Development of a Regional Framework on Public Health, Innovation and Intellectual Property

Report of a Regional Consultation
SEARO, New Delhi, India, 5-6 April 2011

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Contents

Page

List of Abbreviations and Acronyms v

Executive summary viii

1. Introduction 1

2. General objectives of the Regional Consultation 2

3. Specific Objectives of the Regional Consultation 2

4. Inaugural session 2

5. Opening remarks 5

6. Proceedings 6

7. Technical discussions 9

   7.1 Factors promoting technical know-how in Indian micro, small and medium pharmaceutical enterprises: A Study by Prof. Arvind Chaturvedi, International Management Institute, and Mr Deepak Goyal, Director, Ministry of Statistics, Government of India 9

   7.2 Challenges in GSPA deliverables for the Indian pharmaceutical industry after TRIPS – A proposal for R&D cooperation: Prof. Sudip Chaudhuri, Indian Institute of Management, Calcutta, India 18

   7.2 New IPR regime and access to medicines in Sri Lanka – Next steps under WHA61.21: Dr Manuj C. Weerasinghe, Faculty of Medicine, University of Colombo, Sri Lanka 22

   7.3 Identification and prioritization for Regional and National Framework on Public Health, Innovation and Intellectual Property Rights in India: Dr K. Satyanarayana, Senior Dy Director-General and Head, IPR Unit, Department of Health Research, Indian Council of Medical Research, New Delhi, India 25

   7.4 National Action and Regional Cooperation on WHA 61.21 (GSPA): Mr Dinesh Abrol, Scientist (F), National Institute of Science Technology and Development Studies (NISTADS), Council of Scientific and Industrial Research, New Delhi, India 28

   7.5 The implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Time to act! Nicoletta Dentico, PHI consultant 31

8. National presentations....34

8.1 Bangladesh: Dr Choudhury Mahmood Hasan, Department of Pharmaceutical Chemistry, University of Dhaka, Bangladesh (Presentation delivered by Prof. Mahmood Hasan)....34

8.2 India: Dr K. Satyanarayana, Senior Dy Director-General and Head, IPR Unit, Indian Council of Medical Research, Department of Health Research, New Delhi, India....37

8.4 Sri Lanka: Prof. Rohini Fernandopulle, Professor in Clinical Pharmacology, Faculty of Medicine, University of Colombo....50

8.5 Thailand: Ms Chutima Akaleephan, Researcher, International Health Policy Programme, Ministry of Public Health, Thailand....54

9. Group discussion....61

9.1 Eight Elements of GSPA....62

9.2 Recommendations of SEA Region Member States on WHA 61.21, GSPA....62

10. Recommendations....63

Annexes

1. Information on medical products: Bangladesh....67

2. Information on medical products: India....68

3. Information on medical products: Indonesia....72

4. Information on medical products: Sri Lanka....73

5. Information on medical products: Thailand....74

6. Organization chart of the administrative system in relation to public health, innovation and intellectual property....75

7. Template A (Country) (Implementation Plan of WHA 61.21 GSPOA in SEA Region countries)....76

8. Adapted from WIPO database....86

9. Priorities of Member States on Eight GSPA Elements, WHA 61.21....87

10. Priorities of Member States on Element 7 of GSPA....88

11. Agenda....89

12. List of participants....90

List of Abbreviations and Acroynms

AIDS	Acquired immune deficiency syndrome
API	active pharmaceutical ingredients
AYUSH	Ayurveda, Yoga, Unani, Siddha, homeopathy
BCSIR	Bangladesh Council of Scientific and Industrial Research
BIMSTEC	Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation
BIOTEC	National Center for Genetic Engineering and Biotechnology
BIPP	Biotechnology Industry Partnership Programme
BoI	Board of Investment
CAGR	compound annual growth rate
CAM	Complementary and Alternative Medicine
CDDA	Cosmetic Devices and Drugs Act
CDDA	Cosmetic Devices and Drugs Authority
CDRI	Central Drugs Research Institute
CENTAD	Centre for Trade and Development
CEWG	Consultative Expert Working Group
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CMU	Chiang Mai University
CSIR	Council of Scientific and Industrial Research
CT	computed tomography
CU	Chulalongkorn University
CVD	Center for Vaccine Development
DBT	Department of Biotechnology
DCGI	Drugs Controller-General of India
DESC	Drug Evaluation Sub-Committee
DGDA	Director-General of Drug Administration
DHR	Department of Health Research
DRA	Drug Regulatory Authority
DST	Department of Science and Technology's
DTP-Hep. B	DTP-Hepatitis B
EWG	Expert Working Group
FDA	Food and Drug Administration
FDI	foreign direct investment
FTA	Free Trade Agreement
FTA	Free Trade Area
FTO	Freedom to Operate
GATS	General Agreement on Trade in Services

GCP	Good Clinical Practices
GDP	Gross Domestic Product
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practices
GNI	Gross National Income
GPO	Government Pharmaceutical Organization
GRULAC	Group of Latin American and Caribbean countries
GSPA	Global Strategy and Plan of Action
GSPA-PHI	Global Strategy and Plan of Action- Public Health Innovation unit
HIV	human immunodeficiency virus
ICMR	Indian Council of Medical Research
IGWG	Intergovernmental Working Group
IHVCB	Institute for Human Virology and Cancer Biology
IIS	Indonesian Institute of Science
IP	Intellectual property
IPR	Intellectual Property Rights
ISO	International Standards Organization
KMUTT	King Mongkut's University of Technology
LMICs	low- and middle-income countries
MBC	Medical Biotechnology Center
MNCs	Multinational corporations
MoH	Ministry of Health
MoH&FW	Ministry of Health and Family Welfare
MRT	Ministry of Research and Technology
MSME	Micro, Small and Medium Enterprises
NAAAT	National Agency for Assessment and Application Technology
NADFC	National Agency of Drug and Food Control
NCEs	New Chemical Entities
NECTC	National Electronics and Computer Technology Center
NIHRD	National Institute of Health Research and Development
NIPER	National Institute of Pharmaceutical Education and Research
NISTADS	National Institute of Science Technology and Development Studies
NMITLI	New Millennium Indian Technology Leadership Initiative
NMPB	National Medicinal Plant Board
NRB	National Research Board
NSTDA	National Science and Technology Development Agency
OSDD	Open Source Drug Discovery
OTC	Over the Counter
PPP	Public-private Partnerships

R&D	Research and Development
SBIRI	Small Business Innovation Research Initiative
SCs/STs/OBCs	Scheduled Castes/Scheduled Tribes/Other Backward Classes
SEAR	South-East Asia Region
SMEs	Smal and Medium Scale Enterprises
SPMC	State Pharmaceutical Manufacturing Corporation
SPS	Sanitary and Phytosanitary Measures
TB	Tuberculosis
TBT	Technical Barriers to Trade
TKDL	traditional knowledge digital libraries
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
WHA	World Health Assembly
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive summary

A. Introduction

The Regional Office for South East Asia (SEARO) held the first "Regional Consultation for the Development of a Regional Framework on Public Health, Innovation and Intellectual Property Rights" in accordance with the terms of the World Health Assembly Resolution (WHA) 61.21 on 5-6 April 2011. WHA61.21 outlines the Global Strategy on Public health, Innovation and intellectual property, the Global Strategy and Plan of Action (GSPA) that aims to promote new thinking on innovation and access to medicines and medical products. The overall objective of the Regional Consultation was to enhance understanding of GSPA and identify regional and national priorities for future action. Thirty five participants from nine Member States of the South-East Asia Region, all except participants from DPR Korea and Timor-Leste, joined the Regional Consultation.

B. Project management by the World Health Organization

The Regional Consultation was inaugurated by Dr Poonam Khetrapal Singh, Deputy Regional Director, WHO South-East Asia Region, who welcomed the participants and read out the address by the Regional Director, Dr Samlee Plianbangchang. The objectives of the Regional Consultation were outlined by Dr Athula Kahandaliyanage, Director Health Systems and Development Department. The background, context and expected outcomes from the Regional Consultation were outlined by Dr Manisha Shridhar who drew attention to templates in this regard prepared and circulated by WHO-SEARO in advance for eliciting detailed responses from Member States on regional and national priorities for the eight main elements and 25 sub-elements of the GSPA. The representative from Bangladesh, Maj.-Gen. Md Abul Kalam Azad was nominated Chairperson for the proceedings and Mr Trihono from Indonesia was the Rapporteur.

In order to develop a regional and national conceptual framework on public health, innovation and intellectual property and incorporate into it the perspective for the SEA Region, technical presentations were made on the following:

a. Study of Micro, Small and Medium Enterprises Census data for Ascertaining Access to Technical Know how in Pharmaceutical, Traditional Medicines, Dental and Medical Technology Enterprises to meet Public Health Needs in India.

b. Challenges in GSPA deliverables for the Indian pharmaceutical industry after the experience of Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO).

c. The new Intellectual Property Rights (IPR) regime and access to medicines based on experiences from Sri Lanka:

On developing regional and national priorities the participants from Member states of Bangladesh, India, Indonesia, Sri Lanka and Thailand made presentations on the relevance of GSPA and their expectations from WHO-SEARO in this regard. This was followed by group work sessions in which the participants from Member states participated and arrived at a consensus over priority action points on eight main elements and 25 sub-elements of GSPA *(see page 15)*.

C. Conclusions

The eight main elements and 25 sub-elements of GSPA were identified as important parameters defining future focus areas for public health, innovation and intellectual property. The Member states identified priority action points for WHO-SEARO and national priorities on GSPA, WHA 61.21.

D. Recommendations

For Member States

(1) Institute a National Expert Committee for discussion on the GSPA and policy development on IPR and public health. Those Member states which already have some commission or regulatory body in place need to put GSPA on the agenda for discussion.

(2) Member states develop capacity for negotiations in public health, Innovation and IPR with the required assistance from WHO.

(3) Member States develop an appropriate and suitable legal framework under IPT with assistance from WHO.

(4) Member states ensure representation from their Health Ministries in trade negotiations.

(5) Member states should support funding for research and development (R&D) in neglected priority diseases

(6) Member states should promote domestic industries to enhance their capacity to conduct relevant R&D and meet the need of affordable medicines and medical technologies for public health.

For WHO

(1) In view of its importance in public health, WHO-SEARO must facilitate Member states to establish focal points for public health, innovation and intelectual property rights.

(2) WHO must collect information on patents and other relevant databases and play an active role in enhancing understanding on these as well as facilitate sharing of patent information and other relevant databases related to public health.

(3) WHO should provide help to Member states in capacity building on intellectual property and trade (IPT)

(4) WHO should ensure that mechanisms be developed so that states which have made substantial progress can share information and benefits with other statesand promote regional networking and capacity building on public health, innovation and IPT for Member states.

(5) WHO should provide technical assistance and financial support to Member states for IPT in public health.

(6) WHO should build partnerships with other international organizations to address IPT and public health with a focus on access to medicines and essential technologies.

(7) WHO should analyze IPT information for gaps in R&D on major diseases in the Region and also analyze the gaps in the treatment of these diseases in the Region.

(8) WHO should endeavour to seek new strategies for affordable medicines and for promoting downstream R&D and production of medicines as public goods

(9) WHO should develop and seek new financial resources for R&D.

(10) WHO should provide support to ensure that Member states' standards and requirements for safety and quality of health products are met.

(11) WHO should assist the Member states to prepare plans for regional technology platforms with a view to strengthen their capacities for delivery, manufacture and innovation using regional expertise.

(12) WHO should share information on IP filings and grants to maximize the "Freedom To Operate (FTO)" by researchers in the Region.

(13) WHO should help organize consultations of this kind to enhance the capabilities of Member States in IPT, Innovations and Public Health, aspects much needed in the current globalized, trade oriented international environment.

1. Introduction

In May 2003 the World Health Assembly (WHA) set up an independent Commission for analyzing the relationship between intellectual property rights (IPRs), innovation and public health Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)[1].

Member States in WHO have emphasized the importance of analyzing public health in international treaties in a manner that does not limit the production of particular drugs or the access to them[2]. The interdependence of trade and health is increasingly evident in a globalized world. Various international trade agreements have brought out new challenges in the area of management of public health. These involve agreements among Member States themselves, e.g. free trade area (FTA) agreements, and those involving international organizations. There are a number of World Trade Organization (WTO) agreements that affect public health, e.g. Trade-Related Aspects of Intellectual Property Rights (TRIPS), the General Agreement on Trade in Services (GATS), agreements on Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). The Food and Agriculture Organization (FAO) of the United Nations has collaborated with the World Health Organization (WHO) over the FAO/WHO Conference on Food Standards, Chemicals in Food and Food. This has ensured fair practices in food trade and the development of food standards which have had an impact on consumer health and safety[3].

The Doha Declaration of the World Trade organization (WTO) recognizes flexibilities in the application of TRIPS to protect public health[4].

The resulting CIPIH report (2006) made important observations on the status of innovation, IPR and the pharmaceutical industry. This led to the creation of an Intergovernmental Working Group (IGWG) to discuss a medium-term Global Strategy and Plan of Action (GSPA)[5] on Public Health, Innovation and Intellectual Property. The

[1] See 56th World Health Assembly, 28 May 2003. Resolution WHA56.27 *Intellectual Property Rights, Innovation, and Public Health* http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf
[2] See 52nd World Health Assembly Resolution WHA52.19 and its follow-up in the Report by the Secretariat A53/10 "Revised Drug Strategy" of 13 March 2000 at: http://ftp.who.int/gb/archive/pdf_files/WHA53/ea10.pdf and 59th World Health Assembly Resolution WHA59.26 "International Trade and Health" at: http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R26-en.pdf
[3] WHA 56.23, 28 May 2003
[4] See 4th WTO Ministerial Conference, Doha, Qatar, 20 November 2001 WT/MIN(01)/DEC/2 *Declaration on the TRIPS Agreement and Public Health* at; http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[5] See Public Health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health WHO, 2006 at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, 59th World Health Assembly, 25 May 2003 Resolution WHA59.24 *Public Health, Innovation, Essential Health Research, and Intellectual Property Rights: Towards a Global Strategy and Plan of Action* at:

process culminated in the approval, by consensus, of the GSPA contained in Resolution WHA61.21 (May 2008)[6]. The GSPA has identified about 100 action points across eight elements that cut across various sectors.

Developing the SEA Regional Framework for GSPA

The Sixty-third Session of the WHO Regional Committee for South-East Asia held in Bangkok, Thailand, on 7-10 September 2010 requested WHO to support Member States to build capacity in understanding the implications of international trade and trade agreements for health[7]. In the SEA Region, relevant GSPA issues need to be addressed through policies and legislation that take advantage of the potential opportunities that may arise and also consider the potential challenges for health that trade and trade agreements may pose in this Region[8]. This is particularly important in the case of medicines and diagnostic devices where quality, safety and efficacy are major concerns and in which trade agreements create obligations.

2. General objectives of the Regional Consultation

The general objective of the Regional Consultation was to develop a Regional and National Framework on Public Health, Innovation and Intellectual Property.

3. Specific Objectives of the Regional Consultation

The specific objectives of the Regional Consultation were to:

(1) enhance understanding of GSPA in South-East Asia Region; and

(2) identify National and Regional priority areas under GSPA.

4. Inaugural session

Dr Poonam Khetrapal Singh, Deputy Regional Director, WHO South-East Asia Region, welcomed the participants to the Regional Consultation and delivered the inaugural address of the Regional Director. She observed that we live in an increasingly interdependent world where various national and international policies and agreements have led to direct and indirect challenges posed to the management of public and human health. Among the WTO agreements that directly affect health and health policies, the

http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf

[6] 61st World Health Assembly Resolution WHA61.21 *Global Strategy and Plan of Action on Public* Health, Innovation, and Intellectual Property.

[7] Resolution SEA/RC63/R6

[8] Resolution 59.26; 27 May 2006)

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has had far-reaching consequences on access to medical products, medicines and medical technologies for the developing world. TRIPS requires WTO Members to comply with certain minimum standards for protecting and enforcing intellectual property rights. As a result of concerns on access to medicines, Member States of the World Trade Organization adopted the 2001 Doha Ministerial Declaration on Public Health, which enunciated that TRIPS should not prevent Members States from taking measures to protect public health and promote access to medicines for all.

Due to compliance requirements with TRIPS, awareness about the importance of intellectual property rights, particularly patents, has become crucial for the countries of the Region. Health authorities often find it difficult to keep up with the evolving and intricate developments in this area, which fall outside the scope of their normal area of work and responsibility. More important, national health authorities are concerned that some provisions in free trade agreements may go beyond WTO mandates. These extend patent protection for medicines, restrict the grounds for compulsory licenses and establish "data exclusivity" (protection of clinical trial data), making it difficult for generic medicines to be supplied.

The Regional Director's message underlined that developing countries have an apprehension that other WTO agreements such as the Agreement on Sanitary and Phytosanitary Measures (SPS) may be employed to set up non-tariff barriers to protect domestic sectors in developed countries, by using human, animal or plant health as an excuse to restrict access to their markets. Such measures could negate benefits from reduced tariffs and subsidies obtained in trade negotiations. On the other hand, there remain significant challenges for many countries in the SEA Region to create or strengthen regulatory systems required to guide health-related trade in the desired direction, and to develop standards necessary to ensure quality and protect consumer and patient safety.

The General Agreement on Trade in Services (GATS) is the first multilateral agreement dealing with trade in services. Ministries of health in SEA Region face numerous challenges in accurately assessing the risks and opportunities of trade in health services, and identifying policy measures that can be used to ensure quality and accessibility of medical products. The provision of health services across borders is also relevant for our countries.

In order to address these issues, the World Health Assembly set up a Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2003 to examine the challenges in the way meeting the goal of ensuring access and innovation for needed health products and medical devices. This culminated in the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA) in 2008, which identified eight main elements and 25 sub-elements spread across about 100 action points cutting across various sectors. The main elements cover important areas for action to improve delivery and access, such as prioritizing and promoting research and development, building and improving innovative capacity, transfer of technology and application and management of intellectual property to contribute to innovation and promote public health.

SEA Region Member States and the Regional Office contributed to the process of identification of priorities under the strategy by playing a critical role during the Intergovernmental Working Group process leading to the formulation of GSPA. In this context, it is now opportune for Member States of the South-East Asia Region to develop a Regional Framework and identify national and regional priority areas for suitable interventions. While other Regional offices in WHO have initiated action in this regard, this is the first attempt by any Region to outline specific action points for 25 sub-elements of the strategy under the innovation/IPR/trade framework. The objective of this regional consultation is to develop a national and regional framework that corresponds to the specific requirements and needs of the people of the WHO SEA Region and which is acceptable to them. These requirements need to be addressed through interventions that take advantage of opportunities and address the potential challenges for public health. This is particularly important in the areas of medicines and diagnostic devices, where quality, safety and efficacy are major concerns and where trade agreements create obligations.

In order to facilitate this process the SEARO Secretariat developed framework templates for identifying regional and national priorities. The consultation is to provide an opportunity for sharing experiences among countries and participating in identifying priority areas at the national and regional levels. These experiences and the combined wisdom would be useful in improving and refining the templates and in the development of a Framework that is suitable for the social context of Member States in the SEA Region.

Additionally, amid reports suggesting that tie-ups between Indian and multinational drug companies may result in a steady loss of manufacturing capacity for affordable drugs needed in the rest of the developing world, there is a need to examine the pharmaceutical products sector in India (which has been described as the "pharmacy of the developing world[9]"). For this purpose, an analysis of medical products enterprises under the Fourth All India Census 2009 of the Micro, Small and Medium Enterprises Ministry of the Government of India identifies the factors promoting technical know-how for enterprises other than the so-called "Big Pharma" . An outline of the analysis is presented in the Regional Consultation in order to obtain the views of Member States on this important issue.

As a result of the deliberations of the Regional Consultation, the Regional Director's message hoped that these discussions will lead to recommendations and the development of a framework of a high order, enabling the outlining of national and regional strategies of particular relevance to SEA Region.

[9] http://www.oxfamindia.org/content/oxfam-urges-india-remain-%E2%80%98pharmacy-developing-world%E2%80%99 (last visited 23.9.11)

5. Opening remarks

The introduction to the meeting was given by Dr Athula Kahandaliyanage, Director, Health Systems and Development (HSD) Department. In his address, Dr Athula stressed that the Regional Consultation for Development of a Regional Framework on Public Health, Innovation and Intellectual Property, should consider the 2008 World Health Assembly Resolution 61.21 in the SEA regional and national contexts of Member States. The GSPA aims to promote new thinking on innovation and access to medicines and medical products. This provides for a medium-term framework (2008-2015) for action and is meant to secure needs-driven essential health research and development. The GSPA endeavours to deal with issues of importance to developing countries such as diseases which disproportionately affect them. It also proposes the setting up of clear objectives and priorities for R&D and estimating the funding needs in these areas.

In recent years, new initiatives and partnerships have come up to augment access to existing health products and medical devices for public health. Member States, the pharmaceutical industry, charitable foundations and nongovernmental organizations have undertaken partnering initiatives to develop new products against diseases affecting developing countries. Some of these partnerships like the TB Alliance and Medicines for Malaria Venture are financed by public agencies and private foundations, and partner with research institutes and private pharmaceutical companies to develop faster-acting, novel treatments. Other new initiatives include the "patent pool". Concerted efforts, however, are needed to meet the health-related Millennium Development Goals.

The interdependence of trade and health and various international trade agreements have thrown up further challenges in the management of public health. Trade factors are influencing public health in the access and development of medicines and medical products, their regulation, and also national and international trade in these products. E-commerce and the Internet have opened a new range of issues for public health products.

A key issue is that the market demand for diagnostics, vaccines and medicines needed to address health problems mainly affecting developing countries is not attractive. As a result the incentive "pull effect" of intellectual property rights may be limited or nonexistent. There is a need to examine innovate approaches to ensure enhanced financing on a sustainable basis and promote synergy between different partners in public health. It is important for WHO and its Member States to take up the task of transforming GSPA into a workable set of policies and actions that will make a difference.

The Regional Consultation for Development of a Regional Framework on Public Health, Innovation and Intellectual Property, examines the various elements of GSPA to maximize their benefits in the SEA Region. This consultation also endeavours to utilize certain facets of intellectual property as a development tool and enable Member States and WHO-SEARO to identify and address their priorities at the national, regional and international levels.

6. Proceedings

An overview of WHA 61.21, the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) was presented by Dr Manisha Shridhar, Principal Secretary, Government of Himachal Pradesh, India, and formerly Temporary International Professional, Intellectual Property and Trade, WHO-SEARO.

The relevance of WHA 61.21 in the current international trade and economic scenario was outlined. The international trade environment is increasingly affecting public health outcomes for Member States of the Region. In this context a summary table of the membership of countries of the Region to the World Trade Organization (WTO), World Intellectual Property Organization (WIPO) and related international treaties and conventions was presented at Regional Consultation (*see* ***Annex 8***). The several agreements to which various Member States are signatories to reflects the importance of intellectual property issues and this in turn significantly influences public health policies and outcomes.

