1st 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

Final Report
1ST 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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Abbreviations

AIIMS All India Institute of Medical Sciences
AMR Anti-Microbial Resistance
AMZ Andhra Medtech Zone
BIRAC Biotechnology Industry Research Assistance Council
BITs Bilateral Investment Treaties
CDSCO Central Drug Standard Council Organisation
CEPI Coalition for Epidemic Preparedness Innovation
CDRI Central Drug Research Institute
CSIR Council of Scientific & Industrial Research
DBT Department of Biotechnology
DNDi Drugs for Neglected Diseases
EU European Union
FDI Foreign Direct Investment
FTA Free Trade Agreements
GOI Government of India
GARDP Global Antibiotic R &D Partnership
GSPOA Global Strategy and Plan Of Action on Public Health, Innovation and Intellectual Property
ICMR Indian Council of Medical Research
ISIL Indian Society of International Law
ICT Information and Communication Technology
IP Intellectual Property
IPR Intellectual Property Rights
IVDs In vitro Devices
LICs Low Income Countries
MOH Ministry of Health
MOHFW Ministry of Health & Family Welfare
NCDs Non-Communicable Diseases
NIB National Institute of Biologicals
NITI National Institution for Transforming India
OECD Organization for Economic Co-operation and Development
PDP Product Development Partnership
R&D Research and Development
RIS Research & Innovation Systems in Developing Countries
SDG Sustainable Development Goals
SEAR South East Asia Region
SEARN South East Asia Regulatory Network
SMEs Small and Medium Enterprises
TB Tuberculosis
TPP Trans Pacific Partnership
TRIPS Trade-Related Aspects of Intellectual Property Rights
THSTI Translational Health Science and Technology Institute
UNDP United Nations Development Programme
UN HLP UN High Level Panel
UK United Kingdom
UNCTAD United Nations Council for Trade and Development
UNDP United Nations Development Programme
WHA World Health Assembly
WHO World Health Organization
WHO HQ World Health Organization Head Quarters
WIPO World Intellectual Property Organization
USA United States of America
USD US Dollars
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 1st 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 Institute
- 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**

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- 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:*

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*The Indian Society of International Law:*

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*World Health Organization:*

- Dr Poonam Khetrapal Singh, Regional Director, WHO SEARO
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 “1st 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 70th 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 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, 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) in 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.

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### 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**
2. Ms. Ruth Dreifuss, Co-chair, UN High Level Panel on Access to Medicines; Former President, Swiss Confederation, Geneva- *Governance, Accountability and Transparency*
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*
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
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
2. Promote adoption of mechanisms to mobilize resources to build sustainable, coherent solutions for financing of health research and development (R&D), 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 bio-similar 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
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 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 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*

**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.

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**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 consortia 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
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.

Support good antibiotic stewardship by de-linking the profitability of a product from the volume sold, and through responsible marketing.

Coordinate with the UN Inter-Agency Coordination Group (IACG) and the G20 R&D Hub on the access agenda.

Facilitate collaboration of national control labs (NCLs) on preparation of reference reagents and standards.


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.

Develop measures of accountability for fair returns on public financing of biomedical R&D and counting the social returns from such investment.

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:
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,
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 related 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 unmet 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).

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**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.

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**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 Publicly 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

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.


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

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.
Country Wise distribution of International Participants

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

- **USA**: 16%
- **Switzerland**: 16%
- **South Africa**: 4%
- **Thailand**: 3%
- **US**: 4%
- **UK**: 4%
- **Congo**: 4%
- **Colombia**: 1%
- **Nigeria**: 1%
- **Uganda**: 2%
- **Afghanistan**: 1%
- **Iraq**: 1%
- **Tunisia**: 2%
- **Morocco**: 4%
- **Argentina**: 1%
- **Bhutan**: 1%
- **Canada**: 1%
- **France**: 1%
- **Japan**: 1%
- **Macedonia**: 1%
- **Malaysia**: 1%
- **Maldives**: 2%
- **Myanmar**: 1%
- **Netherlands**: 1%
- **Spain**: 2%
- **Srilanka**: 3%
- **Sweden**: 1%
- **Nigeria**: 1%
- **Colombia**: 1%
- **Iraq**: 1%
- **Tunisia**: 2%
- **Morocco**: 4%
- **Argentina**: 1%
- **Bhutan**: 1%
- **Canada**: 1%
- **France**: 1%
- **Japan**: 1%
- **Macedonia**: 1%
- **Malaysia**: 1%
- **Maldives**: 2%
- **Myanmar**: 1%
- **Netherlands**: 1%
- **Spain**: 2%
- **Srilanka**: 3%
- **Sweden**: 1%
- **Nigeria**: 1%
- **Colombia**: 1%
- **Iraq**: 1%
- **Tunisia**: 2%
- **Morocco**: 4%
- **Argentina**: 1%
- **Bhutan**: 1%
- **Canada**: 1%
- **France**: 1%
- **Japan**: 1%
- **Macedonia**: 1%
- **Malaysia**: 1%
- **Maldives**: 2%
- **Myanmar**: 1%
- **Netherlands**: 1%
- **Spain**: 2%
- **Srilanka**: 3%
- **Sweden**: 1%
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
Main Report

I. Setting the scene

The “1st World Conference on Access to Medical Products and International Laws on Trade and Health, in the context of 2030 Agenda for Sustainable Development” began with highest levels of Ministry of Health, Government of India and inter-ministerial participation.

H.E. Mr J.P. Nadda, Minister of Health and Family Welfare (MoHFW), Government of India, and Union Ministers of State H.E. Mr Ashwini Kumar Chaubey and H.E. Ms. Anupriya Patel opened the Conference. Dr R.K. Vats, Additional Secretary, MoHFW, Government of India, welcomed the delegates.

The conference sought to build on the discussions on access to medicines in the 2016 UN High Level Panel (HLP) Report. The matter would also come up in the WHO Executive Board Meeting in January 2018. There is growing realization that cost of health technologies are putting a strain on both rich and poor countries. This is more true for the developing countries that are faced with a double burden of disease – from communicable diseases such as tuberculosis and malaria and lifestyle diseases, the non-communicable diseases such as diabetes, cancer and hypertension.

The conference was uniquely designed on three main thematic areas. These are first, Access to Medical Products, second, Innovation and Research & Development, and third, trade agreements such as WTO and intellectual property rights. Logistical issues to make the conference proceedings interactive, environment-friendly (through paperless deliberations) and accessible to all were highlighted. The website was a one-stop portal for all information related to the Conference. The high-end conference logistics – such as a mobile application and interactive online in-session surveys – was to facilitate a seamless conference experience for the participants.

Dr EMS Natchiappan, President of the Indian Society for International Law (ISIL), New Delhi, emphasized the need for sovereign nations to use the flexibilities offered by Article 27 of the World Trade Organisation’s (WTO) TRIPS agreement, to meet the needs of their people regarding medical products.

Dr Henk Bekedem, WHO Representative to India, highlighted that access to medical products is at the core of the health goal (Goal 3) of the Sustainable Development Goals (SDGs). He applauded India for being the “pharmacy of the world” for generic medicines and vaccines, with the country accounting for 63% of finished pharmaceutical products in the WHO Prequalification of Medicines Programme.
The Indian Prime Minister’s “Make in India” initiative holds opportunities to accelerate the country’s recent foray into medical devices and diagnostics at international standards. For instance, pan-India availability of reuse prevention syringes, as begun in the state of Punjab, could lead to a major dent in the spread of blood-borne diseases given that five billion injections are required every year. The conference’s concrete recommendations will serve as inputs to the upcoming World Health Organization’s Executive Board discussions in January 2018 on access to medicines.

Dr Jagdish Prasad, Director-General of Health Services, Government of India, mentioned India’s contribution to global drug manufacturing. India is the third largest manufacturer of drugs by volume, with affordable, high-quality drugs and 21 vaccines being exported to 150 countries, accounting for 20% of the generic medicines in the world. With the burden of diseases shifting to noncommunicable diseases (NCDs) in countries including India, there needs to be greater focus on innovation and production of affordable drugs for these conditions. The conference should explore ways to facilitate transfer of technology in medical products to promote universal health coverage.

Dr Soumya Swaminathan, Secretary, Health Research, Ministry of Health and Family Welfare and Director-General, Indian Council of Medical Research (ICMR), outlined expected outcomes from the Conference.

Ms. Preeti Sudan, Secretary of the Indian Ministry of Health and Family Welfare, outlined that the Sustainable Development Goals are the first ever globally-agreed development plan 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). The SDGs add new targets, such as noncommunicable diseases and universal health coverage. Of the 17 SDGs, good health and well-being finds direct mention in Goal 3 and is indirectly important to achieve all other SDG goals. India is committed to a robust drug regulatory system, she said. The Central Drugs Standard Control Organization (CDSCO) in collaboration with state drug regulatory authorities prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country. To strengthen and build capacity of the national and state (provincial) regulatory authorities (NRAs) manpower is being scaled up (1000 for CDSCO, 2500 for States) and new laboratories (six for CDSCO and 10 for states) are being installed. The e-governance portal (SUGAM portal) set up at the Central Regulatory Authority is being linked to the state regulatory authorities. As a result, there is greater transparency and dissemination of information for all.

Dr V.K. Paul, Member of NITI Ayog (National Institution for Transforming India), suggested that increasing investments in a range of medical devices from high volume, low cost (e.g. syringes) to low volume, high cost (e.g. MRI) will trigger their demand. Pricing is a key determinant of demand. There is also need for a robust architecture for quality and safety such as preventive maintenance and timely

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**Expected Conference Outcomes**

- Ways to improve use of TRIPS flexibilities by developing countries.
- Alternative models to improve access to medicines.
- Predictable and clear regulatory pathways.
- Increase public investment in R&D in developing countries to foster public patent pools.
- Fast track mechanisms for quick ethical clearances for clinical trials addressing outbreaks.
- Fit-for-purpose access models to improve governance and service delivery in non-manufacturing countries.
- Public-private partnership such as involvement of academia in R&D.

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**Profits are okay; Profitteering is not!**

**Access to medicines is about lives, jobs and products.**
repairs. India’s Small and Medium Enterprises (SME) sector rose to the task by making robust newborn care technology such as for weighing scales or phototherapy units which were eventually certified by regulatory authorities of the United States of America (USA) and the European Union. Dr Paul drew attention to the 150,000 health and wellness centres that are being set up under India’s new health policy requiring innovation and technology for emerging concerns such as hypertension and mental health.

Minister of Health for State Ms. Anupriya Patel said access to medicines is central to the priorities of WHO Member States of the South-East Asia Region in ensuring universal health coverage. WHO’s Constitution states defines health as a “state of complete physical, mental and social well-being, not merely the absence of disease or infirmity”. Health is a basic human right that can’t be guaranteed (genetically inherited diseases, ageing, etc.) but access to health services can be. Providing good health to all citizens is a key priority for governments. At the national level, access to medicines is an important facet in health systems as a whole. The other aspects of importance are adequate human resources for health-care delivery, procurement and supply chain management, health management information systems, service availability and accessibility and financial management. In this process, there is need to ensure better utilization of scarce resources and optimal use of funds.

The implementation of the R&D blueprint for developing new medicines in the SEA Region and leveraging the WHO Global Antibiotic R&D Partnership to address concerns of antibiotics resistance, developing new antibiotics and building a needs-based research pipeline for missing medicines are all very important, she said.

Mr Ashwini Choubey, also Minister of State for Health, shared a video message drawing attention to R&D in public health that has to address two major factors: to enable safe, effective quality medical products for diseases for all populations and to ensure a fast rollout from academia, laboratories, and the field. The rollout of medical products goes through a long process of clinical trials, he said. The trials are a must to make sure the new molecules address what they are expected to. The WHO R&D strategy to bring medical products quickly to affected populations in the wake of emergencies is critical for access to happen.

In India, in the area of research and development, the Indian Council of Medical Research (ICMR) and institutions such as Biotechnology Industry Research Assistance Council (BIRAC) and Translational Health Science and Technology Institute (THSTI) are playing an important role. They do so in their own capacity as well as in collaboration with international stakeholders.

