identify a few potential cross country actions in the implementation of the future plan**

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>Element 1. Prioritizing research and development needs</u>	<u>Score 1-5 (lowest to highest) and describe what have been</u>	<u>Description of challenges</u>	<u>Description of key priority to address</u>	<u>Score 1-5 (lowest to highest)</u>	

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
	<u>achieved?</u>				
<u>(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries</u>					
<u>(1.2) formulating explicit prioritized strategies for research and development at country and regional and interregional levels</u>					
<u>(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples</u>					
<u>Element 2. Promoting research and development</u>					

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area</u>					
<u>(2.2) promoting upstream research and product development in developing countries</u>					
<u>(2.3) improving cooperation, participation and coordination of health and biomedical research and development</u>					
<u>(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries</u>					
<u>2.5 establishing and strengthening national and regional coordinating bodies on research and development</u>					
<u>Element 3. Building and improving innovative</u>					

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>capacity</u>					
<u>(3.1) building capacity of developing countries to meet research and development needs for health products</u>					
<u>(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation</u>					
<u>(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries</u>					
<u>(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments</u>					
<u>(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation</u>					

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>Element 4. Transfer of technology</u>					
<u>(4.1) promoting transfer of technology and the production of health products in developing countries</u>					
<u>(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development</u>					
<u>(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies</u>					
<u>Element 5. Application and Management of intellectual property to contribute to innovation and promote public health</u>					
<u>(5.1) support information sharing and capacity-building in the application and management of intellectual property with respect to health related innovation and the</u>					

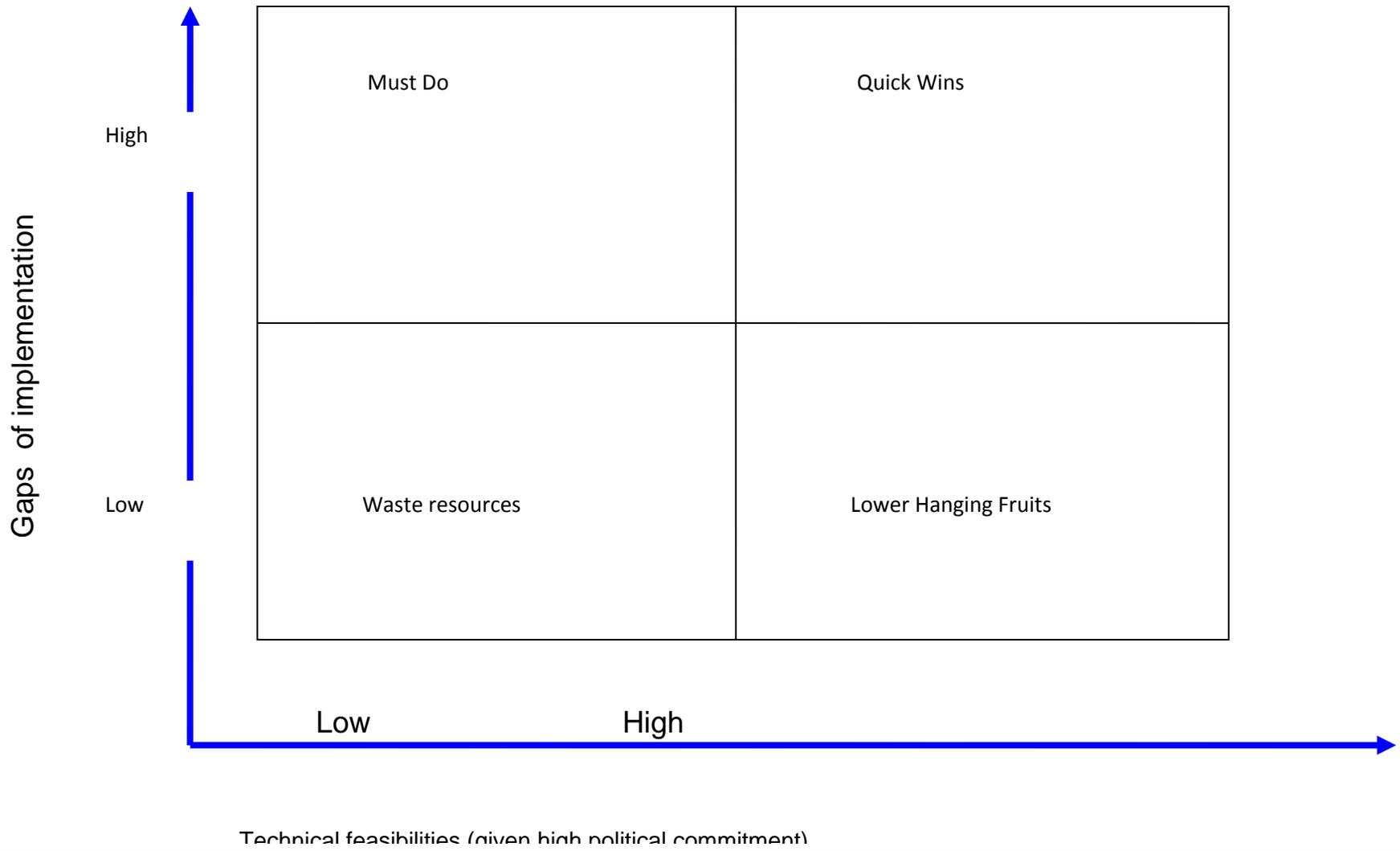
<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>promotion of public health in developing countries</u>					
<u>(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products</u>					
<u>(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II</u>					

