



# 1<sup>st</sup> World Conference on Access to Medical Products and International Laws for Trade and Health

*in the context of the 2030 Agenda for  
Sustainable Development*

21–23 November 2017 | New Delhi, India





**1<sup>ST</sup> WORLD CONFERENCE ON ACCESS TO MEDICAL PRODUCTS  
AND  
INTERNATIONAL LAWS FOR TRADE AND HEALTH**  
*in the context of the 2030 Agenda for Sustainable Development*



**Ministry of Health & Family Welfare, Government of India, Indian Society of International Law and World Health Organization Country Office for India**



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## Acknowledgements

Access to medicines is a critical factor for success of the 2030 Sustainable Development Agenda (SDG Agenda) that aims to ensure healthy lives and promote well-being of all people of all ages. The main objective of the Conference is exchange of knowledge and to expand understanding on contemporary issues in international trade laws and research and innovation for access to medical products to achieve SDG 2030 agenda.

The World Health Organization would like to thank the following for their support and contribution to the 1<sup>st</sup> World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development:

- Ministry of Health and Family Welfare, Government of India
- Indian Society of International Law
- World Health Organization
- Translational Health Science and Technology
- Biotechnology Industry Research Assistance Council
- Indian Council of Medical Research
- Research & Innovation Systems in Developing Countries
- Ministry of Science and Technology
- Ministry of Chemicals and Fertilizers
- Ministry of Commerce and Industry
- Ministry of Law and Justice
- Ministry of External Affairs
- Ministry of Micro Small and Medium Enterprises
- Ministry of Electronics & Information Technology
- Ministry of Culture, Government of India



### **Overall Leadership and Guidance from Ministry of Health and Family Welfare**

- Ms Preeti Sudan, Secretary, Ministry of Health and Family Welfare, Government of India
- Dr RK Vats, Additional Secretary, Ministry of Health and Family Welfare, Government of India

### **Organizing Committee:**

- Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India - Chairman (Working Group)
- Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India
- Mr DN Sahoo, Deputy Secretary, Ministry of Health and Family Welfare, Government of India
- Mr RG Singh, Under Secretary, Ministry of Health and Family Welfare, Government of India
- Dr Eswara Reddy, Joint Drugs Controller India, CDSCO, Government of India

### **Conference Secretariat:**

#### *World Health Organization*

- Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights & Trade and Health, WHO SEARO
- Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India
- Ms Preeti Kharb, Consultant, WHO Country Office for India
- Ms Neha Juneja, Consultant, WHO Country Office for India

#### *The Indian Society of International Law:*

- Dr SK Verma, Secretary General
- Mr Vinai Kumar, Associate Professor
- Ms Parineet Kaur, Assistant Professor

### **Inputs received from World Health Organization:**

- Dr Henk Bekedam, WHO Representative to India
- Dr Prakin Suchaxaya, Coordinator, Health Systems, WHO India
- Dr Hilde Renne Susanne De Graeve, Team Leader, Health Systems, WHO India
- Ms Michele Yvone Vanderlanh Smith, WHO Country Office for India
- Dr Sue Hill, Director, Essential Medicines and Health Products, WHO, HQ

### **Grateful for overall Support:**

#### *Ministry of Health and Family Welfare and Ministry of Science and Technology:*

- HE Mr JP Nadda, Honouable Union Minister, Ministry of Health and Family Welfare, Govt. of India
- HE Mr Ashwini Kumar Chaubey, Hon'ble Minister of State, Health & Family Welfare, Govt. of India
- HE Ms Anupriya Patel, Hon'ble Minister of State, Health & Family Welfare, Government of India
- Dr Soumya Swaminathan, Secretary, Department of Health and Research & Director General, Indian Council of Medical Research, Government of India
- Dr Gagandeep Kang, Executive Director, Translational Health Science and Technology Institute, India
- Dr Renu Swarup, Senior Adviser, Department of Biotechnology (DBT) and Managing Director, Biotechnology Industry Research Assistance Council (BIRAC)

#### *National Institution for Transforming India (NITI) Aayog, Government of India:*

- Dr VK Paul, Member, NITI Aayog

#### *The Indian Society of International Law:*

- Dr EMS Natchiappan, President, Indian Society of International Law

*World Health Organization:* Dr Poonam Khetrpal Singh, Regional Director, WHO SEARO





# **1<sup>st</sup> World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development**

**21-23 November 2017**

## **Executive Summary**

### **I. Introduction**

The Ministry of Health & Family Welfare, Government of India, Indian Society of International Law (ISIL) with the support of WHO organized the “**1<sup>st</sup> World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development**”. The conference was a sequel to the side event on the subject hosted on 24 May 2017 of the 70<sup>th</sup> World Health Assembly.

The Sustainable Development Goals are the first ever comprehensive globally-agreed development plan for our entire planet. They are the world’s to-do list for a fairer, safer and healthier world by 2030. The health goals in the SDGs build on the unfinished business of the MDG era (such as on HIV, tuberculosis and malaria) and adds new targets, such as non-communicable diseases, universal health coverage. Trade and globalization have contributed to international and national movement in medical, food and health products across boundaries resulting in new challenges in the public health spectrum.

The United Nations (UN) High Level Report on access to medicines is proposed to be discussed in a special session in the UN 2018. The Conference in New Delhi enabled deeper discussions for development of a holistic view on access to medicines (including all medical products: medicines, vaccines, devices, and diagnostics).

The present overarching ambit of the SDG agenda and the significant role of international engagements particularly trade and contemporary political developments in national countries make it imperative to engage for tangible solutions. Of the 17 SDGs, Good health and well-being finds direct mention in Goal 3. The latter however, is a prerequisite for almost all other SDG goals. Universal health coverage and the interlinked agenda of access to medicines, is also one of the regional flagship priorities in the WHO South East Asia Region.

### **II. Objective**

The main objective of the Conference was to exchange knowledge and expand understanding on contemporary issues in international trade laws and research and innovation for access to medical products to achieve SDG 2030 agenda.

### **III. Specific Objectives were:**

1. Engage with a wide set of stakeholders in structured debate on access to medicines and medical products and trade agreements for upcoming international discussions in the context of SDGs.
2. Promote pragmatic responses to contemporary policy issues on research and innovation landscape and the paradigm shift needed in the changing innovation landscape for medical products and health technologies.
3. Provide recommendations for possible policy coherence on international trade laws and health, including intellectual property covenants for access to medical products



#### IV. Thematic areas of the Conference

The following three thematic areas were covered:

##### A. **Access to Medical Products-** the sub themes were:

1. Access to Medical products
2. Recommendations of the UN High Level Report on access to medicines
3. Regulatory dimensions to address access for quality, efficacious, safe and affordable medical products including cancer, hepatitis C, etc.
4. Use of Internet and Information Technology for accessing medical and health products (including online pharmacies)

##### B. **Innovation and Research & Development for moving towards SDGs-** the sub themes were:

1. Role of Innovation and R&D for Access to medical products, Competition law for Access to Medicines and health products, Bio-technological products, Patents as a tool of innovation
2. Access to Medical products (new/innovative Medical/ health products/ disease and dosage regimens), Infectious disease control (New initiatives for R&D (Coalition for Epidemic Preparedness Innovation (CEPI) for development of vaccines for infections of epidemic potential
3. New technologies providing innovative solutions for healthcare, fostering local production

##### C. **Intellectual Property Rights and Trade for SDGs in the context of Access to Medical Products-** the sub themes were:

1. International legal framework for access to medicines in the context of R&D and innovation – TRIPS, patent law, competition laws, Right to Health etc.
2. Patent and Trademarks in standard setting in medical products
3. Health-related provisions in Free Trade Agreements and Regional Trade Agreements in the context of medical products

#### V. Expected Outcomes

The expected outcomes from the conference were to:

1. Engage with a wide set of stakeholders, on critical issues of innovation, trade and access to medicines for upcoming international discussions on the UN High Level Report on access to medicines for 2018 Executive Board of WHO
2. Explore strategies to promote innovation and identify linkages between international trade and health policy for access to medical products to achieve SDGs
3. Provide recommendations for improved policy coherence on international trade and health, intellectual property for access to medical products taking into account globally negotiated commitments.

#### VI. Sessions Details

A total of 15 Sessions were held as follows:

- 4 Plenary sessions
- 8 Parallel sessions



- 3 Wrap-Up sessions for collating all recommendations
- 17 Chairs, 12 Co-Chairs, 31 Lead Discussants, and 59 Panelists from various countries and organizations including Ministry Officials, academia, industry, inter-governmental organizations and civil societies.