New initiatives such as the Bio-pharma Mission in India by BIRAC – also named ‘Innovate in India’ (i3) – promise to accelerate India’s bio-pharma hub through focused programs on vaccines as well as medical technology including devices and diagnostics. The institutions facilitate research for the development of vaccines, maternal and child health, point-of-care diagnostics, metabolic diseases and nutrition, and provide training in clinical and product development to improve public health.

India’s Health Minister Mr J.P. Nadda shared how the conference built upon the discussions at the Seventieth World Health Assembly in May 2017. On 24 May 2017 at the Seventieth World Health Assembly in Geneva, India had jointly, with certain like-minded Member States, organized a side-event to discuss the “Recommendations of United Nations Secretary-General's High-Level Panel on Access to Medicines in the Context of the SDG Goals”. At that event he had briefly indicated that India will be organizing a conference to discuss the issues in greater detail. India has kept its word, he said.

The discussions on existing scenarios of intellectual property and trade, regulatory aspects, affordability and fair pricing are well timed. The context of innovation including in research and development models and information communication technologies should provide the
stimulus for bringing medical products at the doorstep of the most vulnerable groups. The dialogue on the role of competition in competitive pricing and discussion on related WTO agreements influencing health should lead to a larger umbrella of suggested policy options for government.

A policy coherence between trade, intellectual property rights and health policies will do well to effectively manage the interface between health and trade aspects besides promoting industry-academia collaboration in R&D of medical products, from the laboratory to the field. Harnessing small and medium enterprises to contribute fundamentally for affordable healthcare product development is necessary. Further, steps will be required to increase transparency and coordination between the national regulatory authorities and the pharmaceutical sector to enable the launch and registration of new health technologies. Innovative thinking is also needed to keep invaluable antibiotics effective and tackle antimicrobial resistance.

The Conference was a result of collaboration with many ministries in the government. The contributions of the Science and Technology Ministry, ICMR, 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 (MSME) Ministry of Electronics & Information Technology and the Ministry of Health will ensure concerted action on the access agenda for health for all.

In addition, India has actively contributed to the formation of and provided support to the new South-East Asia Regulatory Network (SEARN). SEARN will promote collaboration among the countries of the South-East Asia Region. The Minister also reiterated the country’s support to the new SEAR Network on Access to Medicines. The Union Health Minister announced that the “Second World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development” would be held in India from 9–11 October 2018 and invited all participants in advance.

The inaugural session concluded with Dr Madhur Gupta, Technical Officer, Pharmaceuticals, WHO Country Office for India, thanking the ministers, other dignitaries and collaborators for their valuable contributions to the conference.
II. Sustainable Development Goals (SDGs) and The Context of Access to Medical products

The Sustainable Development Goals (SDGs) 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 add new targets, such as on noncommunicable diseases and universal health coverage. Of the 17 SDGs, good health and well-being finds direct mention in Goal 3. The latter, however, is a prerequisite for achieving almost all other SDG goals.

Universal health coverage and the interlinked agenda of access to medicines, is among the Flagship Priorities of the WHO South-East Asia Region. International trade matters such as intellectual property, government procurement, competition laws, environment, and plurilateral agreements have a bearing on national decision-making on public health. The aspirations for trade need to be balanced with the need for access to medical products and the SDGs to achieve both health and trade benefits.

Trade and globalization have contributed to the international and national movement of medical, food and health products across boundaries. 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.

The SDG3 has specific targets to support research, development and access to essential medicines and vaccines. Goal 3.8 states: Achieve universal health coverage, including ... access to safe, effective, quality and affordable essential medicines and vaccines for all.

Goal 3. Ensure healthy lives and promote well-being for all at all ages

The goals within a goal: 3.b states: Support the research and development of vaccines and medicines for communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health and, in particular, provide access to medicines for all.

In the light of the SDG 2030 Agenda, the United Nations Secretary-General convened a High-Level Panel (HLP) on Innovation and Access to Health technologies (HLP) with the mandate to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies, which is a global problem. During the 2017 World Health Assembly discussions on the report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines (UN HLP), WHO Member States decided to raise the matter in its Executive Board so as to inform the UN Special Session on health technology, innovation and access by 2018. It is envisaged that an appropriate balance among national aspirations and technological advancements in research and development (R&D), information and communication technology (ICT) and production and manufacturing practices could lead to collective and collaborative efforts for global solutions. The 1st World Conference resulted in outlining possible policy development on diverse topics such as access to medical products, emerging landscape of innovation in health technologies and medical devices, international laws, trade and development, and settlement of trade and business disputes.
The Lancet Commission papers on Global health (2017) while identifying key problems of the current innovation system received lists of missing essential medicines from WHO and the UN.

Some important unmet public health needs include shorter treatments for latent and active tuberculosis, single-day treatments of malaria, and treatments for multidrug-resistant tuberculosis, and heat-stable insulin and oxytocin. Essential diagnostics are also needed, such as point-of-care tests to distinguish between bacterial and viral infections of the upper respiratory tract. Some essential medicines do exist but have been abandoned—these are no longer produced in volumes that meet global demand because they are not sufficiently profitable. Examples include snake antivenoms and benzathine benzylpenicillin.

A major category of missing essential medicines reflects a historic lack of attention to the specific needs of children. Between 1995 and 2005, 107 (44%) of the 243 medicines authorised in Europe by the European Medicines Agency (EMA) had a potential paediatric use, but no data on use in children were available at the time of authorisation. In 2007, WHO published the first Model List of Essential Medicines for Children and launched the Make Medicines Child Size campaign. A key example is the gap in paediatric treatments for HIV: 2·6 million children are living with HIV (88% of them in sub-Saharan Africa), but this statistic has not attracted sufficient commercial R&D investments. The alarming crisis in antimicrobial development is another example. A market-driven R&D system will not invest in new life-saving antimicrobials if their use will have to be rationed from the start to prevent resistance. The Ebola virus outbreak showcases another example. Clinical testing of an Ebola virus vaccine has shown promising results, but it took 11,000 deaths and extensive political mobilization to take the vaccine candidate off the shelf, where it had been sitting for 10 years after initial development by the Public Health Agency of Canada. Extensive R&D activity only started when the outbreak threatened richer populations. By October 2015, 31 molecules for Ebola virus treatment were under commercial development.

The Lancet Commissions further state that in a widely quoted study by Médecins Sans Frontières, only 15 (1·1%) of 1393 new medicines developed between 1975 and 1999 were for tropical diseases and tuberculosis, which account for 12% of the global disease burden. Between 2000 and 2011, only 37 (4·4%) of 850 newly approved products were for neglected diseases, most of which were new formulations or combinations of existing medicines. Similarly, in December 2011, of nearly 150 000 registered clinical trials, only 1·0% were for neglected diseases.

They further state that in the past decade and a half, new push-and-pull incentive mechanisms have been established. Some new donors, such as UNITAID and the Japanese Global Health Innovative Technology Fund (which includes private companies, among others), have increased funding for R&D of missing essential medicines. The Longitude Prize established a prize fund of £10 million in 2014 for the development of a point-of-care diagnostic test to determine whether (and which) antibiotics are appropriate in a given case. A marketed anti-tuberculosis medicine, Bedaquiline, was offered for prices of around US$ 3000 in Middle Income Countries (MICs) and US$ 900 in Low Income Countries (LICs). Yet in the USA it was marketed for US$30 000 per treatment, despite having received a priority review voucher (PRV) and fast-track approval by the US Food and Drug Administration.

The public often pays twice for R&D. Initial pharmaceutical research is often largely funded from public funds, such as the US National Institutes of Health or the European Horizon 2020 programme. For childhood cancers, virtually all research funding comes from the National Cancer Institute, private foundations, and philanthropic sources. However, the final commercialization steps of the development process are usually done by for-profit pharmaceutical companies, which obtain the intellectual property rights from publicly funded research institutes, thus controlling the technology, including decisions about commercialization and pricing.
Lancet Commissions further state, as a direct result of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008 (WHA61.21), UNITAID established a medicine patent pool (MPP) for HIV medicines in 2010. The MPP initially focused on patents related to HIV medicines to promote low-cost generic production and the development of fixed-dose combinations and paediatric formulations. The MPP has expanded its mandate to cover hepatitis C and tuberculosis. In November, 2015, the MPP signed an agreement with Bristol-Myers Squibb that allows the supply of generic daclatasvir in 112 low- and middle-income countries (LMICs).

Patents present substantial challenges to medicines availability. However, flexibilities in patent law have been used by a number of countries to secure access to generic medicines. The most frequently deployed flexibilities are compulsory licensing of medicines, government use of patents, and the waiver that allows LDCs to postpone granting or enforcing medicines patents and test data protection until 2033. These options have been used more widely than is usually assumed.

New figures show that since 2001, there have been 34 instances of compulsory licensing (CL) of medicines by 24 countries, 51 instances of government use of patents by 35 countries, and 32 of non-enforcement of patents by 24 World Trade Organization LDC Members. The peak of these instances falls between 2004 and 2008, coinciding with increased global funding for HIV. Although originally focused on HIV, 23 out of 85 total instances of CL and government use have concerned non-HIV medicines, including seven instances for cancer medicines between 2008 and 2014, of which five were granted. These measures have improved access to medicines. For example, in Thailand, CLs for erlotinib, docetaxel, letrozole, and clopidogrel save the health-care system US$ 142 million per year. In the past decade and a half, some countries have amended their patent laws to reflect health concerns. For example, India rewards innovation but prevents trivial patents and so-called ever-greening of patents.

*Delinking R&D costs from the price of medicines.* The concept of delinking costs from prices is based on the premise that costs and risks associated with R&D should be rewarded, and incentives for R&D provided by means other than through the price of the product.

The Report of the UN High Level Panel on Access to Medicines and various aspects on access to medical products were taken up in the following themes:

i. Regulatory pathways for safe, quality, efficacious and affordable medical products including in emergencies to achieve SDG goals.

ii. Affordability and fair pricing of medical products.

iii. Role of innovation, research and development for medical products.

iv. Fostering local production, technology transfer and market entry barriers for medical products.

v. Infectious disease control: What are the pathways to technology development and access to medical products.

vi. Alternative models of R&D-industry-academia collaborations.

vii. Achieving SDGs: Use of information and communications technology (ICT) initiatives including in trade agreements.

viii. TRIPS, UN High Level Panel Report and benefit sharing for access to medical products

ix. WTO Trade Agreements influencing health products: Context of SDGs/achieving SDGs: Regional agreements, challenges (TRIPS plus Agreements) and access to medical products.

The topics covered by the Speakers: Chairs, Co-Chairs, Lead discussants and Panelists is outlined (in italics) in the sessions outline to clearly indicate the subjects covered by them.
The conference began with the first of the three thematic areas of the conference: i.e. Access to Medical Products.

Discussions were held on the following:
- UN High Level Panel on Access to Medicines in the context of SDGs
- Regulatory Pathways for Safe, Quality, Efficacious And Affordable Medical Products Including In Emergencies To Achieve SDG Goals
- Affordability and Fair Pricing of Medical Products

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:**
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
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
The UN High-Level Panel (HLP) report addressed four major areas with specific focus:

• **Health Technology Innovation and Access:** (i) barriers to access affordable medical technologies, (ii) policy incoherencies that arise between public health goals, intellectual property norms, international human rights law, and global trade rules.

• **Intellectual Property Laws and Access to Health Technologies:** TRIPS flexibilities - Voluntary licences, Patentability criteria, Compulsory licenses, Limitations to the use of TRIPS flexibilities, Intellectual property generated from publicly-funded research.

• **New Incentives for Research and Development of Health Technologies:** implementation of delinkage, that the costs of R&D should not be determinative of the price of new drugs, vaccines, and diagnostic tools. Build on the Consultative Expert Working Group (CEWG) process and other discussions at the World Health Organization and “initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies.” Calling for “negotiations on a binding R&D Convention that delinks the cost of research and development from end prices to promote access to good health for all.”

• **Governance, Accountability and Transparency:** increased interagency or inter-ministerial coordination at the national level to ensure that policy incoherencies between trade and economic goals, and human rights and public health concerns, are addressed. The transparency section addressed three separate areas where there is a need for transparency in the pharmaceutical sector: R&D costs and pricing of health technologies, clinical trials and patent information.

