Cooperation among Member States is becoming increasingly important due to the complexity of medical products (pharmaceuticals, biologicals, vaccines, diagnostics and medical devices), globalization, supply chains, and growing public expectations.

Access to medical products is influenced by regulatory requirements at national and international levels. The member states in South East Asia region recognize each country is evolving, developing and strengthening their regulatory mechanisms to provide quality pharmaceutical products to achieve the goal of Universal Health Coverage based on national norms and public health needs. During “Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products” at WHO-SEARO, New Delhi, India, 22 to 24 September 2015, the member states felt there is an immediate need to develop a regulatory affairs network for cooperation as most of the countries in the region have limited resources. A Regional regulatory network will create a platform for enabling cooperation and support for quality, safe and efficacious medical products in a timely and efficient manner. Formation of similar regional networks, sometimes defined by economic or political frameworks, is common in many other regions of the world such as the Americas, Africa, the Gulf, Asia-Pacific (APEC), ASEAN region and the European Union.

The representatives at the Regional Meeting supported establishing a network to enhance information exchange and capacity building with a view to encouraging the adoption of international standards, best practices and effective use of regulatory resources. They noted a number of areas of potential collaboration as part of a pragmatic, step-wise approach. Participants supported the idea of convening an annual meeting with a focus on matters that relate to the mandates of National Medicines Regulatory Authorities as a first step in exploring mechanisms and areas of enhanced cooperation as a matter of public health priority.
Promoting cooperation for regulation in trade of medical products

Report of the regional meeting
WHO-SEARO, New Delhi, India
22–24 September 2015
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# Acronyms

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<tr>
<td>ADR</td>
<td>adverse drug reactions</td>
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<tr>
<td>AIDS</td>
<td>acquired immunodeficiency syndrome</td>
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<td>API</td>
<td>active pharmaceutical ingredient</td>
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<tr>
<td>ARVs</td>
<td>Antiretrovirals</td>
</tr>
<tr>
<td>ANVISA</td>
<td>Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency, Brazil)</td>
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<tr>
<td>ASEAN</td>
<td>Association of South East Asian Nations</td>
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<tr>
<td>CBHI</td>
<td>Central Bureau of Health Intelligence, New Delhi, India</td>
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<tr>
<td>CDDA</td>
<td>Cosmetics, Devices and Drugs Act, Sri Lanka</td>
</tr>
<tr>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization, New Delhi, India</td>
</tr>
<tr>
<td>CETP</td>
<td>common effluent treatment plant</td>
</tr>
<tr>
<td>CIPIH</td>
<td>Commission on Intellectual Property Rights, Innovation and Public Health</td>
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<tr>
<td>CMSD</td>
<td>Central Medical Stores Depot</td>
</tr>
<tr>
<td>CPCB</td>
<td>Central Pollution Control Board, New Delhi, India</td>
</tr>
<tr>
<td>CTD</td>
<td>Common Technical Dossier</td>
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<tr>
<td>DGDA</td>
<td>Directorate-General of Drug Administration, Bangladesh</td>
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<td>DGHS</td>
<td>Directorate-General of Health Services</td>
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<tr>
<td>DoP</td>
<td>Department of Pharmaceuticals</td>
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<tr>
<td>EDL</td>
<td>Essential Drug List</td>
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<tr>
<td>FSSAI</td>
<td>Food Safety and Standards Authority of India</td>
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<tr>
<td>GCC DR</td>
<td>Gulf Central Committee for Drug Registrations</td>
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<tr>
<td>GCP</td>
<td>global clinical practice</td>
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<td>GLP</td>
<td>good laboratory practice</td>
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<tr>
<td>GMP</td>
<td>good manufacturing practices</td>
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<tr>
<td>GSPA</td>
<td>Global Strategy and Plan of Action</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HPV</td>
<td>Human papillomavirus</td>
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<tr>
<td>ICDRA</td>
<td>International Conference of Drug Regulatory Authorities</td>
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<td>ICH</td>
<td>International Conference on Harmonization</td>
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<tr>
<td>IDMA</td>
<td>Indian Drug Manufacturers Association</td>
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<tr>
<td>IP</td>
<td>intellectual property</td>
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Promoting cooperation for regulation in trade of medical products

IPC Indian Pharmacopoeia Commission
MHRA Medicines and Healthcare products Regulatory Agency
MoU Memorandum of Understanding
MSD Medical Supplies Division, Sri Lanka
MSME Ministry of Micro, Small, and Medium Enterprises, India
NADFC National Agency for Drug and Food Control, Indonesia
NCD noncommunicable diseases
NGT National Green Tribunal
NMP National Medicines Policy
NPPA National Pharmaceutical Pricing Authority
NMRA National Medicines Regulatory Authority, Sri Lanka
PANDRH Pan American Network for Drug Regulatory Harmonization
PET Polyethylene terephthalate
PV Pharmacovigilance
RHSC (APEC-LSIF) Regulatory Harmonization Steering Committee (Asia-Pacific Economic Cooperation-Life Sciences Innovation Forum)
R&D research and development
SEAR South-East Asia Region
SOPs Standard Operating Procedures
SPC State Pharmaceuticals Corporation, Sri Lanka
SPCB State Pollution Control Board
SSFFC substandard/spurious/falsely-labelled/falsified counterfeit
STO State Trading Organization
TRIPS Trade-Related Aspects of Intellectual Property Rights Agreement
USFDA United States Federal Drug Administration
UHC universal health coverage
UMC WHO Collaborating Centre, The Uppsala Monitoring Centre
UN United Nations
WHA World Health Assembly
WHO World Health Organization
WTO World Trade Organization
Executive summary

Introduction

A regional meeting for promoting cooperation for regulation in trade of medical products was organized at the WHO Regional Office for South-East Asia, New Delhi, India, from 22 to 24 September 2015. The general objective of the consultation was to review the current status with regard to regulation in trade of medical products and develop a framework for strengthening mutual cooperation among Member States in the Region.

The specific objectives of the meeting were as follows:

- to share information on policies and procedures for trade in quality medical products;
- to identify measures for regional cooperation for regulation in trade of medical products; and
- to explore next steps/action plan for mutual cooperation among Member States including skill and capacity-building for trade in quality medical products.

The regional meeting was preceded by technical discussions on 21 September 2015 on background papers prepared by select national experts in the context of national and regional public health governance. These technical discussions subsequently facilitated informed decision-making by representatives of Member States for suitable outcomes from the meeting.

The meeting was attended by 50 participants from nine Member States in the Region, with the exception of the Democratic People’s Republic of Korea and Timor-Leste, as well as technical experts and other stakeholders including from pharmaceutical associations. Dr Shailendra Kumar, Director, Ministry of Health and Family Welfare, India, chaired the meeting and Major-General Md Mustafizur Rahman, Director-General, Directorate-General of Drug Administration, Ministry of Health and Family Welfare, Bangladesh, was the Co-chair. Ms Aishath Mohamed, Deputy Director-General, Pharmaceuticals, from Maldives, was nominated Rapporteur.

Outcome

The meeting resulted in strong and unanimous support from participants in setting up a regional regulatory network to promote affordable and quality intercountry facilitation of medical products in line with World Health Assembly
resolutions WHA61.21 on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA), and WHA67.20 on Regulatory system strengthening for medical products, which was a turning point for the Region.

Member States in the Region recognized that each country was evolving, developing and strengthening its regulatory mechanisms to provide quality pharmaceutical products to achieve the goal of universal health care (UHC) based on national norms and public health needs. In order to achieve this goal, there was an immediate need to develop a regulatory network, as most of the countries in the Region had limited resources. A regional regulatory network would provide them with a platform for communication and meeting, enabling cooperation and support to national regulatory authorities (NRA) for quality, safety and efficacy of medical products in a timely and efficient manner. It was hoped that the network would provide an opportunity for information exchange and sharing on policies, standards, procedures, process and products. The Network would also develop capacity through training to support harmonization and implementation of international standards and guidelines in the Region.

Cooperation among Member States is becoming increasingly important due to the complexity of medical products (pharmaceuticals, biologicals, vaccines, diagnostics and medical devices), globalization and threats to supply chains, and growing public expectations. Access to medical products is greatly influenced by regulatory requirements at national and international levels.

The formation of similar regional networks, sometimes defined by economic or political frameworks, is common in many other regions of the world such as the Americas, Africa, the Gulf, Asia-Pacific Economic Cooperation (APEC), Association of South East Asian Nations (ASEAN) and the European Union. However, there is a void in this respect in World Health Organization’s South-East Asia Region. Hence, this promising initiative will be instrumental in encouraging convergence, effective use of resources and rapid exchange of information on products for countries of the Region.

This report summarizes the discussions held at the meeting, resulting in recommendations for a proposed regional regulatory network amongst Member States of the WHO South-East Asia Region.

**Recommendations**

The following recommendations were made.

**Recommendations for Member States**

It was recommended that Member States:
1. contribute to the development of a network for the SEA Region for access to safe, quality medical products by learning from experiences of other networks such as Association of South East Asian Nations (ASEAN), and Regulatory Harmonization Steering Committee (RHSC) of the Asia-Pacific Economic Cooperation (APEC);

2. request the Regional Office to continue to arrange annual meetings of the interim network until the official network is established;

3. continue discussions on the priority needs of the Region and address some of the specific needs and concerns of Member States after the establishment of the interim regional network and share the progress of the implementation during the next meeting;

4. discuss and formalize potential priority needs such as good manufacturing practices (GMP) inspections, good clinical practices (GCP) inspections, and pharmacovigilance (PV) and other regulatory activities that support access and affordability of medicines in the region;

5. share progress on best practices with Member States and provide a relevant contact within their countries through the interim focal point/s of the regional network; and

6. hold the next meeting of the interim regional network to develop the concept paper and, possibly, a draft resolution before the Sixty-ninth Session of the Regional Committee.

**Recommendations for WHO**

It was recommended that WHO:

1. support and facilitate the establishment of designated focal point(s) from each Member State for this process as well as for the next meeting. The Regional Office will also consider inviting participation from similar regional networks to discuss the inputs for the Sixty-ninth Session of the Regional Committee. The list of focal points designated at the meeting is provided in Annex 3.

2. The WHO Regional Office would act as the secretariat to facilitate this process.
Introduction

A regional meeting for promoting cooperation for regulation in trade of medical products was organized at the World Health Organization’s (WHO) Regional Office for South-East Asia, New Delhi, India, from 22 to 24 September 2015.

This activity was taken up for implementation of SEA Regional Committee Resolution on International Trade and Health, SEA/RC59/R9 and World Health Assembly resolution WHA61.21 on the Global strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA). In May 2015, resolution WHA68.35 endorsed extension of the period of implementation of GSPA until 2022. The meeting is also in line with resolution WHA67.20 on Regulatory system strengthening for medical products, wherein the GSPA has also been cited. The desirability of mutual cooperation for regulation in trade of medical products among Member States in the Region came up during discussions held in Sri Lanka on the next steps to the national assessment of GSPA. It may be noted that Sri Lanka conducted a workshop on promoting innovation and access to health products utilizing the assessment tool developed for GSPA on 28–29 April 2014.. A second national consultation on promoting innovation and access to health products and GSPA implementation took place in Colombo on 26 September 2014. This resulted in a national report that has been launched and formally accepted by the Ministry of Health, Sri Lanka, on 13 March 2015.

The present regional meeting addresses two elements of GSPA – Element 3 and Element 6. Element 3 covers building and improving innovative capacity for framing, developing and supporting effective policies that promote the development of capacities for health innovation; and establish and strengthen regulatory capacity in developing countries. Element 6 serves to further improve delivery and access by establishing and strengthening mechanisms to regulate the quality, safety and efficacy of health products and medical devices. This is achieved by strengthening the capacity of national regulatory authorities to monitor the quality, where appropriate; and initiate programmed actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals. Element 6 also covers support to regional networks and collaborative efforts to strengthen regulation and
Promoting cooperation for regulation in trade of medical products

implementation of clinical trials using appropriate standards for evaluation and approval of medicines.

The 16th International Conference of Drug Regulatory Authorities (ICDRA), 2014, also discussed many of these issues. Participants from the WHO South-East Asia (SEA) Region at this meeting expressed the desirability of holding discussions on a regional platform to enable collaboration in the Region for providing quality pharmaceutical products.

The SEA Regional Committee resolution SEA/RC59/R9 urges Member States to improve the capacity of National Regulatory Authorities. The resolution requests Regional Office to provide necessary assistance for this purpose.

The interdependence of trade and health with various international trade agreements has resulted in many challenges in the management of public health. Trade factors are influencing public health in access and development of medicines and medical products, and regulation at national and international level. Further, E-commerce and the Internet have opened a new range of regulatory issues for public health products.
Objectives

2.1 General objective
The general objective was to review the current status with regard to regulation in trade of medical products and develop a framework for strengthening mutual cooperation among Member States in the Region.