The expected results from the Regional Consultation for Development of a Regional Framework on Public Health, Innovation and Intellectual Property were delineated while giving a brief account on each of the eight Elements of GSPA.

On 24 May 2008, GSPA identified more than a 100 deliverables across 25 sub-Elements and eight main Elements. The eight 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;

(6) improving delivery and access;

(7) ensuring sustainable financing mechanisms; and

(8) establishing monitoring and reporting systems.

These deliverables under the GSPA aim to promote new thinking on innovation, transfer of technology and access to medicines. In order to achieve these deliverables multifarious actions are needed. Some of these actions relate to existing programmes in WHO that focused on neglected diseases and the "Big Three" diseases, i.e. HIV/AIDS, tuberculosis and malaria. Each of these eight elements also has an intellectual property and trade (IPT) component that needs to be explored and developed in order to maximize the results under the GSPA.

The Regional Consultation attempts to identify and prioritize IPT actions in GSPA on Template A for maximizing their benefits in the SEA Region **(Annex 7)**. This also attempts

to utilize certain facets of intellectual property as a development tool and enable Member States and SEARO to identify and address their priorities at the national, regional and international levels.

Methodology

Member States were invited to fill in Template A in order to develop their national and regional priority areas in IPT under the GSPA and in order to outline a concerted plan of action suitable to their specific needs. This identification will also enable WHO-SEARO to provide IPT assistance specially designed to the country's needs. **Template A** takes up the eight main Elements and 25 sub-Elements and delineates an IPT component for consideration by Member States **(Annex 7)**.

The **Annex 7** was taken up for detailed discussions at the Regional Consultation meeting. The deliberations on **Annex 7** benefited from the work of the experts from the countries of Bangladesh, India, Indonesia, Thailand and Sri Lanka discussed earlier. These experts had worked on this template ahead of the workshop. Their work had a direct bearing on the Development of the Regional Framework on Public Health, Innovation and Intellectual Property is included herewith.

The pharmaceutical sector performs a critical role in the supply of affordable medical products. More than many industries, the performance of the pharmaceutical industry is dependent on the economic policy framework set by governments, in particular the patent regime, and regulatory arrangements designed to ensure that products are safe, efficacious and of good quality. Therefore, in order to prepare a focused regional and country-specific action plan it is necessary to examine the pharmaceutical sector. Information on the sectors was obtained from Bangladesh, India, Indonesia, Thailand and Sri Lanka before the workshop on the following:

(1) Pharmaceuticals: Information on local production and transfer of pharmaceutical-related technology to the country.

(2) Traditional Medicine: The current status of traditional medicine in the country. (There is a growing interest on traditional and herbal systems of medicine and its results on public health, and GSPA in Element 1 focuses on research and development in traditional medicine).

(3) Medical technologies: WHO organized the First Global Forum on Medical Devices on 9-11 September 2010 in Bangkok, Thailand. The Global Forum for Health Research has estimated that in 2005, an estimated US$ 160.3 billion was spent globally on health research and development. Of this, 97% was spent by high-income countries used to generate products, processes and services for their own health-care markets. The remaining 3% was spent by low- and middle-income countries. Thus, the position of medical technologies in Bangladesh, India, Indonesia, Thailand and Sri Lanka was outlined.

(4) Dental formulations: this is an often neglected area and the current status of dental formulations supply was attempted to be enumerated for Bangladesh, India, Indonesia, Thailand and Sri Lanka.

In this Report the information obtained from for Bangladesh, India, Indonesia, Thailand and Sri Lanka that is directly related to GSPA has been taken up. A **Template B,** placed below, was designed for an examination of the above mentioned sectors in order to devise effective and suitable regional and country-specific strategies for interventions in public health. Information on **Template B** from Bangladesh, India, Indonesia, Thailand and Sri Lanka was analysed by the country experts and used to identify priorities for **Template A**.

Template B: Information of medical products (pharmaceuticals, herbal medicine dental formulations and medical technologies in the country

S. No.	Country parameters for medical products	Pharmaceutical	Herbal medicine (Homeopathic, Ayurvedic, Unani, Chinese, etc.)	Dental formulations	Medical technologies (machinery and equipment)
1.	Number of companies/units				
2.	Size (no. of employees)				
3.	Investment in plant and machinery				
4.	Quantity of production				
5.	Bulk drugs production				
6.	Formulation production				
7.	Projected growth in production (2011–2014)				
8.	Retail Sales				
9.	Projected growth of Retail Sales (2011–2014)				
10.	Quantity of imports				
11.	Projected growth in imports (2011–2014)				
12.	Quantity of exports				
13.	Projected growth in exports (2011–2014)				
14.	Number of companies/units adhering to good manufacturing practices (cGMP) criteria as stipulated by the World Health Organization				

7. Technical discussions

7.1 Factors promoting technical know-how in Indian micro, small and medium pharmaceutical enterprises: A Study by Prof. Arvind Chaturvedi, International Management Institute, and Mr Deepak Goyal, Director, Ministry of Statistics, Government of India

The World Health Assembly in May 2003 set up an independent commission for analyzing the relationship between intellectual property rights (IPR), innovation and public health. The resulting CIPIH report in 2006 made important observations on the status of innovation and IPRs in the pharmaceutical industry. The performance of the pharmaceutical industry is more dependent than many industries on the economic policy frameworks set up by national governments, and in particular the patent regime, and the various regulatory arrangements designed to ensure that products are safe, efficacious and of good quality. In view of the importance of innovation and technology transfer in matters related to access to medicines by developing countries, it is imperative that these issues are examined in the WHO South-East Asia Region.

The Indian pharmaceutical sector is a major supplier of generic medicines worldwide. For this purpose, a study of the pharmaceutical enterprises under the aegis of the Fourth All-India Census of Micro, Small and Medium Enterprises 2006–2007 conducted by the Ministry of Micro, Small and Medium Enterprises (MSME) of the Government of India[10] was undertaken by the WHO Regional Office for South-East Asia. This census of MSMEs was conducted with reference to the year of 2006–2007.[11]

This study provides information, based on existing census data, of the factors promoting technology adoption for pharmaceutical enterprises other than those that constitute the "Big Pharma" industries in India. An appraisal of the profile of this sector could enable policy interventions to ensure the continuous supply of generic medicines for developing countries. This study focused on examining technical know-how in these pharmaceutical enterprises leading to:

(1) profiling of **pharmaceutical-, traditional medicine-, dental- and medical technology**-based enterprises.

(2) investigating factors promoting technical know-how.

(3) estimating the role and contribution of identified factors influencing technical know-how.

[10] The micro, small and medium enterprises development act, 2006, Annual Report 2009-10 and Acts, Rules & Notifications on the Ministry of Micro, Small and Medium Enterprises (MSMEs) are available in its website http://www.msme.gov.in
Information on organized and unorganized sector enterprises, i.e. latest Report on ASI and NSS 62nd Round Surveys are available in the M/o Statistics & Programme Implementation's website http://www.mospi.nic.in.

[11] Quick results Fourth All-India Census of Micro, Small & Medium Enterprises 2006-2007, Government of India, Development Commissioner [MSME], Ministry of Micro, Small and Medium Enterprises, A Wing 7th Floor, Nirman Bhawan, New Delhi 110011.

For classification of enterprises, the Union Government, in exercise of the powers conferred by sub-Section (i) of Section 7 of The Micro, Small and Medium Enterprises Development Act, 2006 has notified enterprises under the respective categories of "micro", "small" and "medium".[12] For the purpose of this study on pharmaceutical and medical products, the census information on enterprises with investments in plant and machinery (excluding land and buildings) is divided in three segments. These three categories have been identified due to the fact that prior to the Micro, Small and Medium Enterprises Development Act, 2006, an industry was classified as "small" if it had investment in plant and machinery of Rs 10 million. This ceiling was subsequently raised to Rs 50 million by the Act in 2006. Several policy interventions prior to 2006 have promoted the development of small industry.

Group I: Pharmaceutical and medical products

This group includes the following seven subgroups and 122 products. The subgroups are:[13]

(1) vitamins.

(2) hormones, glands and products thereof.

(3) antiserum, blood fractions, immunological products and vaccines.

(4) antibiotics and preparations thereof.

(5) alkaloids and preparations thereof.

(6) other medicaments and preparations thereof.

(7) pharmaceutical products including family planning goods.

[12] 7.1) Notwithstanding anything contained in Section 11B of the Industries (Development and Regulation) Act, 1951, the Central Government may, for the purposes of this Act, by notification and having regard to the provisions of sub-Sections (4) and (5), classify any class or classes of enterprises, whether proprietorship, Hindu Undivided Family, association of persons, cooperative society, partnership firm, company or undertaking, by whatever name called, -
(a) in the case of the enterprises engaged in the manufacture or production of goods pertaining to any industry specified in the First Schedule to the Industries (Development and Regulation) Act, 1951, as:
(i) a micro enterprise, where the investment in plant and machinery does not exceed twenty five lakh rupees;
(ii) a small enterprise, where the investment in plant and machinery is more than twenty five lakh rupees but does not exceed five crore rupees; or
(iii) a medium enterprise, where the investment in plant and machinery is more than five crore rupees but does not exceed Rs 10 crore;
(b) in the case of the enterprises engaged in providing or rendering of services, as:
(i) a micro enterprise, where the investment in equipment does not exceed ten lakh rupees;
(ii) a small enterprise, where the investment in equipment is more than ten lakh rupees but does not exceed two crore rupees; or
(iii) a medium enterprise, where the investment in equipment is more than two crore rupees but does not exceed five crore rupees.
Explanation 1: For the removal of doubt, it is hereby clarified that in calculating the investment in plant and machinery, the cost of pollution control, research and development, industrial safety devices and such other items as may be specified, by notification, shall be excluded.
Explanation 2: It is clarified that the provisions of Section 29B of the Industries (Development and Regulation) Act, 1951, shall be applicable to the enterprises specified in sub-clauses.

[13] According to MSME classification of data.

Group II: Homeopathic, Ayurvedic and Unani medicines

This group includes many subgroups and also includes live trees, plants, bulbs, roots, cut flowers and foliage; forestry products; cosmetics and perfumes, etc. This group has six subgroups and 145 products[14]. These are:

(1) dairy products used in the preparation of AYUSH (Ayurveda, Yoga, Unani, Siddha, homeopathy) products;

(2) live trees, plants, bulbs, roots, cut flowers and foliage;

(3) forestry products used in the preparation of AYUSH products;

(4) homeopathic, Ayurvedic and Unani medicines;

(5) essential oils and essences used in preparation of AYUSH products; and

(6) cosmetics and perfumes.

Group III: Dental and dentistry materials/products

This group includes 12 products such as wax, chlorinated paraffin, dental wax, toothpastes and toothpowders, etc.

Group IV: Pharmaceutical machinery, equipment and parts

This group includes three subgroups and 57 products. Products include films, X-ray films and plates, hosing machinery, hearing aids, etc. They also include:

(1) medical, surgical, laboratory and health fitness equipment.

(2) human safety articles and parts thereof.

In order to identify measures to promote pharmaceutical generics in the country, it would therefore be appropriate to study all enterprises in the following three segments:

(1) **Micro enterprises,** with investment in plant and machinery not exceeding Rs 2.5 million (US$ 56 000)*,

(2) **Small enterprises,** with investment in plant and machinery not exceeding Rs 10 million (US$ 220 000)*, and

(3) **Other enterprises,**[15] with investment in plant and machinery not exceeding Rs 100 million (US$ 2 200 000)*.

* Rs45 = US$ 1

[14] As indicated by Activity and Product Classification for MSME Sector (Based on ASICC 2000 & NIC 2004)
[15] 'Small' and 'Other' enterprises together comprise medium enterprises as under the MSME Act 2006.

The number of enterprises involved with the pharmaceutical products sector as per the MSME Census of 2006–2007 database was 16 159. Of these enterprises a predominant number, i.e. 90.71% or 14 658 enterprises, were in the "Micro enterprises" category; 6.7% or 1083 enterprises were in the "small enterprises" category; and only 2.59% or 418 units were in the "other enterprises" category having an investment in plant and machinery of more than Rs 100 million.

Apart from investigating the profiles of Micro, small and other enterprises[16] as a whole, this study also examines pharmaceutical enterprises with respect to four categories of medical products:

(1) **Pharmaceutical** (and Medical) products,

(2) **Traditional medicines** (homeopathic, Ayurvedic and Unani medicines)**,**

(3) **Dental** (and dentistry materials) products, and

(4) **Medical technology** (pharmaceutical machinery, equipment and parts)**.**

The group-wise distribution of the pharmaceutical product enterprises in the four categories reveals that in Group I there were a total of 2258 enterprises engaged in pharmaceutical and medical products producing 122 products. Group II, or homeopathic, Ayurvedic and Unani medicines, includes 11 758 enterprises producing 145 products. Group III, or dental and dentistry materials and products, comprises 456 units engaged in producing 12 products. Group IV, or pharmaceutical machinery, equipment and parts, covering medical technologies has 1687 units with 57 products (see ***Table 1***).

Table 1: ***Pharmaceutical MSMEs based on*** *investment in plant and machinery (size of enterprises) and products*

Group ↓/size; Class→	Micro	Small	Others	Total
I. Pharmaceutical & Medical products	1 485	568	205	2 258
II. Homeopathic, Ayurvedic and Unani medicines	11 254	374	130	11 758
III. Dental and dentistry materials/products	422	27	7	456
IV. Pharmaceutical machinery, equipment and parts	1 497	114	76	1 687
Overall pharmaceutical sector	**14 658**	**1 083**	**418**	**16 159**

In order to develop policy interventions for the generic drug pharmaceutical sector it is necessary to examine the technical know-how in the 2258 units in the country. Similarly, there is a need to examine the 11 758 enterprises in Group II (homeopathic, Ayurvedic and Unani medicines), 456 enterprises engaged in dental and dentistry materials/products (Group III) and 1687 units in Group IV (pharmaceutical machinery) that produces 57 medical products and devices **(Table 2)**.

[16] 'Enterprises' and 'units' is used interchangeably in the text. Conventionally the MSME uses 'industrial unit' or 'unit' to refer to an enterprise engaged in production.

Table 2: ***Number of enterprises and medical products (in percentage)***

Group	Description	No. of products	No. of units	% share
I	Pharmaceutical and medical products	122	2 258	14.0
II	Homeopathic, Ayurvedic and Unani medicines	145	11 758	72.8
III	Dental and dentistry materials/products	12	456	2.8
IV	Pharmaceutical machinery, equipment and parts	57	1 687	10.4
Total		**336**	**16 159**	**100**

The available Census on MSMEs 2006–2007 database provides information on **65 fields or parameters** related to the different types of enterprises covered under the census.[17] These parameters have a wide-ranging coverage such as type of organization, maintenance of accounts, year of initial production, employment details, production, raw materials consumed, gross output, gross value added, etc. Some of these parameters are not directly or indirectly related to the study of technical know-how, which has been mapped in the census for the enterprise as "technical know-how obtained from abroad", "domestic collaboration company", "domestic R&D institution/ specialized agency/ organization", "none".[18]

For this study and analysis 19 variables[19] are generated from the 65 fields or parameters. These are both metric (ratios) and categorical variables. Metric variables are those that have numbers such as (i) value of plant and machinery, (ii) value of export, etc. Categorical variables are those that reflect qualitative aspects such as: (i) sector: rural or urban; (ii) social status of the owner, etc.

The data is analyzed in three stages: First, the relevant variables having a bearing on technical know-how are identified. Next, sorting is done for those which had a significant relationship with the adoption of Technical know-how. Then a "Causal Model" (logistic regression) is used to assess the role and importance of these variables in determining the adoption of technical know-how for Indian pharmaceutical-based MSMEs.

Summary findings of the study:

The analysis of all 16 159 enterprises reveals the factors that have a positive contribution on the adoption of technical know-how. These are:

- where the enterprise is an ancillary unit for other enterprises,
- those having quality certification,
- organization type,
- nature of operation,

[17] Quick results Fourth All-India Census of Micro, Small & Medium Enterprises 2006–2007 Government of India, Development Commissioner [MSME], Ministry of Micro, Small and Medium Enterprieses, A-Wing 7th Floor, Nirman Bhawan, New Delhi 110011, pp. 403-412.
[18] Item No 8: Technical know-how obtained from abroad, domestic collaboration company, domestic R&D institution/specialized agency/organization, none), Ibid p 399.
[19] 65 parameters in the collected field data is taken up in 19 variables for this analysis of MSME pharmaceutical enterprises.

- gross output,
- socially benefited groups.

Some other factors are seen to have a negative contribution to the adoption of technical know-how on Indian pharmaceutical-based MSMEs. These are enterprises that have taken loans, wages (remuneration paid to the employees), and women-led enterprises.

The parameters that are seen to have a positive impact on technical know-how, innovation and research and Development in Indian MSMEs in the pharmaceutical sector (Micro, small and others) based on the criterion of investment in plant and machinery are given in **Table 3.**

Table 3: ***Factors contributing to technical know-how*** *(based on size of units)*

All 'Micro' units	All 'small' units	Others
Nature of operation	Quality certification	Ancillary units
Ancillary units	Wages	Social group
Output per employee		Quality certification
Quality certification		Organization Type
Urban sector		
Socially benefit groups		

The parameters that are observed to have a positive bearing on technical know-how, innovation and research and development in Indian MSMEs in the pharmaceutical sector for the four product categories (pharmaceutical and medical products; homeopathic, Ayurvedic and Unani medicines; dental and dentistry materials/products; pharmaceutical machinery, equipment and parts) are given in **Table 4**.

Table 4: ***Factors contributing to technical know-how (based** on category of medical product)*

Group I (Pharma)	Group II (Ayurvedic, etc.)	Group III (Dental, etc.)	Group IV (Machinery/ equipment)
Quality certification	Ancillary unit	No. of employees	Urban unit
Power source: Electricity	Exporting units	Value of plant and machinery	Ancillary unit
Wages	Nature of operation		Gross output
Organization types	Gross output		Quality certification
Loan status (-ve)[20]	Loan status (-ve)		Loan status (-ve)
	Gross value added		
	Rural sector		

[20] Has negative contribution on adoption of technical know-how (all other factors are positively contributing to technical know-how adoption)

Policy implications and recommendations

The analysis carried out identifies the drivers and determinants of technical know-how adoption in MSME pharmaceutical enterprises. The importance and role of these determinants vary over each group analyzed. As a result of these analyses the following recommendations emerge for policy considerations:

Promotion of ancillary units

A "Micro" unit associated with another enterprise as an ancillary unit paves the way for technical know-how adoption. Similarly, functioning as an ancillary unit is beneficial to enterprises in Group II and Group IV.

Nature of operation

The Census on MSMEs 2006–2007 mapped enterprises on the nature of their operation: perennial, seasonal or casual. The analysis showed that perennial functioning of enterprises in MSME pharmaceutical sector contributed towards a high degree of adoption of technical know-how. The lack of perennial operations appeared to have hindered the adoption of technical know-how in "Micro" units and in units in Group II (homeopathic, Ayurvedic and Unani medicines). If a unit is working round the year it is more likely to adopt technical know-how than a unit that has irregular operations during the year.

Wages

The Census on MSMEs 2006–2007 mapped enterprises on the basis of wages paid to employees.[21] Payment of higher wages was seen to have a positive effect on technical know-how adoption by MSMEs in the pharmaceutical sector.[22] This correlation is particularly seen in the case of "small" enterprises and those enterprises in Group I (pharmaceutical and medical products).

Organization structure (legal structure)

Private limited or public limited enterprises are seen to have a greater inclination for the adoption of technical know-how than proprietorship units/family-run concerns. Technical know-how adoption shows a marked positive trend in the"Others" category (the larger enterprises which have this structure) and in Group I (pharmaceutical and medical products) category.

[21] Item No. 20 & 21 of Block [2]: Employment & total wage bill during 2006-2007: Employment is comprised of own workers, direct workers or contract/casual employees who contribute to the process of production or rendering of services. Employment is directly related to the factor of production, namely, 'labour'. Total wage bill: the payment made to workers in cash and/or kind. This includes salaries and wages, allowances, bonuses, etc.

[22] The wages paid would necessarily be higher than the prescribed minimum wage.

Special benefit groups

The "Micro" sector analysis reveals that units owned by persons with a certain social background, such as Scheduled Castes/Scheduled Tribes/Other Backward Classes (SCs/STs/OBCs)[23] and religious minorities show a higher adoption of technical know-how**.** It appears that special grant schemes/ specific financial support for these social groups such as SCs/STs/OBCs and also religious minorities enable the adoption of better technical know-how.

Quality certification

This is an important driver for the adoption of technical know-how across pharmaceutical MSMEs. In all three sets of enterprises based on size of the unit—"Micro", "small" and "others"—quality certification positively influences the adoption of technical know-how. Quality certification positively influences Group I and Group IV category enterprises. There is a positive linkage between quality certification and technical know-how with greater linkages observed for International Standards Organization (ISO) certifications**.** The pharmaceutical MSMEs, therefore, should be encouraged to get quality certification, preferable ISO certifications.

Loans

In the overall analysis (and also in other subgroups) it has been found that there is an **inverse relationship** between loans taken and the probability of adoption of technical know-how. The analysis suggests that those enterprises which are financially self-dependent and comfortable (not opting for loans) are more likely to adopt technical know-how. This raises an important question as to why the adoption of technical know-how is less among units which have availed of loans. This finding has significant implications for policies over various schemes of the Government of India that promote loans for MSMEs.

Electricity as source of power

For pharmaceutical and medical products enterprises, using electricity as a source of power positively affects the adoption of technical know-how. The Census on MSMEs 2006–2007 mapped enterprises on their use of fuel and power.[24] This aspect is prominently observed in Group I (pharmaceutical and medical products) enterprises.

[23] As given in the schedule of the Constitution of India

[24] Item No.5: Main source of power (Heads: "no power needed", "coal", "oil", "LPG/CNG", "electricity", "non-conventional energy", "traditional energy/firewood", "others"

Exports

Pharmaceutical MSMEs engaged as exporting units have a greater likelihood of adopting technical know-how measures. This aspect is significant for enterprises in Group III (homeopathic, Ayurvedic and Unani medicines). It appears that regulatory requirements needed for exports result in higher probability of technical know-how adoption by these enterprises. Thus, promotion of exports as a policy measure results in the adoption of better technical know-how in enterprises.

Scale of operation–Number of employees and value of plant and machinery

These two parameters defining the scale of operation of the enterprise—number of Employees and value of plant and machinery—are both related to the size of the operation. Both variables indicate that the larger the scale of the operation the higher will be the likelihood of adoption of technical know-how.

This is specially observed in Group IV units (dental and dentistry materials/products). This suggests that an upgradation of these two parameters would push these enterprises towards adoption of technology and know-how. This could be achieved in two ways: (a) by providing appropriate financial measures to enhance the size of the operation, and (b) by encouraging the units to go for mergers and amalgamations.