Discussion to date, including in the report of the UN High-Level Panel on Access to Medicines, has focused on the effect of research and development costs on prices and, therefore, the need to delink these two issues.

The session identified concrete recommendations on barriers to access to health technologies and balancing public health needs with intellectual property and trade concerns. It is essential that many organisations come together: WHO, World Intellectual Property Organization (WIPO), United Nations Commission for Trade and Development (UNCTAD), various universities and think tanks.


The recommendations of the UN HLP must also result in greater prioritization of R&D as outlined in the GSPOA-PHI.

Co-chair of the UN HLP and Former President of the Swiss Confederation, Ms Ruth Dreifuss, elaborated on the themes of governance, accountability and transparency outlined in the panel’s report. On the accountability front, the report calls on governments to review access to health in countries in the context of human rights. For coordination, it
recommends establishment of national-level inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access. To improve transparency, Governments should require all manufacturers and distributors to disclose the costs of R&D, production marketing and distribution of their products as also details of public funding received. WHO is advised to maintain databases of patented products, including prices of patented, generic and bio-similar medicines. A UN inter-agency task force to increase coherence between multilateral organizations working on health technology innovation and access is necessary. The proposed UNGA Special Session on health technology innovation and access by 2018 are critical for progress.

The panel’s recommendation on IP laws and access to health technologies call on governments to make full use of policy space under TRIPS flexibilities. Legislative provisions be in place for quick, fair and predictable issuance of compulsory licenses and curtailing “ever-greening” but reward genuine innovation. The HLP cautions governments against adoption of TRIPS Plus measures compromising health rights and encourages health impact assessments before entering trade and investment agreements. New thinking on intellectual property systems for pharmaceuticals, consistent with international codes of human rights and public health, safeguarding the rights of inventors and excluding essential medicines from patent protection, is necessary. The HLP report is informing international discussions and decisions such as in MERCOSUR, and the proposals should be contextualised in the WHO programme of work 2019-2023.

The United Nations Development Programme (UNDP) focused on new incentives for R&D of health technologies. The antibiotics resistance and multi drug resistant TB are real challenges. There are just two new classes of antibiotics invented in the last forty years. There is therefore urgent need for public funding for research on health technologies that would give governments, particularly emerging economies, a role in priority-setting for needs driven biomedical innovation. The UN HLP recommendation to initiate negotiations for global R&D agreement/s on coordination, financing and development of health technologies that

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**Mandate of UN HLP**

To review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.

**SDGs and Access to Medicines**

2030 agenda demands an integrated, people centered, multisectoral, rights-based approach to development. Innovation and access are fundamental human rights issues. Universal health coverage is critical to drive progress on several SDGs and innovation and access to affordable and quality medical technologies are critical to achieving the SDG’s commitment to leaving no one behind.

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1 Mercosur is an economic, trade and political bloc comprising Argentina, Brazil, Paraguay, and Uruguay, and Venezuela.
delinks R&D costs from end prices to promote access to good health for all is therefore critical. There is a need to identify ways to increase public investment in research, strategies to ensure fair returns and open and collaborative models of innovation. As a preparatory step, governments should consider a code of principles that would apply to public R&D funds and be adopted by private and philanthropic funders, product development partnerships, universities, and the biomedical industry.

Certain recommendations of the UN HLP report find direct mention in WHO’s work e.g. to expand the Medicines Patent Pool (MPP) to all diseases would provide opportunities for the MPP to license all patented medicines on the WHO Essential Medicines list. The proposal for R&D agreements has been part of the GSPA resolution. WHO undertakes training and collaborative work with WTO and WIPO on trade and access issues through the trilateral cooperation agenda. For instance, WTO Trade Facilitation Agreement holds potential for swift movement of medicines through customs. TRIPS Plus provisions negotiated by Ukraine and Maldova for data exclusivity with European Union limiting access to generic medicines. Similarly, bilateral investment agreements by private companies are questioning Colombia, Ukraine and Uruguay’s public health measures. The WHO, WTO, WIPO Trilateral Study does not provide political recommendations, but is intended to inform training needs of countries.

The patent system affects access to direct-acting antiviral drugs to treat hepatitis C, e.g. in Argentina. The country’s patent law includes safeguards to protect public health. The civil society and local producers have filed patent oppositions under its Article 28, following which several applications are either pending or withdrawn. Approval of two patented products raises risks for government procurement of essential medicines. Companies have sued sovereign governments, including Argentina and India (for patentability provisions), Brazil (for prior consent requirements), Chile (for compulsory licensing), for responsible public health measures under TRIPS. The Global Commission on HIV and the Law has recommended the WTO Members suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries. The proposed international instrument on Transnational Corporations and other business enterprises with respect to human rights by the UN Human Rights Council Resolution 26/9 of June 2014 and the discussions of the Open-Ended Intergovernmental Working Group (OEIGWG) set up since then, hold opportunities to regulate the industry.

The escalating drug prices in the one year since the release of UN HLP report in 2016 are a matter of concern. For instance, insulin prices increased by 7% in the US. In the EU, average cost of new anti-cancer treatments has quadrupled in the last 15 years. Nationally, governments need to prioritise financing for research, make full use of TRIPS flexibilities, exclude TRIPS plus provisions in free trade agreements and ensure transparency in trade negotiations. UN HLP’s call to governments to negotiate R&D agreements that delink cost of R&D from price of products needs serious consideration.

R&D pipeline analyses shows consistent shortfall in the development of antibiotics. Most of the antibiotics that reach the market are “me-too drugs”.

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3 Global Commission on HIV and the Law, 2012
4 Me-too drug is a product that contains an active pharmaceutical ingredient which is chemically related, and usually very structurally similar, to an existing active pharmaceutical ingredient.
Forty percent of antibiotics approved by US Food and Drug Administration over two decades were withdrawn—there times the rate of withdrawal of drugs among other therapeutic classes. Twenty of these 26 antibiotics were withdrawn as they added little to antibiotics. A serious consideration of antibiotic stewardship by limiting prescription to trained providers, dispensing by certified institutions, administration in specific health-care settings, clinical algorithm and diagnostic test finding is recommended. While the industry can support many of these tasks, the health-care delivery systems need to lead antibiotic stewardship.

Following are three policy recommendations:

a) Facilitate bolder experiments in innovation by making the case for greater public sector investment in upfront R&D;

b) Finance transformation of the innovation ecosystem such as innovation platforms, companion diagnostics and clinical trial platforms;

c) Move to proof of concept over de-linking return on investment from price and quantity of antibiotics and complement these interventions with new approaches to ensure access and stewardship of the health-care delivery system.

Affordable medicines and the regulatory environment favouring generic manufactures producing drugs for domestic and international consumption is the need of the hour. The Indian national Intellectual Property Rights Policy of 2016 does not address the recommendations of the UN HLP. In TRIPS flexibilities many countries, despite having legislative provisions, currently do not have patent oppositions from generic manufacturers in large part on account of the expensive process involved. TRIPS Plus provisions, such as data exclusivity, promoted through bilateral investment agreements (BITs) and free trade agreements (FTAs) limit grounds for compulsory licensing and undermine TRIPS flexibilities. Access to medicines for all as envisaged under SDG target 3b will be hampered.

The scope for voluntary licensing for cancer vaccines as a strategy to create competition was explored. The opinion on voluntary licensing is divided as private corporations may set the terms instead of governments as is the case in compulsory licensing. New approaches such as allowing differential treatment of bio-similar products and chemical products may also be considered.

Globally, there is need for policy coherence among UN agencies for access to medical products. The recommended strategies include opening dialogue with WTO, interagency task force on access to medicines. Nationally, there is need for newer models of R&D and increased public investment. Policies requiring disclosure of cost of R&D and marketing, facilitating clinical trials, providing relevant public database are essential.

**Recommendations**
The discussions in the session on "UN High Level Panel on Access to Medicines in the context of SDGs" led to the following 10 recommendations for National governments, 7 recommendations for WHO/International organizations and 4 recommendations for the United Nations:

**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**


2. Promote adoption of mechanisms to mobilize resources to build sustainable, coherent solutions for financing of health research and development (R&D), 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 delinking 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

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

The Parallel Session 1 focused on Regulatory Pathways for Safe, Quality, Efficacious and Affordable Medical Products including in Emergencies to Achieve SDG Goals.

Regulation of medical technologies addresses essential health policy objectives: safe, efficacious and of adequate quality medical products. Regulatory pathways also shape the landscape for access and innovation: higher safety standards require the generation of more data and thus increase the cost of innovation. There is a need for shortened, predictable and more transparent regulatory pathways and marketing authorization procedures to avoid delayed access to needed medical technologies. Most clinical trials are carried out by or on behalf of the companies developing the tested products.

The registration of these trials is a scientific and ethical responsibility and therefore WHO runs the International Clinical Trials Registry Platform. From the perspective of public health policy, clinical trial results should be publicly available and the data should be made transparent, so that researchers and other interested groups themselves can assess the efficacy and potential side effects of new products. By the sidelines of WHA 2017, a Joint Statement on public disclosure of results from clinical trials, was signed by Member States, including India, and partners. The signatories of this joint statement affirm that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Within 12 months of becoming a signatory of this statement, the signatories pledged to develop and implement a policy with mandated timeframes for prospective registration and public disclosure of the results of clinical trials that is funded, co-funded, sponsored or supported by them. The emergence of biological medicines has raised challenges for established regulatory systems, notably how to regulate “bio-similar” follow-on products while still sufficiently incentivizing originator companies.

The regulators face the challenge to balance the benefit of the early release of new products with safety concerns and to define an acceptable level of risk. The need to simplify regulation while maintaining its stringency and cost-effectiveness requires more coordination through regional and international regulatory mechanisms, so as to enable suppliers to service regional markets without undue regulatory complexity or cost.

The objective of medicines regulation is to ensure that:

- products are of the required quality, safety and efficacy,
- products are appropriately manufactured, stored, distributed and dispensed by licensed manufacturers, wholesalers and health professionals,
- illegal manufacturing and trade are detected and adequately sanctioned,
- health professionals and patients have the necessary information to enable them to use products (particularly medicines) in a rational manner,
- promotion and advertising is fair, balanced and aimed at rational use,
- access is not hindered by unjustified regulatory barriers (such as applying different standards for imported and locally manufactured products, lengthy processing time for registration and marketing authorization applications, and duplication of the work of other regulators without delivering added value) side-effects.

International regulatory convergence and harmonization of regulatory pathways and guidelines is a challenge as national and sub-national registration authorities follow their own administrative rules and technical requirements, and they have established their own processes and procedures for medicines registration. Intra-country registration processes are also unpredictable. However, regulatory decisions made by other competent authorities should lead to: (i) more efficient resource use (e.g. international and regional sharing of scientific resources and “best practices”); (ii) better quality applications to register medicines
from manufacturers; (iii) cost savings both at the company and government level; and, as a consequence, (iv) quicker access to quality essential medicines that are safe and efficacious.

WHO has been playing a vital role in terms of improving regulation to provide a platform for regulators to discuss common challenges and identify areas where further guidance for regulators needs to be developed. The WHO has convened the International Conference of Drug Regulatory Authorities (ICDRA) every two years since 1980 to build collaboration between regulators globally, to promote harmonization and exchange of information, to identify good practices and to seek common approaches to problems that medicines regulatory authorities face.

The ICDRA recommendations serve as a guide to the WHO and interested stakeholders in determining priority actions in national and international regulation of medicines, vaccines and other regulated medical products. Furthermore, the WHO Prequalification Programme has greatly facilitated the access to quality medical products in developing countries. WHO has been playing a pivotal role in supporting countries in strengthening their regulatory systems of medical products for human use, and in promoting equitable access to quality, safe, efficacious and affordable medical products. World Health Assembly resolution WHA67.20 on regulatory system strengthening emphasized the WHO mandate and requested both WHO and Member States to invest more in this area and to address all health products and technologies.

**A progressive regulatory system in India**

The Indian government recognizes that effective regulatory systems are essential and contribute to better public health outcomes.