2.2 Specific objectives
The specific objectives of the consultation were to:

- share information on policies and procedures for trade in quality medical products;
- identify measures for regional cooperation for regulation in trade of medical products; and
- explore next steps/action plan for mutual cooperation among Member States including skill and capacity-building for trade in quality medical products.
Opening session

3.1 Opening address

Dr Tawhid Nawaz, Director, Programme Management, WHO Regional Office for South-East Asia, read out the Regional Director’s address. The Regional Director, Dr Poonam Khetrapal Singh, stressed that improving delivery and access is vital for health systems strengthening. This is an important point in – Element 6 of GSPA, which has been extended until 2022 by resolution WHA68.35 in 2015.

The Regional Director’s remarks highlighted that GSPA was an expansive instrument for action and encompasses many aspects and programmes for public health. It is also quoted in a number of resolutions. For example, in 2009, resolution WHA62.13 on Promoting policies on innovation and standard settings to ensure quality, safety and efficacy of traditional medicines referred to GSPA. Again, in 2010, GSPA was mentioned in resolutions WHA63.21 on WHO’s role and responsibilities in health research; WHA67.20 on Regulatory system strengthening for medical products; WHA67.22 on Access to essential medicines, and WHA67.25 on Antimicrobial resistance.

Dr Singh emphasized that the regional meeting sought to promote cooperation for regulation in the trade of medical products for safety, quality and efficacy of medicines and other health products. These aspects coupled with adherence to GMP and effective supply chain management are critical components of a well-functioning health system. The relevant features relate to “developing actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals”.

She noted that the regional meeting was timely and important for many reasons. Member States of the Region have deliberated on World Health Assembly resolutions relating to substandard/spurious/falsely-labelled/falsified counterfeit medical products (SSFFC), including resolution WHA59.26 on International trade and health. These resolutions highlighted the consequences of international trade on public health and encouraged Member States to share evidence for developing policies and strategies related to trade and health.
Since South-East Asia Region was a major supplier and consumer of medical products including drugs, vaccines and diagnostics, she said that the utilization and supply of generic medicines dominated the regional market. Many countries such as Bangladesh and India were important suppliers of generic medicines.

She stated that the SEA Region had taken the lead in the global public health debate on many aspects, and hoped that active involvement of Member States would result in and give rise to significant collaborative mechanisms in the short and long term (see Annex 1 for full text of address).

3.2 Inaugural address

In his inaugural address, Mr K.B. Aggarwal, Additional Secretary, Ministry of Health and Family Welfare, Government of India, emphasized the importance of participation from the ministries of health, trade and commerce and representatives of pharmaceutical associations from Member States of the Region. The main objectives are to strengthen regulation of medical products; develop and improve tools to assist regulatory work; facilitate communication; and, very importantly, to promote harmonization among regulatory authorities in the context of trade of medical products. Since trade took place at both national and international levels, regulatory practices influenced national and international availability of medical products.

He stated that in the Indian Constitution, many health issues such as population control, medical education, medical professions, prevention of spread of infectious diseases across states and vital statistics including registration of births and deaths, fell in the Concurrent List. Food and drugs were also included in the Concurrent List. As such, the Central Government and state governments were jointly responsible for these issues, posing a number of legislative and implementation challenges for public health.

He emphasized the need for a vibrant regulatory structure to deliver on health outcomes. Quoting from the National Health Policy 2015, he stated: “This will entail moving away from reactive, voluminous, poorly implemented regulatory regimes, cobbled up in an ad hoc manner, to a more effective, rational, transparent and consistent regime. The regulatory levers need to be wielded far more consistently and effectively to meet the challenges associated with health care throughout the country, safeguarding the public interest as well as encouraging private initiative”. Regulatory systems had to conform to international standards aligned with WHO and other relevant international guidelines.

India was known as the manufacturing hub and the pharmacy of the world with exports to over 200 economies. The Indian pharmaceutical industry was the
third largest in the world by volume and the tenth in terms of value. The total size of the Indian pharmaceutical industry was about US$ 33 billion, of which exports accounted for about 55%. However, currently, the major focus was on manufacture of drugs. Though rapid progress had been made in manufacturing some of the medical devices, the country was largely dependent on imports. The Indian medical devices sector had the potential to grow into a US$ 50 billion industry by 2025, provided the requisite ecosystem could be created.

A dynamic and responsive regulatory regime was essential to ensure the quality of products and maintain the pharmaceutical industry’s global and domestic reputation and leadership. In order to develop a robust drug regulatory system across the country, both at the center and state levels, the Government of India had recently approved an outlay of US$ 275 million in the next three years to strengthen the drug regulatory system.

The main challenge in ensuring access to free drugs and diagnostics through public services is quality of public procurement and logistics. Models implemented in the states of Tamil Nadu, and more recently Rajasthan, have shown considerable increases in access while limiting irrational prescription practices with quality assured products.

What is move India needed to contribute to international health and leverage the strengths in frugal innovation in the area of pharmaceuticals, medical devices, health-care delivery and information technology and assist other nations to improve access to essential health commodities at much lower costs.

In order to achieve this, India recognized the need to build alliances with similarly situated nations. It is important to develop trade and intellectual property rights regimes that were supportive of national economic growth and health-care priorities, particularly ensuring access to safe, efficacious and affordable medical products. For this purpose, India was happy to work with multilateral institutions such as WHO for an implementation framework. (See Annex 2 for full text of address.)
4. Proceedings

4.1 Background

Delivering on health goals in the SEA Region: putting cooperation on regulation of trade in medical products ‘in context’

Dr Phyllida Travis, Director, Department of Health Systems, WHO Regional Office for South-East Asia, spoke about current health-care challenges, changes, international and national commitments and priorities. She stressed on the evolution of international collaboration for regulation in public health. Globally, 400 million people are still without access to essential health services, while 69 million were further pushed into extreme poverty because of health spending.

The evolution of international collaboration in regulation in public health to deliver on UHC was relevant, including for the Sustainable Development Goals (SDGs), which are endorsed by the United Nations with one overriding health goal. The SEA Region has a priority commitment on achieving UHC, which is increasing people’s access to needed health services without incurring financial hardship. This could be achieved by addressing health financing, and also other factors that affect access to services, safe, affordable and effective medicines, and human resources for health. Another aspect is utilizing the resources more efficiently to support all health systems.

The World Health Report on Financing for universal coverage identified that medicines accounted for three of the 10 leading causes of inefficiency (WHO, 2010). The main reasons are underuse of generics, higher than necessary prices for medicines, use of substandard and counterfeit medicines or inappropriate and ineffective use. The common reasons for inefficiency related to inadequate regulatory frameworks leading to insufficient pharmaceutical regulatory structures/mechanisms, weak procurement systems or inappropriate prescriber incentives and practices, consumer demand and limited knowledge. There was a need to improve regulation and governance, including strong sanction mechanisms; assess transparency and vulnerability to corruption; undertake public spending tracking surveys; and promote codes of conduct.
The present meeting was held to discuss opportunities within the SEA Region for regional cooperation in regulation of medical products. It also addresses the issues of changing markets in the production and distribution of medical products globally and within South-East Asia. The influence of the various international agreements on trade and public health is growing. There are historical examples of international cooperation in public health such as the First International Sanitary Conference in 1851 (response to European cholera epidemics of 1830 and 1847). We recall that WHO was established as a specialized agency of the United Nations to deal specifically with international health issues in 1948. The relatively recent 2006 report from the Commission on Intellectual Property Rights, Innovation and Public Health also discusses ways to promote access to medicines, diagnostics and vaccines that disproportionately affect developing countries.

**The context for cooperation for regulation of trade in medical products**

Dr Manisha Shridhar, Regional Adviser, Intellectual Property Rights and Trade and Health, WHO Regional Office for South-East Asia, outlined the context for cooperation for regulation of trade in medical products. There were complex factors influencing public health such as globalization and trade, dissolving national borders leading to increased trans-border trade, multilateral and regional trading systems, arrival of new medical products such as biologicals and biosimilars, and new forces of technology and Internet that expanded the opportunities on the availability and choice of medical products. Member States of the Region specifically sought to address these issues in the Regional resolution, SEA/RC59/R9. The impact made by GSPA important in this context. The implementation of resolution WHA61.21, was extended until 2022 in May 2015 through resolution WHA68.35. The contribution made by the Sri Lanka National Assessment to facilitate aspirations for cooperation in the SEA Region needs to be acknowledged.

Additional World Health Assembly resolutions important in this context are:

- WHA67.20 - Regulatory system strengthening for medical products
- WHA67.21 - Access to bio therapeutic products including similar bio therapeutic products, and ensuring their quality, safety and efficacy
- WHA67.22 - Access to essential medicines
- WHA67.25 - Antimicrobial resistance

Thus, in the light of the above, it was relevant to review the current status of regulation in trade of medical products, and develop a framework for strengthening mutual cooperation among Member States.
Making a difference: learning from global initiatives

Mr Michael Ward, Coordinator, Regulator Systems Strengthening, WHO headquarters, emphasized that from a trade perspective, regulations might constitute technical barriers to trade, which was one of the subjects of agreements by the World Trade Organization. Medical products, one of most regulated sectors, had their impact on health influenced by the inability of the end-user to differentiate “good” from “bad” products. He stated that national regulatory authorities (NRAs) were on the critical path to innovation. Access to safe and effective medical products and the degree to which NRAs fulfilled their mandates in an effective, efficient and transparent manner had a direct impact on innovation, access and public health.

NRAs must consider more modern and intelligent models of regulation that take into account resource constraints, increasingly complex technologies, globalization and public expectations. Regulatory convergence was the foundation for regulatory collaboration, where convergence did not require harmonization of laws and regulations, but represented a process whereby regulatory requirements across economies became more aligned over time as a result of the adoption of internationally recognized technical guidance, standards and best practices.

Currently, there is increasing prevalence of harmonization, convergence and other forms of cooperation at both regional and international levels. Some of the plentiful examples include: International Conference on Harmonization, (International Medical Device Regulators Forum, or IMDRF), Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S), International Generic Drug Regulators Pilot (IGDRP), APEC, ASEAN, African Medicines Registration Harmonization (AMRH), East African Community (EAC)1, Southern African Development, ZaZiBoNa2, ECOWAS3, Gulf Cooperation Council (GCC), Pan-American Network for Drug Regulatory Harmonization (PANDRH), etc. It was increasingly apparent that intended objectives could not be achieved without implementing products of harmonization and convergence in a consistent and intended manner. This required common understanding and preparation including legal amendments, complementary guidance, standard operating procedures (SOP), training, resourcing and infrastructure.

WHO had long supported regulators in low- and middle-income countries in fulfilling their mandates through developing norms and standards, promoting

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1 Republics of Kenya, Uganda and the United Republic of Tanzania
2 ZaZiBoNa process is a collaboration between national medicines regulatory authorities (NMRAs) in Botswana, Namibia, Zambia, and Zimbabwe
3 Economic Community of West African States: Established on 28 May 1975 via the treaty of Lagos, ECOWAS is a 15-member regional group with a mandate of promoting economic integration in all fields of activity of the constituting countries. Member countries making up ECOWAS are Benin, Burkina Faso, Cape Verde, Cote d’Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone and Togo
regulatory convergence and harmonization, training and capacity-building, and supporting information and work-sharing arrangements. The experience to date had helped characterize the benefits, challenges and potential evolution of such initiatives in accelerating in-country regulatory decisions. WHO supported the strengthening of regulatory systems in accordance with numerous World Health Assembly resolutions and also promoted access to essential medical products as one of the key enablers of health and equality.

The challenge was strengthening the capacity of regulatory authorities to regulate in a manner that was consistent with timely access to priority medicines. Weak regulatory systems did not serve the interests of consumers, patients, industry or the health-care system. At the same time, as countries developed regulatory capacities, it was important that the regulatory systems were science-based, respected international standards and best practices, and adopted an approach that focused on what could not be done by others while leveraging the work of other trusted NRA and regulatory networks for the rest. Some elements of regulatory oversight that could be shared were evaluation of quality, efficacy and safety. Other elements of regulatory oversight must be local, such as licensing decisions; local manufacturing oversight; pharmacovigilance (PV); appropriate distribution controls (stability and cold chain); and product security (protection against counterfeiting and adulteration).

The regulatory framework should also be flexible, providing for expedited waived registration in the case of emergencies or other important public health situations. The hallmarks of a well-functioning regulatory system and good regulatory practices are to put in place a sound but flexible regulatory framework with full understanding of the role of laws, regulations and guidelines. Additionally, it is important to have transparency in operations, decisions and rule-making; regulatory alignment and streamlining of processes; adoption of international standards and best practices; and science- and risk-based organization. It is also essential to make the most effective use of resources, focusing on high-impact activities that no one else could do; doing them well, and adopting innovative approaches for fulfilling other elements of the agency’s regulatory mandate such as networks, work-sharing, and reliance without relinquishing the decision-making authority.

The most important thing to remember is that not all national regulators could perform all regulatory functions; decisions had to be made nationally on which areas to focus on and build capacity, and in which areas to rely on other regulators’ work. Harmonization and convergence alone could not help, but could form a solid basis for the new regulatory paradigm to evolve in the future. Doing locally what nobody was doing/could do, cooperate and rely in a transparent systematic way on other regulatory decisions, and decide in which area to invest...
to specialize to be a “world-class player” contributing to the regional/global regulatory network were other important aspects.