Urbanization

Urbanization appears to be an important factor in technical know-how adoption for pharmaceutical MSMEs as per the Census 2006–2007 data. Enterprises located in urban areas are more likely to go in for technical know-how adoption. Urban "micro" enterprises and Group II and IV units are particularly favourable to technical know-how adoption when located in urban areas than when situated in rural areas. This indicates that urban areas provide certain infrastructural advantages over rural areas that facilitate technical know-how adoption.

Limitations of the study

The limitations of the study are that the analysis on technical know-how is limited to the information parameters of the Census on MSMEs 2006–2007. Specific information parameters on innovation and research and development (R&D) and patents as a measure of innovation are not captured in the data and these are critical to the pharmaceutical sector. Additionally, enterprises obtaining technical know-how from abroad were only about 2% of the total units. Hence, this variable – securing technical know-how from abroad – could not be studied in detail and was used as a binary variable only.

However, an analysis of the enterprises obtaining this know-how placed emphasis on the factors promoting technology absorption by such enterprises. Also, secondary data and case studies need to be made to verify the findings on factors that influence the adoption of technical know-how. There is, for instance, no information on perceptions about the need for adoption of technical know-how. These findings are based purely on a mathematical model, and the interrelationship of variables may have affected the outcome.

In order to address public health needs and ensure a regular supply of medicines and medical products, it is necessary for Indian policy-makers to target the MSME pharmaceutical enterprises that constitute the bulk of the enterprises. There is a need to further examine their innovation and R&D needs, including regulatory prerequisites (WHO GMP certifications, etc.), to enhance their capabilities to meet future domestic and international needs.

This study is unique in that the complete universe of MSME pharmaceutical enterprises sector has been examined as the data from the Census on MSMEs 2006–2007 enumerated all MSMEs within the country. This analysis gives us a base on which to centre future studies to encourage generic pharmaceutical production in enterprises in India.

7.2 Challenges in GSPA deliverables for the Indian pharmaceutical industry after TRIPS – A proposal for R&D cooperation: Prof. Sudip Chaudhuri, Indian Institute of Management, Calcutta, India

Promoting R&D and innovative capacity is one of the major objectives of GSPA. For access to medicines the most important issues are availability, affordability and appropriateness. Few or no drugs exist for neglected diseases (Type II), particularly the very neglected diseases (Type III) such as African trypanosomiasis, leishmaniasis and Chagas disease, etc. There has been some increase in R&D for drug development in the case of neglected diseases by some not-for-profit organizations such as the Drugs for Neglected Diseases Initiative and by certain multinational pharmaceutical corporations (MNCs). But it is widely believed that more needs to be done and particularly by developing countries themselves.

The widely recognized incentives for new drug development include the "Push" mechanism [involving public support such as direct public spending, R&D grants, tax credits, etc.] and the "Pull" mechanism of product and process patent protection.

After signing of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization, India introduced a product patent regime in pharmaceuticals from 1 January 2005. The argument advanced by multinational companies was that developing countries too would benefit from stronger patent protection because it will stimulate private R&D investment on diseases endemic to developing countries.

Table 5: ***Thirteen Indian companies involved in new drug R&D, 2007–2008***

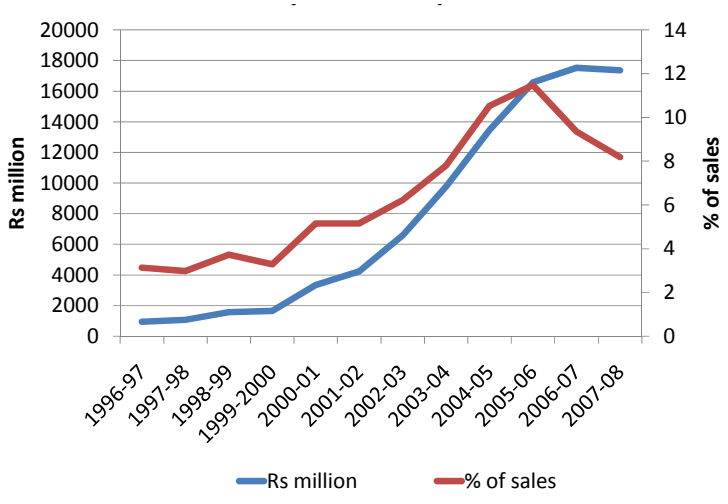
13 Indian companies involved in new drug R&D, 2007-08

	Rs million	% of sales	$ million
Ranbaxy*	4605.1	11.29	114.4
Dr. Reddy's	3334.5	8.82	82.9
Lupin	1933.7	7.52	48.1
Cadila Healthcare	1618	9.43	40.2
Sun Pharm	1443.9	6.27	35.9
Wockhardt	1267.4	10.81	31.5
Torrent Pharm	1131.7	11.37	28.1
Orchid Chem & Pharm	709	5.73	17.6
Glenmark Pharm	659.1	4.89	16.4
Biocon	646.5	7.36	16.1
Piramal Healthcare*	352.8	1.86	8.8
Suven Life Sciences	300.6	25.64	7.5
Dabur (Fresenius Kabi Oncology)*	262.3	10.96	6.5
TOTAL 13 companies	18264.6	8.18	453.9

*: Now taken over by foreign companies

It was also more specifically claimed that local companies will be prompted to spend more on R&D for the development of new drugs more ssuited to their needs. The position on new drug development is given in **Tables 5, 6 and 7.**

Table 6: ***R&D by Indian companies***



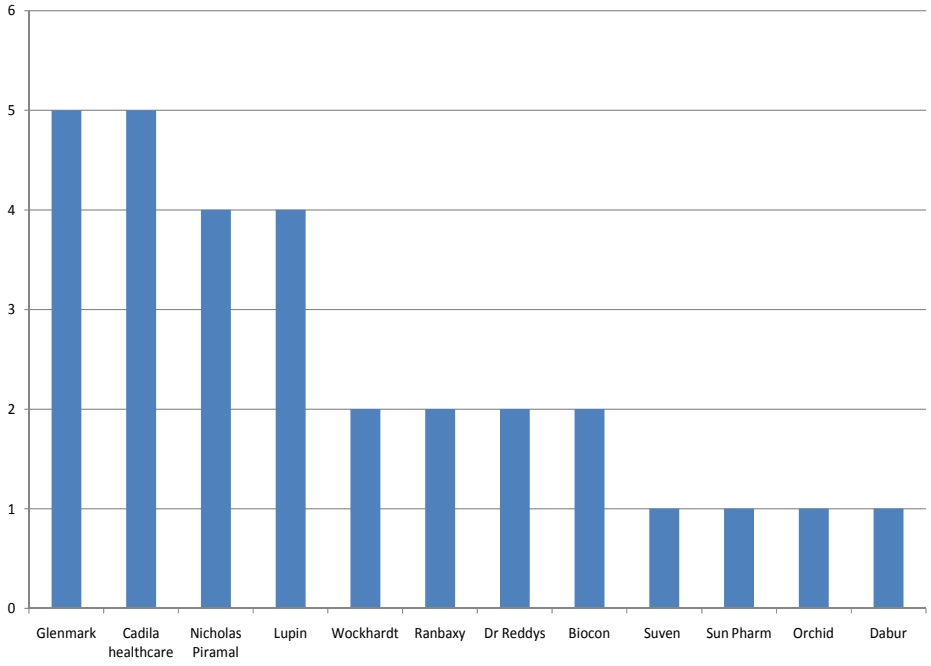
Note: For 11 Indian companies involved in new drug R&D

Indian companies are not yet ready for a start-to-finish model in new chemical entities (NCE) research because of lack of skills and funds. The model followed by them is to develop new molecules up to a certain stage and then licence them to partners from

developed countries, primarily MNCs. As a result of this MNC focus, not surprisingly, New Chemical Entities (NCEs) being developed by Indian companies are related primarily to global diseases such as diabetes, cancer, heart diseases, asthma and obesity rather than the neglected diseases more specific to India. The one exception is the development of one anti-TB and one anti-malaria NCE.

There are other reasons for this collaboration between Indian pharmaceutical companies and MNCs. In the pre-TRIPS era there was no patent on pharmaceutical products. There was only process patent. Hence, Indian companies were not required to promote drugs; only limited phase-III clinical trials were necessary. Hence Indian pharmaceutical companies did not develop the expertise for developing new drugs. In the post-TRIPS new drug development phase Indian companies experienced difficulties in promoting drugs developed independently.

Table 7: ***Number of NCEs under clinical trials by Pharmaceutical Companies***



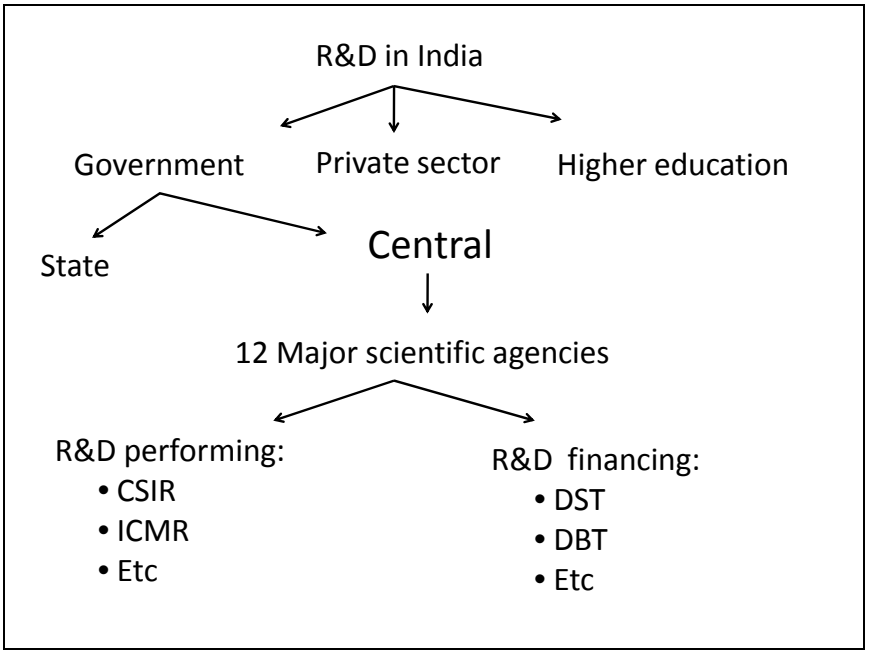
There has not been a single instance of a drug developed elsewhere and successfully marketed in developed countries, particularly in the United States and Western Europe, without the involvement of MNCs. The alliance with MNCs has additional challenges such as inadequate emphasis on drugs for neglected diseases and potential conflict of interest with respect to the marketing of the drugs. Indian companies are now aware of these difficulties and thus new drug R&D has been privately initiated in India initiative even though the Indian private sector has not yet matured to handle independent R&D for new drugs.

There is thus a need for public support and public-private partnerships in India. The "push" incentives of public support are direct public spending, R&D grants and fiscal incentives. India has an elaborate public R&D infrastructure. The Central Drugs Research Institute (CDRI) – which is a laboratory under the Council of Scientific and Industrial Research (CSIR) – has been involved in new drug development since its inception in 1951. It is one of the few public sector organizations in the world which have their own full-fledged drug development infrastructure. This institute has developed about 10 drugs till date but none of them are registered in developed countries or have been commercially successful. One of the major reasons for this is that CDRI has had hardly any interaction with the pharmaceutical industry. The reason for not encouraging industry participation lies not only with CDRI but also with the fact that Indian companies lacked incentives to go in for product development (in the pre-TRIPS era) and were keen to collaborate only in process development for drugs.

There have been significant efforts from the government to induce public-private partnerships (PPP) in the drug industry. Some of the programmes initiated are Department of Science and Technology's (DST) Drugs and Pharmaceuticals Research Programme, the Open Source Drug Discovery Programme of CSIR, CSIR's New Millennium Indian Technology Leadership Initiative (NMITLI), the Department of Biotechnology's (DBT) Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Programme (BIPP).

The basic idea is to synergize the strengths of publicly funded R&D institutions and the Indian pharmaceutical industry and provide a collaborative platform bolstered by grants and soft loans. Major national laboratories and pharmaceutical companies have been involved in this endeavour and the budget for this, though small, is increasing year by year.

Figure 1: *Institutions Engaged in Medical R&D in India*



These programmes promote funding, but it may be seen that funds are not the only problem. Some of the basic issues that pharmaceutical products from developing countries face have not yet been adequately tackled. The challenge is not only the development of a new drug. It is also about how to promote it. This is one of the major challenges in collaborating with MNCs.

The solution then is to propose an R&D model bypassing the role of MNCs and developed countries, and calling for the case for South-South cooperation. In the South-South R&D Model, it is envisaged to expand the Indian PPPs and include organizations from other developing countries, including countries of the South-East Asia Region, to develop new drugs and conduct clinical trials and get internal regulatory approvals.

Marketing initiatives should focus on these countries rather than on developed countries and MNCs. The advantage of this model is that the costs of clinical trials will be significantly lowered due to the lower costs of the same in these countries. Clinical trials can be up to 40% of the cost of developing a new drug and regulatory approvals contribute another 10%. The developing countries will provide a large enough market for the pharmaceutical companies in these countries to participate in the PPPs model and thus also provide an alternative option to collaborating with MNCs. If and when these drugs are successful, efforts may be initiated to get these registered and marketed in developed countries as well.

7.2 New IPR regime and access to medicines in Sri Lanka – Next steps under WHA61.21: Dr Manuj C. Weerasinghe, Faculty of Medicine, University of Colombo, Sri Lanka

Dr Manuj C. Weerasinghe presented his work on the drug regulatory system in Sri Lanka. The WTO agreement on Trade-Related Aspects of Intellectual Property Rights was signed in Marrakesh, Morocco, on 15 April 1994. This agreement seeks to maintain a balance between the long-term social objectives of providing incentives for future inventions and creation and the short-term objective of allowing people to use existing inventions and creations. But the benefits of the TRIPS Agreement for developing countries are still debatable. As a developing country the new Intellectual Property Rights (IPR) regime has been applicable in Sri Lanka from the year 2005.

The Sri Lankan system is governed by the Cosmetic Devices and Drugs Act (CDDA) of 1980. The Drug Regulatory Authority (DRA) that is responsible for the process of registration is under the authority of the Director-General of Health Services. The Drug Evaluation Sub-Committee (DESC) advises the Director-General on all applications for drug registration that they receive. The DESC generally relies on the information presented by the applicant for this purpose.

At present, the need or the cost of the drug is not seriously considered in registering pharmaceuticals in Sri Lanka. Cost of medicinal drugs and their affordability to the ordinary consumer in the developing countries has been a major point of discussion.

This is further complicated by the pursuit of the pharmaceutical industry on extended patent protection on essential medicines. The debate on achieving public health objectives while at the same time ensuring the protection of intellectual property rights is far from over. In this atmosphere, the IPR regime in the world changed drastically with the formation of the World Trade Organization and the enforcement of the TRIPS Agreement (WTO, 1990). Sri Lanka, a founder member of WTO, is a signatory to the TRIPS Agreement.

However, until now IPR status is not recognized as a criterion for the registration process of pharmaceuticals under the CDDA. The present Sri Lankan IPR Act enforced in 2003 incorporated the provisions of the TRIPS Agreement, thus providing exclusive IP rights up to a minimum of 20 years from the date of filing date. Although five years have elapsed since the beginning of the new IPR regime in Sri Lanka, it is yet to examine its impact with respect to prices and degree of availability of pharmaceuticals under patent.

It is crucial to establish a baseline to follow and predict the implications of TRIPS provisions to public health in the country at this juncture as the real effects of the new IPR regime are to be evidenced in the pharmaceutical market within the next decade. There were no systematic research studies undertaken in this area in Sri Lanka till date. Establishing the baseline at this stage will help to track and remedy the unforeseeable effects that could occur in the future. It is particularly important to provide evidence for advocating consumer-friendly approaches in drug selection and registration, and maintaining affordable prices in the pharmaceutical market.

The study examines the patent status of new drugs registered in Sri Lanka during the first five years of the new IPR regime (2005–2010), and the price fluctuations and perceptions of the pharmaceutical regulators on the new IPR regime in respect of the public health implications.

During the past five years about 70 NCEs were registered at the Drug Regulatory Authority by 19 pharmaceutical companies. The NCEs came under 35 therapeutic groups according to ATC classification Level Three.[25] Two NCEs had no ATC codes. Except for four therapeutic groups (bile therapy, other respiratory system products, parathyroid hormones and analogues, and low-ceiling diuretics excluding thiazides) all other groups had alternatives in the Sri Lankan market.

[25] http://en.wikipedia.org/wiki/Anatomical Therapeutic_Chemical_Classification_System
The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of drugs. It is controlled by the WHO Collaborating Centre for Drug Statistics Methodology (WHOCC), and was first published in 1976. The classification system divides drugs into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics. Each bottom-level ATC code stands for a pharmaceutically used substance in a single indication (or use). This means that one drug can have more than one code: acetylsalicylic acid (aspirin), for example, has A01AD05 as a drug for local oral treatment, B01AC06 as a platelet inhibitor, and N02BA01 as an analgesic and antipyretic. On the other hand, several different brands share the same code if they have the same active substance and indications. In this system, drugs are classified into groups at five different levels:
First level: The first level of the code indicates the anatomical main group and consists of one letter. There are 14 main groups.
Second level: The second level of the code indicates the therapeutic main group and consists of two digits. *Example*: C03 Diuretics:
Third level: The third level of the code indicates the therapeutic/pharmacological subgroup and consists of one letter. *Example*: C03C High-ceiling diuretics.
Fourth level: The fourth level of the code indicates the chemical/therapeutic/pharmacological subgroup and consists of one letter. *Example*: C03CA Sulfonamides.
Fifth level: The fifth level of the code indicates the chemical substance and consists of two digits. *Example*: C03CA01 Furosemide

Figure 2: *NCEs on the Sri Lankan or WHO Essential Drug Lists*

Therapeutic group	NCE	WHO essential drug list#	SL essential drug list*
Direct acting antivirals	Efavirenz	√	√
Viral vaccines	Rota virus, live attenuated	√	
Other antineoplastic agents	Sunitinib		√
Immunosuppressants	Mycophenolate Sodium		√
Antidepressants	Duloxetine		√
Drugs affecting bone structure and mineralization	Ibandronic acid		√
Hormonal contraceptives for systemic use	Etonogestrel		√
Other respiratory system products	Beractant		√

WHO EDL 2010 March
* SL EDL 2009

The information on drugs which has been included in the essential drug lists of WHO and Sri Lanka is as follows: out of the 70 NCEs, 7 drugs (10%) were included in the Sri Lankan Essential Drugs List (2009), while two drugs (2.8%) were on the WHO Essential Drugs List (2010 March). Out of the 86 alternatives for the NCEs that were already available in the Sri Lankan market, 63 (73%) and 47 (54%) drugs were included in the Sri Lankan and WHO Essential Drug Lists respectively.

The data from the National intellectual Property Office of Sri Lanka reveals that 874 entries in the database for patent applications with the National Intellectual Property Office from 2006 till date were chemical compounds and patent claims in the patent applications that were compatible with medicinal drugs.

Figure 3: *Pharmaceutical patent applicants in Sri Lanka*

Applicants	Number	Percentage
Janssen Pharmaceutica	193	22.2
Pfizer products	166	18.6
Novartis AG	55	6.2
Eisai R& D management	34	3.9
Others	426	49.1
Total	874	100

The major concerns for Sri Lanka with regard to pharmaceutical patents are as follows: there are a wide range of drugs registered annually and the newer drugs are registered with innovator brands. There are many NCEs that have therapeutic alternatives and there is always an advantage of early entry of generics. The NCEs are generally expensive and certain observed prescription patterns favour their use.

On the intellectual property and patent side, patent applications for medicinal compounds are increasing. There appears to be a possible shift of limited resources towards newer medicines. A major challenge is the widespread entry of counterfeit medicines fuelling the debate on counterfeit versus generic medicines.

Important interventions on behalf of the government for the pharmaceutical sector in Sri Lanka would be:

- Human resource development in IPR.
- Definite separation of the drug registration and IP offices.
- Removing barriers for the entry of generic medicines and medical products.
- Price control for essential drugs.

7.3 Identification and prioritization for Regional and National Framework on Public Health, Innovation and Intellectual Property Rights in India: Dr K. Satyanarayana, Senior Deputy Director-General and Head, IPR Unit, Department of Health Research, Indian Council of Medical Research, New Delhi, India

Dr Satyanarayana expressed certain priority areas of concern in the GSPA. On Element 1: prioritizing R&D, the issue of concern is that there has been systematic mapping of intellectual property, more so for Types II and III diseases. The countries of the WHO South-East Asia Region lack a National IP strategy. The R&D "mapping" is incomplete and there is not enough clarity on choice of databases to perform this kind of mapping. Moreover, there is no national disease-specific R&D strategy and there is very little coordinated effort between various stakeholders and agencies. The issue of R&D should also reflect in the National Health Policy and National Health Research Policy.

There appears to be a lack of clarity on IPR with regard to whether to encourage patents or not. The question whether defensive patenting – where an entity seeks a patent primarily to protect its own IP and does not prioritize dissemination of the product – is appropriate needs to be answered. We need to strike a fine balance between securing out IP rights and benefit-sharing and this may be particularly important when we utilize traditional knowledge digital libraries (TKDL). In the latter context, strategic options need to be evaluated. Issues such as promoting traditional medical systems in a "traditional way" and the rights of indigenous people vis-à-vis developing a catalogue of intellectual property need further discussions. Regulatory issues on traditional medicine are also a point that needs further debate and elucidation.

On Element 2, that of promoting R&D, there have been sporadic efforts. The IP management polices differ, they are both intramural and extramural and are largely unfocused. There is a lack of priority for neglected diseases and most partnerships on R&D focus on Type-I diseases. Moreover, little coordination or collaboration takes place among various agencies. The question remains whether to collaborate or compete and most instances of partnering only take place during epidemics or outbreaks of disease.

On the capacity to access patent data there are few efforts, even in the post-TRIPS regime. The scientists are not IP-savvy and their technology transfer/adoption skills are still rudimentary. There is the need for going into a "National Mission mode" and developing a focused national thinking for upstream research and development.

For building and improving innovative capacity in Element 3, it is important to ensure international collaboration on IP standards setting and legal frameworks. This collaboration is accentuated during epidemics but we need clarity and a national focus instead of sporadic efforts. In order to develop national and regional coordination mechanisms using test data optimally and harmonizing regulatory issues, the need of the hour is to identify and empower a national nodal agency in the department of health research. This could also assist in developing a regional strategy and assist in identifying and developing some policy convergence between trade and health. There is an urgent need to improve collaboration/cooperation between various agencies, even within the departments of health.

For building and improving innovative capacity the issue of lack of national IP or the absence of a viable technology transfer policy with a clear incentive scheme happens to be a major bottleneck. We need to think through different incentive systems or prize funds and develop newer thinking in this context.