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases</u>					
<u>Element 6. Improving delivery and access*</u>					
<u>(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system</u>					
<u>(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices</u>					
<u>(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs</u>					
<u>Element 7. Promoting sustainable financing</u>					

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>mechanisms</u>					
<u>(7.1) endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries</u>					
<u>(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public- private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices</u>					
<u>Element 8. Establishing monitoring and reporting systems</u>					
<u>(8.1) measuring performance and progress towards objectives contained in the strategy and plan of</u>					

<u>GSPA-PHI Elements and sub-elements</u>	<u>Major achievement,</u>	<u>Main challenges</u>	<u>Key priority actions</u>	<u>Technical feasibility for implementation</u>	<u>Source of support</u>
<u>action</u>					

- It is optional. In case the participants wish to contribute, they may please do so.



ANNEX 3

Agenda

1. Opening Session
2. Briefing on background and objectives of meeting of experts on Regional Meeting for Assessment of Progress in Implementing Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) for South-East Asia
3. Present position on the progress made in implementing GSPA on Public Health and Innovation and Intellectual Property for South-East Asia
4. Presentations by international experts in the field GSPA
5. Country Presentations
6. Group Work to formulate Regional position on GSPA
7. Presentations by Groups
8. Conclusions and Recommendations
9. Closing

ANNEX 4

LIST OF PARTICIPANTS

Bangladesh

1. Ms Parveen Akter
Joint Secretary
Ministry of Health and Family Welfare
Government of Bangladesh
Bhavan-3, Secretariat Complex
Dhaka 1000
Ph:029540493
Mobile:01712034786
Email:parveenakter85@gmail.com
2. Ms Salima Jahan
Deputy Secretary
Ministry of Science and
Technology
Government of Bangladesh
Bhavan-8, Secretariat Complex
Dhaka 1000
Email:jahansalima@yahoo.co.uk

Bhutan

3. Mr Ugyen Dendup
Head
Mengong Sorig Pharmaceutical
Ministry of Health
Post Box 297
Thimphu
Ph: 975325731
Mobile : 17990696
E-mail: ugyendendup@health.gov.bt;
menjongssorig@yahoo.com
4. Ms Sonam Yangchen
Programme Officer
Planning and Policy Division
Ministry of Health
Post Box No.726
Thimphu
Mobile: 77208844
E-mail:syangchen@health.gov.bt

India

5. Dr Chander Shekhar
Scientist "G"
Indian Council of Medical Research
Ansari Nagar
New Delhi110029
[Tel:26589880](tel:26589880)
Mobile:9810118206
Email:shekhar57@yahoo.com
6. Mr Ranga Chandrashekar
Deputy Drug Controller (India)
Central Drugs Standard Control
Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhavan, ITO
Kotla Road
New Delhi 110002
Tel: 23212074
Mobile:9650012567
Email:rca.ddci@yahoo.in; dcni@nic.in