### **Subjects covered in Four Plenary Sessions**

- Plenary Session 1- UN High Level Panel on Access to Medicines in the context of SDGs
- Plenary Session 2- Role of Innovation, Research and Development for Medical Products
- Plenary Session 3- Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products
- Plenary Session 4- TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products

### **Subjects of Eight Parallel Sessions**

- Parallel Session 1- Regulatory Pathways for safe, quality, efficacious and affordable medical products including in emergencies to achieve SDG goals
- Parallel Session 2- Affordability and Fair Pricing of Medical Products
- Parallel Session 3- Infectious Disease Control: What are the Pathways to Technology Development and Access to Medical Products
- Parallel Session 4- Alternative Models of R&D-Industry-Academia Collaborations
- Parallel Session 5- Achieving SDGs: Use of Information and Communications Technology (ICT) Initiatives including in Trade Agreements
- Parallel Session 6- Patents , Intellectual Property, Price Control and Competition Law in Access to Medicines
- Parallel Session 7- WTO Trade Agreements influencing Health Products– Context SDGs
- Parallel Session 8-Achieving SDGs: Regional Agreements, Challenges(TRIPS plus Agreements) and Access to Medical products

A summary of the outcomes from each of the Plenary and Parallel sessions follows. The topics covered by the Speakers: Chairs, Co-Chairs, Lead discussants and Panelists is outlined (in italics) in the sessions brief to specify the subjects covered by them.

A total of 142 recommendations emerged for promoting access to medical products to achieve the 2030 SDG agenda from the conference. The recommendations were for national governments, WHO and other international organizations.

<b>Recommendations in Brief</b>	
<b>National Governments</b>	<b>70</b>
<b>WHO/ International organizations</b>	<b>68</b>
<b>United Nations</b>	<b>4</b>
<b>Total</b>	<b>142</b>





## Plenary Session 1: UN High Level Panel on Access to Medicines in the context of SDGs

### Chairs:

1. **Dr VK Paul**, Member, NITI Aayog, Government of India
2. **Ms Preeti Sudan**, Secretary, Health, Ministry of Health and Family Welfare, Government of India
3. **Dr Soumya Swaminathan**, Secretary, Department of Health and Research & Director General, Indian Council of Medical Research, Government of India

### Lead discussants

1. **Ambassador Dr Virander Paul**, Deputy Permanent Representative of India to the United Nations- *Access to Medicines: A Perspective from the Permanent Mission of India to the United Nations*
2. **Ms Ruth Dreifuss**, Co-chair, UN High Level Panel on Access to Medicines; Former President, Swiss Confederation, Geneva- *Governance, Accountability and Transparency*
3. **Dr Jorge Bermudez**, Senior Researcher in Public Health, National School of Public Health, Fiocruz, Ministry of Health, Brazil- *Intellectual Property Laws and Access to Health Technologies*
4. **Dr Mandeep Dhaliwal**, Director-HIV, Health and Development Group, United Nations Development Program, USA- *New Incentives for Research and Development of Health Technologies*

### Panelists

1. **Dr Peter Beyer**, Senior Advisor, Department Of Essential Medicines and Health Products, World Health Organization, Geneva- *WHO's work on Access and Innovation*
2. **Ms Maria Lorena Di Giano**, Executive Director, Fundacio Grupo Efecto Positivo and General Coordinator of RedLam, Argentina- *Intellectual Property Laws and Access to Health Technologies*
3. **Professor Anthony D So**, Professor of the Practice and Director, IDEA (Innovation+Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA- *Innovation and Access to Health Technologies*
4. **Dr Mohga Kamal Yanni**, Senior Health and HIV Policy Adviser, Oxfam GB, UK- *Health Policy and Programming*
5. **Mr Anand Grover**, Former UN Special Rapporteur and Member- Expert Advisory Group, UN High Level Panel on Access to Medicines, India- *International Trade Rules in the Context of Human Rights to Health*



The **objective of the session** was to enable deeper discussions and a take holistic view on access to medicines (including all medical products: medicines, vaccines, devices, diagnostics) and the issues and recommendations made in the UN High Level Panel Report.

The topics addressed in “**Access to Medicines (and Medical products) to achieve SDGs**” are as follows:

1. Governance, Accountability and Transparency
2. Intellectual Property Laws and Access to Health Technologies
3. New Incentives for Research and Development of Health Technologies
4. Health Technology Innovation and Access
5. WHO’s position and next steps on UN HLP
6. New Incentives for Research and Development of Health Technologies
7. Intellectual Property Laws and Access to Health Technologies
8. Innovation and access to health technologies
9. Health policy and programming

## **Recommendations:**

### **Recommendations for National Governments**

1. Ensure coherence at the multilateral, regional and national levels so that all policies advance the right to health, the right to benefit from scientific progress, and to achieve the Sustainable Development Goals, including SDG 3.
2. Establish national level inter-ministerial bodies to co-ordinate laws policies and practices that may impact on health technology innovation and access.
3. Review access to health technologies and make them publicly available in the countries in the light of human rights principles and States’ obligations to fulfil them, with assistance from the Office of the UN High Commissioner for Human Rights.
4. Enable disclosure of the costs of Research and Development (R&D), production marketing and distribution by manufacturers and distributors of their products.
5. Enable disclosure of public funding received in development of health technologies such as tax credits, subsidies and grants.
6. Make publicly available unidentified data on all completed and discontinued clinical trials regardless of whether their results are positive, negative, neutral or inconclusive
7. Establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines.
8. Strengthen with appropriate national interventions the international mechanism of WHO Clinical Trials Registry Platform
9. Increase current levels of investment in health technology innovation to address unmet health needs.
10. Use Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and take into account the impact on public health of TRIPS plus provisions when negotiating any Free Trade Agreements (FTAs).

### **Recommendations for WHO/ International Organizations**

1. Annex the report of “1<sup>st</sup> World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development, 21-23 November 2017, New Delhi, India” in the Executive Board 2018 agenda on Access to medicines for forthcoming WHA .
2. Promote adoption of mechanisms to mobilize resources to build sustainable, coherent solutions for financing of health research and development (R&DS), to advance the right to



health and the right to benefit from scientific progress. Such mechanisms should integrate public health safeguards, as summarized in WHA 66.22 in order to find solutions to the unmet medical needs which ensure a fair public return for public investments, and enable the delinking of R&D incentives from drug prices for affordable and universal access.

3. WHO draft general programme of work 2019-2023 should give adequate focus on Access to medical products.
4. WHO should establish and maintain a database of prices of patented, generic and biosimilar medicines in countries where they are registered.
5. Create easily searchable patent database, periodically updated and consolidated in collaboration with Member States, patent owners and other stakeholders.
6. R&D funders to test new business models, particularly of delinkage including with companies engaged in early stage research and address obligations of access and stewardship.
7. Use the G20 and G77 platforms for collective actions on access to medical products and for Antimicrobial resistance (AMR).

### Recommendations for the United Nations

1. UN Secretary-General should establish an independent review body (with broad membership from various constituencies) tasked with assessing progress on health technology innovation and access.
2. UN Secretary General should establish an inter-agency task force to increase coherence between multilateral organizations working on health technology innovation and access.
3. UN Secretary General should convene a UN General Assembly Special session on health technology innovation and access in 2018.
4. Develop next steps to UN Human Rights Council adopted Resolution 26/9 in June 2014 that mandated to develop “an international legally binding instrument on transnational corporations (TNCs) and other business enterprises with respect to human rights”.

### **Parallel Session 1: Regulatory Pathways For Safe, Quality, Efficacious and affordable Medical Products including in Emergencies to Achieve SDG Goals**

**Chair:** Dr RK Vats, Additional Secretary, Ministry of Health and Family Welfare, Government of India

**Co-chair:** Dr Renu Swarup, Senior Adviser, Department of Biotechnology and Managing Director, Biotechnology Industry Research Assistance Council- Biopharma Mission, India

#### **Lead discussant:**

1. **Dr Gagandeep Kang**, Executive Director, Translational Health Science and Technology Institute, India- *Regulatory Pathways for Vaccines and New Models (Including CEPI) to Achieve SDG Goals*
2. **Dr GN Singh**, Drugs Controller General (India), Central Drugs Standard Control Organization, India- *Regulatory Updates in India*
3. **Dr Stephen B Kennedy**, Coordinator for EVD Research, Incident Management System, Ministry of Health, Liberia- *Regulatory Pathways in Emergencies – From Clinical Trials to Field*

#### **Panelists:**

1. **Dr Anban Pillay**, Director, National Department of Health, South Africa- *Innovative Medicine Supply Models for Access to Affordable Medicines*
2. **Dr Anil Koul**, Director, CSIR-Institute of Microbial Technology, India- *New Drug Development*



for Tuberculosis

3. **Dr Jorge Bermudez**, Senior Researcher in Public Health, National School of Public Health, Fiocruz, Ministry of Health, Brazil- *Health Technology, Local Production and Innovation Including APIs*
4. **Ms Leena Menghaney**, Head- South Asia, Access Campaign, Medecins Sans Frontieres, India- *Challenges to Affordable Medical Products*
5. **Dr Taslimarif Saiyed**, CEO & Director, Centre for Cellular and Molecular Platforms, Department of Biotechnology, India- *Developing and Establishing High End Technologies*

**The objective of this session** was to discuss the ways in which the national regulatory systems can address ever-increasing complexities of medical product supply chains. The steps to enable shorter, transparent and more predictable regulatory pathways for newer medical products including in emergencies were also covered.