In the ensuing discussion, participants highlighted various difficulties faced by the Region such as policies of procurement through public system or price control, delay in introduction of new or patented drugs, and new dimension of e-pharmacies, among others. Member States had issues related to various aspects and hence felt a need for a platform to share information through a regional initiative. Additionally, it was noted that regulators in the Region were faced with many challenges in performing the work due to constraints such as shortage of manpower, transfers of trained personnel, fund shortage and lack of adequate knowledge and forums to discuss issues and develop capabilities. Concern was expressed on the delay in upgrading the regulatory authorities without appropriate budget in the Region.

The need to start with a broad concept of cooperation was highlighted, which eventually leads to harmonization. The regional platform had to develop a common regulatory language in order to start a communication channel. International good regulatory practices had been implemented to assist all regulators in developing procedures and technical guidance. The WHO prequalification programme has been successfully implemented for harmonizing assessment of quality medicines and has facilitated earlier introduction of treatments in developing countries. Similarly, African Vaccine Regulatory Forum (AVAREF) platforms for vaccine clinical development programme assessment has been successfully launched by African nations in very constrained NRAs.

4.2 Technical presentations

Trade and regulations in drugs and pharmaceuticals in Bangladesh

Dr Sitesh C. Bachar, Professor, Department of Pharmacy, University of Dhaka, Bangladesh, described the evolving drug regulations in Bangladesh as the economy changed significantly over the last few decades. Bangladesh graduated from being a lower-income country to a lower middle-income country as per the World Bank report closed on 1 July 2015. It was improving on many health indicators and, in some instances, was ahead of some of its South-Asian neighbours.

Currently, local pharmaceutical manufacturers catered to about 97% of the internal demand and were continuously expanding to meet future growth. Many companies acquired new technologies and started manufacturing all kinds of dosage forms. The pharmaceutical industry in Bangladesh is a developing sector contributing substantially to its economy.
Promoting cooperation for regulation in trade of medical products

These NRA regulated the manufacture of pharmaceuticals and the quality management system (QMS) and good manufacturing practices (GMP). However, clinical trials and pharmacovigilance (PV) activities needed support and capability-building. The Directorate of Drug Administration was established in 1976 under the Ministry of Health and Family Welfare. The organization was upgraded in January 2010 to the Directorate-General of Drug Administration (DGDA), which was responsible for medicines regulation. Its mission was to ensure the quality, safety, efficacy and usefulness of all drugs and medicines produced, imported and marketed in the country.

In 2014, the DGDA constituted a Medical Device Registration Guidelines Committee to prepare “Registration Guidelines for Medical Devices in Bangladesh” by 2015. This guideline was based on the guidelines of the Global Harmonization Task Force, and would help in standardization and harmonization by formulating and introducing the medical device registration process. Currently, more than 80% of active pharmaceutical ingredients (APIs) were being imported to satisfy local demand, and there were 21 local companies manufacturing 41 APIs. However, the producers were mostly conducting final chemical synthesis step(s) with APIs intermediaries, instead of total chemical synthesis. Due to huge demand of APIs and challenges, the government was establishing API Park at Bausia in Munshiganj, about 40 km from Dhaka where 40 API industries would be established under the Bangladesh Small and Cottage Industries Corporation (BSCIC).

It may be noted that under the guidance of WHO, an adverse drug reaction (ADR) advisory committee and adverse drug reaction monitoring (ADRM) cell was established in the DGDA between 1996 and 2000. In 2013, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS), a USAID programme managed by Management Sciences for Health, provided support to DGDA in reviving the Cell and Committee in the Directorate as a part of health systems strengthening. ADRM Cell and ADR Advisory Committee had become fully functional.

In the light of the achievements of the ADRM Cell, the Ministry of Health and Family Welfare declared DGDA as the National Drug Monitoring Centre and it was awarded the 120th membership from the WHO Collaborating Centre, The Uppsala Monitoring Centre (WHO-UMC) in 2013. As a member of WHO-UMC, DGDA had access to VigiBase, the WHO global individual case safety reports database. DGDA had also adopted a UMC web-based tool, VigiFlow, which currently serves as the national database, and allowed individual case safety reports received within the country to be committed to VigiBase.

Since 2014, SIAPS facilitated the signing of a memorandum between the Korea International Cooperation Agency and DGDA on a skills development
training of DGDA officials for 21 days in the Republic of Korea every year based on DGDA’s needs. SIAPS was also organizing basic training on GMP for all superintendents of drugs and district-level officers throughout the country to develop master trainers. The training included mock inspection with hired national and international consultants (such as the Asia Pacific Consultancy Pty Ltd. Melbourne, Australia). The country was developing and strengthening regulatory functions to support its API manufacturing and clinical trials.

While the government should consider the respective concerns of the Regional Office in policy regulation and policy implementation, a roadmap for an action plan on cooperation with and support from the WHO Regional Office for South-East Asia is required for skill-development and capacity-building of NRA.

Trade and regulation in drugs and pharmaceuticals in India

Dr S. Eswara Reddy, Joint Drugs Controller, Directorate-General of Health Services, Government of India, said the Indian pharmaceutical industry was worth approximately US$ 33 billion with an export value of US$ 15 billion and a domestic market of another US$ 15 billion. Its growth rate was pegged at 13%–14% and imports were US$ 5 billion. Pharmaceutical products are currently exported to more than 200 countries. In terms of volume of production, India’s pharmaceutical industry was the second largest in the world and in terms of value of production it stood at tenth position in the world. The sector had 4900 manufacturing units for formulations: 1500 for API, 30 for vaccines, 350 for medical devices and 2800 for miscellaneous (surgical dressings, blood banks and disinfectants). Other industrial sectors coming under the purview of the Drug Controller-General of India (DCGI) were 2300 manufacturing units for cosmetics, 4800 for Ayurveda and Unani traditional medical products, 1000 for homoeopathy, and 800 000 wholesale and retail outlets. Central Drugs Standard Control Organization (CDSCO) was responsible for ensuring the safety, efficacy and quality of drugs, biologicals, medical devices, cosmetics and veterinary drugs.

It may be noted that under the Indian Federal structure, CDSCO came under the purview of the Union Government while state governments performed the functions of the state drug licensing authorities. The responsibilities of the Union Government in New Delhi included new drug approvals/medical devices, import of drugs/medical devices, clinical trials, standards for drugs, amendments to Acts and Rules and pharmacovigilance. The responsibilities of the state governments are to provide the licences for manufacture, sale and distribution, and to monitor the quality of drugs and cosmetics, and regulate investigations and prosecutions.

The sites approved by the United States Federal Drug Administration (USFDA) (formulations + API) numbered 262; those by the European Directorate for the Quality of Medicines and Health Care (EDQM) numbered 253; and those receiving the Certificate of Pharmaceutical Products (COPP) totalled approximately 1300.
The medical devices industry is currently being regulated in line with the Drugs and Cosmetics Act. This would be made a separate subject in the Drugs and Cosmetics Amendment Bill 2015, in which a materiovigilance programme was introduced. The market size totaled US$ 4760 million and only notified devices were regulated. There were about 350 licences mostly granted to imports of implants and medical electronics. In terms of indigenous products, there were disposables and furniture. This area is dynamic in nature and there is great potential for growth.

Dr Raman Singh, Principal Scientific Officer, Quality Manager and Coordinator, Indian Pharmacopoeia Commission (IPC), highlighted the achievements of the institution with regard to regular publications of the IPC, incorporating 3000 monographs. The Indian Pharmacopoeia is shared in the Region as standard reference. IPC was responsible for publication of the Indian pharmacopoeia for standards for drugs in India, and the national formulary of India, which was a guidance document on rational use of medicines. It was also a national coordination centre (for PV programme of India (PvPI)).

Dr Brijesh Sharma, Consultant, described the present regulatory system and the plan for further strengthening the regulatory agency, i.e. the Central Drugs Standard Control Organization (CDSCO), by developing a training centre for the regulators.

Proposed roadmap and action plan for capacity-building and strengthening regulatory mechanisms for medical products in Indonesia

Dr Lucky S. Slamet presented her paper with the standard disclaimer. She presented an action plan for strengthening regulatory mechanisms for the drugs and pharmaceutical trade in Indonesia.

In her presentation she emphasized the need to promote new thinking on innovation and access to medicines that should be needs-driven, relate to essential health research and development, and be relevant to diseases that disproportionately affected developing countries. Limitations in many developing countries include: the small size of the market, lack of indigenous technological and productive capacity, lack of regulatory capacity and independent support mechanisms.

At the 16th ICDRA in Rio de Janeiro in 2014, there was a desire by Member States of SEA Region to organize a regional meeting on cooperation in trade of medical products to strengthen health systems for universal health coverage (UHC). The goal of this meeting would be to outline a common thread for a regional perspective and suggest areas of intervention in order to improve the availability of medical products across borders within the region. For this purpose
there is a need to examine regional cooperation for regulation in trade of medical products to support adoption of policies for trade in quality medical products through mutual cooperation among Member countries.

Dr Slamet’s presentation was based on the concept paper to develop a roadmap aiming at strengthening mutual cooperation in SEA Region countries by developing an institutionalized training and knowledge-sharing mechanism. To do so there is a need to identify gaps in regulatory practices for pharmaceutical and medical devices in Indonesia, she reiterated. She called for Member States to work towards an action plan for capacity building in the context of Indonesia. A questionnaire approach was adopted for the paper to obtain the views of all stakeholders.

Indonesia currently has four state-owned pharmaceutical companies, about 190 local companies and 24 multinational companies. It is important to note that the pharmaceutical market in Indonesia comprises 27% of the total ASEAN pharmaceutical market. Indonesia is the only country in ASEAN where the majority of pharmaceutical products are manufactured by the national industry.

An action plan for further strengthening regulatory mechanisms for the drugs and pharmaceutical trade has been developed for Indonesia. With launching of the National Social Insurance Scheme (NSIS), including Health Insurance Scheme in 2014 to support UHC, a strategic direction was outlined for sustainability and availability of medicine and medical devices of assured quality, safety and efficacy (QSE). This strategic direction recognizes the important role of pharmaceutical industries to ensure sustainable and timely supply of essential medicines, including innovative essential medicines. This is the starting point for Indonesian pharmaceutical industries to transform from being formulation-generic based to an integrated one, with upstream activities covering end-to-end operations such as potential intermediates and active pharmaceutical ingredients (API) conducting clinical trials. This was an important aspect in the strategic direction as it improves the nation’s productivity and boosts the Indonesian economy. There is recognition of the fact that the API of the future relates to biopharmaceutical and natural products.

For access to innovated patented medicine, the presidential decrees on the utilization of patents by the Government in 2004, 2007 and 2012 regulate for antiviral and ARVs. Also, the Ministry of Health’s decree on Medicine Registration provides the criteria and requirements for the registration process for products that are still on patent protection and also the implementation of the Bolar Provision which is an exception to the TRIPs agreement in WTO. To increase access to generic versions of innovated medical products Bolar Provision should be used consistently with the timeline allowed for utilizing of a pharmaceutical patent which is two years before expiration. The revision of the patent law proposed a period of three years before expiration instead of two for this purpose.
The National Regulatory System for pharmaceutical products in Indonesia is well established, and covers regulation for pre- to post-marketing of medicine and medical devices. The critical issue is implementation, which is not optimal due to many different reasons. The obstacles in regulating medicines and medical devices to facilitate trade in Indonesia are, among others: (i) different levels of maturity in understanding and implementing the regulation and guidance among industry and regulatory staff, (ii) inefficiency in implementing regulations and guidelines, and (iii) inadequate resources, such as, well-trained staff and information technology (IT), infrastructure and capability.

This may indirectly influence capacity for pharmaceutical trade and access to products of assured quality, safety and efficacy. There is a need for development of regional harmonization by strengthening MoUs between countries with similar challenges. An improved mechanism of communication among stakeholders through a forum, strengthening national and regional capacity through regular training at the planned site of training (the WHO Global learning Opportunity (GLO)), establishing special share points involving related stakeholders, and an integrated collaborative programme to support innovation and access to pharmaceutical products at the national and regional level are suggested.

**Current status and measures taken for capacity and skill development of the National Medicines Regulatory Authority in Sri Lanka**

Consultant Ms Chinta Abayawardana explained that Sri Lanka was committed to provide free health care and full access to government health institutions. The patients who sought treatment had access to free medicines. Before 1970, there was high expenditure on medicines due to expenses for promotional activities and irrational use of medicines. In 1970, the Wickramasinghe–Bibile Commission recommended formulation of a national policy for the establishment of a state body to regulate trade. The State Pharmaceuticals Corporation (SPC) was thus established and became the single buying agency.