For the transfer of technology in Element 4 the national effort for capacity-building has been practically has been insignificant. Much work remains on capabilities for upscaling pre-clinical toxicity; GMP, Good Clinical Practices (GCP) and certain downstream issues. In many of these areas there is better coordination between institutes outside the country than within.

For developing country models for the development of health products and traditional medicine products, there are no successful "planned models". There is some achievement due to the dedicated efforts of certain committed entrepreneurs as a result of which things are looking up!

For Element 5, i.e. the application and management of IP to contribute towards innovation and promote public health, there is an urgent need to have a national facility for using patent databases. The approach has to be realistic, e.g. currently there are monetary charges imposed for government departments by government departments. The ability to do a freedom-to-operate (FTO) search is currently very minimal. Technical support for the criteria of patenting, under Section 3(d) of the Indian Patents Act, compulsory licenses, IP linkages, etc. need to be enhanced.

Again, linkages between trade and IPRs such as those in emerging Free trade Agreements need to be understood. There appears to be a policy dichotomy between trade and health and a need to sensitize the public on trade and health issues as well as the compulsions of the government, if any. Health is not advocated or represented well in trade negotiations.

The awareness of scientists on IP issues while taking up new R&D needs to be enhanced. Specific incentives for R&D, IP ownership and royalty and priority clearance for regulatory approvals are important issues. There is also a need for clarity on R&D prioritization between Types I, II and III diseases or for the development of some kind of "orphan disease" model as is the case with the United States for which interagency collaboration should be encouraged.

The development of common ethical guidelines and regulatory procedures and harmonization of ethics and regulatory affairs among the Member States of the WHO South-East Asia Region would be beneficial to improve Element 6, which deals with delivery and access.

The way ahead involves the need to address certain national and regional issues. These include:

National

- Setting of priorities.
- Policy environment to stimulate partnerships to increase and accelerate R&D, especially drugs for neglected diseases.
- Develop a consortium of publicly-funded laboratories.
- Develop the parameters to measure the success of universities and public R&D institutes that create upstream leads.
- Focused mission-mode projects.
- New framework for collaborative R&D.
  - Public sector
  - Private sector
- Identify IP management policies to promote innovative R&D in academia, such as with sharing of royalty, etc.
- Develop policy on IP, technology transfer and other skills.
- Fast-track regulatory approvals for Types III and II.
- Indian Council of Medical Research (ICMR)/ Department of Health Research (DHR) National Health Research Policy.

Regional

- Innovation largely continues to be driven by markets.
- Policy discord: TRIPS-compliant national laws versus the flexibilities afforded by the Doha Round vis-à-vis national health needs, e.g., data protection issues in FTAs.
- Plans should be realistic, product-oriented and sustainable.
- The establishment of a regional health research forum.

7.4 National Action and Regional Cooperation on WHA 61.21 (GSPA): Mr Dinesh Abrol, Scientist, National Institute of Science Technology and Development Studies (NISTADS), Council of Scientific and Industrial Research, New Delhi, India

Mr Abrol began by underlining the importance of greater public understanding of the mandated actions under GSPA among stakeholders. An assessment of the level of understanding and awareness of WHA61.21 and GSPA in India was conducted through studies and consultations in respect of mandated actions (CENTAD, NISTADS & NIPER[26]).

Lack of preparedness has its basis not only in the poor state of awareness of mandated actions but also in the prevailing understanding about the place of intellectual property in the generation and diffusion of innovations. There appears to be a fascination for the pathways of growth through global integration and dependence on strong IPR. It is important to understand the origins and causes of market, institutional and systemic failures, elaborating solutions, and for translating solutions into policy.

The global dynamics in respect of health research and innovation reveals that in 1990, the Commission on Health Research for Development specified a target of 2% of the national health budgets of low- and middle-income countries (LMICs) to be spent on public health research The new players (philanthropic foundations and charities) are also not focused on neglected diseases; their priority is mainly global communicable diseases such as HIV/AIDS, TB and malaria. National-level priorities differ in the countries and can be tackled through national-level action in collaboration with regional and international players on a needs-driven basis for programme selection.

WHA 61.21 offers a national and international opportunity for systemic corrections in respect of public health and innovation. There is clear evidence that in each and every Member State of WHO there exists a huge opportunity to undertake actions for the systemic correction and remedying of the situation on public health, and innovation and actions mandated under WHA 61.21 at the national and international level demand a higher level of commitment and can make the stakeholders fulfill their responsibility

[26] CENTAD: Centre for Trade and Development, New Delhi; NISTADS: National Institute of Science Technology and Development Studies, New Delhi and NIPER: National Institute of Pharmaceutical Education and Research S.A.S. Nagar, Mohali, Punjab, India

towards public health and innovation. But the forces that matter and have been responsible for the crisis of R&D and innovation for neglected diseases are not as yet fully ready to adopt the correctives; take the portfolio of measures to be adopted and the actions that are being proposed, such as the Expert Working Group (EWG) process, health research policy and negotiating TRIPS transition for local manufacture and research. Some actions are being taken on account of the vigilance shown at the international level, but it is only a beginning of the journey that will have to be taken amidst varying perceptions and conflicts of interests that have not ceased to exist.

In summary,

- at the international level the WHO process (WHA, EWG, CEWG) has been bumpy but moving.
- at the regional level at SEARO a beginning is yet to be made.

There have been a number of efforts to promote public health issues at the national level in India. For example, efforts undertaken with respect to the incorporation of TRIPS flexibilities and attention to the GSPA process at the level of Ministry of Health and Family Welfare (MoH&FW). There has also been a mobilization of civil society and industry associations to exercise vigilance on the introduction of the Indian version of the Bayh-Dole Act, the development of a manual for patent examination, the work done on the Mashelkar Committee report on the definition of pharmaceutical products and microorganisms, data exclusivity and discussions related to Section 3 (d) of the Indian Patents Act, 1970, etc.

Coherent action is not possible by trade and policy and legislation on IP alone. There is the need to map the state of diversity and the direction of R&D activities at the national level. We need to assess the state of the national system of innovation in respect of the diffusion of products already known to be relevant and the preparation for the development of new products. This may be done by prioritizing the development and diffusion of appropriate health products. For this action is required at many levels, and involving human resources, R&D, regulation, delivery and access, coordination, innovation capacity-building, industrial and institutional development, application and management of IP, financing and procurement, and the like.

The scope of assessment should also be based on a systemic view of the prevailing global and national state of R&D and the innovation gap. This needs to take into account the failure, if any, to generate R&D and innovation in new drugs and other health products for neglected diseases, including insufficient health system research. For this markets, disciplines, governments and institutions have to share the responsibility. The failure of TRIPS in stimulating R&D and innovation for neglected diseases is now a well recognized fact.

We need to begin to assess the progress made at the national level in the following manner:

- Member States need to identify the transition arena and create conditions for the establishment of a transition forum for the implementation of GSPA.

- Member States need to start by undertaking an assessment of the status of completion of activities being undertaken following the mandate under GSPA.
- Member States must institutionalize the assessment and interactions, nurture the transition arenas, identify the pathways and proceed towards the construction of nation- and region-specific pathways.

Example of actions initiated in India on assessment include:

- Initiation of the assessment of progress made in respect of country strategy and plan of action using WHO identified indicators in 2009 in NISTADS and NIPER.
- Improvement in the preparedness and the state of awareness of mandated actions within the government and among the other relevant stakeholders (industry and research agencies).
- Gearing up for a better focus on the development of preparations for intervention from the Indian government in the WHA/IGWG process (2009–2011).

A major issue that needs to be handled is the lack of prioritization of research for health which leads to inordinately low research output on several diseases and conditions that cause a major disease burden in India. This needs examination not only for Type III (overwhelmingly or exclusively incident in India and other developing countries) and Type II (incident in developed and developing countries but with a substantial proportion of the cases in India and also in many developing countries), but also for many Type I (incident in both developed and developing countries, with large numbers of vulnerable populations). The latter includes the new epidemics of chronic diseases such as cancer, diabetes, heart disease, stroke, mental/neurological conditions, etc. driven by poor diet, lack of physical activity, tobacco use and the like.

It is necessary to engage in needs-driven R&D, innovation without monopoly and with dispersion, and decentralization of capacity. Alternate mechanisms to strong private IP rights need to be developed, and these can be achieved in scenarios such as where:

- The government increases biomedical research and places IP in the public domain.
- Companies and universities donate IP rights.
- Big pharma industry is encouraged to set up dedicated units.
- Institutes and universities are encouraged to work on Type II & III diseases
- PPPs are encouraged.
- Tax incentives are promoted.
- Orphan Drug Act-type legislations are promulgated.
- Patent extensions are granted.

- Consortia and patent pooling is ensured.
- Buying out patents.
- Using compulsory licensing.
- Ensuring differential pricing.
- Using advance purchase commitments.
- Incorporating prizes as incentives.
- Creating dedicated institutions.
- Promulgating a new system of rewards for all kinds of actors.

Certain other alternate new proposals for consideration are:

- Providing access to existing and patented drugs through transition countries via regional manufacturing facilities.
- New funding mechanisms and sources and prioritized allocation of funding.
- Proposals fulfilling the criteria of delinking of R&D costs from product monopoly to help build innovation capacity in developing countries.
- Formulating a new R&D treaty.
- Promoting 'Open Source Drug Discovery (OSDD)'.
- Public financing of clinical trials.
- Creating dedicated institutions for R&D.

7.5 The implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Time to act! Nicoletta Dentico, GSPA-PHI consultant, Representative from WHO, Geneva

Ms Nicoletta Dentico said there have been 12 World Health Assembly resolutions on trade and health issues that have been passed since 1996 till date, i.e. on intellectual property and access to medicines, following painstaking debates. These debates have been initiated soon after the signing of the TRIPS Agreement of the World Trade Organization in 1995. Since then, it has been a long road to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property as envisaged by resolution WHA 61.21.

In 2002, the United Kingdom's Commission on IPRs (CIPR) stated that countries need to "ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies". This was followed in 2003 by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) which was in response to the request by Member States to task

an independent commission to analyze the relationship between intellectual property rights, innovation and public health.

The CIPIH's report, published in April 2006, contained 60 recommendations on how to overcome barriers to essential innovation and accessing life-saving drugs for those in need. In particular, in stressed the importance of "the need for countries to strike the best balance, in their own circumstances, between benefits and costs of the IP system".

The World Health Assembly in May 2006 adopted resolution WHA 59.24 requesting the Director-General to establish an Intergovernmental Working Group (IGWG) to draw up a global strategy and plan of action that "aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries". The resolution clearly also defined research priorities and funding needs (CIPIH report recommendation).

The IGWG process was driven by the political leadership of Member States and transformed the CIPIH's analysis to a Member State-driven policy action plan. This process began with its first session in December 2006. The second session of the IGWG was held in November 2007 and then again resumed in April 2008. The follow-up drafting group finalized the strategy at the Sixty-first World health Assembly in May 2008. For the IGWG process the following procedures were adopted:

- Member States made national/regional submissions to provide further inputs to the negotiating text during the process.
- Web-based public hearings were held in November 2006 and August-September 2007.
- Regional consultations were held in all regions from August to October 2007 and continued up to the final stages of the negotiation.

The IGWG process was a historic negotiation for the reason that it was a government-driven process in WHO based on the CIPIH analysis linking innovation with access to medical products. The IGWG engaged in the task of removing existing barriers and designing new incentives aligned with public interest in health R&D. A strong role was exercised by developing countries, in particular Kenya, Brazil, Thailand, India, several Member States of the African Region of WHO, and the Group of Latin American and Caribbean countries of the United Nations (GRULAC). The participating countries sought a sustainable strategy for financing R&D and for ensuring access and a focus on needs that went beyond the "Big Three" (AIDS, tuberculosis and malaria) diseases.

Member States adopted the global strategy and plan of action on public health, innovation and intellectual property (GSPA) at the Sixty-first World Health Assembly in May 2008 (WHA 61.21). The Health Assembly approved the Global Strategy on Public Health, Innovation and Intellectual Property at that session unequivocally by stating that:

- Member States adopted the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property (resolution WHA 61.21).
- The Strategy proposes that WHO play a strategic and central role in the relationship between public health and innovation and IP within its mandates, capacities and constitutional objectives.
- Member States are urged to adopt and support actively the wider implementation of the Global Strategy in particular by providing adequate resources to enhance and implement the specific actions recommended in the strategy vis-à-vis public health, innovation and intellectual property.
- International organizations and other relevant stakeholders were urged to give priority within their respective mandates and programmes to implementing the Global Strategy and plan of action on public health, innovation and intellectual property.
- WHO must coordinate with other relevant international intergovernmental organizations, including UNDP, WIPO, WTO, UNIDO and UNCTAD, to effectively implement the Global Strategy and plan of action.

The GSPA is the most important WHO initiative on pharmaceuticals since the Essential Medicines Concept (1977). Some issues such as stakeholders, indicators and time frames, had remained open at that session and were finalized at the Sixty-second World Health Assembly in 2009 (resolution WHA 62.16). GSPA is a medium-term strategic plan for the period 2008–2015. The Global Strategy on Public Health, Innovation and Intellectual Property promotes new thinking on innovation and access to medicines. GSPA-PHI is the action plan designed by WHO headquarters, Geneva, and this is designed to:

- promote innovation,
- build capacity,
- improve access, and
- mobilize resources.

There are 25 Sub-Elements and 108 Specific Actions in GSPA. Each of the Specific Actions will facilitate its achievement and will be carried out by various stakeholders. The stakeholders are, *inter alia*, WHO Member States, WHO, international and national research institutions, academia, national and regional regulatory agencies, relevant health-related industries (both public and private), public–private partnerships, public-private and product development partnerships, nongovernmental organizations, communities and development partners concerned, charitable foundations, publishers, research and development groups, and regional bodies and regional organizations.

Various departments in WHO at its headquarters and regional offices are in the process of implementing specific aspects of the Global Strategy. The role Public Health,

Innovation and Intellectual Property in WHO (PHI) is to coordinate and facilitate the implementation of the strategy. Others involved in this task are the COHRED (Council on Health Research and Development) and other intergovernmental organizations such as UNCTAD, WTO and WIPO.

The outline of the Implementation Plan from 2011 to 2015 is at the global, regional and national levels. The implementation during these four years will comprise two phases and focus on the country level:

Phase 1: Preparatory phase, from 2009 to 2010.

Phase 2: Pilot phase, from 2011 to 2012.

Phase 3: Broader implementation, from 2013 to 2015.

A few initiatives that are being undertaken include a web-based monitoring & evaluation platform for sharing and reporting of information, national assessments and gap analysis tested in six countries during the pilot phase, technical assistance at the country level, and documentation of national case studies to exemplify good examples of the implementation of GSPA-PHI (as has been the case with case studies from Switzerland and Brazil).

The GSPA has a number of advantages. It is an umbrella instrument but is not too perscriptive, i.e. countries can pick and choose, and adapt the strategy to their needs, contexts, existing skills and visions. It looks at innovation through the lens of accessibility; this goes beyond R&D and emphasizes innovation policy. Common health needs must foster collaboration and promote South-South alliances. The regional dimension is key. The opportunity provided by the GSPA should not be squandered by poor implementation policies. The shape of what will come largely depends on the commitments and the sense of responsibility of those in charge today.

8. National presentations

8.1 Bangladesh: Dr Choudhury Mahmood Hasan, Department of Pharmaceutical Chemistry, University of Dhaka, Bangladesh (Presentation delivered by Prof. Mahmood Hasan)

The status of the pharmaceutical sector in Bangladesh is outlined in **Annex 1.**

1. Allopathic medicine

Pharmaceutical industries are well established in Bangladesh and currently about 97% of medicinal drugs are locally produced, all of these being generic products. Bangladeshi manufacturers are exporting their products, worth US$ 60 million annually, to as many as 84 countries of the world. There are 258 pharmaceutical manufacturing industries, of which the top 20 companies produce 85% of the nation's total produce.

As per a 1982 Ordinance, all these companies must follow the GMP guidelines prescribed by WHO. But the fact is that quite a few of the small-scale companies are not in full GMP compliance. The Drug Administration Office is the controlling agency to implement GMP in all these industries. There is acute shortage of manpower in this regulatory organization. Recently, the Drug Administration Office has been upgraded to a Directorate-General (Directorate-General of Drug Administration) status and a number of new supervisory and inspection-related posts have been created.

At present only 30 technical persons having licensing power are engaged within this office while about 100 posts are waiting to be filled through the recruitment agencies of the government.. This organization is the regulatory body – national regulatory authority – for about 565 Ayurvedic, Unani, homeopathic and herbal companies. The drug retail stores, roughly 100 000 in number, are also regulated by Directorate-General of Drug Administration (DGDA). With the very limited manpower it is almost impossible to enforce regulatory compliance, including GMP compliance. The DGDA must take urgent initiatives to recruit sufficient technical staff to overcome these problems.

There are R&D activities in allopathic companies but limited only to drug formulations. At present, almost 95% active pharmaceutical ingredients (API) are imported. Thus, R&D activities are required in this field.

The patent protection regime under TRIPS flexibilities for Bangladesh and other Least Developed Countries will end in January 2016. The patented API is allowed to be manufactured up to this period under the special flexibilities allowed by the Doha Round of TRIPS. When this deadline expires, patented API (mostly of the new generation) must be procured from external sources at a very high price unless the deadline is extended. As such, the price of the finished products will go up and they will be less affordable to the public.

The Government of Bangladesh must provide funds as loans, with support from international donors, to local API producers. At the same time, efforts must be taken to extend the TRIPS special privileges to Bangladesh and LDCs for a longer period, perhaps up to the year 2025. Otherwise, to ensure people's access to the patented products, the government should manufacture these medicines in generic formulations through the nation's only public sector manufacturing company (the Essential Drug Company) and sell them at affordable or subsidized prices in the market.

As mentioned above, no basic innovative R&D activities are undertaken by local manufacturers although a few manufacturing firms do have a separate R&D unit with very meager fund allocations.

Intellectual property aspects are not seriously invoked in the medicine manufacturing sector. Clinical trials are few in number. Some negligible amount of bioequivalence tests are done in many drug companies and by the testing laboratories of the government.

Before 2005 no foreign company could produce any of their products under license with a local company unless they had a full-scale manufacturing unit in Bangladesh. This was the major impediment in technology transfer from reputed international pharmaceutical companies. The 1982 Drug Ordinance was amended in the year 2005, and since then there is no barrier in technology transfer for the production of medicines in Bangladesh.

2. Traditional medicines

After 1982 the Drug policy was amended by the enactment of the Drug Ordinance, and medicines under the traditional system began to be considered as drugs and came under the purview of the Drug Administration. At present there are 469 units (268 Unani and 201 Ayurvedic) producing traditional drugs worth approximately US$ 100 million every year. Interestingly most of these are small in size and can be classified as SMEs (small and medium-scale entrepreneurs). GMP compliance is very poor, except for a few. In fact it also not easy for all these enterprises to implement GMP guidelines, which seem to be tailored for only allopathic drugs. As a number of people are employed in this sector, strict GMP implementation necessitating cancellation of manufacturing licence upon violation may lead to unemployment.

It is recommended that a separate GMP guideline should be formulated for SME-type traditional drug companies. On the other hand, if the current GMP guideline are to be followed then more time should be allowed for full compliance. WHO-SEARO is currently providing funds through the DGDA to impart training on GMP for technical persons working in these industries.

Quality control is a big issue in this sector. When the products are made combining so many plant and in some case animal parts, it is very difficult to assay the preparation. Qualities of raw materials drastically change with storage condition. In general plant products are safe but the plants if not properly stored may be infected with fungi and some of these produce toxins harmful for the human body. There is a great need for R&D activities in this field. As most of these companies are small-sized with poor financial reserves, they cannot go in for such research. The local government can indeed raise funds to establish a research institute under the Bangladesh Council of Scientific and Industrial Research (BCSIR) which is the only R&D organization in the country. WHO and other international funding organizations may come forward to help establish such R&D institutes.

Intellectual property rights (IPR) play an important role in the case of medicinal plants. Bangladesh is a good repository of plant sources: there are about 5000 flowering plants of which around 500 are used in traditional medicine. There is no database on these plants. Thus, it is strongly felt that WHO may provide support to the national herbarium and the DGDA to establish a traditional knowledge database library.

3. Herbal medicine

Herbal medicine has been recognized as a separate discipline of drug form after the enactment of the amended Drug Ordinance in 2005. Now any local manufacturer, after obtaining a licence from DGDA, can produce herbal preparations if it is included in the recognized herbal formulary of developed countries. Earlier no one could produce any herbal preparation not included in the National Ayurvedic and Unani Formulary. Herbal products make use of only a few plants and quality control is relative easier here than with traditional medicines.

Currently 17 companies produce herbal medicines and most of them are leading allopathic pharmaceutical industries. Since these are large companies they follow GMP guidelines prescribed by WHO.

4. Homeopathic medicine

The homeopathic system is widely used in Bangladesh because it is safe and cheap. There are 79 homeopathic manufactures producing mainly mother tinctures. After the amended drug policy of 2005, manufacturers are allowed to produce homeopathic medicines in dosage form. Again, most of these companies are small-scale ones and cannot follow GMP guidelines properly. Appropriate GMP guidelines suitable for this sector also need to be formulated.

8.2 India: Dr K. Satyanarayana, Senior Deputy Director-General and Head, IPR Unit, Indian Council of Medical Research, Department of Health Research, New Delhi, India

The status of the pharmaceutical sector in India is outlined in **Annex 2.**

This report attempts an extensive research and objective analysis of the health-care sector and medical technologies in India, namely the status of pharmaceutical, herbal and dental formulations and medical equipment and devices in India. Parameters studied include present status, growth drivers, issues and challenges, export status, government initiatives and regulatory framework, as also opportunities critical for the growth of the health-care market in the country.

A demographic transition is underway in India with the rapid growth in the health sector of the past 60 years set to rise further due to better economic status of the people, improved health facilities, better nutrition and overall awareness of good health practices. The percentage of people over 60 in the general population is expected to rise from 6.2% in 2001 to about 9% in 2016. At the same time, the population aged below 14 years is expected to drop to 27.1% in 2016 from about 35.6% in 2001.

The disease profile continues to mirror the ″dual disease burden″ with both infectious diseases and noncommunicable diseases – lifestyle-linked diseases such as hypertension, cancer and diabetes – set to rise to significant proportions.

The share of private or out-of-pocket expenditure by patients has also increased from 60% in 1990–1991 to 80% in 2000–2001, while public expenditure has been stagnant at between 0.9% and 1.2% of GDP during this decade. The cost of providing health care by the private sector is expected to be the largest component of individual spending in 2012 and is likely to double to US$ 35.7 billion. Significantly, almost 90% of all private health-care expenditure is met by the unorganized sector, leaving a huge potential market for this sector open to be tapped. Also, India's expenditure on private health care is perhaps the highest among developing countries with an estimated 13 lakh private health-care providers. Of them, 97% are in the unorganized sector and therefore fragmented. Over a third of these entities are not even registered.