The following topics were taken up:

1. Regulatory Pathways for vaccines and new models (including *Coalition for Epidemic Preparedness Innovations -CEPI-* the Global partnership launched to prevent epidemics with new vaccines ) to achieve SDG goals
2. Regulatory updates in India
3. Regulatory Pathways in emergencies- from clinical trials to field
4. Innovative medicine supply models for access to affordable medicines
5. Health technology, local production and innovation including Active Pharmaceutical Ingredients (APIs)
6. Challenges to affordable medical products

#### **Recommendations:**

##### **Recommendations for National Governments**

1. Build on existing regulatory harmonization/alignment efforts, WHO R&D Blueprint, WHO Pre-qualification (PQ) collaborative and joint review processes, South East Asia Regulatory Network (SEARN), Global Antibiotic Research and Development Partnership (GARD-P), African Vaccine Regulatory Forum (AVAREF), African Medicines Regulatory Harmonization initiative (AMRH), Pan-American Network for Drug Regulatory Harmonization (PANDRH) ASEAN-Network for Drugs, Diagnostics, Vaccines, and Traditional Medicines Innovation (ASEAN-NDI), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), European Medicines Agency's Article 58 procedure.
2. Develop regulatory mechanisms for coordination, cooperation and reliance among various stakeholders working in health sector to facilitate access of healthcare to the population at national and international levels.
3. Track patent working by the holder to enable non-registration to be used as a ground for non-working of the patent on new drugs leading to necessary government action.
4. Make candidates available (pre-final licensure) to most at risk populations (including first responders) via appropriate regulatory mechanism(s), if needed during an outbreak.
5. Explore new treatment options for diseases such as Tuberculosis including single pill regimens.
6. Promote new collaborative mechanisms including using TRIPS flexibilities for enhanced access to newer medical products for diseases specific to certain countries such as for access to bedaquiline, delamanid, Hepatitis, oncology medicines.

##### **Recommendations for WHO/International Organizations**

1. Outline procedures for clinical research in emergency situations including clinical trials, speedy ethics committee and regulatory approvals.
2. WHO to take forward the global regulatory optimization and alignment envisaged in CEPI, assist product developers to better understand the challenges of regulatory and ethics





- processes in the absence of an outbreak.
3. Clarify regulatory and ethical issues surrounding the use of stockpiled products during outbreaks.
  4. Assist national governments to develop coordination, cooperation, reliance regulatory mechanisms among various stakeholders working in health sector for facilitating access of healthcare to the population at national and international levels.
  5. Assist national governments and international agencies to explore new treatment options for diseases such as Tuberculosis including single pill regimens.
  6. Assist national governments to facilitate new collaborative mechanisms including using TRIPS flexibilities for enhanced access to newer medical products for diseases specific to certain countries such as for access to bedaquiline, delamanid, Hepatitis, oncology medicines.
  7. Select study designs judiciously to provide best possible answers at conclusion of studies for global public health consumption.
  8. Leverage community engagements for successful product development initiatives including in outbreaks.

## **Parallel Session 2: Affordability and Fair Pricing of Medical Products**

**Chair:** Mr Jai Priye Prakash, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

**Co-Chairs:** Dr Henk Bekedam, WHO Representative to India, Mr Bhupendra Singh, Chairman, National Pharmaceutical Pricing Authority, Government of India

### **Lead discussants:**

1. **Professor Fatima Suleman**, Discipline of Pharmaceutical Sciences, University of Kwazulu-Natal, South Africa- *Creating a Balance Between Affordable Prices and a Sustainable Pharmaceutical Industry*
2. **Dr Sham Mailankody**, Memorial Sloan Kettering Cancer institute, USA- *Research and Development Costs in Bringing Medical Products to Market*
3. **Dr Andrew Rintoul**, Scientist, Pricing & Health Technology Assessment, World Health Organization, Geneva- *Fair Pricing Mechanisms for Public Health Systems in Developing Countries*

### **Panelists:**

1. **Ms Michelle Childs**, Head of Policy and Advocacy, Drugs for Neglected Diseases (DNDi), Latin America- *Innovation using open Knowledge Principles including WHO Open Knowledge Demonstration Projects*
2. **Mr James Love**, Director, Knowledge Ecology International, USA- *Proposals for Expanding the Production of Knowledge as a Public Good*

**The objective of this session** was to explore policy options on fair pricing of medical products for Universal Health Coverage (UHC) in the context of the SDG 2030 Agenda.

The following topics were discussed:

1. Creating a balance between affordable prices and a sustainable pharmaceutical industry
2. Research and Development (R&D) costs in bringing medical products to Market
3. Fair pricing mechanisms for public health systems in developing countries
4. Promoting transparency in pricing of medical products
5. Price Control of medical products in India





6. Pharmaceutical Policies: Promoting affordability and fair pricing of medical products
7. Innovation using open knowledge principles including WHO open knowledge demonstration projects
8. Proposals for expanding the production of knowledge as a public goods

## Recommendations:

### Recommendations for National Governments

1. Examine to end tariffs and taxes on essential medicines to improve affordability.
2. Address unreasonable markups on medical products throughout the supply chain, also using information technology to create transparency and publicly report markups.
3. Develop alternate models to fund R&D learning from UNITAID example that receives certain funds from airline taxes or levies.
4. Focus on “reasonable bounds” of pricing for transparency and assure sustainability of industry to advance the practice of medicine and contribute to achieving universal access.
5. Collaborate with other payers to increase purchasing power for access to medical products by negotiations such as in initiatives BeNeLuxA.
6. Develop open collaborative models and make R&D more efficient, quicker and cheaper.
7. Ensure knowledge is made freely and widely available by applying conditions to public funding for R&D that require pro public health patenting and licensing practices (e.g. publication, non-exclusive licensing, donations of IP, patent pools, transparency on research data, clinical trial data -negative and positive).
8. Negotiate a Code of Principles for Biomedical R&D.
9. Provide for sufficiently detailed disclosure (including outlays on each trial) of R&D costs and R&D subsidies for every regulated medical technology.
10. Fully support and fund WHO’s normative and technical functions.

### Recommendations for WHO/International Organizations

1. Consider drafting and conforming to an agreement to avoid the complexities and challenges of R&D treaty ratification and modification.
2. Provide technical assistance to Member States for public procurement mechanisms, best procurement practices, increased transparency on pricing, inputs in the value chain and on production of medical products.
3. Focus on incentives for funding priority R&D and not limit benefits of global cooperation to developing countries.

## **Plenary Session 2: Role of Innovation, Research and Development for Medical Products**

**Chair: Ms Aradhana Johri**, Former Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Secretary of Finance (Disinvestment); Former Additional Secretary, Ministry of Health & Family Welfare, GOI

**Co-chair: Dr Gagandeep Kang**, Executive Director, Translational Health Science and Technology Institute, India

### **Lead discussants:**

1. **Dr Renu Swarup**, Senior Adviser, Department of Biotechnology (DBT) and Managing Director, Biotechnology Industry Research Assistance Council (BIRAC)- Biopharma Mission, India- *Bio Pharma Mission: Enabling Environment for Industry Academia Collaboration from Discovery Research to Development for Biopharmaceuticals*



2. **Dr Madhur Gupta**, Technical Officer-Pharmaceuticals, WHO India- *Research and Development and access to Medical Products: Thematic Issues in WHA Resolutions and UNHLP*
3. **Dr Surinder Singh**, Director, National Institute of Biologics (NIB), India- *WHO R&D Blue Print: Way Forward*

**Panelists:**

1. **Mr Ed Whiting**, Director of Policy and Chief of Staff, Wellcome Trust UK- *Supporting Response to Epidemics and Antimicrobial Resistance*
2. **Dr Suman Rijal**, Executive Director, Drugs for Neglected Diseases (DNDi), India- *Global Successful Models of PDPs in R&D*
3. **Dr Nilima Kshirsagar**, National Chair of Clinical Pharmacology, Indian Council of Medical Research, India- *Clinical Trials Landscape in R&D*
4. **Professor Anthony D So**, Professor of the Practice and Director, IDEA (Innovation+Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA- *Grants and Co-Operative Agreements with Academic Institutions in Promoting R&D in Public Health*

**The objective of the session** was to identify the gaps in R&D and opportunities and define priorities for investments, priority setting and coordination in R&D including WHO R&D Blueprint.