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value. Indian manufacturers are the key contributors to the WHO Prequalification Programme (PQP) for medicines and vaccines. It is to be noted that 64% of finished pharmaceutical products are from India. Of these WHO prequalified active pharmaceutical ingredients, 59% are from Indian manufacturers in the segments of HIV-AIDS, tuberculosis, malaria, reproductive health, etc. The government's Make in India campaign is encouraging manufacturing of medicines and devices to foster public health goals.

The Central Drugs Standard Control Organization (CDSCO) in collaboration with the state drug regulatory authorities prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country. Several states in India have already developed best practices in regulation of medicines, biologicals including vaccines, medical devices including diagnostics, through the WHO Good Regulatory Practices (GRP).

The Indian government has shown commitment and strong political will to strengthen and build capacity of the national regulatory authorities (NRA). There is provision of around US$ 275 million for strengthening the drug regulatory system in the country and funds have been allocated appropriately. There is a provision of scaled up manpower (1000 for CDSCO, 2500 for States), new laboratories (six for CDSCO and 10 for states), and the e-governance portal (SUGAM portal) set up at the central regulatory authority to be linked to the state regulatory authorities too for online issuance of licenses. A National Drug Regulatory Academy is also coming up for training of the regulators at central and state levels.
India has also scaled up the risk-based inspections for medicines and active pharmaceutical ingredients (APIs) among manufacturers in the states jointly with state regulatory authorities. The inspection is done by the team comprising of drugs inspectors from the state governments, Central government, a government analyst and the assistant drugs inspector. The benchmarks comprise the regulations and norms of national Good Manufacturing Practice (GMP)/Pharmaceutical Inspection Co-operation Scheme (PIC)/International Conference on Harmonization (ICH), etc. The enforcement offices of CDSCO are ISO accredited and the central laboratories are NABL accredited.

There have been dynamic changes in the regulatory landscape of the country. The recently released Rules for Medical Devices and in vitro diagnostics released in the public domain is one such example.

The 4th WHO Global Forum on Medical Devices will be hosted by the Government of India in October 2018 in New Delhi, India.

**WHO NRA Re-benchmarking in India:** The National Regulatory Authority of India (NRA) competencies were reiterated when the WHO-led team of international experts made a comprehensive review on 13–17 February 2017 with the WHO Global Benchmarking Tool. The benchmarking had been carried out by a WHO team for vaccines and comprising lead experts marking in different areas from WHO headquarters Geneva, WHO India Country Office, experts drawn from the regulators of USA, Italy, Germany, Netherlands, Indonesia, Thailand and Egypt. The assessment has been done in respect of nine different functionalities and Indian NRA has been declared “functional” with a maturity level of 4, i.e. the highest level as per currently evolved definitions in respect of five functions, and maturity level 3 in respect of four functions, which is noteworthy. India continues to meet the standards of the WHO NRA published indicators (WHO Global Benchmarking Tool) on regulatory system for vaccines.

Indeed, it is of utmost importance that the countries importing vaccines are confident that the national regulatory authority in the country of origin is competent in its oversight and the product would be safe and effective for their population. This allows the domestic vaccine manufacturers to apply for WHO vaccine prequalification. It also allows export of Indian vaccines to the world immunization market, and will probably lead to more affordable vaccines.

Indian Pharmacopoeia Commission (IPC), an autonomous institution under the Ministry of Health and Family Welfare, Government of India, recently became the WHO collaborating
centre for pharmacovigilance. Pharmacovigilance and drug safety monitoring is of pivotal importance for improving treatment support and adherence. The Pharmacovigilance Programme of India and its integration with public health programmes is to ensure that adequate systems and practices for reporting adverse drug reactions are in place and that the benefit of use of medicine outweighs the risks associated with its use.

In this context it is worthy to note that Indian NRA has actively contributed to the formation and provided support for the new WHO South-East Asia Regulatory Network (SEARN) among the South-East Asian countries. This move will enhance South-South collaboration and guarantee access to high-quality medical products in the WHO South-East Asia Region Member countries.

The session addressed affordability, accessibility and availability of medicines, in particular challenges posed by epidemics and pandemics. Addressing the challenges led to productive outcomes such as Ebola vaccine, fast track clinical trial process for emergencies and formation of the Coalition for Epidemic Preparedness Innovations (CEPI). Expedited regulatory procedures and framework are needed for emergency situations. Monitoring of quality of drugs, capacity building and skill development, national regulatory assessment and rationalization of regulatory processes and regulatory timelines are important. Fostering mechanisms for access to orphan class of medicines and ease of market entry using facilitative processes and pathways should be considered.

In the context of Indian biopharmaceutical guidelines and also its new regulations on medical devices, clinical trials require to have a well-defined process. The design, understanding the ethical and regulatory pathways, incorporating the community experience and ensuing the well-being of subjects, averting and addressing adverse events are to be taken care of. Ensuring affordability of patented medicines including through price controls, and addressing monopolies and build confidence in prescribers and dispensers is required. TRIPS and in particular Bolar flexibilities in national patent laws are relevant to new medicines.

For local or regional production, there are a number of models and concrete examples that are not being adequately showcased and would be applicable to other countries or regions. Collaborative efforts include South-South cooperation or North-South cooperation, rather than the traditional bilateral cooperation from donor countries. In terms of regional capacity, two concrete examples that should be more showcased are: the UNIDO-supported Pharmaceutical Manufacturing Plan for África, which includes support to Ghana, Kenya (Kenya GMP Roadmap), Zimbabwe, besides the African Union plans in Ethiopia. UN organizations, including WHO, have published documents on that initiative. Another is the Developing Countries Vaccine Manufacturers Network (DCVMN), as it comprises nearly 37 members from 14 countries and have set development goals and examples of collaborative and regional approaches. Several of these vaccine manufacturers are WHO prequalified.

Health technology, local production and innovation related to manufacturing plants for APIs (active pharmaceutical ingredients) are a special case as these plants have a completely different approach than pharmaceutical products. They are commonly chemical synthesis plants with capacity that is usually measured in tons of APIs manufactured. The integration with pharmaceutical plants is crucial, as the large transnational pharmaceutical manufacturers have a verticalized capacity of preparing their own APIs. An additional issue to be discussed is how to ensure the manufacturing of strategic intermediates for APIs, so as to not rely on dependency from exclusive manufacturers and ensure quality of the APIs and consequently of the final products, besides affordable pricing policies.

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5 Bolar flexibility allows generic manufacturers to obtain marketing approval of a patented invention before patent protection expiry so as to market their versions as soon as the patent expires.
Universal access to TB treatment with first-line medicines produced by the BRICS countries would be a huge step forward. The proposal was discussed in successive meetings of the ministers of health of Brazil, Russia, India, China and South Africa and a “Joint Communiqué” was issued in December 2014. The rationale was that as the BRICS countries host almost 50% of the TB cases in the world, also considering that China and India are responsible for the API production for TB and the five BRICS countries have production capacity, they would fulfill the needs of first-line treatment of all the LICs and MICs. That would ensure universal access to TB treatment worldwide and reduce the cases of MDR and XDR-TB. There is a need to 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 access to bedaquiline, delamanid, Hepatitis, oncology medicines.

This proposal must be revisited and implemented, in the context of ensuring universal access to medicines and in concordance with the premises stated on WHO’s Global Tuberculosis (TB) Report 2017, the End TB Strategy (http://www.who.int/tb/strategy/en/) and in line with the expectations from the Global Ministerial Conference on Ending TB in the Sustainable Development Era, Moscow, 16–17 November 2017. The Moscow deliberations will also inform the UN General Assembly High-Level Meeting on TB in 2018.

**Recommendations**

The discussions in the session on “Regulatory Pathways for Safe, Quality, Efficacious and Affordable Medical Products including in Emergencies to Achieve SDG Goals” led to the following 6 recommendations for National governments and 8 recommendations for WHO/International organizations.

**Recommendations for National Governments**


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.

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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

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**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
The Parallel Session 2 focused on Affordability and Fair Pricing of Medical Products.

As countries move towards universal health coverage, new global mechanisms are needed that ensure fair prices for medicines. Fair in that patients can get access to the medicines they need, health systems are sustainable, and industry can produce quality products with a reasonable return on investment (Towards Access 2030, Lancet 2017, p341: Suzanne Hill, Marie Paule Kieny, Department of Essential Medicines and Health Products (SH) and Health Systems and Innovation (MPK), World Health Organization).

Everyone relies on the pharmaceutical industry to manufacture and deliver essential medicines. Yet we have at present a problem with two facets. The pharmaceutical industry is demanding higher prices for most new products that are being developed, so that medicines such as the direct-acting anti-virals for hepatitis C are unaffordable even in high-income and middle-income countries. At the same time, some key essential medicines, such as benzathine penicillin or methotrexate for cancer, are disappearing from the market globally, due in part, we think, to prices that have become so low that it seems no longer commercially viable for manufacturers to supply them.

Equitable access to essential, high-quality and affordable essential medicines and other medical technologies depends on affordable and fair pricing of medical products and effective financing schemes. Promoting affordable and fair prices and cost-effective interventions is central to the achievement of universal health coverage within the mandate of Sustainable Development Goal 3.

An "affordable and fair" price is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country. The “price” of a medicine or a technology is generally a function of markets, and changes over time. Prices can be measured and evaluated as the price paid to the manufacturer, the price paid by the consumer or patient, or prices from suppliers. Usually, a new medicine is launched under patent protection and may have a high price until the patent expires and competition and/or generic products emerge which are available post the expiry of the patents. Currently, high prices of many new medicines and other medical products including medical diagnostics and equipments are challenging public health care systems or patients who have to pay for them out of pocket in most countries lacking universal health coverage.

India and China are one of the major producers of generic pharmaceuticals, vaccines and biologicals, and active pharmaceutical ingredients (APIs). They have played an important role in meeting public health needs in many low-income developing countries, especially in Africa. Their significance can be described from the fact that 80% of all donor-funded annual purchase volumes of antiretroviral medicines (ARVs) in 2008 were supplied by Indian manufacturers. Also most of the global API production is concentrated in India, China and Republic of Korea. According to Bumpas & Betsch (2009), 75% of the API production is exported to rest of the world from India and China. Also, more than half the world’s children are immunized with vaccines produced in India.
Price control: There is potential for manufacturers to exploit market exclusivity when facing demand for medicines that remains relatively constant irrespective of changes in price. This has enabled many countries to regulate prices for at least some portion of the pharmaceutical market, most often patented products. Canada and Mexico, for example, have established price review regulation for pharmaceuticals protected by patents. Various price control schemes have been used. These include, among others, controlling profits of manufacturers, direct price controls, comparing prices to internal or external references, constraining spending by physicians, enforcing prescription guidelines, tying marketing approval to prices, and placing limits on the promotion of medicines.

Price controls can be applied either at the manufacturer, wholesaler or retailer level. The most direct control method is when a government sets the sale price and prevents sales at any other price. Canada's Patented Medicines Prices Review Board protects interests of consumers by ensuring that the prices of patented medicines are not excessive. Another method used by governments is to set an artificially low reimbursement price for a new drug, so that any price above must be borne by the patient. The governments may regularly reduce the reimbursement price of existing marketed drugs. These types of price controls are market interventions, and controlled prices should allow for reasonable profits to the suppliers to sustain in the market.

Price control on medical products in India

India has played a pivotal role in the reduction of prices of hepatitis C medicines by scaling up production under the voluntary license agreements, which are otherwise unaffordable. Course of treatment for hepatitis C from hence is US$ 120 in the Indian province of Punjab. For medical devices, in February 2017, National Pharmaceutical Pricing Authority (NPPA) slashed prices of coronary stents by over 75%, capping the ceiling prices of drug eluting stents (DES) and bioresorbable vascular scaffolds (BVS) at INR 29 600, and bare metal stents (BMS) at INR 7260. Including value added tax, these stents are expected to cost INR 31 080 and INR 7623, respectively. Nearly 100 000 to 150 000 orthopaedic knee procedures are done in India manually every day. In order to facilitate these orthopaedic knee procedures, the National Pharmaceutical Pricing Authority (NPPA) has also slashed the prices of total knee replacement systems by 69% even before its addition to the National List of Essential Medicines (NLEM).