The selection was based on a national formulary and this also saved foreign exchange. In the post-1977 policy, permission was given to the private sector to import multiple brands while SPC continued to supply affordable drugs and was responsible for centralized procurement for the government health sector. In 1987, the Pharmaceuticals Manufacturing Corporation was established to import raw materials for manufacture of generic drugs. In the medicine regulatory system, the legislative framework consisted of cosmetic devices and drugs (CDD) Act No. 27 of 1980 (as amended by Act No. 38 of 1984, No. 25 of 1987 and No 12. of 1993); regulations under the CDD Act were published in the Gazette Extraordinary No. 378/3 of 02/12/1985, provisions to control the use of Cosmetics, Medical Devices and Medicines.
The Director-General of Health Services (CDDA) was responsible for the areas controlled under the CDD Act. These included manufacture, importation, transportation, sale (retail and wholesale), labelling, advertising and distribution of samples, and testing and disposal of outdated/defective products.

Since SPC was the procurement agency for state-sector health institutions, quantities were based on the estimates prepared by the Medical Supplies Division (MSD). Procurement by SPC was based on a worldwide tender procedure, private importers and manufacturers, as well as SPC supplied medical products to the private sector. In the private sector supply system, the medicines were either imported or locally manufactured and distributed through private supply chains: about 85% imported and 15% manufactured. No parenteral or any other sterile products were manufactured in the country and the companies involved in supplying were licensed by CDDA. The licensing conditions were that importers and wholesalers should have appropriate storage facilities, suitable vehicles and personnel to handle transport. Community pharmacies licensed by CDDA should employ at least one registered pharmacist to supervise the sale of medicines both in the wholesale and retail trade.

A National Medicines Policy (NMP) was adopted in 2005 with the major objective of ensuring the availability and affordability of efficacious, safe and good-quality medicines relevant to the health-care needs of the people in a sustainable and equitable manner.

The elements of NMP covered selection of essential medicines, affordability and equitable access, financing options, supply systems and donations, regulation and quality assurance, quality use of medicines, research, human resources, a viable local pharmaceutical industry, and monitoring and evaluation.

A National Medicines Regulatory Authority (NMRA) was established on 1 July 2015 under NMRA Act No. 15 of 2015 of the Democratic Socialist Republic of Sri Lanka. It is a statutory body managed by a Board directly accountable to the Minister of Health. The main objective is ensuring the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices. Therefore, Sri Lanka is presently in the transition period between the CDD Act and the recently introduced NMRA Act.

The problem with the WHO Certification Scheme is that the reliability of the WHO type GMP Certificate depended on the credibility of the competent authority of the issuing country. There was the question of forged GMP certificates, which needed direct communication among regulatory authorities and for which a network for communication would be ideal. This requires a GMP inspection and the availability of competent or trained inspectors to conduct such inspections.
The pharmaceutical manufacturing industry in Sri Lanka is small; there are 12 manufacturers, including one government-owned facility, and the number of products produced as on June 2014 was 131. The product range included tablets, capsules, liquids, dry powder for suspensions, and external preparations such as creams, ointments and lotions. Injectables or any other sterile products are not manufactured and all API and almost all the excipients are imported. Only the formulation of finished products is done locally and no vaccines are currently produced in Sri Lanka. R&D is minimal in the pharmaceutical sector. For the promotion of local manufacture, the Ministry of Health signed a “guaranteed buy-back agreement” with 10 local pharmaceutical manufacturing companies in July 2015. In this, priority was given to local production for state procurement. A Manufacturing Regulatory Division is to be established in NMRA to support the local pharmaceutical industry.

For new chemical entities and vaccines, Sri Lanka relied on the assessments of the medicine regulatory authorities of Australia, Japan, New Zealand, Nordic countries, Singapore, the United States of America and the United Kingdom.

During the 13th ICDRA 2008, WHO was requested to support harmonization approaches. The currently existing harmonization structures are:

- International Conference on Harmonization for Europe,
- Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries, Africa,
- Common Market for Eastern and Southern Africa,
- Southern African Development Community, Latin America and Caribbean,
- Southern Cone Common Market and Caribbean Community.

In 1992, ASEAN decided to use a common technical document and requirements to eliminate technical barriers to pharmaceutical trade among Member States without compromising safety, efficacy and quality. This helped ASEAN countries to develop mutual recognition agreements in a post-marketing alert system, GMP inspections and bioavailability and bioequivalence studies. In this Region, drug regulatory harmonization among countries within the South Asian Association for Regional Cooperation was discussed at the first international conference on pharmaceutical affairs held in Nepal which proposed promoting collaboration among drug regulatory authorities and other stakeholders by establishing a South Asian Network for Drug Regulatory Harmonization.

The cooperation and support of the Regional Office is required to prepare a roadmap for action. The government should consider the respective concerns of the Regional Office in such policy regulation and implementation.
Clinical trial regulations in India: An essential component of drug innovation

Mr Zakir Thomas, Founder Project Director, Open Source Drug Discovery, Council of Scientific and Industrial Research, Ministry of Science and Technology, Government of India, New Delhi, provided a brief historical account of the pharmaceutical industry and clinical trials development. The pharmaceutical industry is a relatively young industry, being an offshoot of the chemical industry. The discoveries of the late 19th and early 20th century such as sulphanilamide, amphetamines and barbiturates with path-breaking therapeutic effects and biologics such as insulin, led to the creation of the pharmaceutical industry in the United States and Europe. Modern clinical trials, as we know them today, emerged only in the second half of the 20th century. The regulatory regime followed and responded to the development of the industry and public health concerns. Concerns about substandard drugs in United States in the late 19th and early 20th century, such as drugs with inert ingredients led to the American Medical Association’s demand for regulation and setting up of testing units in its Council of Pharmacy and Chemistry. Only drugs tested in its laboratories were allowed to be advertised in the Journal of American Medical Association. With the enactment of the Pure Food and Drugs Act, 1906, the Bureau of Chemistry could seize adulterated drug products and this led to the establishment of USFDA.

In 1936, a company released a sulfa drug “elixir sulfanilamide” for streptococcal infections without testing the solvent either on animals or on humans. As a result, 107 people died, mostly children, before the drug could be recalled and this led to the US Food, Drugs, and Cosmetic Act of 1938. Thalidomide led to tougher testing and drug approval procedures in many countries, including the United States and the United Kingdom. These incidents drew widespread attention to clinical trials. Manufacturers were required to prove safety and efficacy of new drugs.

Post-1962 new drugs were allowed for patient use only after well-controlled trials whose results were examined by independent experts; the approvals had to be based on sound science. Further, companies had to monitor safety through post-market surveillance and were required to follow GMP that would lead to consistently safe products. Ethical principles followed as a result of international developments such as the Nuremberg Code. The World Medical Association developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects. The first version was adopted in 1964 and thereafter amended seven times; most recently in 2013.

Other international guidelines on GCP are important. GCP are an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involved the participation of human subjects. In 1968, WHO
convened a Scientific Group on Principles for Clinical Evaluation of Drugs. Another WHO group was convened in 1975 resulting finally in the WHO Guidelines for GCP for trials on pharmaceutical products to be adopted in 1995. The GCP guideline was Topic E6 ICH and the International Standard Organization was the international standard. This stated that clinical trials should be conducted in accordance with ethical principles and applicable regulatory requirements. The Guidelines detailed the roles and responsibilities of the Institutional Review Board/Independent Ethics Committee, investigator and sponsor. They also detail the objective and content of clinical trial protocol/amendments, investigators’ brochure and essential documents for the conduct of a clinical trial.

In India, regulatory developments relating to clinical trials are governed by the Drugs and Cosmetic Act 1940 and Drugs and Cosmetic Rules, 1945. The Act and the Rules regulate import, manufacture, distribution and sale, and control the safety, quality and efficacy of drugs and cosmetics.

CDSCO and the Drugs Controller-General exercise control over the import of drugs, approval of new drugs and clinical trials. Major amendments were carried out to the Rules in 2005; amending Schedule Y extensively to bring Indian regulation at par with global standards, and the 2005 Amendment facilitated global clinical trials. The Indian Council of Medical Research issued the Ethical Guidelines for Biomedical Research on Human Subjects in 2000, while CDSCO released the Indian GCP guidelines in 2001.

Consequent to intervention by the Supreme Court on allegations that an Human papillomavirus (HPV) trial was conducted without real and prior informed consent on school-going girls in the case of Swasthya Adhikar Manch vs Union of India, regulations and approval processes were further strengthened. This led to a debate in the country on whether India remained an attractive destination for the conduct of clinical trials. To ensure true voluntarism was a challenge, given the lack of knowledge and literacy and the exalted doctor status in a doctor patient relationship.

**Sample survey of Indian pharmaceutical enterprises for meeting national and global health needs**

Dr Manisha Shridhar, Regional Adviser, WHO Regional Office for South-East Asia, highlighted the important role of Indian pharmaceutical enterprises securing access to quality medicine at affordable prices. The World Health Assembly resolution WHA61.21 on GSPA identified a number of deliverables that aimed to promote new thinking on innovation, transfer of technology and access to medicines. A survey of Indian enterprises was taken up by WHO, for which the technical partner was the International Management Institute, New Delhi.
First, an analysis of secondary data of Indian pharmaceutical enterprises was carried out by Mr Deepak Goyal, Director (Statistics), Ministry of Statistics and Programme Implementation, Government of India, and the International Management Institute. The data profile was taken from the Fourth All-India Census of Micro, Small and Medium Enterprises 2006–2007 conducted by the Ministry of Micro, Small and Medium Enterprises (MSME), Government of India.

MSME data revealed that there were 16,159 pharmaceutical enterprises, including those manufacturing traditional medicine, dental and medical equipment. The following factors positively contributed to the adoption of technical knowhow in an enterprise: being an ancillary unit for another establishment; having quality certification; type – whether proprietary, company, or partnership; running year-round operation; having larger gross output; and belonging to socially benefited groups.

Limitations of secondary data were as follows: lack of information on R&D and innovation; variation in binary technical knowhow (resulting in little information); no information on attitudes (lack of qualitative information); inadequacy for mathematical modelling; and indicative/suggestive findings. For obtaining detailed information, the need for a survey to be conducted for primary data collection was thus needed.

As a result, a pilot sample survey of pharmaceutical enterprises was conducted by WHO in collaboration with the International Management Institute, New Delhi, India, to test a questionnaire in November–December 2013 at Ahmedabad and Ambala. Dr Arvind Chaturvedi, Professor of Statistics and Marketing Research of this Institute, said that the pilot survey suggested that the questionnaire had to be redesigned and samples needed to be drawn from all registered pharmaceutical units. Hence it was decided to approach pharmaceutical enterprises registered up to 31 March 2014. Therefore, enterprises registered under the Factories Act 1948 and with the Annual Survey of Industries database were also included for the sample survey.

Presently, the survey for promoting production and technology adoption in pharmaceutical enterprises for meeting national and global public health needs was ongoing: (a) to identify measures needed to promote production and technology adoption/transfer for the supply of quality medical products; (b) to develop networks for promoting access to medical products at the national and

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4 (i) Microenterprises: investment in plant and machinery not exceeding Rs 2.5 million (US$ 56,000)*, (ii) Small enterprises: investment in plant and machinery not exceeding Rs 10 million (US$ 220,000)*, and (iii) Other enterprises: with investment in plant and machinery not exceeding Rs 100 million (US$ 2,200,000)*. *Rs 45 = US$ 1 Four Groups of Enterprises were taken up relating to technical knowhow (transfer of technology). Small” and ‘Other’ enterprises together comprise medium enterprises as under the MSME Act 2006.
global levels; and (c) to identify areas/mechanisms for interventions from the Indian Government and for WHO to perform a supporting role.

On 16 September 2014, the WHO Regional Office and the Country Office for India held a meeting with Government of India officials, chaired by Mr Sudhanshu Pandey, Joint Secretary, Ministry of Commerce and Industry. A group to revise the questionnaire in accordance with the discussions was set up at that meeting. Investigators deployed for the survey have experience in conducting similar surveys for the sector/surveys organized by the National Sample Survey Organization, and they visited each pharmaceutical enterprise selected to help fill the questionnaire. The survey covers various parameters such as profile of the company, technical knowhow, R&D and innovation, licensing/legal activities, national/global marketing, storage, transportation/distribution and logistics, information on tax, and quality certification systems adopted by pharmaceutical enterprises.

It is proposed that the results of the survey be shared/validated at a national-level pharmaceutical conference, proposed to be attended by select participating enterprises and relevant authorities. It is envisaged that data from the survey would help guide policy and identify specific areas where the Government of India and WHO could promote quality medical products.

**Pharmaceutical Industry Perspective**

*Improving access to medical products – Bangladesh*

Mr Faez Ahmed, Manager (Regulatory Affairs), Incepta Pharmaceuticals Ltd., Dhaka, Bangladesh, provided a brief overview of the pharmaceutical industry in Bangladesh. The population of Bangladesh is 158.5 million (2014), and the GDP per capita is US$ 1096. Since 1 July 2015 Bangladesh has been classified as a lower middle-income country. Bangladesh has 57% of its population in the most productive stage of their life of 15–50 years. From 1970–1989 a large number of local entrepreneurs came into the pharmaceutical business. From the 1990s onwards many companies went for massive expansion of formulation products, with the country achieving almost self-sufficiency in formulation products. The total number of registered companies is 257 and the number of companies in operation is 194 (including importers). Local production meets 97% of country’s demand of drugs and imports are only 3%. Many neighbouring countries, on the other hand, import significantly from Bangladesh such as Philippines, Pakistan, and Singapore. In 2014, market size was US$ 1.46 billion and growth rate 12.13%. The market is expected to double every five years.