The topics addressed in “**Role of Innovation, Research and Development for Medical Products**” are:

1. Bio Pharma Mission: Enabling environment for Industry Academia Collaboration from discovery research to development for biopharmaceuticals
2. Enabling regulatory landscape for medical devices and diagnostics: alliances, networks and coalitions
3. Research and development and access to medical products: thematic issues in WHA resolutions and UNHLP
4. WHO R&D Blue Print: Way Forward
5. Funding R&D through portfolio development for health care innovations
6. Global successful models of PDPs in R&D
7. Clinical Trials landscape in R&D
8. Grants and Co-operative agreements with academic institutions in promoting R&D in public health

**Recommendations:**

**Recommendations for National Governments**

1. Develop concerted action with the ministries of Science and Technology, Indian Council of Medical Research, Ministry of Chemicals and Fertilizers, Ministry of Commerce and Industry, Ministry of Law and Justice, Ministry of External Affairs, Ministry of Micro Small and Medium Enterprises, Ministry of Electronics & Information Technology and Ministry of Health on the access agenda for health for all.
2. Adapt the R&D blueprint in India and South East Asia Region for sustainable efforts for R&D for newer medical products including antibiotics in collaboration with the science and health ministries.
3. Encourage use-inspired discovery research - promote innovation and R&D for development of affordable products for Indian and global market, support strong technology platforms, create network of clinical sites and testing facilities.
4. Promote commercialization of technology by building translational capacity, support business incubation infrastructure, technology validation, scale-up infrastructure, nurture



- bio-entrepreneurship and build technology repositories.
5. Generate biotech products, processes and technologies to enhance efficiency, productivity, affordable health and wellness.
  6. Create an enabling environment for next generation product innovation through global and national alliances and redesigning governance models for focused, mentored, high quality product development.
  7. Develop early consultation mechanisms with regulatory agencies for product development and use to ease market approval for products.
  8. Develop innovative new technology enabled service delivery access models and relate geographical accessibility to medical products.

### **Recommendations for WHO/ International Organizations**

1. Allocate adequate resources for achieving Global strategy and plan of action on public health, innovation and intellectual property (GSPA) outcomes, including the results in the programme review and Consultative Expert Working Group (CEWG) for achieving SDG 2030 goals.
2. Track progress on the GSPA and follow up resolutions including the CEWG Report on an annual basis.
3. Leverage regional regulatory networks such as South East Asia Regulatory Network (SEARN) for building cross linkages with regulatory and access agenda.
4. Build consortiums of partners to move innovation to scale (in-country & global network of research entities) and establish inclusive development models.
5. Build proficiency in intellectual property support and management.
6. Create a global network of experts/mentors/ advisors to work and partner for enhancing product innovation and bring together isolated Centers of Excellence.
7. Integrate cross platform technologies for application in other disease areas and utilization in other programs.
8. Strengthen entrepreneurial ecosystem and build regional competencies and enhanced bio-clusters ecosystem.
9. Leverage the Ebola learnings of WHO to consider adaptive R&D blueprint- call for action for devices, diagnostics, medicines and vaccines.
10. Revisit Global Clinical Trials requirements and abbreviated clinical trials model with risk based approach followed by risk minimization and post marketing plan in place.
11. Support public funded early drug development stage joint collaboration with academia, regulators and leverage Product Development Partnerships Models, CEPI, Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), Global Antibiotic Research and Development Partnership (GARDP), Global Health Innovative Technology (GHIT).
12. Deliver value for money by offering the right amount of reward for the right products, and not 'paying twice' and ensuring access using mechanisms such as patent pooling.
13. Support good antibiotic stewardship by de-linking the profitability of a product from the volume sold, and through responsible marketing.
14. Coordinate with the UN Inter-Agency Coordination Group (IACG) and the G20 R&D Hub on the access agenda.
15. Facilitate collaboration of national control labs (NCLs) on preparation of reference reagents and standards.
16. Promote human resource development and use of ICT initiatives for process & product development, preparation of reference standards & reagents in labs & regulation of medical products.
17. Explore Public Intellectual Property Resource for Agriculture (PIPRA) model to reset norms in technology transfer and licensing of biomedical innovation from publicly funded research institutions.



18. Develop measures of accountability for fair returns on public financing of biomedical R&D and counting the social returns from such investment.
19. Host a global discussion on the clinical trials framework with a view to support R&D and access initiatives including predictable regulatory pathways for emergencies- focusing on pharmaceuticals, vaccines, devices and diagnostics.

### **Plenary Session 3: Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products**

**Chair: Mr Sudhansh Pant**, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

**Lead discussants:**

1. **Dr Jitender Sharma**, CEO, Andhra Medtech Zone, and Advisor, Kalam Institute of Health Technology, Andhra Pradesh, India- *Integration of Research, Industry Promotion and Service Delivery*
2. **Dr Gaby Vercauteren**, Senior Advisor, Regulatory Systems Strengthening Team, Essential Medicines and Health Products Department, WHO HQ, Geneva- *WHO Model Regulatory Framework for Medical Devices*
3. **Dr Eswara Reddy**, Joint Drugs Controller, Central Drug Standard Control Organization (CDSCO), India- *Regulatory Framework for Medical Devices in India*

**Panelists:**

1. **Dr Andrew Rintoul**, Scientist, Pricing & Health Technology Assessment, World Health Organization, Geneva- *Developing Countries Collaborative Arrangements to Boost Local Pharmaceutical Manufacturing Capacity*
2. **Dr Diana Tay**, Business Development Manager, Wellcome Trust, UK- *Funding R&D through Portfolio Development for Health Care Innovations*
3. **Ms Deepanwita Chattopadhyay**, Chairman & CEO, Innovation Knowledge Park, India- *Nurturing Innovative Companies and Developing a Sustainable Innovation Cluster*
4. **Dr Eur Ing Muthu Singaram**, CEO, Healthcare Technology Innovation Centre, Indian Institute of Technology Madras, India- *Addressing Diverse Parameters on Medical Devices Operability for Public Health Needs*

**The objective of the session** was to examine how to facilitate local production and technology transfer and address collaborative arrangements to enable access to medical products.

The topics addressed **“Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products”**

1. WHO model regulatory framework for Medical devices
2. Regulatory framework for medical devices in India
3. Developing and establishing high end technologies
4. Developing countries collaborative arrangements to boost local pharmaceutical manufacturing capacity
5. Nurturing innovative companies and developing a sustainable innovation cluster
6. Addressing diverse parameters on medical devices operability for public health needs

**Recommendations:**

**Recommendations for National Governments**

1. Develop sustainable innovation clusters bringing together academic and R&D institutions,





industry, innovators, innovation support systems like incubators, funding agencies – grants, venture capital, regulatory professionals, intellectual property professionals, vendors, contract research organizations (CROs), pilot scale manufacturing facilities and supply chain mechanisms.

2. Develop India as a hub for affordable medical devices as has been the contribution of the country in the pharmaceutical and vaccines sectors.
3. Focus research on critical components pertaining to medical devices by supporting institutions involved in R&D, industry and knowledge repositories.
4. Encourage diffusion of knowledge and sharing of regulatory information, through common facilities for API, medical device parks, innovation clusters.
5. Revitalize the bulk drug segment in India by focus on the Small and medium enterprises (SME) sector to meet national and global public health needs.

#### Recommendations for WHO/ International Organizations

1. Strengthen National Regulatory Authorities (NRAs) and provide technical support for capacity building for all medical products including medical devices and diagnostics.
2. Facilitate access to safe, appropriate and affordable quality *in-vitro* diagnostics in an equitable manner and suitable for use in resource-limited settings.
3. UNITAID to collaborate and support WHO for R&D, access, regulatory capacity building for quality *in-vitro* diagnostics in countries including technical support for prequalification for IVDs.

#### Parallel Session 3: Infectious Disease Control: What are the Pathways to Technology Development and Access to Medical Products?

**Chair:** Dr VK Paul, Member, NITI Aayog, GOI

**Co-chair:** Dr RK Vats, Additional Secretary, Ministry of Health and Family Welfare, GOI

#### Lead discussants:

1. **Dr Stephen B Kennedy**, Coordinator for EVD Research, Incident Management System, Ministry of Health, Liberia- *Country Perspectives on R&D in Infectious Diseases including the Ebola Epidemic*
2. **Dr Gagandeep Kang**, Executive Director, Translational Health Science and Technology Institute, India- *Building strong Inter-Disciplinary Research Teams for Technology Development and access to Quality Health Products*

#### Panelists:

1. **Ms Sunita K Sreedharan**, Lawyer, SKS Law Associates, India- *Intellectual Property Management for Technology Development and Access to Medical Products*
2. **Ms Michelle Childs**, Head of Policy and Advocacy, Drugs for Neglected Diseases (DNDi), Latin America- *Implementing Internationally agreed R&D Principles for Innovation and Access including for AMR*
3. **Mr Damiano De Felice**, Director of Strategy, Access to Medicines Foundation, Netherlands- *Challenges of Access to Medicine Worldwide: The Access to Medicine Index*
4. **Dr Pramod Garg**, Professor, Department of Gastro Enterology, All India Institute of Medical Sciences, India- *Clinician's Perspective on Technology for Infectious Disease Control*
5. **Mr Christoph Spennemann**, Legal Officer and Officer-in-Charge, Intellectual Property Unit, United Nations Conference on Trade and Development, Geneva- *Current Challenges for Investing in R&D in Antibiotics*
6. **Dr Kamal Jayasinghe**, Director General, Chief Executive Officer, National Medicines





Regulatory Authority, Sri Lanka- *Regulatory support for Local Production, Technology Transfer and Market Entry Barriers for Medical Products*

**The objective of the session** was to discuss R&D initiatives for development of vaccines for infections of epidemic potential and WHO's leadership in Global Antibiotic Partnership for infectious disease control. R&D Blueprint which can be effectively used to address the issue of epidemics and improve R&D preparedness and response, focusing on a list of priority diseases in line with recommendations from a number of expert panels and commissions.