Indonesia

7. Ms Selma Siahaan
Researchers
Centre for Humaniora
Health Policy and Community
Empowerment
National Institute of Health
Research and Development
Ministry of Health
Jakarta
[Tel: 62 81382754097](tel:6281382754097)
Mobile:62 2081382754097
Email:selmasiahaan@yahoo.com
8. Dr Basundari Sri Utami
Researchers
Centre for Applied Health Technology
and Clinical Epidemiology
National Institute of Health

Research and Development
Ministry of Health
Jakarta
Tel: 62 81282585444
Mobile:62 081282585444
Email:basundari_su@yahoo.com

IP Section
Ministry of Science and Technology
Yangon
Tel: 09 5178926
Email: moemoe.thwe6@gmail.com

9. Ms Rika Rianty
Center for International Cooperation
Ministry of Health
JLHR Rasuda Said KAV 5-7
Jakarta
Tel: 6221 521 4879
Mobile:81387444561
Email: rika.rianty85@gmail.com;
multilateral.pkln@gmail.com

Maldives

10. Ms Shareefa Adam Manik
Director-General
Maldives Food and Drug Authority
Sosun, Magu
Male'
Tel: 960 7772025
E-mail: shareefa@health.gov.mv
11. Ms Aishath Mohamed
Director Pharmaceutical
Maldives Food and Drug Authority
Male'
Tel:9603014307
Mobile: 960 7732901
E-mail:
aishathmohamed@health.gov.mv

Myanmar

12. Dr (Ms) Myint Myint Wai
Deputy Director (Planning)
Department of Health
Office No.4
Nay Pyi Taw
Tel: 9567411163
Mobile: 95 9 8303006
Email: mmwai2011@gmail.com
13. Dr (Ms) Moe Moe Thwe
Deputy Director

Nepal

14. Mr Bal Krishna Khakurel
Director-Generel
Department of Drug Administratin
Ministry of Health and Population
Bijuli Bazar, Baneshwar
Kathmandu
[Tel:977 1 4780432](tel:97714780432)
Mobile: 98600016474
Email:bkkhakurel@yahoo.com;
director@dda.gov.np
15. Mr Hari Prasad Ghimire
Under Secretary
Ministry of Science, Technology
and Environment
Singha Durbar
Kathmandu
Tel: 97 1 4211946
Mobile: 977 9841364043
Email: hpghimire_5@yahoo.com

Sri Lanka

16. Dr B.V.S.H. Benaragama
Director (Family Health Bureau)
Ministry of Health
De Seram Place
Colombo 10
[Tel:9411 2690790](tel:94112690790)
Mobile: 0777699647
Email: fhb.dmch@gmail.com
17. Dr Rasika Induruwage
Medical Officer, ET&R Unit
Ministry of Health
Colombo
Email: rasdil2@gmail.com

Thailand

18. Dr Pathom Sawanpanyalert
Deputy Secretary-General
Food and Drug Administration
Ministry of Public Health
Tiwanon Road
Nonthaburi 11000
Tel: 66 2 590 7007
Mobile:66816124480
Email: pathom@health.moph.go.th;
pathoms@fda.moph.go.th

19. Dr Kriskrai Sitthiseripratip
Principal Researcher
National Metal and Materials
Technology Center
National Science and Technology
Development Agency
Ministry of Science and Technology
Bangkok
Mobile: 66 8 41541000
E-mail: kriskrs@mtec.or.th;
kriskrai@gmail.com

20. Mrs Sitanun Poonpolsub
Pharmacist, Professional Level
Technical and Planning Division
Food and Drug Administration
Nonthaburi 11000
Tel: 66 2 590 7021
E-mail: psitanan@gmail.com;
psitanan@fda.moph.go.th

21. Dr Chutima Akaleephan
Pharmacist, Professional Level
International Health Policy
Programme
Bureau of Policy and Strategy
Office of the Permanent Secretary
Ministry of Public Health
Tiwanond Road
Nonthaburi
Tel: 66 2590 2366
Mobile:66814431766
Email: chutima@ihpp.thaigov.net

Mrs Achara Eksaengsri
Deputy Managing Director
Government of Pharmaceutical
Organization
Nonthaburi