5 http://data.worldbank.org/country/bangladesh
Bangladesh’s pharmaceutical industries are capable of producing all types of dosage forms such as tablet, capsule, liquid preparations, dry suspension, injections, ointment/cream, nasal spray, granules in sachets, lyophilized vials, eye-drops, metre dose inhalers, large volume parenterals, pre-filled syringes etc. Bangladesh is capable of producing high-quality pharmaceutical products. The industry employs state-of-the-art manufacturing facilities, sophisticated production and analytical equipment, and highly skilled human resources. A number of pharmaceutical companies have already obtained GMP certifications from the United States Food and Drug Administration (USFDA), the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (UK-MHRA), the European Union (EU), Therapeutic Goods Administration (TGA) Australia, Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil, and MoH Turkey, etc. Bangladesh exports pharmaceutical products to 97 countries. A number of biotech products are now produced by Bangladeshi companies, such as erythropoietin, filgrastim, peg-interferon alpha 2a, human insulin, etc. Bangladesh is also capable of producing high-quality vaccines. One of the leading vaccines companies has a filling capacity of 180 million unit/year. They also have dedicated bulk production facility, R&D and animal house. Already nine vaccines manufactured by local manufacturers are available in the market.

The driving force of the pharmaceutical industry is its highly educated and skilled human resource base. Along with this the industry has the required technology and confidence to produce high-quality products. Huge expansion is taking place in the country and all major players are investing significantly for future growth.

**Means to improve quality and regional cooperation**

- Director-General of Drug Administration (DGDA) needs to be fully functional. DGDA is working to get functional status from WHO. Many guidelines have been prepared and shared with the industry. DGDA has started GMP inspection as per WHO guidelines.
- The National Control Laboratory (NCL) and Drug testing Laboratory (DTL) need to have the necessary skills and resources to test products to ensure that only high-quality products are available in the market.
- DGDA already has the required facility, machines and analysts for NCL and they need regular training and reagent supplies.
- DGDA can apply to become PIC/S member which will increase regional cooperation and will benefit the pharma industry tremendously.
- Bangladesh needs favourable environment to establish a high-quality contract research organization (CRO) industry.
Promoting cooperation for regulation in trade of medical products

Perspectives on trade of medical products, regulation, suggestions to improve quality and regional cooperation

Dr Rao VSV Vadlamudi, President, Indian Pharmaceutical Association, said that it was essential to define medical products to develop policies to regulate trade and ensure quality. Pharmaceutical products consisted of API, finished formulations, solid orals, liquid injectables, sterile products, innovator products versus generic products and biopharmaceuticals, vaccines and biosimilars. In addition, there were medical devices and diagnostics. Medical products might also encompass herbal products, traditional medical products, nutritional and dietary supplements and cosmetic products.

Each of these products brought different complexities to the table while regulating trade in medical products. To ensure that medical products of quality were made available at affordable prices to reduce human and veterinary disease burden, morbidity and mortality, and to improve quality of life, regional, economic and political barriers had to be addressed. To reach and ensure efficacy and safety to the target patient population, a drug had to go through a process: pharmaceutical product drug substance (API) + excipients + defined process = drug product (finished formulation) + suitable packaging. There were specific procedures for testing and release of drug products for marketing and for being ready to transport under defined storage conditions. All this was under defined GXPs\(^6\) for ensuring quality of products for trade.

A harmonization of all the quality standards (GXP) and regulatory requirements removed several quality-related issues. Therefore, harmonization of compendial requirements across countries participating in trade was an essential requirement. There were hurdles in achieving these objectives completely as there were different regulatory paradigms and significant cultural variations. It was important to convert non-binding “guidance” into binding regulation and have mutual recognition procedures.

Different Member States required different data due to requirements relating to the strenuous process of compendial harmonization, pharmaceutical product-related hurdles, generics vs biosimilars (quality specifications and bioequivalence necessary for approval of generics, while these were still very vague for biosimilars) and stability at widely varied climatic conditions. The herbal and traditional medicinal products needed to be identified as to their source, authenticity, standardization and efficacy markers; and there were safety concerns. This was also relevant for dietary supplements and cosmetic products.

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\(^6\) GXP is a general term for good practice quality guidelines and regulations. Three most commonly-used GXP in the pharmaceutical industry are good laboratory practices (GLP), good manufacturing practices (GMP) and good clinical practices (GCP).
Moreover, there was concern on lack of basic amenities in the supply chain in different regions. Guidelines were often vague and yet to be developed. The prime objectives were to ensure efficacy and safety to the target patient population, and understanding pharmacogenomic differences among different patient populations in responding to treatments.

Containing emerging antimicrobial resistance was another major concern for which global or regional pharmacovigilance (PV) programmes were highly essential. It is important to have sufficient measures to prevent infiltration by spurious medicines, which impacts efficacy and safety, and introduction of track and trace systems are to be implemented to establish authenticity. For this, research and regional cooperation mechanisms are needed. Research towards finding solutions for unmet medical needs of different regions; to discover drugs for orphan diseases and endemic diseases specific to regions; and to find newer agents to combat emerging drug-resistant pathogens is important. Public–private partnerships and funding for generating intellectual property (IP) that could be shared and research into developing economic and cost-effective processes to make drugs affordable are also needed.

**Pharmaceutical perspective on current status of trade of medical products, regulation and suggestions on policies and procedures to improve quality – Indian Drug Manufacturers’ Association (IDMA)**

Mr Ashok K. Madan, Executive Director, Indian Drug Manufacturers’ Association (IDMA), New Delhi, India, informed that though the Association was founded in 1961, the first pharmaceutical unit, Bengal Chemicals & Pharmaceuticals Works, was established in 1901 at Kolkata. In 1947, domestic production was about US$ 1.53 million and in 2013–2014, it was US$ 30 billion, which comprised a domestic share of US$ 15 billion and exports to more than 200 countries of US$ 15 billion.

In addition to the legislations mentioned earlier, the Food Safety & Standards Act, Pollution Control Act and the Legal Metrology Act 2009 impacted pharmaceutical industries.

In collaboration with the Department of Pharmaceuticals, the Association was conducting GMP workshops for small and medium enterprises (SME) throughout India. These workshops were conducted in association with USFDA. Additionally, a pharmaceutical analysts’ convention was being organized every year, and the industry was sensitized on the implementation of issues of track-and-trace mechanism. The Ministry of Commerce had issued public notices. Bar coding had already been implemented on the secondary and tertiary packs meant for exports. Parent and child relationship for the secondary and tertiary packs is to be implemented and uploaded on the Directorate-General of Foreign...
Trade server w.e.f. 1 October 2015. There were certain areas of concern such as multiple supply points, e.g. 80 000 wholesalers and more than 600 000 retail outlets, which made implementation of track-and-trace mechanism domestically difficult. The implementation of prices under the Drug Price Control Order 2013 was also a challenge for the industry leading to logistical difficulties in revision of prices. The implementation period was within 45 days, leading to recall of stocks. The notices of overcharging by the price regulator were cumbersome, especially if an old priced pack was recovered anywhere in the country. There was a need for rationalization of environmental laws, especially relating to capacity expansion/product basket aspects. The present environment approval times needs to be reduced from the existing average period of two years.

The government needed to pay attention to soft funding needs for SME to upgrade to WHO GMP. Clarity of sourcing was required for branded versus generic drugs to clear the present situation of uncertainty. Another aspect related to the use of PET vs glass bottles as specified by the (National Green Tribunal) raising safety/environmental issues. There was a need for customs duty rationalization to rectify an inverted duty structure. We also need to make efforts not to be over dependent on any single country for API. Non-tariff barriers needed to be addressed including the varied product registration procedures, which may take over two years. In the Regional Office, a regional platform for manufacturing practices, methods of testing, quality and harmonized product registration would be useful to identify and adopt best practices of South-East Asian countries and work towards the creation of an awareness module for stakeholders in collaboration with the Association.

**Pharmaceutical perspective – Organization of Pharmaceutical Producers of India (OPPI)**

Mr Tabrez Ahmad, Secretary-General, Organization of Pharmaceutical Producers of India (OPPI), said that OPPI had 46 member companies and were leaders in pharmaceutical innovation. The top 15 global innovator brands in 2013 were from OPPI companies and they conducted ongoing research for unmet medical needs. Since 2009, OPPI partnered with the National Institute of Pharmaceutical Education and Research (NIPER) and the Council for Scientific and Industrial Research (CSIR) to recognize excellence, with OPPI best scientists awards. The members adhered to a stringent code of pharmaceutical practices for marketing and the global current GMP.

The collaboration for improving access related to partnering with stakeholders to increase access to health care where access was defined as physical proximity, quality, functionality and affordability. OPPI promotes academia interaction with

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7 Intercontinental Marketing Services - IMS Health.
the National Institute of Pharmaceutical Education and Research, Ahmedabad, Indian Institute of Health Management Research, Jaipur, Indian Institute of Management, Trichy and others. The market share of OPPI members in the Indian pharmaceutical market was 25% while that of others was 75%, of which generics were 90% and innovator products 10% of the market share.

In 2013, the average spending on health care per capita in India was only US$ 214, which was very low compared with US$ 649 in China. The expenditure on health as a percentage of gross domestic product (GDP) was also low – 4% compared with 5.6% in China. Additionally, the figure for health-care workforce (doctors and nurses) of 1.9 per 1000 population lagged behind the WHO benchmark of 2.5 per 1000.

Therefore, it is a matter of concern that India’s health-care infrastructure and resources fell short of WHO guidelines and the global average, and the health sector has seen decades of low public spending on health care. While total spending on health care in India is about 4.1% of GDP, public spending on health care is only 1.04% of GDP. Health-care infrastructure metrics are among the lowest in the world and the limited public spending is skewed towards curative tertiary care rather than preventive, primary and secondary care. Additionally, health-care spending represents a limited amount of the budget of the states. There is a wide variation among the states, with Gujarat, Karnataka and Tamil Nadu spending more than Bihar, Madhya Pradesh and Uttar Pradesh. It is to be noted that health outcomes in the states reflected this overall spending pattern. The barriers to health-care access are: inadequate infrastructure, lack of credible and in-time information, distribution system, cultural issues, lack of financial resources, low purchasing power, price control and poor IPR protection.

It was noted that mature health systems focus on cost containment, but emerging economies could benefit from allocating additional resources for health care and treating it as an investment rather than a cost. Over the last two decades, Peru tripled its per capita health investments contributing to a rise in health-adjusted life expectancy (double the global average). The US Centers for Disease Control and Prevention (CDC) estimates a US$ 10 return on investment for every US$ 1 spent on childhood vaccinations. Investments in health care by establishing UHC can improve socioeconomic well-being and represent a factor contributing to wealth and economic productivity. In view of fiscal deficits and budgetary constraints, increased public investment in health care, as articulated in the government’s draft national health policy, must be implemented. While improved efficiency and reduced waste at the state level is a necessary condition for success, it is not sufficient, and current levels of spending in India are inadequate even if state-level spending became more efficient. There is also a need to take advantage of mobile telecommunication penetration in
the country and integrate cellular technology in health care for detection and disease management programmes.

4.3 Country presentations

Bangladesh

Major-General Md Mustafizur Rahman, Director-General, Directorate-General of Drug Administration, Ministry of Health and Family Welfare, Dhaka, said, the burden of noncommunicable diseases (NCD) surpassed infectious diseases in the country and accounted for 61% of all adult deaths. A new Drug Act 2015 and new drug policy, which included NCDs, is being developed by the NRA. The pharmaceutical industries are capable of fulfilling 97% of the country’s demands and only 3% of drugs are being imported. Bangladesh exported different dosage forms to 95 countries. Some of the companies had achieved recognition of international regulatory bodies such as United States Federal Drug Administration (USFDA), the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (UK-MHRA), European Medicines Agency (EMEA), Australian Therapeutic Goods Administration (TGA), Gulf Central Committee for Drug Registrations (GCC DR), Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency of Brazil) (ANVISA), and so on. The country produces high-quality and low-cost medicines as well as specialized products such as vaccines, insulin, biosimilars, drugs for cardiovascular diseases, hypertension, cancer, diabetes and antibiotics of international standards. Besides regular formulation products, the country also exports hi-tech, specialized products such as vaccine, insulin, anti-cancer drugs, inhalers, sprays, injectables and infusions. From 2009 to 2014, the market for pharmaceutical products had doubled.