The following topics were discussed:

1. Country perspectives on R&D in infectious diseases including the Ebola epidemic
2. Building strong inter-disciplinary research teams for technology development and access to quality health products
3. Intellectual property management for technology development and access to medical products
4. Implementing internationally agreed R&D Principles for innovation and access including for AMR
5. The World Health Organization and pandemic protection in a globalized world
6. Challenges of access to medicine worldwide: the Access to Medicine Index
7. Clinician's perspective on technology for infectious disease control
8. Current challenges for investing in R&D in antibiotics

**Recommendations:**

**Recommendations for National Governments**

1. Provide impetus to TB research consortium activities identified for next five years relating to new drugs, shorter drug regimens and cost effective indigenous diagnostic tools.
2. Facilitate implementation processes for clinical trials, licensing of products and mass immunization of innovative vaccines to counter epidemics.
3. Develop national observatories and/ or coordinate with the global observatory envisaged in the GSPA.
4. Provide for private sector companies to have a publicly available policy on their contribution to improving access to health technologies setting out general and specific objectives, timeframes, reporting procedures, lines of accountability and a governance system that includes direct board-level responsibility and accountability.
5. Monitor hospital acquired infections and antibiotics resistance through intensive care unit (ICUs) rating and mandatory hospital audits.

**Recommendations for WHO/International Organizations**

1. WHO Global Health Observatory to provide analyses of gaps in health R&D in all areas of public health importance to guide priority-setting, develop and support national and global systems.
2. WHO Expert Committee, follow on from the Advisory Committee on Health Research for health R&D, to initiate calls for proposals by analyzing product profiles and the existing pipeline of products and technologies.
3. Provide technical support for risk-benefit analysis, toxicity study, Pharmacokinetic / pharmacodynamic interactions on fixed dose combinations (FDCs) which have been recommended for concomitant administration.
4. Explore feasibility of inclusion of neglected diseases for facilitating fast track regulatory approval pathway, such as in HIV and HCV etc. for combination products.



## **Parallel Session 4: Alternative Models of R&D-Industry-Academia Collaborations**

**Chair:** Mr Ed Whiting, Director of Policy and Chief of Staff, Wellcome Trust UK

### **Lead discussants:**

1. **Dr Renu Swarup**, Department of Biotechnology, BIRAC, Government of India, *Biotechnology – Next Frontier for Medical Products- National Ecosystem and Bio-Incubators*
2. **Dr Madhu Dikshit**, Director, Central Drug Research Institute (CDRI), India- *CDRI Experience in Drug Discovery Research in India*
3. **Dr YK Gupta**, Professor and Head Department of Pharmacology, All India Institute of Medical Sciences, India- *Implementing Government Commitments to Provide Quality Medicine at Affordable Prices: Challenges before National Essential Medicine Committees*

### **Panelists:**

1. **Dr Mohga Kamal Yanni**, Senior Health and HIV Policy Adviser, Oxfam GB, UK- *International Agencies Support for Models of R&D-Industry-Academia Collaborations*
2. **Ms Siti Aida Abdullah**, Deputy Director, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia- *Clinical Trials - the Malaysian Experience*
3. **Dr Viviana Munoz Tellez**, Coordinator, South Centre, Switzerland- *Promoting Innovation in new Antimicrobial Medicines, Vaccines, and Diagnostics*
4. **Professor Margo A Bagley**, Asa Griggs Candler Professor of Law, Emory University School of Law & Senior Fellow, Centre for International Governance Innovation, Atlanta- *Innovative Approaches for Research on Neglected Diseases: The Emory Experience*

**The objective of the session** was to discuss the industry- academia collaboration to promote R&D of medical products.

The following topics were discussed:

1. Biotechnology – next frontier for medical products- national ecosystem and bio incubators
2. CDRI experience in Drug discovery research in India
3. Implementing Government commitments to provide quality medicine at affordable prices: challenges before National Essential Medicine Committees
4. International agencies support for Models of R&D-Industry- Academia Collaborations
5. OECD perspectives on Models of R&D Industry-Academia Collaborations
6. Promoting Innovation in New Antimicrobial Medicines, Vaccines, and Diagnostics
7. Developing novel therapeutic proteins targeting infectious diseases
8. Innovative approaches for research on neglected diseases: the Emory experience

### **Recommendations:**

#### **Recommendations for National Governments**

1. Explore to create separate entities with universities to engage people experienced in the drug development process with focus on technology in areas of expertise including for mixed portfolio of projects (in major market and neglected diseases).
2. Consider the establishment of public private partnership models in the area of Clinical Research Organizations (CROs) to provide speedy and reliable clinical research support for quality studies to encourage medical professionals to conduct clinical trials.
3. Consider partnership with industry to support high risk, transformational technology/process development on a cost sharing basis.
4. Prioritize and increase sustainable public financing for R&D that addresses key un-meet health needs for emerging infectious and non-communicable diseases.



5. Fund incentive mechanisms that de-link the financing of research from sales and prices of health technologies.
6. Induct medical and pharmacy colleges into drug development and R&D including for clinical trials
7. Focus on development of inter- disciplinary skills for product innovation.
8. Build an environment for accelerating translational research by promoting industry-academia collaboration.

**Recommendations for WHO/International Organizations**

1. Strengthen institutional capacities for Good Laboratory Practices (GLP) for safety pharmacology studies & acute toxicity studies
2. Develop fit for purpose access models – (countries that can do the innovation to be linked with countries who need the innovations through mechanisms such as e- platforms).

**Parallel Session 5: Achieving SDGs: Use of Information and Communications Technology (ICT) Initiatives including in Trade Agreements**

**Chair:** Dr Sanjay Mehendale, Additional Director General ICMR, Government of India

**Co-chair:** Dr GN Singh, Drugs Controller General (India)

**Lead discussants:**

1. **Dr VG Somani**, Joint Drugs Controller, Central Drugs Standard Control Organization, India- *E-Governance Initiative at Central and State Level National Regulatory Authorities*
2. **Dr Ananda Sen Gupta**, CEO & Founder, Trackmybeat Health Care Private Limited, India- *Innovative Health Technologies and Health Care Management*

**Panelists:**

1. **Professor Brook K Baker**, Professor of Law, North Eastern University, USA- *Negotiating for Better Access to Promote Early Market Entry of Medical Products*
2. **Professor Suptendra Nath Sarbadhakari**, Project Director, National Health Portal, India- *Improve Access to Services through IT Enabled Tools: National Health Portal in India*
3. **Dr Vinay Goyal**, Professor, Department of Neurology, Neurosciences Centre, All India Institute of Medical Sciences, India- *Clinical Perspectives on ICT Tools in Health Care*

**The objective of the session** was to discuss the use of ICT tools for better health care innovation and management. The National Health Portals role in dissemination of information is critical. Policies which could be implemented by the national governments to provide e-healthcare information to ensure transparency and greater accessibility for healthcare management were covered.

The following topics were discussed:

1. Innovative health technologies and health care management
2. Collaborating for medical technology development: the India- Stanford biodesign experience
3. E- governance initiative at Central and State level National Regulatory Authorities
4. Negotiating for better access to promote early market entry of medical products
5. Improve access to services through IT enabled tools: National health portal in India
6. Clinical perspectives on ICT tools in health care

**Recommendations:**



### Recommendations for National Governments

1. Foster e-governance initiatives in regulatory authorities for ease of business, real time status of applications, instant communication and efficient workflow with auto generated legal forms, data analysis and digital archival of records
2. Develop rules & regulations that are unambiguous and may be used countrywide with equally acceptable for e-Prescriptions, mobile Health (m-Health) applications, Telemedicine, including tele-homecare applications.
3. Harmonize different Standards like EHR (Electronic Health Record) Standards, M2M (Machine to Machine) Standards and all other related Standards for achieving optimal outcomes.
4. Ensure quality control for safe online pharmacy applications
5. Develop domain experts (Health Informaticians) in regulatory system for e-Health / Digital Health
6. Create database of retail and wholesale licenses in the country through ICT tools.

### Recommendations for WHO/International Organizations

1. Drive local evidence based research on, and, with usage of ICT, and promote understanding for long term value of collecting large volume of Patient data, and population data analytics
2. Build relevant capacity for health informatics professionals for all countries.
3. Encourage creation of local and global health and service delivery protocols.