According to WHO, India spends about 5% of its gross domestic product (GDP) on the health-care sector. It is expected that this figure will rise to 6.1% of GDP by 2012. About 50% is spent on curative and primary care and another 40% on secondary care, including medical specialists in major hospitals with expensive diagnostic equipment. The remaining 10% of the expenditure is on preventive care such as health education, weight reduction plans and similar programmes. With both government and the private sector contributing to rapid growth in the industry and a growing population of over 1.1 billion, the demand for infrastructure and high-quality service is immense in India.

India's health-care sector is diverse, comprising the entire gamut of drugs and pharmaceuticals, medical devices, hospitals and health insurers. The health-care industry includes doctors and other health-care providers, hospitals/nursing homes, medical diagnostic and pathology laboratories, and other supportive facilities. In terms of revenue and employment alone, the health-care sector is perhaps India's largest service-sector industries. Since the 1990s, the Indian health-care sector is growing at a compounded annual rate of 16%. According to industry estimates, the total current value of the sector is well over US$ 34 billion or about 6% of the GDP. There are also estimates to suggest that by 2012, health-care spending could contribute 8% of GDP and employ around 9 million people. By 2014 it is expected to touch US$ 78.6 billion.

The pharmaceutical sector

The Indian pharmaceutical industry is among the most organized industries in India with an estimated worth of US$ 4.5 billion and is growing at about 8% to 9% annually. The Indian pharmaceutical industry also ranks high among the same in developing countries in terms of technology, quality and the vast range of products that are manufactured: from simple painkillers to sophisticated anti-cancer drugs and complex cardiovascular compounds. The industry has the capability to manufacture almost every type of medicine now required in India. Thus the pharmaceutical industry in India meets over 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles, etc.

The industry, however, is highly fragmented with over 20 000 registered units currently. It has significantly expanded in the last two decades. The pharmaceutical and chemical industries in India are a extremely fragmented market with severe price competition and government price control. There are about 250 large units and 8000 small-scale units, including five central public sector units that form the core of the pharmaceutical industry in the country.

Despite widespread poverty and inadequate public health-care provisions, India has much to offer the leading drug-makers. An increase in lifestyle diseases resulting from the proliferation of unhealthy diets and junk food consumption combined with a growing middle class that has more disposable income to spend on treatment is poised to provide new opportunities for global pharmaceutical firms.

Manufacturing India has emerged as a major supplier of several bulk drugs, producing these at prices lower than those of formulation producers worldwide. The US Food and Drug Administration (FDA) already has approved 85 APIs and formulation plants in India, the highest such number outside of the United States.

India is also poised to become a major exporter of pharmaceuticals, particularly generic and over the counter (OTC) drugs, to global markets. By 2010, India could be producing 15% of the world's bulk pharmaceuticals and drug intermediates. However, achieving that level of growth will require an investment of an estimated US$ 1.2 billion in production capacity. With the advantage of being a highly organized sector, the pharmaceutical companies in India are growing at the rate of US$ 4.5 billion, or a growth of about 8% to 9% annually. About 250 leading Indian pharmaceutical companies control 70% of the market share with the MNCs still struggling to penetrate the market with new drugs.

The Indian pharmaceutical industry is currently the third largest in the world in terms of volume, and 14th in terms of value. According to data published by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry in 2008–2009 was US$ 21.04 billion. Of this, the domestic market was worth US$ 12.26 billion. The Indian pharmaceuticals market is expected to touch US$ 55 billion in 2020 from US$ 12.6 billion in 2009. The market has the potential to breach the US$ 70 billion mark by 2020 in this current aggressive growth scenario.

The drugs and pharmaceuticals sector, therefore, has attracted foreign direct investment (FDI) worth US$ 1.87 billion between 2000–2010, while hospitals and diagnostic centres have received FDI worth US$ 980.38 million during the same period. Companies such as GE Healthcare plan to invest US$ 50 million to set up more facilities for developing diagnostic services, including anaesthesia, ventilation, computed tomography (CT) systems and molecular imaging, etc., according to several analysts.

Generics continue to drive the market. India tops the world in exporting generic medicines (worth US$ 11 billion annually at the moment) and currently the Indian pharmaceutical industry is one of the world's largest and most developed for generics. Moreover, the Indian generic drug market is expected to grow at a compound annual growth rate (CAGR) of around 17% between 2010–2011 and 2012–2013 in the foreign markets. Overall, the Indian domestic pharmaceutical market has seen growth at a CAGR of about 12% in the last five years. People of the 67+-year-age-group spend around three to four times more on drugs than people in the younger age-groups. This indicates substantial growth for the pharmaceutical industry. Patented drugs had a 10% market share of the pharmaceutical industry in 2010.

R&D in pharma

There are 13 Indian companies which are actively engaged in R&D for the development of new drugs. These 13 companies together spent Rs 18 264.6 million on R&D during 2007–2008, which was almost 9% of their total turnover. Among the larger spenders as percentage of turnover are Suven (25.64%), Torrent (11.37%), Ranbaxy (11.29%), Wockhardt (10.81%) and Fresenius Kabi Oncology (10.96%).

The R&D expenditure of these companies has increased at a compound annual growth rate of 34% from Rs 1659.1 million in 1999–2000 to Rs 17 355.8 million in 2007–2008. NCE R&D is not yet a significant part of the R&D activities of Indian companies. Few of the large R&D spenders invest in NCE development. Cipla, for example, is the third largest spender on R&D but yet has no NCE in its portfolio.

The R&D spend is still minimal when compared with the global pharma. While the 13 Indian companies together spent US$ 454 million in 2007–2008, Pfizer, the largest MNC, alone spent US$ 8.1 billion in 2007. The model that the Indian companies have adopted, rather, is to develop new molecules up to a certain stage and then licence them out to companies abroad, primarily MNCs.

According to industry estimates, the Indian pharmaceutical industry (formulations & bulk drugs) is expected to grow at a CAGR of 14.2% to around US$ 50 billion in 2015–2016. Exports driven by contract research are expected to grow at a CAGR of 16.2% while the domestic market is expected to grow by 12.5%. In last six years exports, accounting for about 47% of the total industry, grew at a CAGR of 27% while the domestic market grew at a CAGR of 14%. The Formulation segment, which constitutes 73% of the total industry, reported a CAGR of 17% while bulk drugs aided by exports grew at 28%. Contract research, a new entity still in India, has, however, grown significantly in the past couple of years.

To promote R&D in the pharma sector, the Indian government allows 100% foreign direct investment (FDI) under the automatic route in the drugs and pharmaceuticals sector including those involving use of recombinant technology (DIPP). The government is also planning to set up a US$ 639.56 million venture capital (VC) fund to give a boost to drug discovery and strengthen the pharmaceutical infrastructure in the country.

The MNCs are setting up R&D facility in India. MSD Pharmaceuticals Pvt Ltd plans to set up a research and development (R&D) centre with UK-based Wellcome Laboratories in India with a total investment of US$ 130 million. Fortis Healthcare has joined hands with technology solutions provider TotipotentRX Cell Therapy Pvt Limited to set up centres of excellence offering cellular therapies and stem cell clinical trials across select Fortis hospitals.

R&D for NCEs being developed by the Indian companies follow the global trend. They are primarily on Type I diseases (13) such as diabetes, cancer, heart diseases, asthma and obesity. These diseases clearly have larger and more attractive market in developed countries, though they are also prevalent in developing countries. The neglected diseases

(Type II and III diseases) are absent from the list except for malaria and TB. Even for this the funding is largely from the public sector or philanthropic sources.

There is a clear trend towards growing global interest in Indian companies with both the pharma and biotech sectors throwing up as many as five mergers and acquisitions worth US$ 250 million in the recent past.

The major challenges for the Indian pharmaceutical industry in the near future include: the impact of the new product patent regime; drug price control system; drug regulatory reforms; need for infrastructure upgradation; quality management; and conforming to global standards such as GMP, GCP, etc.

Herbal drugs

Traditionally, India has always had a good market potential for Ayurveda, Yoga, Unani, Siddha and homeopathy (AYUSH) medicines as these traditional medicinal systems are still widely practised, especially in rural areas, due to their affordability and minimal side-effects. AYUSH is fast moving into the domain of lifestyle drugs, neutraceuticals, cosmoceuticals and other means of allied treatment.

The Government of India has, therefore, established the Department of AYUSH (Ayurveda, Unani, Siddha and Homeopathy) as a new department under the Ministry of Health and Social Welfare for the promotion and development of, and education and research in, these Indian systems of Medicine. This is in addition to the individual councils established in each of the AYUSH sectors to safeguard the traditional procedures of treatments. These councils look into developments in treatment and infrastructure development, consider the establishment of hospitals and medical colleges in their respective fields, and encourage research activities besides setting up appropriate regulatory structures to ensure the safety of medicines.

The market for products under the ISM indigenous systems of medicines category in India in 2004–2005 was estimated to be worth US$ 400 million. Of these, over 82% was in the Ayurveda sector and 14% in homeopathy. Herbal health care and the personal care market in India is estimated to be between US$ 550 million and US$ 650 million. In addition to AYUSH products, a huge services market has emerged in the last few years. India's total export of AYUSH products during 2004–2005 was US$ 23.3 million, about 8% more than in 2003–2004. The industry is currently dominated by about 30 companies, each with revenue of over US$ 1 million. There are over 20 000 manufacturing units most of which are small or micro. The industry is currently dominated by about 30 companies, each with a revenue of over US$ 1 million. Most of the large companies offer FMCG (fast-moving consumer goods) products with herbal ingredients along with ISM medicinal products.

Opportunity in the AYUSH sector in India largely lies in the supply of raw materials. The AYUSH identified about 1500 medicinal plants of which 500 are used in the preparation of drugs. The National Medicinal Plant Board (NMPB) has also identified 32

prioritized medicinal plants which are in demand for both the national and international markets.

AYUSH has many issues to be addressed and challenges to be met for its growth in India and for export. Pricing of the drugs and other products continues to be a major issue. Quality is still a concern as no systematic clinical trials are conducted in terms of drug dosage. Hence the Drugs Controller of India has not been able to address the issue of pricing of these drugs. Most of the 20 000 units that manufacture alternative medicines are neither registered with the department of AYUSH nor follow good manufacturing practices for drug preparation.

Inconsistency of quality, policy issues, technology modernization, and competition with allopathic drugs are some of the other challenges faced by the ISM. In order to harness the potential in this market, a few issues that need to be addressed include IPR protection systems for traditional medicines, disseminating correct knowledge about herbal drugs, proper and adequate scientific documentation, and proving the safety and efficacy of drugs through large clinical trials.

Medical devices

Medical devices are health-care products that achieve their primary intended purpose by not being metabolized. Medical devices include electromedical equipment and related software, furniture, supplies and consumables, orthopaedic appliances, prosthetics and diagnostic kits, reagents and other equipment.

Medical devices are classified according to their medical utility or technical design and manufacturing aspects. However, regulatory authorities across the world have classified them based on their safety requirements and standards of quality to be achieved. Several criteria are considered to evaluate the potential risk: degree of invasiveness, duration of contact, affected body systems and local versus systemic effects. The classification of medical devices differs from country to country as given below:

Table 8: ***Classification of medical devices in various countries***

Europe	US FDA	GHTF (Japan)	Examples of medical devices included
Class I	Class I	Class A	Non-sterile items or sterile items with a low potential risk: surgical instruments, urine bags, stethoscope, examination gloves.
Class IIa	Class II	Class B	Sterile items, surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes, IV sets
Class IIb	Class II	Class C	Blood bags, condoms, non-absorbable sutures, anaesthesia machines
Class III		Class D	Absorbable sutures

In India medical, dental and surgical equipment constitute the largest segment with about 40% to 50% share of the market. Plastic and disposables make up 25% to 30% of the market and the remaining 20% to 25% of market share is held by implants and medicated implants such as cardiac stents.

In the light of its widespread applicability, the medical devices market has registered a steady growth. Currently valued at US$ 220 billion, the huge global market is expected to drive the Indian market as demographics and market drivers step up the demand for new and innovative product offerings at affordable prices.

Imports continue to constitute over 50% of the market. Most imported products are sold at high profit margins. However, the market is becoming increasingly competitive due to low entry barriers for MNCs, an increasing number of players and an expanding consumer base. By value, imports are about three times the exports.

In India the medical devices sector makes up only 15% of the total pharmaceutical market as against 28% worldwide, indicating underutilization of medical devices in Indian health care. This also indicates a large untapped market.

The regulation of medical devices is complex with legal technicalities. In India, the Department of Health has the jurisdiction over medical devices through the Drugs Controller-General of India (DCGI). But as is evident from the large-scale illegal reprocessing and repackaging of used syringes for resale and the easy availability of equipment that fail minimum safety and quality standards – including unsterilized implants that cause infection and stents coated with immuno-suppressant drugs that could impair the body's immune system – a lot needs to be done.

All medical devices carry a certain degree of inherent risk. Therefore, the Global Harmonization Task Force (GHTF) has identified potential areas of danger to patients that warrant consideration. These include the degree of invasiveness, the duration of contact, the body system affected, and the local-versus-systemic effects. An invasive device is usually considered to have a higher potential hazard than an equivalent non-invasive one. Similarly, devices that have a long duration of contact are assigned higher classes of potential hazard or risk.

The medical technology market in India was worth an estimated US$ 2.75 billion in 2008, a growth of approximately 14% over 2007. The market is expected to reach US$ 5 billion by 2012 with an annual growth rate of nearly 15%. However, the data are not well documented in the Indian context. Estimates of the market size, therefore, vary from US$ 1.9 billion in 2009 to US$ 3 billion in 2010.

The global medical devices and equipment market is estimated to be at US$ 215 billion in 2008, and has grown at a CAGR of 4.5% during the period 2004–2008. The Indian medical equipment and supplies market during 2008 was estimated at US$ 2.75 billion, with an annual growth of 14% since 2003.

Medical instruments and appliances used in specialized procedures such as ophthalmic, dental and other physiological cases account for almost 25% of the total market. The other major segments include the orthopaedic/prosthetic goods segment (20% of total market share), medical supplies (12.4%), high-end speciality electromedical equipment (10.2%), and X-ray apparatus (9.4%). Diagnostic kits continue worth almost US$ 300 million were traded during 2008, marking a growth rate of 30% to 35% over the previous year. Overall imports continue to constitute to over 50% of the Indian market.

Some key growth drivers for the medical technology industry in India include: (i) rising economy; (ii) increasing health-care spending; (iii) increasing health-care expenditure; (iv) shift in the demographic profile; (v) changes in disease profile and increase in lifestyle diseases; (vi) spurt in diseases such as ophthalmologic, cancers, cardiovascular, diabetes and renal diseases; and (vii) neurological and other mental disorders; as well as (viii) growing cases of addiction to psychotropic substances.

Some opportunities and challenges for the medical devices sector include:

(1) increasing dependence on imports for supply of medical devices;

(2) inadequate and unclear regulatory environment;

(3) low level of health-care insurance;

(4) inadequate health-care facilities and awareness in rural and semi-urban areas.

Oral health

In India, oral health care constitutes an important segment of overall health care and its relevance is rising with more and more people becoming aware of the need for the same.

The most common oral diseases in India include dental caries and DMFT [27](that occurs in almost 60% of 15-year-olds and over 80% among adults in the age-group of 35–44 years), periodontal and other gum diseases (in almost 70% of young people and as much as 90% among >35-year-olds), malocclusion or crooked tooth (affecting 30% to 40% of Indian children), rising numbers of oral cancer cases and pre-cancerous lesions (almost 10 in every 100 000 males and females), rising instances of dental abscess, bad breath and tooth discolouration.

The dentist-population ratio in 2008 was 1:10 000 in urban India and 1:250 000 in rural areas. As far as the overall ratio of dentists to the general population is concerned, there was a marked improvement between 2005 and 2008, from 1:42 500 to 1:16 120. There are about 280 dental colleges with over 15 000 dentists being produced each year. Of these, almost 140 colleges also offer postgraduate degrees in various fields of dentistry.

[27] DMFT and DMFS describe the prevalence of dental caries in an individual. DMFT and DMFS are means to numerically express the caries prevalence and are obtained by calculating the number of decayed (D), missing (M), filled (F) teeth (T) or surfaces (S).

The Indian dental care services market and dental ancillary services grew at a CAGR of 11.37% during 2004–2008. It is expected to touch US$ 660 million in 2009. Currently, the Indian dental equipment and appliances market was estimated at US$ 87 million. Due to the increasing awareness about personal hygiene the dental/oral care market has been growing rapidly over the past decade and in 2009 touched US$ 1 billion. The segment is largely dominated by three products: toothpastes (US$ 0.5 billion), toothbrushes (13%) and toothpowder (12%).

The global dental industry market continues to be lucrative and enjoys a high degree of competition. It was estimated to be around US$ 18 billion in 2009 (excluding large equipments) and is growing at around 6.5%. The dental consumables market was US$ 11 billion in 2009. The United States enjoys the largest share (37%) of the global dental consumables market, followed by Europe (32%). Japan's dental equipment market had a share of 14% of the global and rest of Asia has a share of around 7%.

India is a net importer of dental equipment and supplies and the major dental imports in 2008–2009 included dental furniture (US$ 940 million), dental instruments (US$ 18.92 million) and radiation apparatus (US$ 10.27 million). India's major dental exports include dental furniture (US$ 297.31 million), dental hygiene preparations (US$ 54.71 million), and surgical wound closures (US$ 8.43 million).

The Indian dental equipment industry is expected to reach US$ 116.43 million by 2014 with an annual growth of 6%, according to industry estimates. Similarly, the dental care services market is also expected to touch US$ 1.16 billion and oral care market US$ 2 billion by 2014.

In India, awareness about oral health is still not up to desired levels. Some tangible degree of improvement in dental health care has been observed in the past decade through measures such as water fluoridation, introduction of fluoride toothpastes and growing awareness about dental hygiene. However, there is scope for considerable improvement yet.

8.3 Indonesia: Dr Martuti Budiharto, Pharmacist, National Institute of Health R & D, Jakarta, Indonesia

The status of the pharmaceutical sector in Indonesia is outlined in **Annex 3.**

Dr Martuti Budiharto explained that her report is to fulfil the deliverables for identifying priority areas under resolution WHA 61.21 by ascertaining status of pharmaceuticals, herbal medicines, dental formulations and medical technologies in Indonesia. To prepare a focused regional and country-specific national action plan for the countries of the SEA region, the data collection was conducted through interviews of

several stakeholders in related areas, and a thorough review of documents from libraries and websites[28].

Indonesia has been implementing a decentralization policy for public health since 2001. The revised decentralization law of 2004 delegates authority in health services to the districts. This covers the authority for procurement of medicines. However, on the other hand, the government has not yet encouraged the establishment of pharmaceutical companies outside of Java Island.

Pharmaceutical companies are the main source for medicine supply, providing more than 90% of the domestic need, and thus also contributing significantly to Indonesian economic growth. The government's policy at the moment encourages free competition among pharmaceutical companies. Therefore, there is no restriction in establishing pharmaceutical companies, or on production, even of generic products. This has resulted in the emergence of several pharmaceutical brands, and the price of medicine is determined by the market. There are four state-owned pharmaceutical companies: Kimia Farma, Indonesia Farma, Bio Farma and Phapros. Bio Farma has a specific qualification for producing vaccines and sera only.

The main products of the other companies are generic medicines for public supply. At the beginning of the implementation of the generic drugs prescribing policy, there was reluctance and disbelief among most doctors due to the very low price of generic medicines. The Ministry of Health slowly improved the image of generic medicines by social marketing, community promotion, and through efficacy-proven evidence. Since the financial crisis of 1997, generic medicines became the only products eligible to meet 80% of the community's needs. This was supplemented by the implementation of the National Drug Policy, National Essential Drugs List, generic prescribing, etc.

The state-owned companies are the backbone of the production of more or less 200 generic medicines by the Ministry of Health (legislation law No. 1799/2010).

[28] Pharmaceuticals data Respondents: 1. Dra. A. Retno Tyas Utami, Director of Therapeutic Products and Hazardous Substance Control, National Agency of Drug and Food Control, and 2. Subowo DT, Secretary, Manufacturing Department, Indonesian Pharmaceutical Association. *Herbal Medicines data* Respondent: 1. Dr Linda S. Sitanggang, Director of Traditional Medicines, Cosmetics, and Complementary Product Control, National Agency of Drug and Food Control, 2. Dra. Rumandang, Staff of Directorate of Traditional Medicines, Cosmetics and Complementary Product Control, NADFC, 3. Dra. Detty, Staff of DG of Pharmaceutical Services and Medical Devices, 4. Dra. Sari, Staff of DG of Pharmaceutical Services and Medical Devices, and 5. Dra. Lucie Widowati, Researcher, NIHRD. *Dental Formulation data* Respondents: 1. Dr Linda S. Sitanggang, Director of Traditional Medicines, Cosmetics, and Complementary Product Control, National Agency of Drug and Food Control, 2. Dra Rumondang, Staff of Directorate of Traditional Medicines, Cosmetics, and Complementary Product Control, NADFC. *Research and Development Respondents*: 1. Dr. Trihono, MDDG of NIHRD, 2. Emmy Basundari, Researcher. *Patent issues* Respondent: DG of IPR, Ministry of Law and Human Rights. *Data collection by website* ipdl.dgip.go.id.patent, http//www.pom.go.id/profile, http://ipdl.go.id_ext/Topjax servi et H2H www.businessmonitor.com.pharmaceutica
Data collecting by documents
Private Sector Supply of Pharmaceutical and Health Products, World Bank, 2009.
Ministry of National Education, Training on Advantageous of Research Results, subordinate for public student creation, for patent potential, workshop training, Jakarta 10-12 March 2011.
National Institute of Health Research and Development Report on Basic Health Research, 2010.
Sukasediati, et al, Report on Preliminary Study on Raw Material for Medicines, Jakarta 1998.
Websites of NADFC, DG of IPR.

Major research institutes in Indonesia conduct various health researches. These include the National Agency for Assessment and Application Technology (NAAAT), Indonesian Institute of Science (IIS), Institute for Human Virology and Cancer Biology (IHVCB), National Institute of Health Research and Development (NIHRD), as well as research and development units in pharmaceutical companies. The Ministry of Research and Technology is a coordinating body for research activities. There is also a National Research Board (NRB) which promotes, maintains and prioritizes research activities in Indonesia.

There is a Directorate-General of Intellectual Property Rights (DG of IPR) under the Ministry of Law and Human Rights. DG of IPR has ratified several international treaties, and these include the agreement establishing the World Trade Organization in 1994, Patent Cooperation Treaty of 1997, the Trademark Law Treaty of 1997, the Berne Convention for the Protection of Literary and Artistic Works of 1997, the WIPO Copyright Treaty of 1997 and the WIPO Performances and Phonograms Treaty of 2004.The role of IPR in the modern era is to support technological products as creations of the people for the benefit of the people.