Price control mechanisms, reference pricing: Reference pricing can determine, or be used for, negotiating the nationally regulated price or reimbursement level of a product based on the price(s) of a pharmaceutical product in other countries or within the country.

Columbia’s experience is a case in point: National Medicines Pricing Commission fixes reference prices for all medicines commercialized in the country’s public sector at least once a year. To do so, it takes into account the average price in the domestic market for a group of homogenous pharmaceutical products, i.e. products with identical composition, doses and formulas. If the price applied such a medicine is above the reference price for homogenous products, direct price controls are applied and a maximum retail price is fixed by the Commission. Direct price controls are also applied if there are less than three homogenous products on the market. In such cases, the Commission establishes an international reference price (IRP) by comparing the price applied for the same product in at least three of eight selected countries from the region (Argentina, Brazil, Chile, Ecuador, Mexico, Panama, Peru and Uruguay) and in Organization for Economic Co-operation and Development (OECD) countries. The lowest price found in any of these countries is fixed as the maximum retail price for Columbia.

The application of price controls has played a prominent role in the case of lopinavir and ritonavir provided to HIV/AIDS patients in Columbia. In 2009, the Columbian Ministry of Health rejected a 2008 application for a compulsory licence on the grounds of lack of public interest. As this medicine was listed on the national EML, its supply by insurers to patients
was mandatory, and therefore the price applied by the right holder would not block access. At the same time, the Commission decided to regulate the price of the medicine concerned. The prices were fixed at US$ 1067 for the public sector and US$ 1591 for the private sector, representing an average reduction of between 54 per cent and 68 per cent per person per year (Brazilian Interdisciplinary AIDS Association, 2009). The right holder’s appeal against the decision was rejected. In 2010, the originator company agreed to sell the medicine at the price fixed by the Commission.

*Health technology assessments:* Assessing health technologies is a diverse process wherein the information about the medical, social, economic and ethical issues relating to the use of a health technology are captured in transparent and systematic manner so as to formulate, safe and effective health policies to serve the patients at large. Such an assessment of medical products and technologies is an overall assessment of safety, efficacy, cost-benefit analysis amongst other aspects of the use of a medical technology. It further helps to analyse whether the costs are proportionate to the health outcomes, and thus whether the medical product should be provided to the patient.

*Differential pricing strategies:* Differential pricing allows pharmaceutical companies to indicate that their pricing policies are socially responsible and consistent with their obligations to society and not just aimed towards maximizing profits. In addition, differential pricing on selected medicines opens opportunities to serve low and middle-income markets and creates economies of scope for pharmaceutical companies.

As differential pricing divides the markets into different tiers or groups, the practice is also known as tiered pricing. Such a price discrimination is feasible to segment the markets and prevent the purchase of products in lower-price market and the subsequent sale in the higher-price market.

Tiered pricing can be practiced in different ways. Private companies can negotiate individual agreements with other companies. They can also negotiate price discounts with governments or through regional or global bulk purchasing arrangements and the licensing of production for specific markets. Differential pricing can make medicines more affordable to larger segments of the population and could also lead to increased sales, thus benefiting pharmaceutical manufacturers. But it reaches a limit when the marginal costs of manufacturing is higher than the affordability level of the patients so this can only be used as a complimentary policy as providing access to affordable medical products should be the flagship priority of any government.

An example of differential pricing is the **Accelerating Access Initiative**, a partnership established in May 2000. Among five UN organizations (UNAIDS, UNICEF, the United Nations Population Fund (UNFPA), the World Bank and WHO) and five pharmaceutical companies. The objective was to address the lack of affordable HIV medicines and of HIV/AIDS care in selected developing countries. The pharmaceutical companies involved agreed to either donate medicines and/or provide significant cost reductions.

Differential pricing is already well established in the vaccine market. A three-tiered pricing structure is used for most vaccines sold in both developed and developing countries. Companies charge the highest prices in high income countries, low prices in countries prioritized by the GAVI Alliance, and intermediate prices in middle-income countries. Vaccines are also the sector where differential pricing is more widespread within a country: for example, one company offers its hepatitis B vaccine at two different prices within India, with the public sector only paying about half the price paid by the private sector.

*Taxes:* Certain practical tax measures can be used to reduce the price of medical products. A measure could be applied on medicines which the patients would buy regardless of their price. For example, Mongolia removed taxes on imported omeprazole sold in private pharmacies, a step that led to a price fall of between US$ 5.91 and US$ 4.85 for a 30-
capsule pack, while the Philippines removed 12 per cent VAT thus reducing the price of a ten generic co-trimoxazole tablets (480 mg) from 14.90 pesos to 13.30 pesos. Another measure that may improve access to medicines is alterations in tax rates. It should be possible to evaluate the consequences of defined changes in tax rates that either improve or reduce access to medicines and then propose tax policy changes accordingly. Removing Customs duties is a similar measure that can have a direct bearing on prices and access.

Mark-ups: A mark-up represents the add-on charges and costs applied by different stakeholders in the supply chain in order to recover overhead costs and distribution charges, and make a profit. The price of a medicine includes mark-ups that have been added along its supply chain distribution. Medicine mark-ups can be added by manufacturers, wholesalers, retailers, pharmacists and many others who play a role in the supply chain distribution. Like taxes, a mark-up also contributes to the price of medicines and thus has a direct bearing on access to medicines. Mark-ups on medicines also vary depending on the type of medicines.

High prices of Hepatitis C medicines have also been a major barrier to access. The new hepatitis C medicines have treated over million people in low and middle income countries with a cure rate of over 95% but their initial price of US$ 85 000 has been unaffordable even to patients in high-income countries. Egypt, however reduced the price of a three-month treatment from US$ 900 in 2014 to less than US$ 200 in 2016. On the other hand, a recent study found that the median nominal factory price of a 12-week course of sofosbuvir across 26 Organization for Economic Co-operation and Development (OECD) countries was US$ 42 017 and ranged from US$ 37 729 in Japan to US$ 64 680 in the United States. Treatment for rare diseases can be very heavy on pocket. For example, ivacaftor, an effective medicine for some people with cystic fibrosis, costs as much as US$ 294 000 per patient per year in developed countries. These price differences also reflect the negotiating capacity of countries.

Local production, appropriate licensing mechanisms and technology transfer agreements have paved a way to treat patients affected with infectious diseases involving higher treatment cost thus making the healthcare services more affordable and accessible.

WHO’s Fair Pricing Forum

The Dutch Government has recently given a grant to an initiative called Fair Medicine. This initiative could serve as a potential game changer for the development of new medicines. Fair Medicine brings together all stakeholders around the development of a new pharmaceutical product at an early stage.

In May 2017, The Dutch Ministry of Health, Welfare and Sport together with WHO hosted the Fair Pricing Forum to facilitate discussion on strategies that could lead to a fairer price setting and pricing system sustainable for health systems. The discussions included innovation, identifying research gaps including the need for transparency of research and development costs, production costs, and profit margins. The forum also explored approaches for high- and middle-income countries to remedy shortages of essential medicines that may be due to low profit margins.

The multi-stakeholder discussion was seen as a first step towards identifying an actionable agenda towards fair pricing. Fair pricing means pricing that allows for a reasonable return on investment in exchange for an affordable price, which is to say one that does not bankrupt health systems and other payers. It is with such “sustainable pricing” that the growth of the pharmaceutical sector will be supported and universal access to essential medicines and other health technologies will be ensured.

It is advisable for the governments to be enabled to play a stronger role in negotiating prices and where appropriate, incentivizing needs-based R&D. More cooperative approaches
would be helpful, for example with governments sharing information on pricing, and gaining
greater leverage when negotiating prices.

Governments should see funding for health as an investment that will contribute to greater
economic benefits, for example by enabling more health sector jobs in the public and private
sectors, in addition to keeping the population healthy. Greater investment in R&D
prioritization should result in development of products that respond to public health needs.

With regard to pricing drivers and strategies, it was discussed that a “value-based” pricing
model is not viable in many countries because it does not take into account affordability and
total cost.

Another important point which was taken into consideration was that there is a need to fully
understand the concept and consequences of “de-linkage” with respect to development of
medicines. At present, there is little transparency on what inputs actually feed into decisions
about medicines prices, and there is very little evidence regarding many elements such as
the actual R&D investment or the public sector contribution. Before de-linkage models are
pursued, better definitions of the inputs into price setting are needed, noting that R&D has to
be paid for in order to have the necessary medicines and health technologies.

The need for greater transparency was a recognised as a recurring theme. More
transparency on pricing is needed from all stakeholders: from public research
entities, defining how much public money is spent on discovery research; from companies, on how
much they spend on clinical trials and other development activities, and how much on
production costs; and from countries, on how much each one pays for a medic

There is a need for further discussion, in order to find solutions to the many different facets
of the prices/access issue, to develop a constructive and concrete action plan that can be
implemented.

A commentary authored by the Dutch health minister H.E. Mrs. Edith Schippers in The
Lancet stated that:"The current pharmaceutical system is out-of-balance", and "It is time to
set a new course... We should take measures to better control the price of medicines."

The session brought to the fore the fact that the current situation with respect to medicines
prices highlights two problems: high prices causing access issues on the one hand, and low
prices leading to shortages on the other. Universal health coverage is intended to enable
risk pooling and make medicines more affordable. Importantly, this shifts the ability to pay for
medicines from the capacity of individuals to the fiscal capacity of countries. Many factors
affect access to medicines. Besides the availability of medicines, the next important factor is
their unaffordability.

Affordability is a one dimension of access. Affordability becomes a particularly serious
problem when medicines are needed for chronic conditions, including non-communicable
diseases (NCDs).

The prices of many medicines are unsustainable, with even those not patented like insulin
becoming unaffordable. Several studies indicate the R&D contribution to drug prices is not
as high earlier projections. There often appears to be more spending on drug marketing than
R&D. The prices also do not indicate the quantum of subsidies and public spending that the
drugs receive during the development phase. A sound definition of fair pricing, along with
effective price enforcement mechanisms, delinking of the cost of R&D from the price of
products is critical. Transparency in drug pricing through disclosures of the cost of R&D, subsidies received and marketing expenditure will help move towards fairer pricing.

Open models of innovation such as DNDi can be effective in reducing prices. Newer funding
models can also help ensure transparency and fair pricing. The models need to consider
how to plough the benefits of innovation from public funding back to the people. Facilitating competition from generics and biosimilars can drive the price down. The search for alternative models of R&D needs to continue.

Recommendations

The discussions in the session on “Affordability and Fair Pricing of Medical Products” led to the following 10 recommendations for National governments and 3 recommendations for WHO/International organizations:

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.
IV. The second of the three thematic areas of the conference: i.e. Innovation and Research & Development discussed the following:

- Role of Innovation, Research and Development for Medical Products
- Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products
- Infectious Disease Control: What are the Pathways to Technology Development and Access to Medical Products?
- Alternative Models of R&D-Industry-Academia Collaborations
- Achieving SDGs: Use of Information and Communications Technology (ICT) Initiatives including in Trade Agreements

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<td><strong>Co-chair</strong>: Dr Gagandeep Kang, Executive Director, Translational Health Science and Technology Institute, India</td>
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<td>4. <strong>Professor Anthony D So</strong>, 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- <em>Grants and Co-Operative Agreements with Academic Institutions in Promoting R&amp;D in Public Health</em></td>
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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

The Plenary Session 2 focused on the Role of Innovation, Research and Development for Medical Products. Government agencies and research institutes, private organizations, public–private partnerships (PPPs) and community-based organizations have all worked to reduce the burden of infectious diseases, yet the challenges persist. Lifesaving innovations, including very simple yet effective interventions, still remain out of the reach of many (Global Report for Research on Infectious Diseases of Poverty, World Health Organization on behalf of the Special Programme for Research and Training in Tropical Diseases 2012). Various recommendations that have previously been made for increased financing of R&D, notably the call of the Commission on Health Research and Development for 2% of health expenditures and 5% of development assistance for health to be devoted to health R&D. It has been proposed that countries should consider these targets:

• Developing countries with a potential research capacity should aim to commit 0.05–0.1% of GDP to government-funded health research of all kinds
• Developed countries should aim to commit 0.15–0.2% of GDP to government funded health research of all kinds (Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination, Report of the Consultative Expert Working Group -CEWG-on Research and Development: Financing and Coordination, 2016).