## Plenary Session 4: TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products

**Chair:** Mr Anadee Nath Misshra, Additional Secretary (OSD), Ministry of Law and Justice, Government of India

**Co-chair:** Justice Ravindra Bhat, Judge, High Court of Delhi, India

#### Lead discussants:

1. **Dr Biswajit Dhar**, Professor, Jawaharlal Nehru University, India- *Role of Publically Funded Universities, Research Institutions, Patenting and Licensing Practices for Prioritizing Public Health*
2. **Professor SK Verma**, Secretary General, Indian Society of International Law, India- *Implementation of TRIPS Provisions and UN HLP Recommendations to Strengthen IP Laws for Ensuring Global Access to Medical Products and health technologies*

#### Panelists:

1. **Professor Brook Baker**, Professor of Law, Northeastern University, USA- *Public Health in Bilateral Investment Treaties*
2. **Dr Olasupo Owoeye**, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia- *Role of PDPs for Access to Health Technologies and Affordable Medical Products*
3. **Dr Carlos Correa**, Special Advisor, South Centre, Switzerland- *Access, Benefit Sharing and New Models to Encourage R&D for Medical Products*
4. **Dr Greg Perry**, Executive Director, Medicines Patent Pool, Switzerland- *Innovative Mechanisms and Voluntary Licensing (Including MPP): Access to Medical Products*
5. **Dr Tjandra Yoga Aditama**, Senior Advisor, World Health Organization-South East Asia Regional Office, India- *Pandemic Influenza Preparedness (PIP) Framework, Access and Benefit Sharing*
6. **Mr Shiba Phurailatpam**, Director of the Asia Pacific Network of People Living with HIV





(APN+), Thailand- *UN HLP Report: Ensuring Access for All*

**The objective of the session** was to discuss the TRIPS Agreement and the impact on access to medicines in the context of the SDG goals. This Session also focused on PDPs (Product Development Partnerships) which is a novel method of product development wherein a non-profit organizational structure enables the public, private, academic, and philanthropic sectors to aggregate for access to medical products.

The topics addressed in “**TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products**” are:

1. IP issues in medical products including trademarks and patents in TRIPS Agreement
2. Role of publically funded universities, research institutions, patenting and licensing practices for prioritizing public health
3. Implementation of TRIPS provisions and UN HLP recommendations to strengthen IP laws for ensuring global access to medical products and health technologies
4. Public health in Bilateral Investment Treaties
5. Role of PDPs for access to health technologies and affordable medical products
6. Access, benefit sharing and new models to encourage R&D for medical products
7. Innovative mechanisms and voluntary licensing (including Medicine Patent Pool): Access to Medical products

#### **Recommendations:**

##### **Recommendations for National Governments**

1. Develop negotiation platforms with qualified mediators for voluntary licenses with industry for access at affordable costs.
2. Use compulsory license for access and reduce the cost of medical products in line with TRIPS agreement of WTO.
3. Set up an advisory body in legal institution, such as Indian Society of International Law (ISIL), to provide technical inputs and legal support for health products for achieving the SDG 2030 agenda across all the ministries.
4. Set up appropriate mechanisms to reduce the time to reach clinical proof of concept in medicine development for cancer, immunological, respiratory, neurological and neurodegenerative diseases.

##### **Recommendations for WHO/ International Organizations**

1. Explore benefit sharing partnership models such as the Pandemic Influenza Preparedness or PIP framework for anti-virals and vaccines based on assessment of public health risk and need.
2. Conduct detail review of the WHO's work on TRIPS flexibilities for access to medical products for the past five years.
3. Create an online repository for PDPs and develop systems for tracking progress on PDPs in medical products space.
4. Create a legal framework for voluntary license agreements and facilitate negotiation with companies for access at affordable costs.
5. Develop diagnostic and treatment biomarkers for priority diseases taking into account clinical relevance, and approval by regulators to increase the success rate in clinical trials of priority medicines.
6. Develop regional strategy for using PDPs including for LDCs and African countries.





## **Parallel Session 6: Patents, Intellectual Property, Price Control and Competition Law in Access to Medicines**

**Chair:** Mr Anadee Nath Misshra, Additional Secretary (OSD), Ministry of Law and Justice, Government of India

**Co-chair:** Mr GR Raghavender, Joint Secretary, National Mission for Justice Delivery and Legal Reforms, Ministry of Law and Justice, GOI

### **Lead discussants:**

1. **Dr Luca Arnaudo**, Senior officer at the Italian Competition Authority, Rome- *Role of Competition authority for adequate and affordable supply of medical products*
2. **Dr Peter Beyer**, Senior Advisor, Department Of Essential Medicines and Health Products, World Health Organization, Geneva- *New Global initiatives in access to medical products: Global Antibiotic Research and Development Partnership (GARDP)*

### **Panelists:**

1. **Professor Stephen Sammut**, Senior Advisor ABLE and Biotechnology Industry Organization, USA- *Health Technology and Entrepreneurial Education Models for the Emerging Markets*
2. **Mr Christoph Spennemann**, Legal Officer and Officer-in-Charge, Intellectual Property Unit, United Nations Conference on Trade and Development, Geneva- *Role of International Agencies including UNCTAD in Facilitating Public-Private Cooperation for access to medical products*
3. **Professor Christoph Rademacher**, Associate Professor, Waseda University, School of Law, Japan- *Protecting and stimulating pharmaceutical innovation – a short review of the Japanese Experience*
4. **Ms Judit Rius Sanjuan**, Consultant, United Nations Development Program, USA- *New Models of Innovation: Practices in Various Countries*

**The objective of the session** was to discuss the role of Patents, Intellectual Property, and Price Control through Competition Law for Access to Medical products.

The following topics were discussed:

1. Patentability Criteria in national laws for medical technologies and biologicals
2. Role of competition authority for adequate and affordable supply of medical products
3. New global initiatives in access to medical products: Global Antibiotic Research and Development Partnership
4. Role of international agencies including UNCTAD in facilitating public-private cooperation for access to medical products
5. Patent Enforcement in Japan
6. Price Control Mechanisms for access to medical products: perspectives on practices in various countries

### **Recommendations:**

#### **Recommendations for National Governments**

1. Engage proactively for safeguarding public health in international trade aspects that are becoming increasingly important such as intellectual property, government procurement, competition laws, environment, etc.
2. Develop tracking mechanisms for pay-for-delay agreements in medical products by collaborating with competition commissions/ antitrust bodies.



3. Governments should be encouraged to raise the issues of undue pressure on their policies during the Trade Policy Review Mechanism (“TPRM”) of WTO.

### **Recommendations for WHO/International Organizations**

1. WTO should revisit and examine the 2003 Para 6 system of the Doha declaration to make it workable.
2. Engage in capacity building at national and international levels for public health, including capacity building of patent examiners by the trilateral cooperation forum of international agencies, WHO, WIPO and WTO.
3. Engage on technical content development on trade and intellectual property rights for access to medical products taking into account declarations such as Max Planck institute ‘Declaration on Patent Protection – Regulatory Sovereignty’.
4. Engage with international organizations such as UNDP to explore new public & private collaborative models for technology transfer for public health, learning from NIH engagements, Bayh Dole Act & relevant public & private engagements in other jurisdictions.
5. Collaborate with UN organizations such as UNCTAD to facilitate public-private cooperation on public health, develop a framework for health and medical products.
6. Leverage the implementation of GARDP framework for R&D stewardship and access to medical products.

### **Parallel Session 7: WTO Trade Agreements influencing Health Products– Context SDGs**

#### **Chair:**

1. **Mr Sudhanshu Pandey**, Joint Secretary- Trade Policy Division, Ministry of Commerce and Industry, Government of India
2. **Mr Sudhansh Pant**, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

#### **Lead discussants:**

1. **Dr Sachin Chaturvedi**, Director General, Research & Information System for Developing Countries (RIS), New Delhi, India
2. **Dr Manisha Shridhar**, Regional Advisor, World Health Organization- South East Asia Regional Office, India- *Interpreting public health provisions in trade agreements for achieving SDG Goals*

#### **Panelists:**

1. **Dr Gregory Messenger**, Lecturer in Law, School of Law and Social Justice, University of Liverpool, UK- *Sustainable Development Goals, subsidies and trade*
2. **Dr Reji K Joseph**, Associate Professor, , Institute for Studies in Industrial Development, India- *Measures to reduce import dependence on bulk drugs*
3. **Dr VG Hegde**, Professor, Centre for International Legal Studies, School of International Studies, Jawaharlal Nehru University, New Delhi- *UNICTRAL’s contribution to the development of trade and health law*

**The objective of the session** was to analyse various options to facilitate the national policy on the issues of trade and health interface for purposes of nutrition, labelling, packaging and information on foods according to international standards such as Codex Alimentarius for public health goals in the framework of TBT and SPS Agreements. The session explored preventive measures in trade that are necessary for public health in the wake of increasing incidence of communicable diseases (CDs) and non-communicable diseases (NCDs) across all countries.



The following topics were discussed:

1. Interpreting public health provisions in trade agreements for achieving SDG Goals
2. Policy coherence between trade and health policies with reference to Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade Agreement (TBT) of WTO.
3. Emerging Challenges in genetically modified (GM) technologies for public health

#### Recommendations:

##### Recommendations for National Governments

1. Develop expertise to negotiate and interpret public health provisions in WTO, Free Trade Agreements (FTAs) and international investment agreements.
2. Focus attention to direct and indirect public health impact of trade interface in the SDG goals for long term sustained gains.

##### Recommendations for WHO/International Organizations

1. Engage with UNCITRAL (predating WTO agreements such as TRIPS, SPS, TBT), a core legal body of the United Nations system in the field of international trade law in the context of growing burden of CDs and NCDs, for forward looking legal engagement on trade and health interface for the 2030 SDG agenda.
2. Engage in rule making, such as for food labelling, in TBT agreement of WTO for appropriate balance in the health and trade interface.
3. Explore the impact of related WTO agreements such as the Agreement on Subsidies and Countervailing Measures (ASCM) for healthy food choices and tackle subsidies in certain potentially harmful foods.
4. Assist Member countries in consultative mechanisms with legal, finance, public health expertise at national and international levels.