Pharmaceutical companies have grown enormously since Indonesia applied for an open policy to foreign investment in 1980. In 1970 there were only about 150 pharmaceutical companies; the number increased to 224 companies in 1995 but later decreased to 193 during the financial crisis of 1997. Currently the number of pharmaceutical companies is 203 and they are categorized into joint venture companies (12), state-owned companies (4), and local companies (187). The standard for pharmaceutical raw material is the Indonesia Pharmacopoeia, the last edition of which was published in 2007.

Many research institutions had begun to explore medicinal herbs to generate raw material. The standard for herbal medicinal plants is the Indonesian Herbal Pharmacopoeia published by the Ministry of Health, the first edition of which was in 2008. Besides, the NIHRD published the Vademecum of Traditional Medicines in 2010.

A large population in Indonesia, especially in Java island, usually uses traditional medicine. One traditional medicine type is called *jamu,* a powder or solutions mix of various kinds of medicinal herbs. According to the Directorate-General of Pharmaceutical Services and Medical Devices, Ministry of Health, there are 91 traditional medicine companies in Indonesia.

In general, Indonesia has no medical devices industry. Most medical devices are imported from other countries. Locally only spare parts for instruments are manufactured. Data from the DG of Pharmaceutical Services and Medical Devices (2010) shows there are 20 large companies, 246 small industries and 869 distributors for medical devices.

In 1991–2009 the number of applications for patent were 76 831; these included 70 253 from foreign countries and 6578 from Indonesia. Of these 6578 applications, about 3600 came from the health sector. According to information from Directorate-General of IPR, Ministry of Law and Human Rights, the health applications were related to medicines, vaccines, cosmetics, biological agents, pesticides, etc. These were from both Indonesia as well as foreign countries. These foreign counties included United States, Japan, Germany, the Netherlands, Switzerland, the United Kingdom, France, the Republic of Korea and Australia.

Annex 3 lists the number of pharmaceutical companies at the time of the study at 203, herbal medicines industries at 79, and also states that there are 1395 small and medium enterprises for herbal medicines. The number of dental formulation companies was 21, and there were 20 companies for medical devices.

According to the Directorate-General of Pharmaceutical and Medical Devices there were 246 companies listed as "inventor companies", 869 as "distributors" and 91 as "herbal medicines". There is no information about investment in plant and machinery in pharmaceuticals, traditional herbs, dental formulations and medical devices.

The formulation production of pharmaceuticals was around 16 000, but only 15 411 medicines have registered in National Agency of Drug and Food Control (NADFC) in various dosage forms. In 2010 the formulation production of herbal medicines was 14 445 items, while dental formulations totalled only 145 items during 2008–2010.

The projected growth in production (2011–2014) for pharmaceuticals is about US$ 12.7 billion, and retail sales about US$ 4.6 billion for medical technologies. The volume of imports of pharmaceuticals in 2009–2010 was US$ 133 million. Medical technologies have a 15% projected growth for imports and 5% projected growth for exports in 2011–2014.

Regarding the parameter of the number of pharmaceutical companies/units adhering to GMP criteria stipulated by WHO, NADFC reports the number to be 203, and there is no information on herbal medicine companies as well as dental formulation companies. The Indonesian Medical Devices Companies Association noted only 16 of 20 companies to be adhering to GMP criteria stipulated by WHO.

Summary of recommendations to Government of Indonesia and WHO-SEARO

(1) Each of the 25 sub-Elements outlined in Template A are of highest relevance to the country (Scale 4).

(2) Indonesia has enough resources for IPR and the necessary regulations are already in place.

(3) Collaboration and coordination among stakeholders should be encouraged.

(4) Most pharmaceutical companies are located in Java Island; and this reflects a significant development gap between islands. This condition will have consequences on equal access to pharmaceuticals and will lead to maldistribution of expertise at places outside Java. The scope of traditional medicine is very promising. The government, therefore, has to support research on traditional herbs leading to obtaining patents.

(5) The Ministry of Research and Technology (MRT) is the coordinating body to enforce compliance of research institutes. The MRT has developed a national research agenda that should be followed by research institutions, and also has a role in strengthening research management and facilitate technology transfer to secure IPR and achieve patent products.

(6) The research institutions as well as the government and private sector are able to communicate to the D-G IPR, Ministry of Law and Human Rights, to seek information on patent certification. The NIHRD (responsible for health R&D) should encourage studies on public health innovation, especially on indigenous knowledge such as on herbal medicine. The NIARD (responsible for agriculture R&D) should encourage upstream studies on medicinal plants/herbal medicines to regulate the quality of raw material.

(7) The Ministry of Health (MoH) is developing a roadmap for creating pharmaceutical products to overcome diseases such as:

- Communicable disease : vaccines, drugs or diagnostic kits.
- Noncommunicable disease: model of intervention in the field, including legislation.

(8) The MRT and technical ministries must also expand the scope of South-South collaboration on R&D, especially in the production of vaccines, drugs and traditional medicines, as well as collaboration with UN agencies for capacity-building on R&D.

Table 9 shows that in Indonesia there are 91 big medical herb companies distributed in eight provinces located on three islands. Similar is the situation with the location of pharmaceutical companies. However, the NADFC has explained that there are 2358 traditional medicine industries, which include 1454 Indonesian industries, 153 American, 227 Chinese and 138 Malaysian. The number of traditional medicines registered is 6895 items.[29]

Table 9: ***Number of traditional/herbal medicine industries in Indonesia****

No.	Province	Total
1.	North Sumatra	3
2.	South Sumatra	2
3.	Banten	20
4.	Jakarta	2
5.	East Java	17
6.	West Java	32
7.	Central Java	14
8.	Bali	1
	Total	91

*Data source: D-G of Pharmaceutical Services and Medical Devices

[29] References:

1. Indonesian patent information ipdl.dgip.go.id.paten
2. Private Sector Supply of Pharmaceutical and Health Products, World Bank, 2009.
3. Ministry of National Education, Training on Advantageous of Research Results, subordinate for public student creation, for patent potential, workshop training, Jakarta 10-12 March 2011.
4. NADFC, http//www.pom.go.id/profile/e- Background of NADFC.
   http://ipdl.go.id_ext/Topjax servi et H2H
6. National Institute of Health Research and Development Report on Basic Health Research, 2010.

8.4 Sri Lanka: Prof. Rohini Fernandopulle, Professor in Clinical Pharmacology, Faculty of Medicine, University of Colombo

The status of the pharmaceutical sector in Sri Lanka is outlined in **Annex 4.**

The pharmaceutical scenario in Sri Lanka

The pharmaceutical market in Sri Lanka is one of the smallest in the South-East Asia Region on account of the size of the population. Globally, Sri Lanka ranks 67th out of the 83 markets surveyed as part of the ever-expanding pharmaceutical universe. However, the *Business Monitor International* (BMI) forecasts that the country's overall pharmaceutical expenditure will post a CAGR of 12.1% in local currency terms till through to 2014 to reach Sri Lankan Rupee 68.98 billion (US$ 657 million).

The Government of Sri Lanka strongly encourages the prescribing of generic drugs with the mission of making medicines affordable and more accessible. Currently around 90% of the demand for pharmaceutical products is met through imports. However, dependence on imports has been recently shaken by an epidemic of low-quality imported medicines. Issues of quality of imported medicines has led to shortages of essential medicines in the public sector, and loss of confidence in generic medicines by health-care professionals and consumers, and has also cost the Sri Lankan government US$ 3.96mn in 2009 – an increase of more than 106% on 2008 – according to a report submitted to Parliament by the Auditor-General. Therefore, this report is timely in promoting the need for developing a national action plan and identifying national priority areas in GSPA.

Regulation of pharmaceuticals

Allopathic medicines

The legislative framework for regulation of allopathic medicines is the Cosmetic Devices and Drugs Act No. 27 of 1980 and the Regulations of 1984. The areas covered by the Act include the pre-market assessment and evaluation of the quality, safety and efficacy of medicines, including compliance of manufacturing sites and processes with good manufacturing practices and standards; and the maintenance of a register of available drugs, licensing of all manufacturers, importers, retail and wholesale dealers of drugs, transporters of drugs, and all promotion and advertising of drugs.

The Cosmetic Devices and Drugs Authority (CDDA) is the controlling body for the implementation of GMP in the local manufacture of allopathic medicines. As the Cosmetic Devices and Drugs Act of 1980 specifically excludes Ayurveda and homeopathic medicines, the CDDA is not involved in the implementation of GMP in the manufacturing sites of traditional medicines. The allopathic medicine manufacturing facilities are required to closely adhere to the requirements of GMP as laid down by WHO. One of the key objectives of the draft National Medicines Policy is to promote the local manufacture of essential medicines

Traditional medicines

Traditional medicines in Sri Lanka include Ayurvedic, Siddha and Unani medicines, and acupuncture and homeopathy treatments. The National Policy on Traditional Medicines and Complementary and Alternative Medicine (CAM) is currently being developed. Laws and regulations on traditional medicines/CAM were issued in 1961, and the national programme was initiated in 1982.

The Department of Ayurveda in the Ministry of Health was established in 1961. The National Expert Committee and a National Research Institute on Traditional Medicine, Complementary Medicine and Herbal Medicine were established in 1962. The National Pharmacopoeia and the Ayurveda Pharmacopoeia were published in 1979. The Compendium of Medicinal Plants contains 100 national monographs and was published in 2002. The information contained therein is considered to be legally binding. No traditional medicine has been included in the National Essential Medicines List.

Intellectual property rights

(9) In the past Sri Lanka did not face any rigours of strong patent systems. The future situation could be totally different, with the formation of the World Trade Organization (WTO) and the enforcement of the Trade-Related Intellectual Property Rights Agreement in 1990. Sri Lanka is a founder signatory to the TRIPS Agreement. As a developing country the IPR regime has been applicable in Sri Lanka from 2005. Currently the pharmaceutical registration process in Sri Lanka under the CDDA does not recognize IPR status as a criterion. The current Sri Lanka IPR Act enforced in 2003 incorporates the provisions of the TRIPS Agreement.

Section 62 and 63 comply with Article 27 of TRIPS and Section 86 with Articles 30 and 31 of TRIPS. It is proposed that a co-relation between the pharmaceutical policy and patent laws has to be established to the maximum extent so that the industry is able to play its role adequately to facilitate easy access to medicines at competitive prices. A recent study on the patent status of new chemical entities (NCEs) suggests that none of the NCEs registered from 2006–2010 are patented in Sri Lanka.

Local manufacture

Allopathic medicines

In Sri Lanka, the local allopathic pharmaceutical manufacturing industry is very small. All the medicines manufactured by the local industry are generics and account for just over 10% of the total medicine consumption in the country. There are only nine local manufacturers which include Glaxo and SmithKline Beecham. These two companies are the subsidiaries of foreign companies. Inter-Pharma is another pharmaceutical company which manufactures pharmaceuticals on license from a foreign company.

In addition to these three companies which have foreign links, there are only six other pharmaceutical manufacturing companies, one of which is the State Pharmaceutical Manufacturing Corporation (SPMC). SPMC is the only state-sector corporation engaged in manufacturing pharmaceuticals in Sri Lanka.

The data and basic analysis of the pharmaceutical, herbal/traditional medical sector, and dental and medical technologies in the country are described in Template B.

Traditional medicines

The Ayurvedic Drug Corporation is the biggest single manufacturer of Ayurvedic drugs in the country. The corporation exports locally available crude drugs and locally manufactured drugs to foreign countries. A variety of items for Ayurveda, Siddha and Unani systems of medicine are manufactured. These include the production of *rasa* medicines (metallic preparations).

With regard to research in Ayurvedic drugs very little innovative R&D has been carried out. The corporation also imports and sells Ayurveda, Siddha and Unani products (both raw and manufactured drugs). The corporation maintains an Ayurvedic herbaria and grows some indigenous varieties of Ayurvedic herbs required for the manufacture of drugs.

Regulatory requirements for manufacturing include adherence to information in the pharmacopoeia and monographs as well as the same GMP rules that apply to conventional pharmaceuticals. However, no control mechanism exists for these requirements. There are no post-marketing safety requirements.

Quality control is done but it is to a limited extent by the corporation and is far from adequate. Sri Lanka is a member of the Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation (BIMSTEC) Network of National Centers of Coordination in Traditional Medicine. Sri Lanka has been delegated the task of designing "Collaborative research on traditional medicine among BIMSTEC countries".

Devices

No devices are manufactured in Sri Lanka nor are there any plans for the same in the near future.

Dental

Currently only toothpaste is manufactured locally.

Obstacles to local production and transfer of pharmaceutical-related technology:

Allopathic medicine

(1) There is an acute shortage of pharmacists in the CDDA for conducting activities related to regulation of allopathic medicines. There are only nine permanent and three contract pharmacists overlooking all aspects of regulation. In addition to the acute shortage of human resources the technical skills available for GMP inspections are inadequate.

(2) Currently there is no manufacture of parenteral dosage forms. Only oral dosage forms are manufactured locally. The human expertise and infrastructure available for production of parenteral dosage forms are inadequate.

(3) There are very limited R&D activities and these are mainly in formulation development. At present there is no manufacture of the active pharmaceutical ingredients, all of which are imported. As no basic innovative R&D activities are undertaken by local manufacturers, IPT issues have so far not arisen in the country.

(4) There are no national barriers to technology transfer for the manufacture of medicines in the country. There are also multinational pharmaceutical companies in Sri Lanka, but no transfer of technology has taken place till date. There have been no instances of compulsory licensing and manufacture.

(5) Issues identified by local manufacturers include the following:

   (a) No declared pharmaceutical industrial policy for local manufacture.

   (b) Inadequate lobbying and debate by local manufacturers with the Ministry of Health when compared with importers of medicines.

   (c) Very little R&D collaboration with academia.

   (d) Tariff protection not in place as is the case with other industries.

   (e) Price is the only criterion for winning government bids.

   (f) Rate of taxation for manufacturers vis-à-vis taxes on importation of pharmaceuticals.

   (g) Lack of proper training on WHO-mandated GMPs.

   (h) Lack of formulation expertise.

   (i) No government support for training of private sector employees.

Traditional medicines

There is an immediate need for R&D and development of quality control mechanisms in this area. More collaboration is needed with academia.

Conclusion and recommendations

Although it is not cheaper to manufacture medicines locally than to import them, Sri Lanka in recent times has faced an epidemic of imported sub-standard medicines which has led to shortages of several essential and critical medicines. Thus from a public health perspective, the developmental gains are greatest if local production increases the supply of good quality and affordable essential medicines. The decision to support local manufacture of pharmaceuticals should specifically address the question of which medicines should be produced locally. The CDDA should also provide a list of good candidate medicines for local production based on what is registered and also where there is no registered source.

Local firms currently manufacture medicines which are sustainable but they may also need to produce drugs other than those identified in order to be sustainable in the long run as a public health service. Sri Lanka needs to build their human resource base in relevant fields such as industrial pharmacy and chemistry. Training in good manufacturing practices is an urgent need for both the public and private sector involved in allopathic and traditional medicine manufacture. Collaborative research between allopathic and traditional medicine should be encouraged.

8.5 Thailand: Ms Chutima Akaleephan, Researcher, International Health Policy Programme, Ministry of Public Health, Thailand

The status of the pharmaceutical sector in Thailand is outlined in **Annex 5.**

Thailand's population was 65.4 million in 2010 (National Statistical Office 2011) and nearly 95% are Buddhists, followed by Muslims (4.5%), Christians and others. Based on the latest country profile, the crude birth rate and crude mortality rates are 10.9 and 6.8 per 1000 population respectively. As a result, the natural growth rate is 0.4. Male life expectancy at birth is 69.9 while that for females is 77.6. Like developed and some developing countries, Thailand is gradually becoming an ageing society (Economic and Social Statistics Bureau 2007; Ekachampaka and Taverat 2008). Due to the steady increase in gross national income (GNI) per capita – currently at US$ 4210 – Thailand was upgraded from the lower-income country category to the upper-middle income category as per the World Bank's classification in 2011.

The research and development system

Many organizations and institutes are engaged in research and development (see ***Annex 6***). Research institutes in the Ministry of Science and Technology, in particular the

National Science and Technology Development Agency (NSTDA) – which is the managing centre for its research institutes and research units in universities – are the key research hubs of the country (*Figure 1*). However, along the process of research through production, several agencies get involved, i.e. policy-makers, civil society and consumer groups, researchers and manufacturers with R&D units, funding agencies, and R&D management.

National policy and roadmap

The National Science Technology and Innovation Policy Office is the main body for national policy development and plans of action. Currently, the 2012-2021 National Policy and Plan on Science Technology and Innovation is being finalized.

Analysis on R&D through production capacity

There is fragmented information on evaluation of R&D capacity on health products. Studies and systematic analysis were found in modern medicines (pharmaceutical products) and vaccines.

(1) Medicines and pharmaceutical products

So far, no drug has passed through all steps of R&D, from target discovery to manufacturing, in Thailand.

Furthermore, in the aspect of diseases and public health problems, Maleewong U., et al identified 231 researches which are able to link their indications to diseases during the past decade (1999–2010). Of these, 33.8%, 22.9% and 8.2% are researches for type I, II and III diseases,[30] respectively. The other researches (35.1%) relate to other diseases in general. About 64% of R&D for Type I diseases related to anti-cancer drugs; 34% to Type II related to anti-retrovirals; and 89.5% to type III related to anti-malarial drugs *(Maleewong, Isulpisalkul, et al. 2011*).

Unfortunately there is no evidence revealing the magnitude of indicators of Thailand's capacity in patent holders as well as transfer of technology. For instance, 14 process and/or product patents and petty patents belong to NSTDA, Chulalongkorn University and Mahidol University. A patent is also jointly held by Chiang Mai University and an international drug company. On transfer technology, there is the case of transfer from NSTDA to a French raw material producer. The GPO transferred the technology on production from Chinese and Indian drug companies (*Maleewong, Isulpisalkul, et al. 2011*).

[30] Since the definition on types of diseases is broadly defined and non-specific to disease, this study additionally categorized diseases to these three types: Type I diseases include cancer, DM, hypertension, hyperlipidemia, influenza, hepatitis B and C, and cardiovascular diseases. Type II diseases include AIDS, TB, hepatitis A, infectious diseases, meningitis, rabies, etc. Type III diseases include African sleeping sickness, African river blindness, dengue haemorrhagic fever, malaria, etc.

It was suggested that owing to lack of all types of resources and capacity for R&D on active pharmaceutical ingredients, Thailand should strengthen capacity on downstream research for manufacturing in the future.

(2) Herbal medicines

Traditional and herbal medicines are addressed and highlighted in the 10th National Economic and Social Development Plan as well as other policies and strategies on health. The Department for the Development of Thai Traditional and Alternative Medicine was established in 2002 under the Ministry of Public Health in order to promote use, improve quality and protect such knowledge which forms part of Thai heritage (Department for Development of Traditional and Alternative Medicine, 2011).

As a result of the differences in the philosophy of science and the concept of treatment, R&D on herbal medicines is more simply classified into basic research (targeting crude extracts and standard extracts), preclinical trials, clinical trials and production. For publications on modern medicines, 24.8% of 1093 publications relate to basic research, 73.4% pre-clinical, 1.7% clinical and 0.1% to production.

Regarding types of diseases, it was reported that the proportion of research for Type I is equal to that for Type II (32.3% and 32.8% respectively) whereas only 0.2% of all research relates to Type III diseases. Regarding patent grants, 20 patents and petty patents are identified and all belong to research units and universities. Hence, most of the herbal medicine supply is limited to internal demand; the technology transfer of herbal medicines being usually from public research institutes to local producers. Major concerns on herbal medicines include reference standards as well as the quality and uniformity of raw materials (*Maleewong, Isulpisalkul, et al. 2011*).

(3) Vaccines

During the past decade (1999–2010), 222 researches relating to biological products were carried out, which could be categorized into 83% related to vaccines, 1% to immune serum, 2% to antivenom and 41% to human protein. Many vaccines are in the R&D pipeline and some are in the production process. However, at present, none of the vaccines are thoroughly researched, developed and produced in Thailand.

Most vaccines are imported for clinical trials and are likely to be sponsored by drug companies. *Muangchana C., et al* conducted a situation analysis of all vaccines in 2009. Their categorization into a group current under manufacture with conventional methods and a group in the R&D pipeline is summarized in Tables 3 and 4.

Table 10: ***Vaccine production capacity in Thailand***

Vaccine	Production level	
	Upstream	Downstream (blending, filling, packaging, testing)
BCG	✓	
Inactivated mouse brain derived JE	✓	
Measles		✓
OPV		✓
MMR		✓
Hepatitis B		✓
DPT-HB		✓
ERIG (rabies immunoglobulin)	✓	
Vero cell rabies vaccine		✓
Influenza		✓
Antivenum for poisonous snakebite	✓	
DTPw	✓ (in process of standardization)	
TT		
dT		
TAT		
Source: Adapted from Table 5 to Table 7 of *Siripitayakunkit, Muangchana, et al. 2009*.		

Table 11: ***Vaccines in R&D pipeline***

Vaccine	Type and technology	Step of development	Main research unit
Dengue	Cell-based (whole virus); Cell-based (chimeric virus); DNA vaccine; subunit vaccine	Preclinic Preclinic Preclinic	CVD; BIOTEC (SI, CMU, CVD); BIOTEC (CU, CMU)
JE	Cell-based; chimeric JE	Preclinic Preclinic	CVD, GPO; BIOTEC (CMU, CVD)
Influenza	H5N1/H3N2: cell-based; H5N1: liposome (vaccine delivery vehicle) Avian influenza	Preclinic Preclinic Preclinic	BIOTEC (CVD, KMUTT) SI BIOTEC (SI)
HIV	rBCG and rVaccinia	Process of scaling up production	MBC
Allergy	Dp/Df; American cockroach	Bioequivalent study	SI

Note: CVD: Center for Vaccine Development, Institute of Molecular Bioscience, Mahidol University; BIOTEC: National Center for Genetic Engineering and Biotechnology, as funding agency; SI: Siriraj Faculty of Medicine, Mahidol University; CMU: Chiang Mai University; CU: Chulalongkorn University; GPO: Government Pharmaceutical Organization; KMUTT: King Mongkut's University of Technology, Thonburi; MBC: Medical Biotechnology Center, Department of Medical Science, Ministry of Public Health.

Source: Adapted from Table 4 of *Siripitayakunkit, Muangchana, et al. 2009*.

All vaccines indicated in Table 4 are researched and developed by national research institutes in government organizations or academic institutes. Some projects are expected to be a collaboration between the public and private sector (public-private partnership (PPP)), or North-South collaboration (between developed and developing countries). Table 5 summarizes such partnerships and collaboration. *(Siripitayakunkit, Muangchana, et al. 2009; Maleewong, Isulpisalkul, et al. 2011)*.