The current landscape of Research and Development highlights the following issues which must become a flagship priority for all stakeholders:

• The current model of innovation in medical technologies is facing considerable challenges, including changing markets, higher costs, and more stringent regulatory standards.
• The public sector significantly impacts the innovation cycle at various stages, directly providing key R&D inputs, helping to shape private companies’ R&D priorities, and influencing how health products are procured and disseminated.
• The lack of transparency in providing the real costs of medical research thereby leading to high costs of medical products creates access issues for public at large.
• Intellectual property rights (IPRs) are a useful incentive, but it is debatable whether the IP system can incentivize inventions in areas where there is no market.
• The WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) found that the innovation cycle is self-sustaining in industrialized countries which have a large market, thus enabling companies to recoup their investments in innovation. This is not the case in low and middle income countries where the markets are small, the healthcare system is underfunded and there is no health insurance.
• Innovation policy instruments can differ to an extent where the research is publicly funded and executed, publicly funded but privately executed or privately funded and privately executed research which again creates policy incoherencies and leads to a non-transparent situation.
• The WHO has established a clinical trials registry that makes clinical trial data publicly available. The publication of results of clinical trials is in the interest of both public health and science.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoa): This key WHO resolution of GSPA, WHA61.21 identified several deliverables on public health, innovation and intellectual property (IP) to promote innovation,
transfer of technology and access to medicines for public health. The project outlined 108 specific actions across eight elements and 25 sub elements.

These elements include:
1. Prioritizing research and development needs;
2. Promoting research and development;
3. Building and improving innovative capacity
4. Transfer of technology;
5. Application and management of intellectual property to contribute to innovation and promote public health;
6. Improving delivery and access;
7. Promoting sustainable financing mechanisms; and
8. Establishing and monitoring reporting systems.

On 26 May 2015 with the World Health Assembly resolution WHA68.18, the Member states extended time frame of Global strategy and plan of action on public health, innovation and intellectual property (GSPA, WHA61.21) from 2015 until 2022. Further the resolution asked to conduct:
1. comprehensive evaluation of GSPA in line with WHO evaluation policy and guided by WHO evaluation practice handbook with terms of reference as specified in document WHA68/35.
2. overall programme review and present the final report of the overall programme review of GSPA in 2018.

The Comprehensive Evaluation Report (CER) for GSPA, presented in WHA 2017 was contracted to Capra International Inc. Input was also received from an ad-hoc evaluation management group comprised of six independent content experts and two evaluation experts from the United Nations Evaluation Group and the WHO Evaluation Office. A mixed method approach was used, based on primary and secondary data. All Member States were invited to nominate a single focal point to facilitate data collection from all relevant government entities. Of the 194 Member States, 101 (52%) nominated a focal point, and 68 (35%) contributed to the evaluation.

Subsequently an overall programme review of GSPA was taken up. The review also takes into account the CER. The review is intended to be a forward-looking exercise. The expert review panel held several meetings between March and September 2017. Five focus areas served as the basis for the programme review: (i) changes to the policy context since adoption of the GSPA-PHI in 2008; (ii) current activities related to research and development (R&D) and access; (iii) assessment of the comprehensive evaluation report; (iv) definition of core priorities and drafting of recommendations; and (v) responsibility for implementation and advocacy. One of the eight elements of the GSPA focuses on financing and coordination of R&D for diseases that mostly affect developing countries and this point was raised in the Expert Working Group (EWG) and a Consultative Expert Working Group (CEWG) on Research and Development, in 2009 and 2011 respectively.

The CEWG highlighted open approaches to R&D and innovation, pooled funds, direct grants to companies, milestone prizes, end prizes and patent pools and the general principle of de-linking the costs of R&D from the price of the medicine, meaning that the investor does not have to recoup its R&D investment through the sales revenues. The report was also discussed by the WHO Member States in an open ended meeting in November 2012 and there was an agreement on a strategic work plan that included the creation of a WHO global health R&D observatory, implementation of a number of health R&D demonstration projects, and exploration of a potential financing mechanism for pooled contributions and coordination. The work plan also addresses available data on funding for health R&D, health products in the pipeline, clinical trials, and research publications.
WHO's R&D Blueprint for Outbreaks - an example of Priority Setting and Coordination

The 2014-2015 Ebola outbreak in West Africa revealed that the world is largely unprepared for major outbreaks caused by emerging and highly infectious pathogens. There was a lack of medicines and vaccines at the time of outbreak and there was no time to develop or control the widespread disaster which occurred due to lack of appropriate medicines.

Therefore, according to resolution WHA 68(10), WHO developed a Blueprint for R&D preparedness and response to emerging pathogens likely to cause severe outbreaks in the near future, and for which few or no medical counter measures exist. The WHO R&D Blueprint for action to prevent epidemics addresses the question of how to 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 development of vaccines, therapeutics and diagnostics is costly. Based on recent research, the R&D Blueprint presents estimates of the funding needed to develop drug and vaccine candidates as well as diagnostics, taking into account average failure rates in the development process. These numbers allow a rough estimate of the cost of preparedness, with a sufficient number of drug and vaccine candidates developed for the different pathogens included in the Blueprint. As most of the pathogens prioritised by the Blueprint are poorly researched, it is estimated that up to $1.17bn would have to be invested for each pathogen, although R&D could be considerably cheaper, if built on existing technologies. An essential condition for better R&D preparedness and response is the availability of funding. However, there is currently insufficient funding to cover the required R&D to address pathogens included in the Blueprint. New and innovative funding models are needed to more sustainably fund R&D for emergency response and preparedness. In previous years, many different innovative funding models have been discussed for R&D for neglected diseases and other poverty-related illnesses.

The R&D Blueprint presents options on how to ensure that the required research activities are financed and take place in the most efficient way, involving all necessary stakeholders. The Consultation on Financing for R&D preparedness and response to public health emergencies due to highly infectious pathogens took place in Oslo and highlighted the need to start quickly, with the focused objective of defining target product profiles for medical products to address a specific set of the identified pathogens. One of the Consultation’s recommendations was to seek mechanisms to ensure sustainable financing, starting by engaging those stakeholders who are ready to move.

Discussions in different fora such as the G7 and the G20 and the UN General Assembly are ongoing and will hopefully result in the creation of a funding mechanism. However, while it is important to work towards more sustainable R&D funding, there is also a need for short-term action. To that end, the Blueprint explores possible ways to make more efficient use of existing funding through better coordination, using the experience from the pilot project on Middle East respiratory syndrome coronavirus (MERS-CoV) and the experience gained with R&D coordination in the development of malaria vaccines. The R&D Blueprint is an effective roadmap which can be dynamically and effectively used to prepare for outbreaks and emergencies caused by pathogens in advance.

Antimicrobial resistance: The Global Antibiotic Research and Development Partnership

Antibiotic resistance poses a serious challenge to public health, but also raises the important concern about the lack of much needed research and development models, lack of adequate investment in the antibiotics are being done as there is an insufficient financial return or lack of incentive for the private sector to develop new antibiotics. In order to address the crucial problem of Antimicrobial Resistance, WHO has taken its leadership with its Global Action Plan on Antimicrobial Resistance (GAP-AMR) which combines new
medicines, discovery, development and stewardship (WHO Secretariat (2016) Global action plan on antimicrobial resistance (A69/24 Add.1). This new initiative draws its strength from both: WHO’s mandate to drive the global response to antimicrobial resistance and set health priorities, and DNDi’s expertise in harnessing partnerships to develop new antibiotics and build a pipeline for neglected diseases and deliver not-for-profit, needs-driven R&D for resource-limited settings.

**The GARD-P**

- Addresses global public health and the specific needs of low- and middle-income countries
- Targets products that industry will not develop due to foreseen lack of incentives
- Pilots the use of alternative incentive models that support conservation of and access to new antibiotics based on DNDi’s experience in implementing alternative R&D models for neglected diseases
- Ensure that new antibiotics are affordable to all in need worldwide.

This collaboration is based on the following principles:

- Affordability of new antibiotics
- are an effective global mechanism to finance and conserve new antibiotics. Public investment into development of new antibiotics to come with appropriate obligations to governments, regulators, producers, and distributors with respect to the marketing and responsible use of these new products to avoid the rapid build-up of drug resistance
- Sustainable investment should be coordinated at country and international level to avoid waste of resources
- R&D should focus on the most significant drug-resistant bacterial infections

This product development partnership is hoped will effectively be used to address the serious issue of antimicrobial resistance.

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**Global Observatory on Health Research and Development- an example of Priority Setting and Coordination**

On 19th January 2017, the Global Observatory on Health Research and Development was released by the WHO which aims “to consolidate, monitor and analyse relevant information on health research and development needs of developing countries, with a view to contributing to the identification and the definition of gaps and opportunities for health research and development priorities”. It includes new elements, such as indicators for monitoring activities in and resources for health research and development, comprehensive analyses of data on health research and development by disease, comparative analyses of health research and development activities between countries and across diseases, and a section on classifications and standards, as a first step towards harmonization of future data collection efforts. Therefore, The Sixty-ninth World Health Assembly (May 2016) re-
emphasized the Observatory’s central role and the importance of expediting its development. In resolution WHA69.23 it also requested the establishment of an expert committee on health R&D to set priorities for new investments based on information primarily provided by the Observatory.

The R&D needs relating to the following two specific areas of health concern are tracked through the Observatory:

- antimicrobial resistance and the need to develop new medical products to protect populations from the risks of failing treatments against infectious pathogens;
- a comprehensive R&D Blueprint preparedness plan that allows the rapid activation of R&D activities during future epidemics, such as the epidemic that occurred due to Ebola virus disease.

The primary scope of the Observatory as outlined by Member States in World Health Assembly resolution WHA69.23 is:

- type II and type III diseases (i.e. diseases incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries, and diseases that are overwhelmingly or exclusively incident in developing countries respectively);
- the specific R&D needs of developing countries in relation to type I diseases (i.e. diseases incident in both rich and poor countries, with large numbers of vulnerable populations in each);
- potential areas where market failures exist;
- antimicrobial resistance and on emerging infectious diseases likely to cause major epidemics.

It adheres to a broad definition of health R&D, including all types of research for health and its ultimate goal is to inform the development of new health products, hence many of its data sources support this goal. As more data and resources become available, the Observatory will expand the diseases and types of health R&D it covers.

**Coalition for Epidemic Preparedness and Innovations- Product Development Partnership, (CEPI)**

CEPI is working towards overcoming barriers with a new model for funding vaccine developments against epidemic diseases. CEPI is alliance between industry, academia, WHO, civil society, government etc.

Its aims to:

- Stimulate, facilitate and finance the development of new vaccines against infections of epidemic potential, especially where pathways to regulatory approval and commercialisation are highly unpredictable.
- Advance candidate vaccines through the development process, so safety and efficacy are proved in principle through human trials, before epidemics begin. This will enable rapid full trials or emergency deployment in outbreaks.
- Establish the technical capabilities and processes necessary to accelerate research, development, manufacturing and clinical trials in the context of an outbreak.
- Work with industry, regulators and other bodies to ensure any vaccines developed get licensed and reach the people who need them.
- Support the long-term development of epidemic vaccine preparedness within the countries most at risk from epidemic threats.

**Innovative Medicines Initiative (IMI)**

IMI is a public-private partnership (PPP) in medical sciences. It is a European centric partnership between the European Union and the pharmaceutical industry. This platform facilitates open collaboration in research, for development such as to accelerate patient access. The areas are of unmet medical need in Europe of personalised medicines for the
health and wellbeing. The Innovative Medicines Initiative (IMI) works to improve health by accelerating the development and patient access, to innovative medicines especially in areas of unmet medical or social need.

This is done by facilitating collaboration between the stakeholders involved in healthcare research, that are universities, research centres, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators.