#### **Parallel Session 8: Achieving SDGs: Regional Agreements, Challenges (TRIPS plus Agreements) and Access to Medical Products**

**Chair:** Mr Rajiv Aggarwal, Joint Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, GOI

**Co-chair:** Professor SK Verma, Secretary General, Indian Society of International Law, India

##### **Lead discussants:**

1. **Professor TC James**, Consultant, Research and Information System for Developing Countries (RIS), and President, NIPO, India- *TRIPS-Plus Provisions in Trade and Investment Agreements: Advocating for Public Health*
2. **Dr Olasupo Owoeye**, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia- *Building Regional Trade Blocs Reflective of the Needs of Developing Countries for Public Health Objectives*

##### **Panelists:**

1. **Professor Anthony D So**, MD, MPA, Professor of the Practice and Director, IDEA (Innovation+Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA- *Making Intellectual Property Work for Global Health*
2. **Ms Michelle Childs**, Head of Policy and Advocacy, Drugs for Neglected Diseases (DNDi),



- Latin America- *Negotiating Licenses in R&D for Patented Compound Libraries and Data*
3. **Dr Burcu Kilic**, Legal Counsel, Public Citizen, USA- *IP Policy, Trade Agreements and TRIPS-plus Rules and Safeguards*
  4. **Ms Kajal Bhardwaj**, Consultant, Access to Drugs and Intellectual Property- *Free Trade Agreements after WTO: Public Health Concerns*
  5. **Professor Rujitha Shenoy**, Inter-University for IPR Studies, India- *Access to Biomedical Technologies: Biomedical Patents and Sustainable Development Goals*

**The objective of the Session** was to discuss the challenges to the States in fulfilling their public health obligations in new free trade agreements and explore cooperation for public health goals.

The following topics were discussed:

1. Global governance for public health
2. TRIPS-Plus provisions in trade and investment agreements: advocating for public health
3. Building regional trade blocs reflective of the needs of developing countries for public health objectives
4. Making Intellectual Property work for Global Health
5. Negotiating Licenses in R&D for patented compound libraries and data
6. Free trade Agreements after WTO: Public health concerns
7. Access to biomedical technologies: Biomedical patents and SDGs
8. South-South cooperation for global health and SDGs

#### **Recommendations:**

##### **Recommendations for National Governments**

1. Balance the aspirations for trade with access to medical products (medicines, vaccines, medical technologies, and diagnostics) to achieve the Sustainable Development Goals.
2. Make a critical appraisal of public health impact, keeping in view the SDG 2030 aspirations, during any negotiations on bilateral, regional and multilateral agreements (FTAs, RTAs) and in existing agreements.
3. Examine and address public health implications in trade agreements such as bilateral investment treaties (BITS) and investor-state dispute settlement (ISDS) on a continuous basis.

##### **Recommendations for WHO/International Organizations**

1. Promote availability of intellectual property as non-exclusive licenses and develop public patent pools with public funded research.
2. Take necessary steps towards the adoption of an R&D Convention
3. Address the costs of new molecules/ biologicals in clinical trials where monetary incentives are not available for R&D in diseases specific to developing countries.

## **VII. Participants in the Conference**

The Ministry of Health, Government of India sought participation from experts from all over the world to deliberate on access to medical products for promoting innovation to attain 2030 Agenda for Sustainable Development. During the side event in WHA 2017, India mentioned that WHO should take the opportunity to engage with all stakeholders to address both innovation and access including rising prices of new pharmaceuticals and rapidly changing requirements for health technologies.

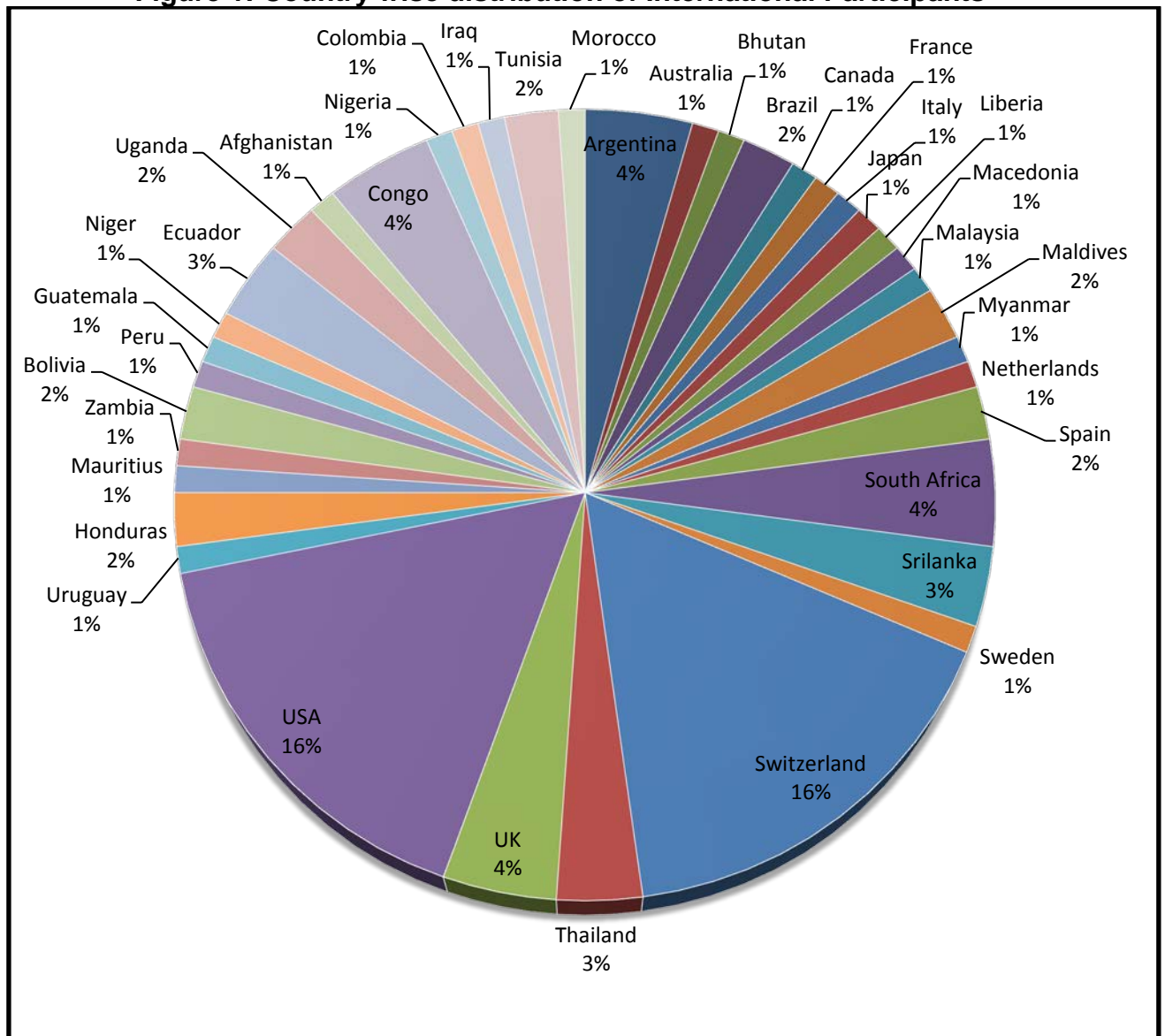




Approximately 285 experts and participants attended, coming from 40 countries including India and from many intergovernmental organizations. There were 191 national and 94 International participants. The distribution of the international participants is given in Figure 1. The attendees came from all six WHO regions. The countries which participated other than India were Argentina, Australia, Bhutan, Brazil, Canada, France, Italy, Japan, Liberia, Macedonia, Malaysia, Maldives, Myanmar, Netherlands, Spain, South Africa, Sri Lanka, Sweden, Switzerland, Thailand, United Kingdom, United States of America, Uruguay, Vietnam, Mauritius, Honduras, Zambia, Bolivia, Peru, Guatemala, Afghanistan, Uganda, Ecuador, Niger, Congo, Morocco, Tunisia, Iraq and Nigeria. Attendees represented a variety of organizations, with the largest numbers from the government or public agencies and academic sectors.

The participation was also from high-level delegates representing United Nations High Level Panel on Access to Medicines, United Nations (UN) organizations, Ministries of Health, Commerce, Foreign Affairs, partner agencies, academia, SAARC & WHO South-East Asia Region countries, civil society organizations and private sector including pharmaceutical and medical device associations.