Table 12: ***R&D of vaccines and technology transfer***

National level		International level
Public-public	Public-private	North-South, South-South (public-private)
JE	Dp/Df allergy	Dengue
	Non-cell diptheria	influenza
		American cockroach
		DTP-Hep B

Vaccines are the only health products that have a national policy, strategies and a centre for comprehensive management. Strategies were set up for all aspects, i.e. promoting R&D, domestic production, quality assurance and quality control, immunization, and inter-organizational collaboration. Five vaccines (JE, dengue, influenza, DTP-Hep. B and TB) were prioritized and R&D roadmaps drawn for each *(Muangchana, Siripitayakunkit, et al. Maleewong, Isulpisalkul, et al. 2011*).

However, limitations were reported in each aspect along the R&D and production stages depending on the specific requirements of each vaccine. There are some common problems that R&D and vaccine production will confront. These include lack of some animal species, primate and ferret, required in preclinical trials; pilot plants for scaling up vaccine production from the laboratory scales; grants for product development for market competition; and availability of experts in scaling up vaccine, in vaccine formulation for final bulk products, and in quality control *(Siripitayakunkit, Muangchana et al. 2009)*.

(4) Diagnostic tests

Two types of the tests were identified, i.e. diagnostic reagents using automatic test machines and diagnostic test kits. During 1999–2010, two thirds of 99 publications were for diagnostic test kits. When classified by types of disease, 83% of researches were found to be for Type II diseases which are mostly infectious or genetic diseases. These include thalassemia, elephantiasis, melioidosis, dengue, leptospirosis, malaria, HIV, hepatitis and tuberculosis. Twenty eight patents and petty patents were reported. The problem with transfer of technology related to these diseases is that these products are not of interest to the private sector because of lack of marketing potential. In addition, domestic tests will yield less profits than imported goods. Thus, the investment in production scale is based on the public sector (*Maleewong, Isulpisalkul, et al. 2011*).

(5) Medical equipment

Medical equipment is defined differently from medical supplies (condoms, rubber gloves, syringes, etc.) for which case Thailand is a net exporter. Equipment requires medium-to-advanced and harmonized technology. It was mainly divided into five groups, i.e. robots and medical automation; biomaterials; medical and public health software; biosignal monitoring devices; and medical image devices.

Of 123 researches, 15.4% involved robots and medical automation; 34.1% biomaterials; 10.6% were in software; 13.8% involved biosignal monitoring devices; 7.3% were in medical image devices; and that rest comprised 18.7%. Publication from the SCOPUS[31] database indicated an upward trend in biomedical engineering research in Thailand since 2004, NECTEC cited in *Maleewong, Isulpisalkul, et al. 2011*. Fifty one patents and petty patents were recorded, of which Chulalongkorn University and Mahidol University held 44 patents whereas seven belonged to NSTDA. All the technology transfer is a type of public to private for commercial purpose.

Resources and infrastructure

The proportion of the total R&D expenditure to GDP was between 0.21% to 0.26% between 2002 and 2008. Thailand falls below the world average on this score, it being 1.01% to 1.30%. The figure is also less than that for Malaysia, India, Singapore and China. In 2008, Thailand showed additional scarcity with other indicators, that is, with the least ratios of private-public R&D expenditure (0.08% versus an average of 0.63%); full-time equivalent of R&D personnel per population (6.8 FTE versus 24.9 FTE per 10 000 population); and FTE of R&D personnel in the private sector (1.07 FTE versus 14.32 FTE per 10 000 population) [*IMD World Competitiveness Yearbook* cited in Durongkavaeroj, 2010].

In monetary terms, it was estimated that the total expenditure for R&D in 2007 was 18 225 million Baht in which the government's share was 10 015 million Baht and that of the private sector was 8210 million Baht. Further, the 2008 survey revealed that the estimated expenditure on R&D in the manufacturing sector was 7278.40 million Baht, which is a 9% decrease from the 2006 survey (7998.63 million Baht) (National Science Technology and Innovation Policy Office 2011; National Science Technology and Innovation Policy Office 2011). This information indicated that compared to the public sector, the private sector spent more on R&D in Thailand. However, this current data provided very limited information. It could not reveal trends of R&D expenditure or the proportion as well as specific information on health products.

On promotion on R&D and biotechnology as well as production of medicines/active pharmaceutical ingredients, the Board of Investment (BoI) provides an incentive for foreign and domestic investment. R&D and biotechnology activities are classified as a

[31] Scopus, now officially named SciVerse Scopus, is a bibliographic database containing abstracts and citations for scholarly journal articles.

priority on account of their special importance and the benefits they provide to the country. While R&D includes basic research, applied science and experimental development; biotechnology includes R&D and manufacturing based on such technology.

In general, the incentives for R&D include mainly tax incentives, i.e. exemption of import duties on machinery; and eight-year corporate income tax exemption. In addition, the Revenue Department provides incentives such as a 200% tax deduction for R&D expenses and accelerated depreciation rates for R&D machinery and equipment. Specifically, biotechnology activities located in science and technology parks will be granted a five-year additional 50% corporate income tax reduction for net profits after the end of the corporate income tax exemption period.

Production of medicines or active pharmaceutical ingredients is classified as a priority activity. As a result, the business will be granted similar tax exemption except the eight-year corporate income tax exemption which is subject to a cap (and no additional benefits according to the geographical zone where the activity is located) (Thailand Board of Investment 2011; The Revenue Department 2011).

Limitations and constraints

Limitations of and concerns regarding R&D were reflected by experts in each technical area through in-depth interviews. Apart from limitations mentioned earlier with many of the health products, *Maleewong U., et al* addressed the constraints that were common across entities, such as lack of a national policy and coordinator to direct and target the R&D except for vaccines; insufficient investment in infrastructure; inadequate, unspecific, fragmented and unequal funding support across health products as well as pro-substantial funding to basic research; lack of infrastructure, e.g. pilot plants, national compound library, genetic library, pilot plant including standard and qualified laboratory; the existing gap between researchers and private manufacturers; and no participation of the private sector whatsoever in the process of R&D. Compared with other health products, R&D in vaccines has been more successful (see Section 4.2) (*Maleewong, Isulpisalkul, et al. 2011*).

Annex 5 summarizes some key indicators on the manufacturing capacity on three health products of interest in Thailand. Unfortunately, only little useful information could be gathered. These figures are also specific to medical products for humans.

Policy recommendation

It was concluded that:

(1) The national policy on R&D impacts health and therefore it is necessary to prioritize research on diseases which are the major burden for Thailand. However, this does not mean neglecting support for R&D on other diseases.

(2) Accelerating the implementation of the existing policies supporting R&D should be a priority.

(3) The relatively successful model of research on vaccines may be adopted for other health products, i.e. medicines, traditional medicines, medical supply equipment and machines.

(4) There should be concerted cooperation among experts from different areas, particularly over R&D for pharmaceutical and traditional/herbal medicines. In addition to the scarcity of financial and human resources and infrastructure, other existing limitations of Thailand need to be addressed. Research in packages, and pooling and sharing of resources may be a solution and this requires professional coordination.

(5) To maximize the benefits of TRIPS, the strategy could be to counterbalance the promotion of R&D by giving market exclusivity to innovators on the one hand and to expand this privilege to others through explicit information and innovation sharing and transfer on the other.

(6) With regard to the limited capacity of Thailand and its focus on downstream R&D, intellectual property rights are an impediment which needs to be addressed in GSPA nationally and internationally.

(7) Improving or setting up user-friendly information systems that support and update the situation on R&D while explicitly indicating that intellectual property is a priority as well. This will facilitate R&D and as a result, time and resource utilization will be more efficient.

(8) In sharing information across countries, WHO headquarters and the Regional Office should plan an active role in facilitating, coordinating and setting up a platform for discussion as well as in providing technical support.

9. Group discussion

The representatives from Member States were briefed on the subject of group discussions that were scheduled to consider eight main Elements and 25 sub-Elements of the GSPA. The eight Elements, as indicated earlier, 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;

(6) improving delivery and access;

(7) ensuring sustainable financing mechanisms;

(8) establishing monitoring and reporting systems.

The representatives from Member States developed regional and national priorities on the basis of this Regional Consultation by covering all the eight Elements of GSPA vide resolution WHA 61.21. This exercise was based on the Templates A **(Annex 7)** and B mentioned earlier.

9.1 Eight Elements of GSPA

The eight Elements were taken up for discussion by four groups of participants. Each group discussed two elements of the GSPA as under:

Groups I

Element 1. Prioritizing research and development needs.

Element 2. Promoting research and development.

Group II

Element 3. Building and improving innovative capacity.

Element 4. Transfer of Technology.

Group III

Element 5. Application and Management of Intellectual Property to contribute to innovation and promote public health.

Group IV

Element 6: Improving delivery and access.

Element 7. Promoting Sustainable Financing mechanisms.

Element 8. Establishing monitoring and reporting systems.

9.2 Recommendations of SEA Region Member States on WHA 61.21, GSPA

After the four groups identified the priorities, these were collated by them to develop the Regional and National Framework. Thus, based on the output of the four groups, identification and prioritization for the Regional and National Framework on Public Health, Innovation and Property under WHA 61.21 was done.

Each Member State of the WHO South-East Asia Region stated its priority for each element of GSPA. The indications were captured on a Likert[32] scale from one to four

[32] A **Likert scale** is a psychometric scale commonly involved in research that employs questionnaires. It is the most widely used approach to scaling responses in survey research, such that the term is often used interchangeably with *rating scale*.

where one is of least priority and four is of maximum importance. This exercise includes the priorities for WHO and the Member country, the details of which are outlined in **Annex 9.**

Certain Elements of GSPA are of little importance to some Member States. For example, **Annex 9** shows that certain Elements 1, 2 and 3 are of little importance to some countries such as Maldives and Bhutan. However, for Maldives, Element 7 – ensuring sustainable financing mechanisms – is very important, while for Bhutan Element 7.2 is least important and Element 7.1 is most important. Again, for Bhutan Element 8 is of less importance.

For certain countries like India and Indonesia almost all Elements are rated as most important. The importance accorded for Element 7 is given separately in **Annex 10.**[33] For Bangladesh and Bhutan Element 7.2 is least important, while for India, Indonesia and Maldives both Element 7.1 and 7.2 are most important. For Thailand Element 6 – improving delivery and access – is less important, providing an indication of the relatively robust systems in place in the country. Thailand, however, rates Element 1 and 2 as most important. Based on these indicators, Recommendations for the Regional Framework on Public Health, Innovation and Intellectual Property were arrived at during the Regional Consultation.

10. Recommendations

The eight main Elements and 25 sub-Elements are seen as important parameters defining the future focus areas for public health, innovation and intellectual property. The Member States identified priority action points for WHO-SEARO and national priorities on GSPA, WHA 61.21. Specific actions for certain Member States were suggested and these have been given separately.

Actions recommended for Member States

(1) Institute a National Expert Committee for discussion on the GSPA and policy development on IPR and public health. Those Member States which already have some commission or panel in place need to include GSPA in the agenda for discussion.

(2) Member countries should be assisted to develop capacity for negotiations in public health, innovation and IPR.

(3) Member countries be assisted to develop an appropriate and suitable legal framework under IPT.

(4) Member countries to ensure representation from the Health Ministry in trade negotiations.

[33] In view of the work of the Consultative Expert Working Group under WHA 63.28

(5) Member countries must identify funding for R&D in neglected priority diseases.

(6) Member countries should promote domestic industries to enhance their capacity to conduct relevant R&D and meet the needs of affordable medicines and medical technologies for public health.

Actions recommended for WHO

(1) In view of its importance in public health, the Regional Office to facilitate Member States to establish focal points for public health, innovation and intelectual property rights.

(2) Collect information on patents and other relevant databases and play an active role in enhancing understanding and facilitate the sharing of patent information and other relevant databases related to public health.

(3) Provide help in capacity-building on intellectual property and trade (IPT) to Member countries.

(4) Develop mechanisms so that countries which have made substantial progress can share information and benefits with other countries and promote regional networking and capacity-building on public health, innovation and IPT for Member States.

(5) Provide technical assistance and financial support to Member States for IPT in public health.

(6) Build partnerships with other international organizations to address IPT and public health with a focus on access to medicines and essential technologies.

(7) Analyse IPT information for gaps in R&D for important diseases in the Region and analyse these gaps in the need for treatment of these diseases in the Region.

(8) Seek new strategies for affordable medicines and for promoting downstream R&D and production of medicines as public goods.

(9) Develop and seek new financial resources for R&D.

(10) Support and ensure that standards are maintained and requirements for the safety and quality of health products are fulfilled.

(11) Assist Member States to prepare plans for regional technology platforms with a view to strengthen their capacities for delivery, manufacture and innovation using regional expertise.

(12) Share information on IP filings and grants to maximize the freedom to operate (FTO) in the Region.

(13) Organize consultations of this kind to enhance the capabilities of Member States in IPT, innovations and public health, aspects that are crucial in the current globalized, trade-oriented international environment.

Recommendations specific to Select Member States

Certain recommendations emerged from the Regional Consultation which were specific to certain Member States. These recommendations were delineated both by the participants from these countries as well as other delegates and deemed to be areas of focus and importance for these countries.

Bangladesh

- Nominate a focal point to promote innovation and R&D for public health. This could be the drug administration authorities of the Ministry of Health and Family Welfare (MoHFW). A committee could be formed exclusively for R&D activities. For this the Director-General of Drug Administration and Licensing Authority (Drugs) could be designated as the chairman with members from the MoHFW and the Ministry of Commercial Industry along with co-opted members and legal officers.
- Interact with all stakeholders including WHO-SEARO and other UN agencies to implement GSPA.

India

- Need to get into mission mode for the development of new drugs.
- Actively identify potential partners from other developing countries to promote R&D for new drugs.
- Establish a focal point for implementing GSPA involving relevant ministries and stakeholders in Ministry of Health and Family Welfare.

Indonesia

- Make a roadmap for making medical products to combat the following diseases:
  - Communicable diseases: vaccines, drugs or diagnostic kits.
  - Noncommunicable diseases: model of intervention in the field including legislation.
- Facilitate South-South collaboration on R&D especially in the production of vaccines, drugs, including traditional medicines
- Facilitate collaboration with UN agencies for innovation and capacity-building on R&D.

Myanmar

- Prioritize R&D and include this in the National Health Plan (currently IPR is not yet included in the National Health Plan).

Sri Lanka

- Establish a focal point with the Drug Regulatory Authority to interact with all stakehodlers including WHO-SEARO.

Thailand

- Incorporate GSPA in the national plan for R&D and universal access to health products.
- Set up a national focal point for monitoring and evaluation.

Annex 1

Information on medical products (pharmaceuticals, herbal medicine, dental formulations and medical technologies): Bangladesh

No.	Country parameters for medical products	Pharmaceutical	Herbal medicine (homeopathy Ayurvedic, Unani, Chinese, etc.)	Dental formulations	Medical technologies (machinery and equipment)
1.	Number of companies/units	258	Homeopathic 79, Unani-268, Ayurvedic 201, berbal 17	8	10
2.	Size (no. of employees)	90 000	30 000	2000	500 (approx.)
3.	Investment in plant and machinery	US$ 7800 million (approx.)	US$ 75 million	US$ 15 million (approx.)	US$ 3 million (approx.)
4.	Quantity of production	US$ 1224 million (approx.)	US$ 110 million	US$ 30 million (approx.)	US$ 5 million (approx.)
5.	Bulk drugs production	US$ 57 million (approx.)	None	None	--
6.	Formulation production	US$ 1165 million	US$ 110 million	US$ 30 million (approx.)	--
7.	Projected growth in production (2011-2014)	35% (approx.)	40% (approx.)	15% (approx.)	5% (approx.)
8.	Retail Sales	$1040 Million	$85 Million	$25 million	$4 (approx.)
9.	Projected growth in retail sales	30% (approx.)	30% (approx.)	15% (approx.)	5% (approx.)
10.	Quantity of imports	US$ 148 million	US$ 30 million (approx.)	US$ 8 million (approx.)	US$ 140 million (approx.)
11.	Projected growth in imports (2011-2014)	5% (approx.)	25% (approx.)	10% (approx.)	20% (approx.)
12.	Quantity of exports	US$ 60 million	US$ 5 million (approx.)	US$ 2 million (approx.)	None
13.	Projected growth in exports (2011-2014)	200% (approx.)	10% (approx.)	5% (approx.)	None
14.	Number of companies/units adhering to good manufacturing practices (cGMP) criteria as stipulated by the World Health Organization (WHO)	Most of the private sector manufacturing units are following all aspects of the GMP guidelines of WHO.	Very few are following any guidelines.	Not regulated by Directorate-General of Drug Administration; Regulated by BSTI (Bangladesh Standard Testing Institute, of the Industries Ministry)	Regulated by the Directorate-General of Health Services, MoHFW.

Annex 2

Information on medical products (pharmaceuticals, herbal medicine, dental formulations and medical technologies) Pharmaceuticals: India

No.	Parameters	Status		
1	Number of companies/units	53504	*India mart.com*	*2010*
2	Size (no. of employees)/ market size	US$ 11.6 billion	**CII**	*2009*
		4.2 million employees; Rs 55 454 crore		
3	Investment in plant & machinery	NA		
4	Quantity of production/value	US$ 22 billion-plus Rs 1 lakh crore		*(2009-2010)*
5	Bulk drugs production/value	US$ 16.91 billion		*2014*
		US$ 2.48 billion		*2007*
6	Formulations production/value	US$ 2.33 billion Number: 57000		*2004*
	Domestic formulations	US$ 8.4 billion		*2008*
7	Projected growth in production (2011-2014)	NA		
8	Retail sales	US$ 10 billion		*2010*
	dDomestic sales	US$ 11.92 billion		*2009*
	Total turnover	US$ 21.04 billion		*2009*
9	Projected growth in retail sales (2011-2014)	US$ 12-13 billion		*2012*
	Domestic sales	US$ 20 billion		*2015*
10	Quantity of Imports	US$ 306.5 million		*2000*
		Rs 8649 crore		*2009*
11	Projected growth in imports (2011-2014)	NA		
12	Quantity of exports	US$ 8.25 billion		*(2008-9)*
		US$ 6.33 billion		*2009*
		Rs 40 422 crore # Rs 29 140 crore !		*(2007-08)*
13	Projected growth in exports (2011-2014)	US$ 18.3 billion		*(2010-11)*
		Rs 50 000 crore #		*2010*
		Rs 90 000 crore !		*~2014*
14	Number of companies/units adhering to cGMP criteria as stipulated by WHO	814 CDSCO)		*2010*

From various sources

Herbal medical products: India

No.	Country parameters for medical products	Herbal medicine (hom., Ayurvedic, Unani, Chinese, etc.)		
1	Number of companies/units	20 000 manufacturing units (*Cygnus)* 9173 manufacturing units (Ayush) 18 221	*India mart.com*	2006 *2008* *2010*
2	Size (no. of employees)/ market size	Ayurveda: US$ 333.3 m Homeopathy: US$ 57.2 m, Unani: US$ 9.5 m, Siddha: US$ 0.5 m Total US$ 500 m Rs *570.8 crore* {*commerce.nic.in*}	*Cygnus*	*2006* *2009-2010*
3	Investment in plant & machinery	NA		
4	Quantity of production/value	US$ 1 billion	(Ayush)	*2008*
5	Bulk drugs production/value	NA		
6	Formulations production/value Domestic formulations	Ayurveda: 82 900 Unani-115 300 Siddha-12950	PIMR	*2010*
7	Projected growth in production (2011-2014)	NA		
8	Retail sales Domestic sales Total turnover	Rs 2300 crore	(PIMR)	*2010*
9	Projected growth in retail sales (2011-2014)	NA		
10	Quantity of imports	NA		
11	Projected growth in imports (2011-2014)	NA		
12	Quantity of exports	US$ 1071.19 m Rs 2275.64 crore Rs 570.8 crore	Cygnus Ayush Market News	(2009) *(2007-08)* 2009-2010
13	Projected growth in exports (2011-2014)	Rs 2510.07 crore Rs 2626.44 Rs 2742.81 Crore 16.8 % CAGR annual growth rate	Ayush, 2008 Market News	*(2010-2011)* *(2011-2012)* *(2012-2013)*
14	Number of companies/units adhering to cGMP criteria as stipulated by WHO	GMP: 5129 Non-GMP: 4044 (Ayush, 2008)		

Medical Technologies: India

No.	Country parameters for medical products	Medical technologies (machinery & equipment)	
1	Number of companies/units	2204	*2010*
2	Size (no. of employees)/market size	US$ 2.7 billion	(2008)
		US$ 5 billion *Source: Cygnus*	*2012*
3	Investment in plant & machinery	US$ 62 billion	2008
4	Quantity of production/value	US$ 106.90 billion *(www.osec.ch)*	*(2006)*
		130 725 products @ Rs 1081.5 m	(2010) *Cygnus*
5	Bulk drugs production/value	NA	
6	Formulations production/value Domestic formulations	NA	
7	Projected growth in production (2011-2014)	NA	
8	Retail sales Domestic sales Total turnover	US$ 24 600 m	(2008)
		US$ 2352 m *(www.espicom.com/bricm)*	(2010)
9	Projected growth in retail sales (2011-2014)	4.86 by (2015) 15% growth	
10	Quantity of imports	US$ 1274 million)	(2008
11	Projected growth in imports (2011-2014)	NA	
12	Quantity of exports	US$ 447.4 m	(2008) *Cygnus*
13	Projected growth in exports (2011-2014)	NA	
14	Number of companies/units adhering to cGMP criteria as stipulated by WHO	NA	

Dental formulations: India

No.	Parameters for medical products	Dental formulations	
1	Number of companies/units	2191	*2010*
2	Size (no. of employees)/market size	US$ 660 m	*2009*
3	Investment in plant & machinery		
4	Quantity of production/value	US$ 1081.5 m 1033 products	*2010*
5	Bulk drugs production/value		
6	Formulations production/value Domestic formulations	NA	
7	Projected growth in production (2011-2014)	US$ 1166.14 m (equipment) US$ 116.43 m (oral care)	*2014*
8	Retail sales Domestic sales Total turnover	US$ 48 b NA	*2009*
9	Projected growth of retail sales (2011-2014)	US$ 88 b	*2014*
10	Quantity of imports	US$ 1010 m	*2009*
11	Projected growth in imports (2011-2014)	NA	
12	Quantity of exports	US$ 376 m	*2009*
13	Projected growth in exports (2011-2014)	NA	
14	Number of companies/units adhering to cGMP criteria as stipulated by WHO	1	*2010*

Annex 3

Information on medical products: Indonesia

No.	Country parameters for medical products	Pharmaceutical*	Herbal medicines*	Dental formulation *	Medical technology **
1.	Number of companies/units	203	79 1395 (SME[34])	21	20
2.	Size (No. of employees)	25-600 personnel	10-100 personnel	-	3400
3.	Investment in plant and machinery	-	-	-	-
4.	Quantity of production	8750 billion . units (2009-2010)	-	-	200 million units
5.	Bulk drugs production	-	-	-	-
6.	Formulation production	15411	14 445 items	145 items	-
7.	Project growth in production (2011-2014)	US$ 127 billion	-	-	10%
8.	Retail sales	-	-	-	US$ 459 million
9.	Project growth in retail sales (2011-2014)	-	-	-	10%
10.	Quantity of imports	US$ 132 billion (2009-2010)	· 3765 items · 579 items	78 items	-
11.	Project growth in imports (2011-2014)	-	-	-	15%
12.	Quantity of exports	US$ 156 billion	· CFS = 54 s · CoPP = 91 · TW = 17	-	US $ 767 million
13.	Project growth in exports (2011-2014)	-	-	-	5 %
14.	Number of companies/units adhering cGMP criteria stipulated by the WHO	203	-	-	16