Tel 66 2 2038101
Email: aeksaengsri@yahoo.com

Temporary Advisers to the Regional Director

22. Professor Harun-Ar-Rashid
Professor of Public Health and
Research
Management and
Director, Research and International
Collaboration
School of Health Sciences
State University of Bangladesh
Dhaka, Bangladesh
Mobile:88-01711 351 000
Email: harashid@citech.net,
harun.rashid@sub.edu.bd

23. Dr Halla Thorsteinsdóttir
Small Globe and the University of
Toronto
264 Indian Road Crescent
Toronto, Ontario M6P 2G7
Canada
Tel: 1 647 294 7069
E-mail:
halla.thorsteinsdottir@gmail.com

24. Professor N.K. Ganguly
Visiting Professor of Eminence
(former Director General-ICMR)
Policy Centre for Biomedical Research
National Institute of Immunology
Aruna Asaf Ali Marg
New Delhi 110067
India
Mobile:9811504314
Email: nkganguly@nii.ac.in

25. Dr Tjandra Yoga Aditama
Chairman
National Institute of Health
Research and Development
Ministry of Health
Jl Percetakan Negar No.29
Jakarta 10560
Indonesia
Tel:62 21 4245214
Mobile:62 21 4216059
E-mail: doctjand@gmail.com

26. Dr Ophelia M. Mendoza
47 Pook Dagohoy
University of the Philippines Campus
Diliman, Quezon City
Philippines 1101
Mobile: 63 9154297000
Email: opheliamendoza@gmail.com

Boston MA 02118
USA
Tel: (617) 414-8960
Mobile: 617 784 4031
E-mail: keusch@bu.edu

27. Professor Vajira H. W. Dissanayake
Professor in Anatomy
Human Genetics Unit
Faculty of Medicines
University of Colombo
Kinsey Road
Colombo 8
Sri Lanka
[Tel:94112689545](tel:94112689545)
Mobile: 94777351835
Email: vajirahwd@hotmail.com

28. Dr Bernard Pécoul
Executive Director
Drugs for Neglected Diseases
Initiative
Chemin Louis-Dunant 15
CH1202 Geneva
Switzerland
Tel: 41 22 906 92 30
Mobile: 41 79 219 65 60
E-mail: bpécoul@dndi.org

29. Dr Simon Lawrence Croft
Professor of Parasitology
Head, Faculty of Infectious and
Tropical
Diseases
London School of Hygiene and
Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Tel: 44 (0)20 7927 2601
Mobile:44 7515 189395
E-mail: simon.croft@lshtm.ac.uk

30. Dr Gerald T. Keusch
Professor of Medicine and
International
Health
Boston University
School of Medicine
620 Albany Street

Resource Persons

31. Mrs Pascale Boulet
DNDi IP and Policy Consultant
Drugs for Neglected Diseases initiative
15 Chemin Louis Dunant
1202 Geneva, Switzerland
Tel: 33 61 964 0119
Email: pboulet@dndi.org

32. Mr Francisco Viegas Neves da Silva
International Affairs Office – AISA
Minister’s Cabinet
Brazilian Ministry of Health
Bloco G - Esplanada dos Ministérios,
Brasília - DF, 70058-900
Tel: + 55 61 3315-2226
Email: francisco.viegas@saude.gov.br

33. Dr K. Satyanarayana
Flat 51, IES Apartments
Plot No.9, Sector 4, Dwarka
New Delhi 110029
India
Mobile:9868807583
Email:kanikaram_s@yahoo.com

WHO Secretariat

WHO-HQ

34. Ms Claudia Nannei
Technical Officer

WHO-SEARO

35. Dr Manisha Shridhar
Regional Adviser
Intellectual Property Rights,
Trade and Health
WHO-SEARO
[Operational Officer]

36. Mr Sunil Kumar Jain
Secretary, IPT Unit
WHO-SEARO

WHO Country Offices

37. Dr Nima Asgari-Jirhandeh
Public Health Administrator
WHO-Thailand

38. Dr Arifuzzaman Khan
NPO (HSF & ECP)
WHO-Bangladesh

39. Dr Madhur Gupta
Technical Officer-Pharmaceuticals
WHO-India

40. Dr Noviane Chasny
Temporary National Professional
HIS/IER, WHO-Indonesia

41. Dr Thushara Ranasinghe
National Professional Officer
WHO-Sri Lanka

42. Ms Thitaree Khotchasenee
GEAs Assistant
WHO-Thailand