**Figure 1: Country wise distribution of International Participants**







## **Dignitaries in the Conference, Chairs, Co-chairs, Lead Discussants and Panelists**

1. HE Mr JP Nadda, Union Minister, Health & Family Welfare, Government of India
2. HE Mr Ashwini Kumar Chaubey, Hon'ble Minister of State, Health & Family Welfare, Government of India
3. HE Ms Anupriya Patel, Hon'ble Minister of State, Health & Family Welfare, Government of India
4. Dr VK Paul, Member, NITI Aayog, Government of India;
5. Ms Preeti Sudan, Secretary, Health, Ministry of Health and Family Welfare, Government of India;
6. Dr Soumya Swaminathan, Secretary, Department of Health and Research & Director General, Indian Council of Medical Research, Government of India
7. Justice Ravindra Bhat, Judge, High Court of Delhi, India
8. Ambassador Dr Virander Paul, Deputy Permanent Representative of India to the United Nations
9. Dr Jagdish Prasad, Director General Health Services, Government of India
10. Dr EMS Natchiappan, President, Indian Society of International Law, India
11. Dr RK Vats, Additional Secretary, Ministry of Health and Family Welfare, GOI
12. Mr Anadee Nath Misshra, Additional Secretary (OSD), Ministry of Law and Justice, Government of India
13. Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India
14. Mr Lav Agarwal, Joint Secretary, Ministry of Health and Family Welfare, GOI
15. Mr Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India
16. Mr GR Raghavender, Joint Secretary, National Mission for Justice Delivery and Legal Reforms, Ministry of Law and Justice, GOI
17. Mr Sudhanshu Pandey, Joint Secretary- Trade Policy Division, Ministry of Commerce and Industry, Government of India;
18. Mr Rajiv Aggarwal, Joint Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, GOI
19. Ms Aradhana Johri, Former Secretary Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, Secretary of Finance (Disinvestment); Former Additional Secretary, Ministry of Health & Family Welfare, GOI
20. Dr GN Singh, Drugs Controller General (India), Central Drugs Standard Control Organization, India
21. Dr Henk Bekedam, WHO Representative to India
22. Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights and Trade and Health, WHO SEARO
23. Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India
24. Dr SK Verma, Secretary General, Indian Society of International Law
25. Ms Ruth Dreifuss, Co-chair, UN High Level Panel on Access to Medicines; Former President, Swiss Confederation, Geneva
26. Dr Jorge Bermudez, Senior Researcher in Public Health, National School of Public Health, Fiocruz, Ministry of Health, Brazil
27. Dr Mandeep Dhaliwal, Director-HIV, Health and Development Group, United Nations Development Program, USA



28. Dr Peter Beyer, Senior Advisor, Department Of Essential Medicines and Health Products, World Health Organization, Geneva
29. Ms Maria Lorena Di Giano, Executive Director, Fundacio Grupo Efecto Positivo and General Coordinator of RedLam, Argentina
30. Professor Anthony D So, Professor of the Practice and Director, IDEA (Innovation+Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA
31. Dr Mohga Kamal Yanni, Senior Health and HIV Policy Adviser, Oxfam GB, UK
32. Mr Anand Grover, Former UN Special Rapporteur and Member- Expert Advisory Group, UN High Level Panel on Access to Medicines, India
33. Dr Renu Swarup, Senior Adviser, Department of Biotechnology and Managing Director, Biotechnology Industry Research Assistance Council- Biopharma Mission, India
34. Dr Gagandeep Kang, Executive Director, Translational Health Science and Technology, India
35. Dr Stephen B Kennedy, Coordinator for EVD Research, Incident Management System, Ministry of Health, Liberia
36. Dr Anban Pillay, Director, National Department of Health, South Africa
37. Dr Anil Koul, Director, CSIR-Institute of Microbial Technology, India
38. Ms Leena Menghaney, Head- South Asia, Access Campaign, Medecins Sans Frontieres, India
39. Dr Taslimarif Saiyed, CEO & Director, Centre for Cellular and Molecular Platforms, Department of Biotechnology, India
40. Mr Bhupendra Singh, Chairman, National Pharmaceutical Pricing Authority, Government of India
41. Professor Fatima Suleman, Discipline of Pharmaceutical Sciences, University of Kwazulu-Natal, South Africa
42. Dr Sham Mailankody, Memorial Sloan Kettering Cancer institute, USA
43. Dr Andrew Rintoul, Scientist, Pricing & Health Technology Assessment, World Health Organization, Geneva
44. Ms Michelle Childs, Head of Policy and Advocacy, Drugs for Neglected Diseases (DNDi), Latin America;
45. Mr James Love, Director, Knowledge Ecology International, USA
46. Dr Surinder Singh, Director, National Institute of Biologics (NIB), India
47. Mr Ed Whiting, Director of Policy and Chief of Staff, Wellcome Trust UK;
48. Dr Suman Rijal, Executive Director, Drugs for Neglected Diseases (DNDi), India;
49. Dr Nilima Kshirsagar, National Chair of Clinical Pharmacology, Indian Council of Medical Research, India;
50. Dr Jitender Sharma, CEO, Andhra Medtech Zone, and Advisor, Kalam Institute of Health Technology, Andhra Pradesh, India;
51. Dr Gaby Vercauteren, Senior Advisor, Regulatory Systems Strengthening Team, Essential Medicines and Health Products Department, WHO HQ, Geneva;
52. Dr Eswara Reddy, Joint Drugs Controller, Central Drug Standard Control Organization (CDSCO), India
53. Dr Andrew Rintoul, Scientist, Pricing & Health Technology Assessment, World Health Organization, Geneva
54. Dr Diana Tay, Business Development Manager, Wellcome Trust, UK
55. Ms Deepanwita Chattopadhyay, Chairman & CEO, Innovation Knowledge Park, India
56. Dr Eur Ing Muthu Singaram, CEO, Healthcare Technology Innovation Centre, Indian Institute of Technology Madras, India
57. Ms Sunita K Sreedharan, Lawyer, SKS Law Associates, India
58. Mr Damiano De Felice, Director of Strategy, Access to Medicines Foundation, Netherlands



59. Dr Pramod Garg, Professor, Department of Gastro Enterology, All India Institute of Medical Sciences, India
60. Mr Christoph Spennemann, Legal Officer and Officer-in-Charge, Intellectual Property Unit, United Nations Conference on Trade and Development, Geneva
61. Dr Kamal Jayasinghe, Director General, Chief Executive Officer, National Medicines Regulatory Authority, Sri Lanka
62. Dr Madhu Dikshit, Director, Central Drug Research Institute, India;
63. Dr YK Gupta, Professor and Head Department of Pharmacology, All India Institute of Medical Sciences, India
64. Dr Mohga Kamal Yanni, Senior Health and HIV Policy Adviser, Oxfam GB, UK;
65. Ms Siti Aida Abdullah, Deputy Director, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia;
66. Dr Viviana Munoz Tellez, Coordinator, South Centre, Switzerland;
67. Professor Margo A Bagley, Asa Griggs Candler Professor of Law, Emory University School of Law & Senior Fellow, Centre for International Governance Innovation, Atlanta
68. Dr Sanjay Mehendale, Additional Director General ICMR, Government of India
69. Dr VG Somani, Joint Drugs Controller, Central Drugs Standard Control Organization, India
70. Dr Ananda Sen Gupta, CEO & Founder, Trackmybeat Health Care Private Limited, India
71. Professor Brook K Baker, Professor of Law, North Eastern University, USA;
72. Professor Suptendra Nath Sarbadhakari, Project Director, National Health Portal, India
73. Dr Vinay Goyal, Professor, Department of Neurology, Neurosciences Centre, All India Institute of Medical Sciences, India
74. Dr Biswajit Dhar, Professor, Jawaharlal Nehru University, India
75. Professor SK Verma, Secretary General, Indian Society of International Law, India
76. Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia
77. Dr Carlos Correa, Special Advisor, South Centre, Switzerland
78. Dr Greg Perry, Executive Director, Medicines Patent Pool, Switzerland
79. Dr Tjandra Yoga Aditama, Senior Advisor, World Health Organization-South East Asia Regional Office, India
80. Mr Shiba Phurailatpam, Director of the Asia Pacific Network of People Living with HIV (APN+), Thailand
81. Dr Luca Arnaudo, Senior officer at the Italian Competition Authority, Rome;
82. Professor Stephen Sammut, Senior Advisor ABLE and Biotechnology Industry Organization, USA
83. Professor Christoph Rademacher, Associate Professor, Waseda University, School of Law, Japan
84. Ms Judit Rius Sanjuan, Consultant, United Nations Development Program, USA
85. Dr Sachin Chaturvedi, Director General, Research & Information System for Developing Countries (RIS), New Delhi, India
86. Dr Manisha Shridhar, Regional Advisor, World Health Organization- South East Asia Regional Office, India
87. Dr Gregory Messenger, Lecturer in Law, School of Law and Social Justice, University of Liverpool, UK
88. Dr Reji K Joseph, Associate Professor, Institute for Studies in Industrial Development, India
89. Dr VG Hegde, Professor, Centre for International Legal Studies, School of International Studies, Jawaharlal Nehru University, New Delhi
90. Professor TC James, Consultant, Research and Information System for Developing Countries (RIS), and President, NIPO, India;
91. Dr Burcu Kilic, Legal Counsel, Public Citizen, USA;
92. Ms Kajal Bhardwaj, Consultant, Access to Drugs and Intellectual Property;
93. Professor Rujitha Shenoy, Inter-University for IPR Studies, India