Progress of Health Research and Development in India

India is a major vaccine producer that has 21 major vaccine manufacturing facilities. These vaccines are used for the national and international market (150 countries), which makes India a major vaccine supplier across the globe. India continues to meet the standards of the WHO NRA published indicators (WHO Global benchmarking Tool) on regulatory system for vaccines.

The Government of India has taken some more promising initiatives to foster research and development by setting up of research organizations such as Biotechnology Industry Research Assistance Council (BIRAC). New initiatives such as the Biopharma Mission in India, by BIRAC also named as ‘Innovate in India’ (i3 ) (and a collaboration between the World Bank and the Government of India contributing equally to the overall mission’s budget of US$250 million) promise to accelerate India’s biopharma hub through focused programs on vaccines as well as medical technology including devices and diagnostics. The aim of the mission is to enable and nurture an ecosystem for preparing India’s technological and product development capabilities in biopharmaceutical to a level that will be globally competitive over the next decade, and transform the health standards through affordable product development.

The BIRAC, Translational Health Science and Technology Institute (THSTI), and Indian Council of Medical Research (ICMR) in its own capacity as well as in collaboration with international stakeholders in the area of Research and Development facilitate research for the development of vaccines, maternal and child health, point-of-care diagnostics, metabolic diseases and nutrition, and training in clinical and product development to improve public health and improve biotechnological research in India.

The session began with an introduction to India’s new Bio Pharma Mission set up with a 5-year initial investment of USD 250 million to nurture bio medical research for drugs and vaccines. The mission, with World Bank’s support, seeks to increase India’s share from 3-5% of the global biopharma market by developing biosimilars for biotherapeutics that would soon go off patent, shifting focus from small molecules to biopharmaceuticals and leveraging the growing global requirement for outsourcing market for bio manufacturing, validation and discovery. As a product development partners, BIRAC aims to create an ecosystem (Figure 3) that will facilitate innovation and development of specific products through shared infrastructure, and strengthened skills and technology transfer capabilities.
In the wake of the Ebola outbreak, WHO developed the R&D Blue Print to Prevent Epidemics. This was tested during the Zika outbreak in the Americas, and target product profiles for diagnostic tests and vaccines were developed and two diagnostics shortlisted for procurement. WHO can guide member states in these areas, besides fostering local production and leveraging regional networks such as South East Asia Regulatory Network Network (SEARN) for building cross linkages between regulatory and access agenda.

The WHO R&D Blue Print for Action to Prevent Epidemics, triggered by the Ebola outbreak of 2013, provides guidance to fast-track the availability of effective tests, vaccines and medicines to save lives and avert large scale crisis during outbreaks. Since then nine public health risks of epidemic potential and some counter measures have been prioritised for action.

Welcome Trust UK shared its response to epidemics and anti-microbial resistance (AMR). Apart from funding basic science, the Trust’s innovation strategy has focused on translation of research for the greatest impact, and supporting structures to maximise efficiency and impact of R&D such as through the WHO Blue Print for Epidemics and Germany’s proposal to G20\textsuperscript{10} for an AMR Coordination Hub. As depicted in Figure 4, the tripod of gaps between access, innovation and conservation speeds up AMR\textsuperscript{11}.

Another successful model of PDP for R&D in Neglected Diseases is DNDi which is a patient needs driven partnership that promotes open knowledge innovation and seeks to develop drugs as public goods. Its current PDP working landscape explores vaccine R&D, Diagnostics R &D and R &D for new or improved treatments by establishing a robust pipeline. The model offers lessons including the importance of prioritizing needs of patients

\textsuperscript{10} Group of Twenty (G20) comprises of the world’s largest advanced and emerging economies: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Republic of Korea, Mexico, Russia, Saudi Arabia, South Africa, Turkey, the United Kingdom, the United States and the European Union.

in developing countries upfront at the start of the innovation process, breaking the link between the cost of R&D and the price of products and ensuring the fruits of innovation are accessible and affordable.

Figure 4: Tripod for Addressing Antimicrobial Resistance

Studies show that clinical trials account for 50% of the time lost in drug development, which needs improvement. Priority should be given to neglected population such as women, children, elderly and those in rural and remote areas, with a focus on formulations, dose adjustments and safety. Further, the clinical trial information needs to be disseminated to address diverse stakeholder expectations (Figure 5), gain greater community acceptance and effect policy change and access.

Figure 5: Stakeholder expectations from clinical trials

USA’s Bayh-Dole Act provides safeguards for publicly funded research done by universities, teaching hospitals and non-profit research institutions. It outlaws exclusive licensing unless necessary for commercialization, transparency in patenting and licensing of publicly funded research and government authority to issue additional licenses, government use rights and access to end products. While it has allowed the government to retain licenses, the provision has been underutilized—academic institutions derived only 5% of their academic revenue from technology licensing over 25 years of the law coming into effect; 70% of these revenue went to top 10% universities in the country. 130 universities did not generate enough licensing income in 2012 to recover licensing fees and pay their technology transfer staff (2013 Brookings Institute analysis). The Public Intellectual Property Resources for Agriculture (PIPRA), a network consisting of more than 50 institutions from over 15 countries provides a range of services such as IP landscape & FTO reports, institutional IP policies and contract support, workshops and needs assessment. This provides a good practice for the medical space.

<table>
<thead>
<tr>
<th>Product developer</th>
<th>Academia/research</th>
<th>Government</th>
<th>Society</th>
<th>Health care worker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerate to bring to market, return on investment</td>
<td>Concept/hypothesis to proof of concept</td>
<td>Improvement in public health</td>
<td>Access to appropriate product, ethics</td>
<td>Rational use of drugs</td>
</tr>
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Measures to Improve Academic Partnerships for Public Good

- Accountability measures for fair returns on public financing of biomedical R&D
- Safeguards for health technologies licensed by publicly funded research
- Sharing knowledge from open access policies to open science.
- Open science, institutional arrangements, for biomedical innovation and a semi-commons patent pool to park IP for open licensing
- Pilot efforts to bring R&D on public health priorities to market under humanitarian access conditions.
The Hopkins Alliance for a Healthier World, a University-wide initiative, reviews affordability at every step of the project, bring together scientists with different motivations to get their innovations past the technology transfer office at affordable rates, and offer public funding for R&D.

WHO SEAR and India have undertaken a survey of pharmaceutical enterprises exploring their priorities, needs and capacity gaps. The report, provides detailed insights into the technological capabilities and gaps and recommendations for diverse sectors of the government.

**Recommendations**

The discussions in the session on “Role of Innovation, Research and Development for Medical Products” led to the following 8 recommendations for National governments and 19 recommendations for WHO/ International organizations:

**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.
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.
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,
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

The Plenary Session 3 focused on Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products. In order to become economically viable, local producers, particularly those based in low-income countries, have to address a number of challenges. These challenges may include: weak physical infrastructure, scarcity of appropriately trained technical staff, dependence on imported raw materials, including active pharmaceutical ingredients (APIs), weak and uncertain markets, lack of economies of scale, high import duties and taxes, lack of a conducive policy environment and policy coherence across sectors, weak quality control and regulation measures, existence of patents on key products or technologies, delayed regulatory clearances, high cost of manufacturing, lack of advanced technologies, lack of collaborations between relevant stakeholders (government, industry, academia etc.).

Local production of vaccines in most developing countries is less common than that of pharmaceuticals and is more situated within the public sector. Developing country manufacturers with WHO prequalified vaccines on the market include Brazil, Bulgaria, Cuba, India, Indonesia, the Republic of Korea, the Russian Federation, Senegal and Thailand. Manufacturers from 14 countries (Argentina, Brazil, Cuba, Egypt, India, Indonesia, the Islamic Republic of Iran, Mexico, China, the Republic of Korea, Romania, South Africa, Thailand, Vietnam) have formed the Developing Countries Vaccine Manufacturers Network (DCVMN). This is a voluntary public health-driven alliance of vaccine manufacturers from developing countries whose aim is ensure a consistent supply of good-quality vaccines accessible to developing countries, especially the vaccines used in the WHO Expanded Programme on Immunization.

The situation for diagnostics is more complex. Manufacturers of diagnostic tests range in size and scope, from large multinational corporations to small local companies employing only a handful of people. The market is less dominated by large multinational corporations compared with other medical product sectors, with an estimated 42% share of global revenues being taken by small companies in 2008. Diagnostics developed by large multinational companies are targeted primarily at developed country markets, and most make their way to developing countries through donor programmes. There is often segmentation of the market due to the presence in the market of large numbers of small companies. Complexities of manufacture, due to non-availability of advanced technologies, lengthy and unpredictable regulatory processes, difficulties in technological upgrading, restrict production of some products, shifting the focus of most developing country manufacturers on simple technologies. There is a dire need for technological advancements.
promoting newer models of R&D to foster local production and technology transfer of medical products globally.

The need for public health concerns to be at the center for local production of medical products is thus essential for the following reasons:

• the presence of local production alone is insufficient to reap the benefits of greater access to medicines in developing countries;
• to develop a common understanding for policy coherence for both industrial development and health development;
• to guarantee that public investments in institutional development of national regulatory bodies are made to ensure locally produced medical products are quality-assured;
• to assist governments identify and justify the various fiscal and non-fiscal incentives to local producers;
• as one means to address a future scenario where the supply of affordable generic medicines at a global level is uncertain;
• to coordinate international support for industrial development and health development

Technology transfer remains a top priority for countries all over the world, and intellectual property protection is often seen as a tool to control access to technology and maintain strategic dominance in the market. The TRIPS Agreement on the one hand has set higher standards of patent protection, but on the other hand in Article 7 WTO Members have agreed that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

The WHO guidelines on transfer of technology in pharmaceutical manufacturing have proven useful in this area. A fine example is the WHO technology transfer for pandemic influenza vaccines and enabling technologies:

**The WHO Global Pandemic Influenza Action Plan, published in 2006**, identified the construction of new influenza vaccine production plants in developing countries as a priority, so as to increase global capacity and pandemic preparedness. The WHO has provided seed funding to 14 vaccine manufacturers in Brazil, China, Egypt, India, Indonesia, Iran, Kazakhstan, the Republic of Korea, Mexico, Romania, Serbia, South Africa, Thailand and Viet Nam to enable domestic production.

The classical methods of manufacturing influenza vaccine, such as the 1940s vintage hen egg-derived technology that still accounts for the bulk of influenza vaccine production, are not protected by IPRs. A central technology transfer hub was established in the Netherlands, thereby concentrating expertise in a single location from which technology transfer to multiple recipients could be carried out efficiently. Personnel from the majority of the countries who provided funding for the project, as well as personnel from national regulatory agencies, have received training at this technology transfer hub.

**Enabling technologies- Live attenuated influenza vaccine technology**: Several of the manufacturers opted to use the live attenuated influenza vaccine technology, which produces a high-yield, low-cost vaccine that is easy to administer. In order to facilitate access to the know-how, clinical data and seed strains required for this technology, the WHO, on behalf of developing country vaccine manufacturers, negotiated and acquired a transferable non-exclusive licence. Sublicences were granted to three developing country vaccine manufacturers. Adjuvant technology: Adjuvants have been shown to permit dose-sparing for pandemic influenza vaccines, and thus multiply capacity, enabling a larger number of people to be immunized. However, the know-how on these adjuvants has been predominantly in the hands of a few multinational vaccine manufacturers.
The WHO determined that the IPRs on one of the lead adjuvants had limited geographical scope, and therefore could be produced in developing countries. To transfer the necessary know-how on how to produce the adjuvant, the WHO facilitated the establishment of an adjuvant technology transfer hub at the University of Lausanne. The hub established production processes for the adjuvant, and has already successfully transferred the technology to Indonesia and Vietnam.

Some other existing technology transfer projects are designed to involve LDCs in local and regional manufacturing initiatives through collaborations with private companies and national governments. One such initiative is a joint venture between an Indian generic manufacturer and a Ugandan company.

Under this programme, Indian experts provided training to local staff. This partnership resulted in the establishment of a manufacturing plant near Kampala to produce ARV medicines and antimalarials. The plant has been certified by the WHO as compliant with good manufacturing practices (GMPs) and has obtained WHO pre-qualification for two products.