Under DGDA, there are two drug testing laboratories: the National Control Laboratory at Dhaka (which had two wings for drugs and vaccines) and a drug testing laboratory at Chittagong. The functions of these laboratories are to test and analyse locally produced and imported drugs and vaccines, test and report pre-registration drug samples and other samples of any kind on request, and test evaluation of post-marketed drug samples. The National Public Sector Drug Procurement policy dictated that public sector medicines be purchased from EDCL\(^8\) (70%), CMSD (25%) and local sources (5%). While EDCL generally supplies Essential Drug List (EDL) drugs, the Central Medical Stores Depot (CMSD) mainly supplied non-EDL drugs and medical equipment. CMSD was the government procurement unit for all medical supplies and it operated at Chittagong port. There are extensive written Standard Operating Procedures (SOPs) following the Public Procurement Act of 2006 and the Drug Procurement Regulation of 2008,

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\(^8\) Essential Drugs Company Limited (EDCL) is a 100% state-owned pharmaceuticals company in Bangladesh.
which did not have any separate requirement for drugs. A procurement primer 1998–2003 was also used. The procurement process has greatly improved since 2010, resulting in reduced lead times (from 18 months in 2010 to 12 months currently). Nevertheless, the procurement process involved 19 steps with an overall lead time of 45–60 weeks (as opposed to a 12-week lead time for EDCL to manufacture items).

Challenges mentioned concerning procurement included “locking” of product specifications due to WHO pre-qualification requirements; difficulty to harmonize quality, budget and procurement guidelines; high bid prices due to unseen collusive practices; and difficulty in taking strong punitive measures for supplying poor quality medicines owing to 80% of the payment having already been made before receipt of the consignments.

A regional cooperation framework may contribute to move towards a pharmaceuticals harmonization scheme. The goal is to create common regulations for pharmaceutical products and medical devices in the Region, reduce barriers to trade and ensure that pharmaceutical products and medical devices penetrating the regional markets conform to safety, quality and efficacy/performance standards. Therefore, a regional cooperation framework is needed.

**Bhutan**

Mr Sonam Dorji, Drug Controller, Drug Regulatory Authority, Thimphu, explained that the Drug Technical Advisory Committee oversaw the work of the Bhutan Medicines Board and the Drug Regulatory Authority. The latter had a registration, inspection and post-marketing control division. The morbidity and mortality reports of 2014 showed the dual disease burden of both communicable and non-communicable diseases with the latter increasingly being more prevalent in the population. Free health care is a constitutional right in Bhutan. Major health coverage is in the form primary health care. Ninety per cent of medicines are provided by the government through different levels of health facilities and the list of essential drugs is periodically updated. The Global Fund to Fight AIDS, Tuberculosis and Malaria provided funds for the care of human immunodeficiency virus / acquired immunodeficiency syndrome (HIV/AIDS), TB and malaria patients and WHO and UN agencies were involved with vaccines; only pre-qualified vaccines were employed. Bhutan maintained six-monthly drug consumption reports by all the health facilities and national-level quantification was taken up annually for procurement. The maintenance of 30% buffer at district and national levels was taken up to secure the availability of medicines. For imports in 2014–2015, more than 1000 import authorizations of the value of US$ 2–3 million were issued. Six export authorizations were issued for API, as there was also one API manufacturing unit in the country.
The laws governing the supply of medicines are: the Medicines Act of the Kingdom of Bhutan 2003 and Bhutan Medicines Rules and Regulation 2012. The Bhutan Medicines Board and Drug Technical Advisory Committee is entrusted with the responsibility of ensuring the availability of medicines. They provide guidelines for product and vaccines registration and procedures for issuance of import/export authorization.

Due to Bhutan’s small market size, manufacturers are often reluctant to register and supply medicines, leading to price escalation. Cheaper medicines are selected on an annual basis through government tenders. Non-availability of drug-testing facilities in the country has resulted in drugs becoming expensive and not all the procured drugs could be tested. This leads to delay in getting test reports for medicines and an inadequate quarantine period. Due to limited funds received for GMP inspection, only high-risk manufacturers are inspected.

There is a need for promoting mutual recognition of regulatory functions to facilitate safe, quality drugs trade in the Region. Harmonization and regional cooperation is recommended for promoting mutual recognition of regulatory mechanisms, sharing of data on the status of market authorization of medicinal products, regulatory procedures among non-producing small countries of the Region, and capacity development of GMP auditing. It is also imperative to facilitate combined GMP auditing of the generic drug manufacturers in the Region.

India

Dr S. Eswara Reddy, Joint Drugs Controller of India, Central Drugs Standard Control Organization (CDSCO), presented the plan to upgrade and further develop the regulatory authority with a budget allocation of about US$ 300 million from the Central government, which includes US$ 140 million for CDSCO and US$ 132 million for state governments. The major component is to increase human resources by recruiting 1000 persons for CDSCO and 2500 for states; upgrading the infrastructure of their facilities; developing e-governance and a national drug regulatory academy.

The suggestions to address quality or other issues in the Region are to: establish contact details and prepare standard protocol for communication; share information on their strengths; update country regulators’ website; create a sharepoint; and follow uniform pharmacopoeial standards. There is a need for a platform to discuss various issues and prepare a white paper on various matters for meetings in the Region to facilitate consensus-building.

Dr V. Kalaiselvan, Principal Scientific Officer, Indian Pharmacopoeia Commission (IPC), gave an overview of the PV programme of India (PvPI) launched
in the year 2010 to monitor the safety of medicines in India. IPC functioned as a national coordination centre for PvPI since 15 April 2011. For this, there exists a suspected adverse drug reactions (ADR) reporting form, a medicines side-effect reporting form (for patients) in 10 Indian languages, a toll-free helpline and a mobile application.

Dr Om Parkash Mehta, Director, Office of the Development Commissioner (MSME), gave an outline of the Ministry of Micro, Small and Medium Enterprises schemes affecting the pharmaceutical industries, namely the “Credit Linked Capital Subsidy Scheme” for technology upgradation of micro and small enterprises. The scheme aims at facilitating technology upgradation of micro and small enterprises by providing 15% capital subsidy limited to a maximum of US$ 223 500 for purchase of plant and machinery. The maximum limit of eligible loan for calculation of subsidy under the scheme is US$ 1 500 000. The development of pharmaceutical clusters under the scheme of the Cluster Development Programme of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers is also being taken up. There is a need for more cooperation among members and the WHO South-East Asia Regional Office to intervene on time in seasonal diseases with regard to dengue, malaria, chickengunia, etc. in the region. More regional efforts and cooperation are also required to make quality medicines in time in Member States.

**Indonesia**

Ms Dita Novianti, Deputy Director, Drugs Independence and Raw Materials, Ministry of Health, Jakarta, Indonesia, and Ms Togi Hutadjulu, Director, Directorate of Therapeutic Products Production Control, The National Agency of Drug and Food Control, Indonesia, informed that the National Drug and Food Control System (NADFC) of the country was established in 2001 based on Presidential Decree No. 103/2001. This is a government agency mandated for drug and food control to promote and protect public health. This relates to ensuring safety, efficacy and quality of medicine including vaccines, according to the national and international standards, and facilitating easy access to affordable medicines that are regarded as having public health importance without compromising safety, efficacy and quality.

The Agency has 54 units, including 33 provincial offices. It has recognized functional status by WHO for vaccines regulatory system (6 functions) since 2006. The last assessment was in 2012 using the new WHO tools for vaccine, and it has had an impact not only on vaccine regulatory system but also on pharmaceutical control (producers, distributors, etc.) and led to an improved Institution Development Plan (IDP) of NADFC.
NADFC is the 41st member of PICs (2012) and has acquired ISO 9001: 2008 on Quality Management System for all 54 units (since 2012). NADFC actively participates in ASEAN collaboration.

The Agency has the mandate to conduct pre- to post-marketing control for pharmaceutical products. For the evaluation of pre-market products, the Agency is supported by the National Committee on Drug Evaluation which consists of experts in the field of clinical pharmacology, pharmacy, biology and relevant clinicians who are recruited from universities and other institutions. They sign a statement of independence (for ascertaining conflict of interest) and conduct meetings regularly to discuss the result of evaluations on the safety, efficacy and quality of drugs. For production control, the implementation of current good manufacturing practices is based on the MoH Decree No 1799/MenKes/Per/XI/2010 and Head of NADFC Regulation, which refers to the PICs standard. In terms of pharmacovigilance activities, several instruments such as MoH Decree No. 1010/Menkes/Per/XI/2008 on Drug Registration, Article No. 22, MoH Decree No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry, Article No. 9, and Head of NADFC Regulation No. HK.03.1.23.12.11.10690 of 2011 on Pharmacovigilance Implementation for Pharmaceutical Industry and its Technical Guidelines, ensure a vibrant pharmacovigilance programme.

The current challenges in controlling medical products identified relate to globalization (where barriers to trade) are reduced allowing for unfettered imports, Further, information technology, public expectations for health protection, lifestyle changes, advanced technology and risk management, universal health-care coverage, growth of the pharmaceutical industry, wholesale distribution which depends on business operator’s compliances, dependency of APIs, new drugs, and their development, public empowerment, challenges with regard to spurious/substandard/falsey-labelled/falsified/counterfeit (SSFFC) medicines and product competitiveness also impact access.

Certain focus areas for collaboration are:

- strengthening trust and capacity-building for NRA on control of quality, safety and efficacy of pharmaceutical and medical devices;
- exchange of information on policies, regulations on pharmaceutical and medical devices, implementation of flexibility related to IPR protection in order to improve access to medicines;
- establishing network on regional rapid alert system;
- facilitating transfer of knowledge and technology for local manufacturers, e.g. biotechnology medicines.
For the way forward it is proposed to enhance efficiency and effectiveness in pre- and post-market evaluation of medicines, ensure the supply chains and overseas manufacturers’ compliance with GMP and GDP, contribute to the delivery of Indonesia’s national and global public health responsibilities, collaborate with other countries through ASEAN and other neighbouring countries (e.g. SEA Region Member States) and develop a framework for joint review of dossier, joint GMP inspection, joint regional clinical trial for the regional diseases and unmet needs.

**Maldives**

Ms Aishath Mohamed, Deputy Director-General (Pharmaceuticals), Maldives Food and Drugs Authority, Ministry of Health, Malé, explained that all pharmaceutical products in the country are imported. There are 25 medicine importers – one public, State Trading Organization (STO) and 24 private parties. There are 337 pharmacies with 86 in Malé and 248 in other islands and all medicines are covered under the insurance scheme. The approved drug list had 3503 products and the essential medicine list was reviewed every two years. There are 327 generics in the Essential Medicines List 2013. The majority of medicines are covered under the insurance scheme and there is an Memorandum of Understanding (MoU) between the Ministry of Health and the State Trading Organization to open pharmacies in remote islands where there were no pharmacies at all and to supply essential medicines and consumable to all health facilities in Maldives. STO had opened 163 pharmacy outlets in total. Medicine regulation covered import, distribution, storage and sales of medicines and SOP were available for pharmacies/medicines, registration of warehouses and pharmaceutical products, clearance of pharmaceuticals at the port of entry, and pharmacy inspection. Only medicines in the approved drug list could be imported and sold. A number of issues affected availability such as company transfer or merging process; subcontracting; lack of an efficient procurement system; lack of market exclusivity; too many importers and pharmacies; and lack of qualified human resources.

Recommendations for a regional cooperation framework are: networking among the regulatory authorities in information exchange regarding medicine regulatory issues; information-sharing among the regulatory authorities (product registration, GMP inspections, product alerts, identified quality defects of products); and facilitation in identifying regional laboratories for testing pharmaceuticals for countries such as Maldives. The regional framework should include a provision that countries such as Maldives with zero manufacturing capacity could establish an efficient procurement system and procedures in order to ensure uninterrupted supply of essential medicines and contacts in facilitating the import of medicines in emergencies.
Myanmar

Dr Tin Wah Wah Win, Deputy Director (Drug Control), Department of Food and Drug Administration, Ministry of Health, Naypyitaw, stated that the Central Medical Stores Depot (CMSD) procures all essential medicines. The state and regional health departments procured medicines from government manufacturers and importers do so from the private sector. Procurement of pharmaceutical products, medical devices and equipment from CMSD is rising over the years. The types of pharmaceutical licences issued were: product licence (drug registration certificate), importer’s licence (import approval certificate), manufacturers licence and drug-seller’s licence (retail, wholesale). Drug registration was done by review of dossiers (in line with ASEAN Common Technical Dossier (CTD)), laboratory analysis and confirmatory clinical trials. Without registration, drugs cannot be imported or sold and inspection of manufacturers, importers and distributors (complying with GMP, GSP, GDP) is taken periodically. To protect the public from unsafe drugs, there is the 1972 Public Health Law and 1992 October National Drug Law amendment (2014).

Most of the drugs and devices are imported; only some essential drugs are manufactured. NRA has to perform all functions for quality assessment. Therefore, a regional regulatory platform will support maintenance of the quality of drugs. There is a need for e-procurement tools and equipment to establish a procurement information system for collection and monitoring procurement statistics.