*) Data Resource: NADFC

**) Data Resource: Indonesian of Medical Devices Company Ass.

[34] SME: small and medium enterprises by Indonesian definition

Annex 4

Information on medical products: Sri Lanka

Template B: Information on medical products (pharmaceuticals, dental formulations and medical technologies in Sri Lanka)						
	GSK	**Interpharma**	**MSJ industries**	**SPMC**	**Astron**	**Ceylinco Pharmaceuticals Limited**
Employees	161	66	193	215	150	75
Investment in plant/machinery (LKR)	251×10^6	861×10^6	108×10^6	815×10^6	120×10^6	30×10^6
Quantity of production	16 23 MT	328×10^6 tabs	1100×10^6 tabs	1800×10^6 units per year	Tablets only	120×10^6 capsules per year
Bulk drug production	-	-	-	-	-	-
Formulation production	16 23 MT	328×10^6 tabs	1100×10^6 tabs	1800×10^6 units per year	Tablets only	Yes - Capsules
Projected growth in production (2011 - 2014	6.20%	15%	43%	5%	25%	100%
Retail sales (LKR)			627×10^6	1370×10^6	1200×10^6	100×10^6
Projected growth in retail sales (2011–2014)			44%		25%	300×10^6
WHO cGMP implementation	Yes	Yes	Yes			100×10^6

Annex 5

Information on medical products: Thailand

No.	Country parameters for medical products	Pharmaceutical	Herbal medicine (homeopathy, Ayurvedic, Unani, Chinese, etc.)	Medical technologies (machinery and equipment)
1	Number of companies/units	169	1 099	1 946
2	Size (no. of employees)	n/a	n/a	n/a
3	Investment in plant and machinery	n/a	n/a	n/a
4	Quantity of production	n/a	n/a	n/a
5	Bulk drugs production	n/a	n/a	n/a
6	Formulation production	27,070[1]	5,298[1]	n/a
7	Projected growth in production (2011-2014)	n/a	n/a	n/a
8	Retail sales	186 330.8 m Baht[2]	n/a	n/a
9	Projected growth in retail sales (2011-2014)	n/a	n/a	n/a
10	Value* of imports	70 607.22 m Baht[3]	83.20 m Baht[3]	27,578.0 m Baht[4]
11	Projected growth in imports (2011-2014)	n/a	n/a	
12	Value* of exports	3,886.32 m Baht[5]	n/a	38 371.9 m Baht[4]
13	Projected growth in exports (2011-2014)	n/a	n/a	n/a
14	Number of companies/units adhering to cGMP criteria as stipulated by WHO	158	52	30

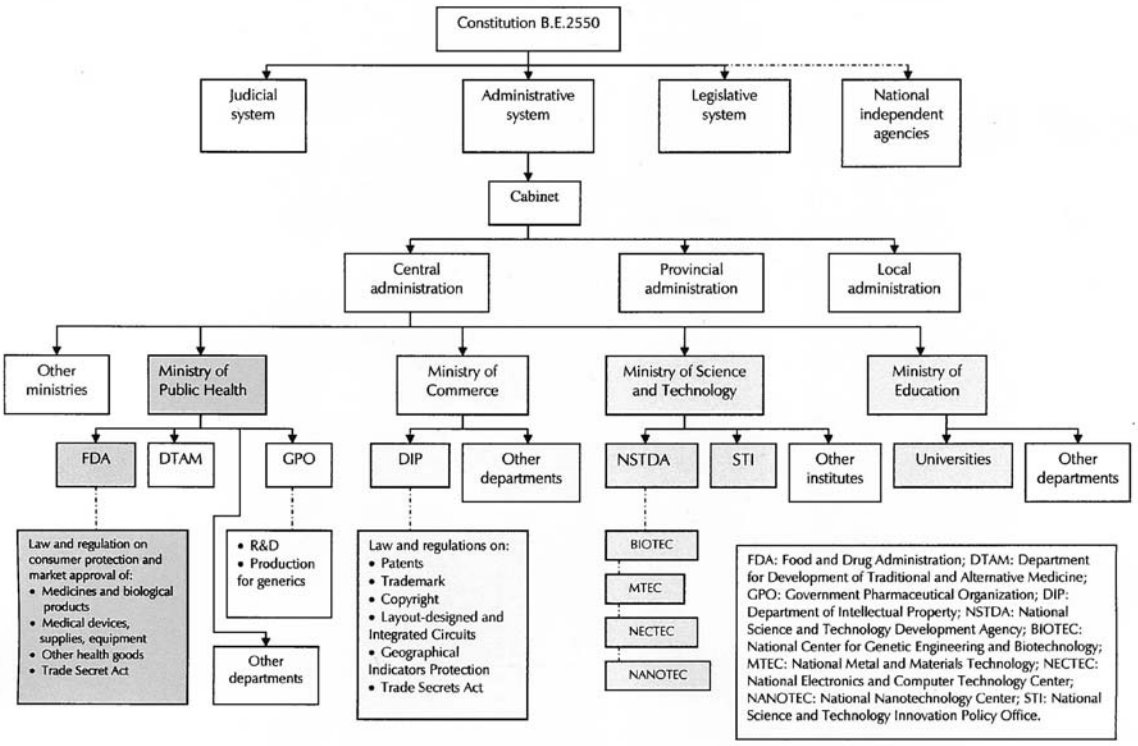
Note: # deletion on dental formulation due to n/a: no data available (see details in section 1); * replace on quantity;

[1] = counting on registration numbers in 1999; [2] data in 2006; [3] data in 2009; [4] data in 2010; [5] data in 2008

Source: Bureau of Drug Control, FDA, Ministry of Public Health; Medical Devices Control Division, FDA, Ministry of Public Health; Department of Custom Duties, Ministry of Finance

Annex 6

Organization chart of the administrative system in relation to public health, innovation and intellectual property, Thailand



Annex 7

Template A (Country)
(Implementation Plan of WHA 61.21 GSPOA in SEA Region countries)

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	**BHU**	**IND**	**INO**	**MAV**	**MMR**	**NEP**	**SRL**	**THA**	
Element 1. Prioritizing research and development needs												
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	Examine IPR and patent information in various databases to map global research in diseases relevant to the country in public health in order to set up national/ regional strategies											
(1.2) formulating explicit prioritized strategies for research and development at the country and regional and inter-regional levels	Survey existing strategies for research and development. Examine technology in research in public health and patterns of ownership (according to patent holder, and territorial effect of patents in force) to identify potential partners and possible barriers; employ IPR[39] and patents to design around/ adapt to local requirements for medicines (dosage etc) and medical technologies											

[35] IPT: Intellectual property and trade
[36] Stakeholders identified as relevant to the country in the specific element (e.g. WHO-SEARO, national government, research institution, civil society, NGOs etc.)
[37] On a scale of 1-4 with 1 least relevant and 4 most relevant to the country
[38] Current Position of the sub-Element in the country; Priority intervention/expectations from WHO-SEARO, any additional areas/ points for consideration etc.
[39] IPR: Intellectual property rights

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	**BHU**	**IND**	**INO**	**MAV**	**MMR**	**NEP**	**SRL**	**THA**	
(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	Enhance understanding of traditional medical knowledge for public health; examine benefit sharing, particularly in the context of the Nagoya Protocol; explore the development and utilization of Traditional Knowledge Database Libraries (TKDL)-type databases in the country											
Element 2. Promoting research and development												
(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	Examine IP management policies and strategies for public health, including questions of ownership, access and control over research outcomes; Assessment of freedom to operate, status of existing technology, and technology partnering, access and pooling options; Explore IPR licensing as a means to develop research programmes and establish strategic research networks.											
(2.2) promoting upstream research and product development in developing countries	Incentivise product development from upstream research for public health; Examine incentives for investment in research and other contributions (including financial and other resources, background technology, infrastructure,											

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA	
	scientific and technology management expertise, risk exposure, and opportunity cost); Negotiation of terms and conditions covering research and development, including using IP in negotiating guarantees of development and access to finished product; and negotiation or implementation of public interest safeguards ensuring adequate access to research outcomes through government schemes within/outside IPR framework											
(2.3) improving cooperation, participation and coordination of health and biomedical research and development	Enhance cooperation and technology partnering by examining ways of blending incentives and public interest safeguards in public health, forms of IP management and leveraging IP coordination by participating in health related trade and IPR developments in various global forums											
(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries	Develop capacity to access patent/other relevant data bases for greater access to knowledge and technology for public health needs											
2.5 establishing and strengthening national and regional coordinating	Establish and strengthen national and regional coordinating bodies for negotiation of											

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	**BHU**	**IND**	**INO**	**MAV**	**MMR**	**NEP**	**SRL**	**THA**	
bodies on research and development	terms and conditions covering research and development, including using IP in negotiating guarantees of development and access to finished products; Use IPR and Patents proactively to generate R&D in developing/ LDC country low cost settings											
Element 3. Building and improving innovative capacity												
(3.1) building capacity of developing countries to meet research and development needs for health products	Examine international cooperation, specific international initiatives, standard-setting and the operation and development of the international legal framework for public health [e.g. Global Forum for Health Research, international treaties on IP and related treaties]											
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	Examine regional and national policy and legal settings with bearings on IP and interaction with other aspects of the regulatory system [e.g. research exemptions, use of clinical test data, interplay between the patent system and drug approval etc.] in public health											
(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	Examine IPR in public health for adaptation/adoption to developing country settings including consideration of alternative technologies and approaches to											

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA	
	health care in order to promote innovative capacity in accordance with the country's needs											
(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	Examine and establish access and benefit sharing in traditional medicine/knowledge leading to enhanced value for and protection of traditional medical knowledge with implementation of principles of prior informed consent and equitable benefit-sharing in public health											
(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation	Consider, where appropriate, how existing incentive structures and access mechanisms can be applied or adapted for public health-related innovation and develop appropriate incentive schemes for health-related innovation (within and outside IPR structure)											
Element 4. Transfer of technology												
(4.1) promoting transfer of technology and the production of health products in developing countries	Enable transfer of technology and know how and examine trade/ IPR strategies that promote technology transfer for public health products (in order to extract maximum benefit by using indigenous capacities to leverage access to external technologies).											
(4.2) supporting improved collaboration and	Develop collaboration and coordination											

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA	
coordination of technology transfer for health products, bearing in mind different levels of development	mechanisms for IPR related technology transfer for public health products (Art 66.2 of WTO Agreement) for developing countries											
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	Develop models for country strategies on new mechanisms for public health such as outsourcing (this is an age of outsourcing) research on TM etc. when they do not have capacity to do so. (This could function like the Doha Declaration where there is a move beyond the territoriality principle).											
Element 5. Application and management of intellectual property to contribute to innovation and promote public health												
(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries	Provide access to necessary skills and information, and capacity building for effective negotiations with technology partners on IP issues related to public health including institutional-level and/or project-level policies and strategies for IP management, for example to leverage IP arrangements in technology partnerships to ensure guaranteed levels of access to new technologies for promotion of public health											
(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations	Provide technical support on TRIPS Agreement of WTO: compulsory licensing, parallel imports, Doha Declaration for											

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA	
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	access to pharmaceutical products, etc.; Introduce trade and IPR curricula appropriately in medical education											
(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases[40]	Explore incentive schemes for R&D within and without the IPR and trade related framework for public health. Consider specific patent law issues that arise in relation to research in the life sciences field, such as the legal implications of patent pooling, patent exceptions applicable to medical research,											

[40] ***Type I diseases*** are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and *Haemophilus influenzae* Type b, and examples of noncommunicable diseases abound (e.g. diabetes, cardiovascular diseases and tobacco-related illnesses). Many vaccines for Type I diseases have been developed in the past 20 years but have not been widely introduced into the poor countries because of cost. ***Type II diseases*** are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 per cent of cases are in the poor countries. ***Type III diseases*** are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	**BHU**	**IND**	**INO**	**MAV**	**MMR**	**NEP**	**SRL**	**THA**	
	and the development of protocols and strategies for the use of 'research tools' and the impact and extent of 'reach through' claims on products developed with research tools.											
Element 6: Improving Delivery and Access												
(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system	Examine IP management strategies[41] in public health including access to manufacturing, drug delivery and platform technologies for promoting health-delivery infrastructure and financing of health products in the context of IPR and trade framework[42].											
(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	Examine IP aspects in public health such as mutual recognition of regulatory approvals, sharing of data, negotiating access to clinical trial data, arrangements for generating, protecting and accessing clinical											

essentially no commercially-based R&D in the rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans. Type II diseases are often termed *neglected diseases* and Type III diseases *very neglected diseases* (CIPIH p. 13).

[41] Differential ownership, role of IP in tiered pricing, 'march in' rights and other forms of guarantees of access to public or philanthropic funded research, etc.

[42] 4.1Governments need to invest appropriately in the health delivery infrastructure, and in financing the purchase of medicines and vaccines through insurance or other means, if existing and new products are to be made available to those in need of them. Political commitment is a prerequisite for bringing about a sustained improvement in the delivery infrastructure and health outcomes. Health systems research to inform policy-making and improve delivery is also important. The integration of traditional medicine networks with formal health services should be encouraged.4.2 Developing countries should create incentives designed to train and retain health-care workers in employment. (CIPIH p104).

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA	
	trial, incentives for investing in this process, and the legal and policy settings that govern this; mechanisms for facilitating or reducing the cost of regulatory approval, such as push and pull incentives in 'orphan drugs' schemes etc[43].											
(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs	Examine anti-trust/ competition, trademarks, industrial designs, protection of test data and undisclosed information interface in IPR and trade context for Member countries including tariff implications for public health											
Element 7. Promoting sustainable financing mechanisms												
(7.1) endeavouring to secure adequate and sustainable financing for research and development (R&D), and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	Identify sustainable financial mechanisms within and outside the IPR and trade framework for public health for developing countries[44]											

[43] WIPO report para 14.

[44] As one form of market exclusivity, intellectual property arrangements could form part of incentive mechanisms. This could also involve a focus on cross-jurisdictional opportunities, including differential pricing arrangements, 'social marketing' and public sector pricing structures, and IP management strategies that provide for cross subsidization of newly developed drugs in developing country markets of need. (Preliminary Comments of WIPO to the WHO Commission on Intellectual Property Rights, Innovation and Public Health , in short WIPO Report).

1.	2.	3.	4.									5.
Sub-Elements and specific actions as specified in WHA 61.21 (GSPOA)	**Potential issues on IPT[35] in each element**	**Stakeholder(s)[36]**	**Relevance[37] to the country**									**Remarks[38]:**
			BAN	**BHU**	**IND**	**INO**	**MAV**	**MMR**	**NEP**	**SRL**	**THA**	
(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	Examine IPR and trade management mechanisms for promoting public-private and product development partnerships in order to develop and deliver safe, effective and affordable public health products and medical devices.											
Element 8. Establishing monitoring and reporting systems												
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	Measure/track from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and trade related issues (addressed in report of the Commission on Intellectual Property Rights, Innovation and Public Health), on the development of, and access to, health care products											

Annex 8

Adapted from WIPO database for South-East Asia Member States

Summary Table of Membership of the UN, World Trade Organisation WTO, World Intellectual Property Organization (WIPO) and Treaties

STATES	W	P	B	PCT	PLT	MI	MM	MP	H	GH	N	LI	RO	LO	IPC	PH	VC	BP	S	NOS	TLT	WCT	WPPT	WAS	SG		UN	U	WTO
Bangladesh	X	X	X																							3	X		X
Bhutan	X	X	X				X	X																		5	X		
Democratic People's Republic of Korea	X	X	X	X			X	X	X		X	X		X	X			X								12	X		
India	X	X	X	X												X		X		X						7	X		X
Indonesia	X	X	X	X																	X	X	X			7	X		X
Maldives	X																									1	X		X
Myanmar	X																									1	X		X
Nepal	X	X	X																							3	X		X
Sri Lanka	X	X	X	X		X														X	X					7	X		X
Thailand	X	X	X	X																						4	X		X
Timor-Leste																										0	X		

W	WIPO Convention	**P**	Paris Convention	**B**	Berne Convention	**PCT**	Patent Cooperation Treaty
PLT	Patent Law Treaty	**MI**	Madrid Agreement (Indications of Source)	**MM**	Madrid Agreement (Marks)	**MP**	Madrid Protocol
H	Hague Agreement	**GH**	Geneva Act of Hague	**N**	Nice Agreement	**LI**	Lisbon Agreement
RO	Rome Convention	**LO**	Locarno Agreement	**IPC**	Strasbourg Agreement	**PH**	Phonograms Convention
VC	Vienna Agreement	**BP**	Budapest Treaty	**S**	Brussels Convention	**NOS**	Nairobi Treaty
TLT	Trademark Law Treaty	**WCT**	WIPO Copyright Treaty	**WPPT**	WIPO Performances and Phonograms Treaty	**WAS**	Washington Treaty
SG	Singapore Treaty	**UN**	United Nations (UN)	**U**	UPOV Convention	**WTO**	Agreement establishing the World Trade Organization (WTO)

Annex 9

Priorities of South-East Asia Member States on Eight GSPA Elements, WHA 61.21

Headings	Elements	BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA
1. Prioritizing R&D needs	1.1	4.00	2.00	4.00	3.00	1.00	4.00	4.00	4.00	4.00
	1.2	4.00	2.00	4.00	4.00	1.00	3.00	2.00	2.00	4.00
	1.3	4.00	4.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00
2. Promoting R&D	2.1.	4.00	3.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00
	2.2	3.00	2.00	4.00	4.00	1.00	2.00	2.00	3.00	3.00
	2.3	4.00	3.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00
	2.4	4.00	4.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00
	2.5	4.00	2.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00
3. Building and improving innovative capacity	3.1	3.00	2.00	4.00	4.00	1.00	4.00	4.00	3.00	3.00
	3.2	2.00	3.00	4.00	4.00	1.00	3.00	3.00	4.00	4.00
	3.3	4.00	2.00	4.00	4.00	1.00	3.00	3.00	4.00	4.00
	3.4	4.00	4.00	4.00	4.00	1.00	4.00	4.00	4.00	4.00
	3.5	3.00	4.00	3.00	3.00	1.00	3.00	3.00	3.00	4.00
4. Transfer of technology	4.1	3.00	2.00	3.00	4.00	2.00	2.00	3.00	4.00	3.00
	4.2	3.00	2.00	3.00	4.00	3.00	3.00	3.00	4.00	4.00
	4.3	3.00	1.00	4.00	4.00	3.00	2.00	2.00	4.00	4.00
5. Application and management of IP	5.1	2.00	4.00	4.00	4.00	4.00	4.00	4.00	3.00	4.00
	5.2	4.00	4.00	4.00	4.00	4.00	3.00	4.00	4.00	4.00
	5.3	3.00	2.00	4.00	4.00	2.00	2.00	2.00	2.00	3.00
6. Improving delivery and access	6.1	2.00	3.00	3.00	4.00	3.00	4.00	3.00	4.00	2.00
	6.2	4.00	3.00	4.00	4.00	3.00	4.00	2.00	3.00	2.00
	6.3	1.00	1.00	4.00	4.00	4.00	4.00	4.00	3.00	4.00
7. Ensuring sustainable financing mechanisms	7.1	4.00	3.00	4.00	4.00	4.00	3.00	4.00	4.00	3.00
	7.2	1.00	1.00	4.00	4.00	4.00	3.00	3.00	3.00	4.00
8. Establishing monitoring & reporting systems	8.1	4.00	2.00	4.00	4.00	4.00	3.00	3.00	4.00	3.00

	least important		Less important
	important		Most important

Annex 10

Priorities of Member States on Element 7 of GSPA

Headings	Elements	BAN	BHU	IND	INO	MAV	MMR	NEP	SRL	THA	# of '4'	# of '3'	# of '2'	# of '1'
7. Ensuring sustainable financing mechanisms (7.1-) endeavouring to secure adequate and sustainable financing for research and development (R&D), and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	7.1	4.00	3.00	4.00	4.00	4.00	3.00	4.00	4.00	3.00	6	3	0	0
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	7.2	1.00	1.00	4.00	4.00	4.00	3.00	3.00	3.00	4.00	4	3	0	2

	least important		Less important
	important		Most important

Annex 11

Agenda

(1) Address of the Regional Director, Dr Samlee Plianbangchang, delivered by Dr Poonam Khetrapal Singh, Deputy Regional Director

(2) Objectives of the Consultation: Dr Athula Kahandaliyanage, Director, Health Systems Development Department

(3) Development of a Regional Framework on Public Health, Innovation and Intellectual Property: Dr Manisha Shridhar

(4) Access to Technical Know-how in Pharmaceutical, Traditional Medicines, Dental and Medical Technology Enterprises to meet Public Health Needs, An Indian Analysis: Professor Arvind Chaturvedi

(5) Challenges in GSPA Deliverables for Indian Pharmaceutical Industry after TRIPS: Prof Sudip Chaudhuri

(6) New IPR Regime and Access to Medicines in Sri Lanka: Next steps under WHA 61.21: Dr Weerasinghe

(7) Developing Regional and National Priorities on Public Health, Innovation and Intellectual Property: Perspective from Countries

- Bangladesh: Prof. Mahmood Hasan
- India: Dr Satyanarayanan
- Indonesia: Dr Martuti Budiharto
- Sri Lanka: Prof. Rohini Fernandopulle
- Thailand: Dr Chutima Akaleephan

(8) Group Work: Identification and Prioritization for a Regional and National Framework on Public Health, Innovation and Intellectual Property

(9) Overview of Regional Cooperation and National Action for GSPA: Dr Dinesh Abrol

(10) Implementation of GSPA: Perspective from WHO HQ: Dr Nicoletta Dentico

(11) Closing Remarks by Dr Poonam Khetrapal Singh, Deputy Regional Director

Annex 12

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The development of a National and Regional Framework on Public Health, Innovation and Property Rights, suitable to the South-East Asia Region of WHO became pertinent in view of the 108 action points under 25 sub-elements and 8 major elements identified under the Global Strategy by WHO in 2008. This report is the result of a detailed regional consultation held in New Delhi, India where participants from Member States identified how to address their priorities at the national, regional and international levels. It was also endeavoured to utilize certain facets of Intellectual Property as a development tool relevant to regional and national contexts in South-East Asia Region of WHO.

Additionally, the supply of quality medical products is closely linked to the performance of the pharmaceutical industry which, in turn, is dependent on the economic policy framework set by governments. Presentations made in this regional consultation examined the status of this industry including traditional medicines, medical technologies and dental requirements while preparing a focused regional and country-specific national action plan.

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