Nepal

Dr Som Nath Aryal, High-Level Policy Adviser (Drug Regulator), Ministry of Health and Population, Kathmandu, stated that Nepal manufactured limited pharmaceutical products, and imported the rest. The total brands available in Nepal are 8831 foreign and 6416 domestic, with a total market value of US$ 298 000 000, of which approximately two thirds was imported. The drug regulatory body had guidelines, acts and procedures for import and export of pharmaceutical products. Any Nepalese drug wholesale firm registered with the Department of Drug Administration authorized by the foreign manufacturer could apply for drug import registration. The Drug Act 2035 (1978) prohibited the misuse or abuse of drugs and allied pharmaceutical materials, as well as false or misleading information relating to efficacy and use of drugs. The National Drug Policy 1995 promotes the rational use of drugs and the establishment of a drug information system. The existing regulations are: Regulation on Constitution of Drug Consultative Council and Drug Advisory Committee 1979, Drug Registration Regulation 1981, Drug Investigation and Inspection Regulation 1983, Drug Standard Regulation 1985, Codes on Drug Manufacturing 1984, Codes on Drugs Sale and Distribution 2014, Hospital Pharmacy Guidelines 2013, new import provisions 2014 and drug donation guidelines., These cover the safety, efficacy, quality and availability of medical products.
The Department of Drug Administration was established in 1979 under the Ministry of Forests. This department was later incorporated under the Ministry of Health in 1983 and has three branches at Biratnagar, Birgunj and Nepalgunj. The National Medicines Laboratory (NML) was brought under the Ministry of Health in 1993 to function as the national quality control laboratory. The Nepal Pharmacy Council Act 2000 came into effect from January 2001.

The identified constraints are: no functional electronic drug management information system to monitor consumption; stock-outs; expiry and improvement of quantification; insufficient storage space and poor storage conditions; no prequalification of suppliers; lack of adequately trained human resources, including pharmacists, to deal with drug-related matters at district level hospitals; and inadequate infrastructure and resources.

A regional cooperation framework would be useful for pooled procurement, setting up international reference price, and harmonizing regulations, including: evaluation, licensing, inspection, laboratory testing, health technological products, bioequivalence, biologicals, technology transfer/common facility centre. It is also important to continue the provisions for TRIPS waiver and Doha Declaration on the TRIPS Agreement and Public Health for access to affordable products.

Sri Lanka

Dr PDSP Dissanayake, Deputy Director, National Medicine Regulatory Authority, Sri Lanka, said that the regulatory framework (NMDRA) working authority is in transition. A new category of products has been introduced – “borderline products: products having combined characteristics of medicines and foods, medicines and medical devices or medicines and cosmetics”. In classifying these, the points for consideration are the intended use, level of efficacy and concentrations of API, and therapeutic claims.

Sri Lanka is known to the world for providing cost-effective health care free of direct cost to the patient, as the Ministry of Health is the main stakeholder, providing stewardship to health services. Sri Lanka has a dual burden of disease, both communicable and noncommunicable. NCDs are the leading cause of mortality, morbidity and disability at present (causing approximately 71% of annual deaths). In 2014, the Government spent US$ 272 000 000 on medical products, of which 85% was imported and only 57 products procured from local manufacturers.

To ensure the availability of pharmaceutical products, there is a list of selected products with the number of registered products, name and country of selected manufacturers. The level of care, and the second determinant (the level of care/classification of hospitals) is defined as follows:
Level 1 = Primary medical care units (central dispensaries, maternity homes)
Level 2 = Divisional hospitals (district hospitals, rural hospitals, peripheral unit)
Level 3 = District base hospitals, district general hospitals
Level 4 = Provincial general hospital, teaching hospital.

The drug regulatory authority has SOPs for registration of pharmaceutical products; issuance of manufacturing, wholesale, sample import, personal user and transport licences; formulation approval letter, duty waiver for packaging material/raw materials and recall of pharmaceuticals.

In the import and export of pharmaceutical products, the major challenge is quality failure. For this, certain solutions proposed are requesting a National Drug Control Authority certificate in case the failure is provincial and to verify the certificate. The other provision that might be developed through regional cooperation is requesting for a hotline for verification of the medical product from its source.

**Thailand**

Dr Yuppadee Javroongrit, Expert on Pharmaceutical Standards, Bureau of Drugs, Food and Drug Administration, Ministry of Public Health, Nonthaburi, explained the role of the country in global/regional cooperation for regulation and gave an overview of ASEAN – Regulatory Harmonization Scheme.

She said that the scope of global/regional regulatory harmonization/convergence/ cooperation is vast. This was taking place for technical, guideline, procedure, and coverage issues: New chemical entities (NCEs), generic, herbal medicines topic-wise GMP inspection, drug evaluation, Pre-qualification of Medicines Programme) certification (PQP)-vaccine, Developing Country Vaccine Regulators’ Network (DCVRN), and through WHO (>190 countries). Moreover, there were a number of initiatives, such as International Conference on Harmonization International Conference on Harmonization (ICH) (EU, Japan, United States), Regulatory Harmonization Steering Committee (Asia-Pacific Economic Cooperation-Life Sciences Innovation Forum (RHSC (APEC-LSIF)), Pan American Network for Drug Regulatory Harmonization (PANDRH), Southern African Development Community, Gulf Central Committee for Drug Registrations (GCC DR), and BIMST-EC (South Asia). It was important to note that this was not an easy process as ICH, which began in the 1990s, was still continuing with the process.

Different processes are taken up in these initiatives, e.g. the RHSC/APEC-LSIF with the aim of capacity-building/strengthening and regulatory convergence through a “roadmap” that involve the following:
Promoting cooperation for regulation in trade of medical products

- Roadmap on medicinal product/vaccine, which relates to the MRCT and GCP inspection roadmap (Japan and Thailand), promotes harmonization and convergence of regulatory pathways for biotherapeutic products (South Korea), advanced therapies (cell and tissue therapy) and MRCT Centre of Excellence (Singapore).

- Roadmap on medicinal product/vaccine and medical devices is for good review practices on medical products (GRevP) (Chinese Taipei) and to promote regulatory convergence of combination products.

- Roadmap for overall regulation is global medical product integrity and supply chain security (United States) and to promote regulatory convergence for PV (South Korea).

The ASEAN community also supports the process through the political, economic and sociocultural community. Thailand recommended development of regional cooperation based on mutual needs and benefits. She suggests certain priority cooperation areas considering issues common to the Region. These should include consideration of the following:

- public welfare and facilitation of trade,
- avoiding duplication and utilizing existing regional/global cooperation,
- emphasizing important good practices such as (GCP, GMP, GRegP, GRevP, GSubP), and thereby not re-inventing the wheel.

It is important to keep in mind that all countries had limited resources (personnel, finance, time). The cooperation of regulatory authorities for facilitating trade should not compromise the quality, safety and efficacy, should be of mutual benefit, and help enhance the patient’s accessibility to medical products. Select activities that may assist for regional cooperation are:

- platform for regular meeting and communication including a stand-alone one at ICRDA; and
- capacity-building and strengthening activities such as remote training and face-to-face workshops.

Thailand presented the scenario of the dual burden of diseases with an increasing burden of NCDs. Availability and information on source of pharmaceutical products for disease burden and UHC is of concern. The government sector procurements are done by the National Health Security Office for medicines in the essential drugs list, and for regional/provincial/community hospitals by the group purchasing at various levels. The price negotiation for imported branded medicines is done at the central level. The country requirements for pharmaceutical products were fulfilled by imports (71%) and the rest by local production. The regulatory agency has a Drug Act that governs the function

Certain challenges to be addressed are the need to take up the issue of access to new drugs due to patent laws, increasing workloads under the government downsizing policy, high expectation on speed/deregulation from the Government, e.g. Licensing Facilitation Act, B.E. 2558 (2015), and lack of expertise both in terms of in-house and external facilitation. A need to implement an international strategy towards collaboration with neighbouring countries in the Region is required for building and strengthening capacities for regulatory authorities. Initiating a platform for an annual meeting on medical products, developing close cooperation within WHO and providing support to SEA Region Member States to attend and be present at International Conference of Drug Regulatory Authorities (ICDRA) should be taken up as initial steps in this direction.
Recommendations

There is recognition that cooperation among Member States is becoming important due to the complexity of medical products (pharmaceuticals, biologicals, vaccines, diagnostics and medical devices). Further, access to these medical products is influenced by trade and regulations at national and international levels. Existing and new multilateral and bilateral trade agreements also influence access to medical products. Moreover, movement of medical products across boundaries is increasing and is further influenced by the use of the Internet, resulting in further challenges over quality, safety and efficacy concerns. These resulted in greater demands on the regulators of these medical products, as a wide range of activities had to be performed by them. In addition, it was recognized that there was inadequate communication among regulatory authorities.

The resources available with Member States and regulating agencies are limited. Therefore, all regulatory functions might not be delivered optimally. In order to optimize decision-making processes, it would be judicious to focus and build capacity while also relying on other regulators’ work. Harmonization and convergence alone would not yield optimal results; however, they could form a solid basis for a new regulatory paradigm to evolve in the future. (In this context, convergence implies having the same guidelines across national boundaries, good regulatory practices and promoting consistency while harmonization is considered a subset of this. Unlike the SEA Region, other regions had economic blocs where they covered these issues. Steps had to be taken to develop a framework for strengthening mutual regulatory cooperation among Member States in the Region against this background.

Taking stock of the absence of a network for regulatory cooperation within the SEA Region, participants support the establishment of a network to enhance information exchange and capacity-building with a view to encouraging the adoption of international standards and best practices and more effective use of regulatory resources.

Participants support the idea of convening an annual meeting with a focus on matters that relate to the mandates of NRA as
a first step in exploring mechanisms and areas of enhanced collaboration as a matter of public health priority. They noted a number of areas of potential collaboration as part of a pragmatic, step-wise approach.

Member States decided that a regulatory network was needed, as most of the countries in the Region had limited resources, and a regional regulatory network would support the role of the national NRA to ensure quality, safety and efficacy of medical products in a timely and efficient manner.

The objective of this network would be to improve access of quality, safe and efficacious medical products in the Region through building trust and sharing regulatory information. The scope of the network comprises the following:

- Information-sharing on policies, standards, procedures, processes and products
- Capacity-building, e.g. training, and identification of focal points.
- Working towards the same perception on regulatory standards requirement.

**Recommendations for Member States**

The following recommendations were made for Member States:

1. Member States must contribute to the development of a network for the SEA Region for access to safe and quality medical products by learning from other experiences of other networks such as the Association of South-East Asian Nations (ASEAN) and Regulatory Harmonization Steering Committee (RHSC) of the Asia-Pacific Economic Cooperation (APEC).

2. Member States must ensure that the Regional Office must continue to arrange annual meetings of the interim network until the official network is established.

3. Member States must continue discussions on the priority needs of the Region and address some of the specific needs and concerns of Member States after establishment of the interim regional network and share the progress of the implementation during the next meeting.

4. Member States must discuss and formalize potential priority needs such as good manufacturing practices (GMP) inspections, good clinical practices (GCP) inspections, and pharmacovigilance (PV) and other regulatory activities that support access to and affordability of medicines in the Region.
5. Member States must share progress on best practices with each of them and provide a relevant contact within their countries through the interim focal point/s of the regional network.

6. Member States must organize the next meeting of the interim regional network to develop the concept paper and, possibly, a draft resolution before the Sixty-ninth Session of the Regional Committee.

**Recommendations for WHO**

The following recommendations were made for the Regional Office:

1. The Regional Office must support and facilitate the establishment of designated focal point(s) from each Member State for this process as well as for the next meeting. The Regional Office will also consider inviting participation from similar regional networks to discuss the inputs for the Sixty-ninth Session of the Regional Committee. The list of focal points designated at the meeting is provided in Annex 3.

2. The Regional Office must act as the secretariat to facilitate this process.
Annex 1

Address by Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia

I warmly welcome you to this regional meeting for “Promoting cooperation for regulation in trade of medical products”. Improving delivery and access is vital for health system strengthening and is an important element – Element 6 of resolution WHA61.21 on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) which, as many of us are aware, has been extended by Member States in WHO until 2022 by resolution WHA68.35 of the Sixty-eighth World Health Assembly.

GSPA is an expansive instrument for action and encompasses many aspects and programmes for public health. This is why the GSPA resolution is quoted in a number of WHA resolutions in diverse domains. For example, in 2009, resolution WHA62.13 for promoting policies on innovation and standard settings to ensure quality, safety and efficacy of traditional medicines referred to GSPA. Again, in 2010, GSPA was mentioned in resolutions WHA63.21 on WHO’s role and responsibilities in health research; WHA67.20 on regulatory system strengthening for medical products; WHA67.22 for access to essential medicines and WHA67.25 on antimicrobial resistance.

This regional meeting seeks to promote cooperation for the regulation of trade of medical products for the safety, quality and efficacy of medicines and other health products, coupled with adherence to GMP and effective supply chain management, critical components of a well-functioning health system. The relevant aspects relate to “developing actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals”. The GSPA Element 6 also encourages pooled procurement mechanisms and promoting competition to improve availability and affordability of health products consistent with public health policies and needs. This also calls for an increase in information among policy-makers, users, doctors and pharmacists regarding generic products. The desirability of mutual cooperation among Member States in the South-East Asia Region through trade in medical products also came up during the national GSPA assessments such as the detailed one done by Sri Lanka.

This regional meeting is timely and important for many reasons. Member States of the Region deliberated on World Health Assembly resolutions relating to substandard/spurious/falsely-labelled/falsified counterfeit medical products (SSFFC) including resolution WHA59.26, which highlights the consequences of international trade on public health and encourages Member States to generate
and share evidence for developing policies and strategies related to trade and health.

As you are all aware, the South-East Asia Region is a major supplier and consumer of medical products including drugs, vaccines and diagnostics. The utilization and supply of generic medicines dominate the regional market and many countries such as Bangladesh and India are notable suppliers. Many Member States in the Region, in particular, countries that source generic drugs, have requested initiation of a dialogue on trade aspects for ensuring quality cross-border supply. Moreover, in the changing scenario of global trade, a product for health may be created in one place, but consist of components or services procured from various countries. This is also true for API, which are key components for drug production. In this scenario, concerted action and developing mechanisms for maintaining health product standards is important to ensure consistent implementation of adequate and well-defined regulations across borders to maintain quality and standards as well as proper management of supply chains.

Many of these issues came up for discussion at the latest 16th ICDRA, which highlighted the impact of globalization and free trade agreements on health products. New developments place heavy demands on the regulatory systems of all countries. The expansion of markets and development of cutting-edge health and health-care technologies, improvement and sophistication of products and extensive use of the Internet contribute to public health complexities. At this meeting, participants from the Region expressed a need for holding discussions on a regional platform to jointly address issues of national and international importance to enable active collaboration for public health.

Our Region has taken the lead in the global public health debate on many aspects, and we hope the active involvement of Member States of our Region will result in and give rise to significant collaborative mechanisms in the short and long term. I am happy to note the presence of international and national experts, senior public health officials from the ministries of health and trade from our Member States, experts from government and academic institutions, representatives from various organizations interested in public health issues and WHO national focal points. We hope the presence of pharmaceutical organizations will spur efforts for affordable health products for all.

This meeting is being held at a time when world attention is focused on public health. As you are aware, we faced significant threats from the Ebola epidemic. We are also in the process of setting our health priorities for the future through the Sustainable Development Goals designed to follow up on the Millennium Development Goals. I hope this consultative process would promote discussion and develop regional consensus and collaborations with a global perspective.
I am happy to note that we have participation from the ministries of health and also from other ministries such as trade and commerce and representatives of pharmaceutical associations from Member States of our Region.

I understand that the subject matter for this Regional meeting for promoting cooperation for regulation in trade of medical products relates to strengthen regulation of medical products, develop and improve tools to assist regulatory work; facilitate communication and very importantly to promote harmonization among regulatory authorities in the context of trade of medical products. Since trade takes place at both national and international levels, regulatory practices influence national and international availability of medical products. Proliferation of illicit medicines and spurious medical products is a problem, and experience has shown that combating this issue requires active engagement not only of the regulatory authorities, police and the customs in various countries but also of health professionals, manufacturers, wholesalers, retailers and consumers’ organizations.

In India, we are proud that a country as diverse as ours has made remarkable achievements in the areas like polio elimination, despite the fact that health is a subject allotted to States in the Indian Constitution. Items such as population control, medical education, medical professions, prevention of spread of infectious diseases across States and vital statistics including registration of births and deaths, fall in the Concurrent List of the Indian Constitution. Food and drugs are also included in the Concurrent List and as such, the Central Government is jointly responsible for enactments related to matters on food and drugs.

There should be no doubt that a vibrant regulatory structure is key to deliver on health outcomes. To quote from our draft National Health Policy, 2015, “This will entail moving away from reactive, voluminous, poorly implemented regulatory regimes, cobbled up in an ad-hoc manner to a more effective, rational, transparent and consistent regime. The regulatory levers need to be wielded, far more consistently and effectively to meet the challenges associated with health care throughout the country, safeguarding the public interest as well as encouraging private initiative”.

We are aware that regulatory systems have to be at par with international standards and aligned with WHO and other relevant international guidelines.
Post-market surveillance programme for drugs, blood products and medical devices need to be strengthened to ensure a high degree of reliability and to prevent adverse outcomes due to low quality and/or refurbished devices/health products. Building capacities in line with international practices in our regulatory personnel and institutions is our highest priority.

India is known as the manufacturing hub and pharmacy of the world with exports to over 200 economies. The Indian pharmaceutical industry is the third largest in the world by volume and the 10th in terms of value. The total size of the Indian pharmaceutical industry is about US$ 33 billion, of which exports account for about 55%. However, currently we are majorly into manufacturing of drugs. Though we are making rapid progress in manufacturing some of the medical devices, we are largely dependent on imports. The Indian medical devices sector has the potential to grow into a US$ 50 billion industry by 2025 provided the requisite ecosystem could be created.

In order to provide the requisite ecosystem to the pharmaceutical industry and to ensure more effective regulatory controls, we are in the process of amending the Drugs and Cosmetics Act 1940. A Drugs and Cosmetics (Amendment) Bill 2015 has been drafted, which is likely to be introduced in the Winter Session of Parliament. The Bill contains a separate chapter on medical devices so that devices could be dealt with in a distinct manner. The Bill also includes provisions for conduct of clinical trials and is aligned with the best practices globally.

We are aware that to ensure the safety, efficacy, and quality of drugs and medical devices and cosmetics that are manufactured, imported, or sold, a dynamic regulatory regime is essential to safeguard the public from substandard or unsafe drugs and medical devices and to ensure the Indian pharmaceutical industry’s global and domestic reputation and leadership. Recognizing the need for a more robust drug regulatory system across the country, both at the central and state levels, the Government has recently approved a proposal to invest US$ 275 million in next three years for strengthening the drug regulatory system in the country.

One of the challenges to ensuring access to free drugs and diagnostics though public services is the quality of public procurement and logistics. Public procurement and distribution, when well done, as our states of Tamil Nadu, and more recently Rajasthan, have shown, reduces out-of-pocket expenditures on account of drugs and diagnostics considerably and increases access while limiting irrational prescription practices. Quality assurance of a very high order has also been demonstrated to be possible in such systems.

The availability of drugs and medical devices also requires corresponding industrial growth and trade policies. The Indian pharmaceutical industry has
established itself as a leader in the production of generic drugs and indeed a large part of the drugs used not only in developing countries, but also in developed countries, are Indian generics. We recognize the importance of an appropriate alignment of our policies in trade, commerce, industry and science and technology and external affairs so that these are in consonance with the public health goals of access to new drugs at affordable rates and sustaining our advantage in generics.

India needs to contribute to international health and leverage our strengths in frugal innovation in the area of pharmaceuticals, medical devices, health-care delivery and information technology to assist other nations to improve access to essential health commodities at much lower costs. For this, we need to examine the health priorities of the developing world, for improving quality of care, for better facilitation as well as regulation of the private sector and also towards advocacy for increasing public investment in health.

We recognize that we need to build alliances with nations in similar situations to develop trade and intellectual property rights regimes that are supportive of national economic growth and health-care priorities, particularly access to safe, efficacious and affordable medical products. We are happy to work together with multilateral institutions such as WHO for an implementation framework for this purpose.

We live in an increasingly interdependent and transforming world. More changes have taken place in all spheres in the past few years than in previous decades. Trade factors and agreements such as the World Trade Organization are influencing public health in access and development of medicines and medical products and their regulation across boundaries. Moreover, access for health and food products through e-commerce and Internet has resulted in new paradigms for which we need legal instruments and capacity-building in countries.

I hope that this meeting will bring out the best ideas to formulate appropriate, practical and sustainable outcomes. I eagerly look forward to your recommendations and I wish you all the best for a very productive meeting.
# Annex 3
## List of focal points

<table>
<thead>
<tr>
<th>Country</th>
<th>Designation</th>
<th>Contact number</th>
<th>Contract address</th>
<th>Website and email</th>
</tr>
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<tbody>
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<td>Drug Controller</td>
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</tr>
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Annex 4

Agenda

1. Opening session
2. Review trade/market and related regulatory framework for medical products
3. Review current status of bilateral and/or regional trade agreements and potential implications of the international trade agreements, including on intellectual property rights relating as a whole to access to medicines, drug regulatory framework, and the pharmaceutical industry
4. Industry presentations on trade in quality medical products
5. Trade/supply of vaccines – processes applicable from vaccine cross-border movement to supply of medical products
6. Evolve consensus on action and opportunities for strengthening cooperation on regulation of trade in medical products
7. Conclusions and recommendations
8. Closing session
Annex 5
List of participants

Bangladesh
1. Ms Nazneen Begum
   Additional Secretary
   Ministry of Commerce
   Dhaka
2. Major General Md Mustafizur Rahman
   Director-General
   Directorate General of Drug Administration
   Ministry of Health and Family Welfare
   Dhaka

Bhutan
3. Mr Dophu Tshering
   Joint Director
   Department of Trade
   Ministry of Economic Affairs
   Thimphu
4. Mr Sonam Dorji
   Drug Controller
   Drug Regulatory Authority
   Thimphu

India
5. Dr Shailendra Kumar
   Director (Drugs)
   Ministry of Health and Family Welfare
   New Delhi
6. Dr Om Parkash Mehta
   Director (MSME Policy)
   Ministry of Micro, Small and Medium Enterprises
   New Delhi
7. Mr RG Singh
   Under Secretary (Drugs)
   Ministry of Health and Family Welfare
   New Delhi
8. Dr S Eswara Reddy
   Joint Drugs Controller of India
   Central Drugs Standard Control Organization
   New Delhi
9. Mr Ankit Sharma
   Assistant Drug Controller (I)
   Central Drugs Standard Control Organization
   New Delhi

Indonesia
10. Ms Dita Novianti
    Deputy Director
    Drugs Independence and Raw Material
    Ministry of Health
    Jakarta
11. Ms Yenni Hernawati
    Head of Section (UN Bodies)
    Directorate APEC and International Organization Cooperation
    Ministry of Trade
    Jakarta

Maldives
12. Ms Aishath Mohamed
    Deputy Director General - Pharmaceuticals
    Maldives Food and Drug Authority
    Ministry of Health
    Malé
13. Mr Abdul Raheem Adam
    Director
    Ministry of Health
    Malé
Myanmar

14. Dr Tin Wah Wah Win  
Deputy Director (Drug Control)  
Department of Food and Drug Administration  
Ministry of Health  
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15. Mr Lwin Myo Zaw  
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Department of Trade  
Ministry of Commerce  
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16. Dr Som Nath Arjyal  
High-Level Policy Advisor (Drug Regulator)  
Ministry of Health and Population  
Kathmandu

17. Mr Balkrishna Khakurel  
Director-General  
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Ministry of Health and Population  
Kathmandu

Sri Lanka

18. Dr PDSP Dissanayake  
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National Medicine Regulatory Authority  
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19. Mr PGK de Silva  
Pharmacist  
National Medicine Regulatory Authority  
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20. Dr Yuppadee Javroongrit  
Expert on Pharmaceutical Standard  
Bureau of Drugs  
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21. Ms Pornpimon Chantrakunapars  
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22. Ms Suhoung Thitisatthayakorn  
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23. Ms Pattawadee Orkoonsawat  
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Drugs Controller General of India  
Central Drugs Standard Control Organization  
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National Agency of Drug and Food Control  
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33. Ms Dwiana Andayani  
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34. Ms Chinta Abayawardana  
Demalagama  
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37. Mr Ashok Kumar Madan  
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Indian Drug Manufacturers’ Association  
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Organization of Pharmaceutical Producers of India  
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39. Dr V Kalaiselvan  
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WHO Regional Office for South-East Asia, New Delhi, India

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Regional Adviser  
Essential Drugs and Other Medicines

44. Dr MRN Abeysinghe  
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Immunization Systems Strengthening

45. Dr Martin Eisenhawer  
TIP- Vaccine Quality and Management

46. Dr Anita Kotwani  
TIP–Essential Drugs and Other Medicines

**WHO country offices**

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

49. Dr Nima Asgari-Jirhandeh  
Public Health Administrator  
WHO-Thailand
Cooperation among Member States is becoming increasingly important due to the complexity of medical products (pharmaceuticals, biologicals, vaccines, diagnostics and medical devices), globalization, supply chains, and growing public expectations.

Access to medical products is influenced by regulatory requirements at national and international levels. The member states in South East Asia region recognize each country is evolving, developing and strengthening their regulatory mechanisms to provide quality pharmaceutical products to achieve the goal of Universal Health Coverage based on national norms and public health needs. During “Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products” at WHO-SEARO, New Delhi, India, 22 to 24 September 2015, the member states felt there is an immediate need to develop a regulatory affairs network for cooperation as most of the countries in the region have limited resources. A Regional regulatory network will create a platform for enabling cooperation and support for quality, safe and efficacious medical products in a timely and efficient manner. Formation of similar regional networks, sometimes defined by economic or political frameworks, is common in many other regions of the world such as the Americas, Africa, the Gulf, Asia-Pacific (APEC), ASEAN region and the European Union.

The representatives at the Regional Meeting supported establishing a network to enhance information exchange and capacity building with a view to encouraging the adoption of international standards, best practices and effective use of regulatory resources. They noted a number of areas of potential collaboration as part of a pragmatic, step-wise approach. Participants supported the idea of convening an annual meeting with a focus on matters that relate to the mandates of National Medicines Regulatory Authorities as a first step in exploring mechanisms and areas of enhanced cooperation as a matter of public health priority.