The Brazilian government is cooperating with the Mozambique Ministry of Health to establish Mozambique’s first manufacturing facility for the production of first-line ARV medicines, based on the portfolio of drugs produced by the Oswaldo Cruz Foundation. The year 2011 saw the signing of an agreement to construct the facility. As part of this agreement, Brazil will supply equipment and training for local technicians working in the facility.

Andhra Medtech Zone (AMZ), a partnership of central and a state government in India, presents the experience of integrating research, industry promotion and service delivery under one roof. The medical devices industry of USD 3.9 Billion in 2015 is the fastest growing sector in the Indian economy. Accounting for 1.7% of the global medical device market (among the top 20 markets), it is projected to grow to USD 8.16 Billion by 2020. Government need to direct to earmark certain percentage of the permitted 100% Foreign Direct Investment via automatic route in greenfield and brownfield projects in medical devices.

The Kalaam Institute of Technology augments these services through facilitation of technology transfer, inputs guiding R&D investment and mitigation of trade barriers among others. The Institute developed a priority list across the disease and trade spectrum, which informs the national Bio-Pharma Missions. It also pools patents, prototypes, technology and manufacturing rights from research and academic institutions and auctions them exclusively to industry or sells them at base cost to reach the products to the market. The funds generated go to resource further R &D. Further it is setting up a bio medical consortium to bring equivalence in qualification, competency and experience of bio-engineers.

India’s initiatives promoting medical device manufacture

- Ease of doing business policy
- Perpetual validity of Licenses
- Regulations specific to devices
- FDI policy
- Medical devices parks
- Custom duty exemptions
- Incentives for R&D
- Regulator support for innovation
- National Institutes of Pharmaceutical Education and Research
- Draft Medical Devices Policy
The WHO Model Regulatory Framework for Medical Devices provides, in addition to a definition and classification, essential principles and enabling conditions for effective regulation of medical devices. It proposes a stepwise approach to regulating medical devices and advises on disposal, substandard and falsified product and reprocessing single use medical devices. *In vitro* devices (IVDs) attract additional scrutiny for risk to personal health and public health. The enabling conditions for effective regulation include a legislative framework that delineates the responsibilities of manufacturers, importers, gap analysis, an implementation plan, monitoring and evaluation. Section 4 of the Model Framework entails stepwise approach to regulation beginning with export only certificates to import controls and addressing adverse reports, surveillance and corrective actions. Substandard and falsified products undermine the health system, markets and access and therefore receive special attention in Section 5 of the framework.

Wellcome Trust, UK’s approach to developing portfolios in health care includes prioritizing neglected and neurological diseases and mental health. The portfolio seeks to mitigate risks, develop a thriving eco system, maximize translation of research into products, involve young researchers and raise public awareness. It addresses barriers by involving academia and developing PDPs to reduce time delays. The Trust’s Award criteria include publishing results, registering clinical trials and maximizing patient access while ensuring sustainability for manufacturers.

Innovation Knowledge Progress (IKP) Knowledge Park, a not-for-profit science park and incubator in Hyderabad and Bangalore in India supports 270 companies, including over 230 startups focused on access to medical products, funding 180 innovations and filing over 270 patents. Young startups need support grants and skilling by Ministry of Skill Development. One of its innovations, 99 DOTS works with 17 state governments in India on the national TB programme where by sensor technology enables health care providers to track patients’ treatment compliance. The Park has a mixed funding model, supported by government resources, coupled with private sector, development agencies like USAID and philanthropies like Bill and Melinda Gates Foundation.

Several participants drove home the need for an Essential Diagnostics List. WHO has begun to put together an Essential Medical Devices list and a formal meeting is anticipated in 2018. India’s National Diagnostics Programme has developed a list of Essential Diagnostic Services that identifies the free diagnostic services that are to be delivered to the public at

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**Figure 6: Scientific Facilities Andhra MedTech Zone**

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primary to tertiary health care. 21 states have launched the programme, such as through public private partnerships in public institutions.

Setting-up of Two Support cells in India for providing guidance to the Indian manufacturers for the (WHO) Prequalification of In Vitro Diagnostics Programme in India

The setting up of two support cells in India for providing guidance to the Indian manufacturers on the WHO Prequalification of In Vitro Diagnostics (IVDs) Programme were announced viz. National Institute of Biologicals in North India and Andhra med-tech Zone in south India. WHO would provide the required training to the support cell staff to guide the manufacturers about WHO Prequalification expectations.

Recommendations

The discussions in the session on “Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products” led to the following 5 recommendations for National governments and 3 recommendations for WHO/ International organizations:

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:
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*
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

The Parallel Session 3 focused on Infectious Disease Control: What are the Pathways to Technology Development and Access to Medical Products. Infectious disease epidemics cost the world US$60 billion each year. They endanger lives, disrupt societies and jeopardize economies globally. Like SARS before it, and Zika since, Ebola showed how vulnerable the world is to epidemics of infectious diseases. The most recent Ebola outbreak in West Africa killed over 11,000 people and caused an estimated economic loss of $2.2bn in the worst-affected countries in 2015 alone.

According to WHO, an estimated 1.7 billion people in 185 countries needed mass and/or individual treatment and care for neglected tropical diseases (NTDs) in 2014. Despite NTDs accounting for approximately 12% of total disease burden, just 4% of therapeutic products registered between 2000 and 2011 were indicated for these diseases. There is an urgent need for rapid point of-care diagnostics, particularly for use in resource-limited settings and in health emergencies, such as Ebola and Zika. But diagnostics can be complex and costly to develop, resulting in an inadequate number on the market.

There are many challenges in Medical innovation and research and development. It has been noted that despite the funding of over US$ 3.4 billion reported by the 2015 G-Finder to support research and development (R&D) of new products for neglected diseases, R&D...
pipelines are still limited for products treating diseases primarily targeting low- and middle-income countries (LMICs), compared to products with higher market values (Health Product Research & Development Fund: A Proposal for Financing and Operation, Special Programme for Research and Training in Tropical Diseases (WHO, TDR) (2016).

The Report of the UN Secretary-General’s High-Level Panel on Access to Medicines, calls upon UN member States, private sector and other stakeholders to increase investment in this area and to develop new and additional models for financing R&D models to address the issue of antimicrobial resistance.

Furthermore, in January 2016, representatives of the pharmaceutical, biotechnology and diagnostics industries adopted a Declaration on Combating Antimicrobial Resistance. The declaration was adopted by almost 100 companies and 11 industry associations committing to increasing investment in R&D by extending collaborative initiatives between industry, academia and public bodies to increase and improve research into new antibiotics, diagnostics, vaccines and other health technologies. These initiatives are important but the pressing concern still persists that the production of health technologies and the investment into R&D of these health technologies is insufficient and the sustainable and effective solutions are not yet available to address these urgent healthcare needs.

The session also discussed lack of interdisciplinary approaches in R&D. Ebola outbreak in Liberia exposed the gaps in technology development and health care delivery. Ebola crisis led to the setting up the Partnership for Research on Ebola Vaccine In Liberia (PREVAIL). Similarly the GARDP Business Plan 2017-2023 is an enabler for countries to move forward in the development pathway. Epidemic preparedness is key. Regulatory pathways need to be in place before the next epidemic. Fit for purpose development and subsequent evaluation can rarely be done by one person. Multidisciplinary teams or working with other disciplines makes helps identify solution that requires expertise across a range of disciplines. The ways to make multi-disciplinary collaborations work need to be learnt from other experiences.

The gap between R&D and public health needs is also important to consider. There has been no benchmarking of pharmaceutical companies on their policies to improve access to health technologies. Lack of attractive market for antibiotics and lack of private sector investment are also challenges in the pathway to technology development.

**Recommendations**

The discussions in the session on “Infectious Disease Control: What are the Pathways to Technology Development and Access to Medical Products” led to the following 5 recommendations for National governments and 4 recommendations for WHO/ International organizations:

**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.
Recomme
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
The Parallel Session 4 focused on Alternative Models of R&D-Industry-Academia Collaborations. Collaboration between academia and industry is a critical component of efficient innovation systems. It is important to understand the different types of university-industry collaborations, motivations to form these agreements, possible barriers to such cooperation as well as the role of public policy in fostering such linkages.

University-industry collaboration also lead to the generation of new models of R&D which are carried out in public institutions, foster the commercialization of R&D Outcomes as well as increase the employment of labor between public and private sectors.

Alternative models of R&D

Product development partnerships (PDPs) have been a significant development, drawing together not-for-profit entities and industry players, with major philanthropic funding, significantly increasing the number of products in development for neglected diseases, and identifying pathways regarding existing research gaps.

• They integrate public-sector and private-sector approaches, and generally use industry practices in their R&D activities.
• They manage neglected diseases R&D portfolios and they target one or more neglected disease.
• They are created in order to pursue public health objectives rather than commercial gains, and also in order to provide funding to cover existing research gaps.
• They ensure that the developed products are affordable.

Public Private Partnerships and Product Development Partnerships

Publicly funded innovation carried out by academic institutions and public research organizations are aimed at increasing basic scientific knowledge and generally do not undertake commercialization. The stakeholders collaboration has the potential to foster access to medical products. Collaboration between academia and industry is a critical component of efficient innovation systems. It is important to understand the different types of university-industry collaborations, motivations to form these agreements, possible barriers to such cooperation as well as the role of public policy in fostering such linkages. University-industry collaboration also lead to the generation of new models of R&D which are carried out in public institutions, foster the commercialization of R&D Outcomes as well as increase the employment of labor between public and private sectors.

The outcomes from the seminal work on development of new diagnostics, vaccines and medicines to treat these diseases is still relevant. The Commission on Intellectual Property Rights, Innovation and Public Health- CIPIH, 2006 concluded that for early stage research WHO should bring together academics, small and large companies in pharmaceuticals and biotechnology, governments in the form of aid donors or medical research councils, foundations, public–private partnerships and patient and civil society groups for a standing forum to enable more organized sharing of information and greater coordination between the various players.

Ideally, basic research discoveries are quickly transformed into drugs, treatments, or methods for prevention. There is a need to develop new partnerships of research with organized patient communities, community- based health care providers, and academic researchers… This vision will require new paradigms in how clinical research information is recorded, new standards for clinical research protocols, modern information technology platforms for research, new models of cooperation between NIH and patient advocates, and new strategies to re-energize our clinical research workforce.

Product development partnerships (PDPs) have been a significant development, drawing together not-for-profit entities and industry players, with major philanthropic funding, significantly increasing the number of products in development for neglected diseases, and
identifying pathways regarding existing research gaps. PDPs benefit from lower capital costs as a result of their capacity to leverage in-kind inputs. They also benefit from the fact that they do not have to fund a fully loaded development pipeline. Instead, they select their projects from a pool of existing public and private domain projects. (Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade, World health organization, World intellectual Property organization and World trade organization, reprinted with index, 2013).

A 2005 study, which examined the portfolios of five PDPs as well as the portfolios of a selected number of pharmaceutical companies, identified 63 new drug development projects for neglected diseases (including tropical diseases, malaria and TB). A significant finding was that one quarter of development projects came from the pharmaceutical industry working alone; one quarter from the pharmaceutical industry together with PDPs; and the balance from PDPs working with a diversity of small companies, developing country companies, academics and the public sector. Thus, PDPs were involved in three quarters of all identified neglected diseases drug development projects in 2005 PDPs form alliances with stakeholders drawn from the public and private sectors because PDPs and these entities have the potential to capitalize on the opportunities that each may offer the other. PDPs are serving the purpose of bringing different inputs from a diverse set of stakeholders to fulfill research and development needs. PDPs lower the overall research costs than research based only in pharmaceutical companies. PDPs select their projects from a pool of existing public and private projects and do not have a completely loaded development pipeline.

**Intellectual Property Regimes and Technology Transfer Offices**

The creation of technology transfer offices (TTO) in universities has become a common mechanism to assist researchers in patenting their findings and obtaining license fees and royalties. TTOs provide a wide range of services aimed at improving the technology transfer cycle, such as support in the patent application process, licensing agreements, search for partners and funding sources, and training and support in the creation of university-based spin-offs. Consistent efforts in R&D are needed to develop appropriate technological set ups and collaborations before relevant returns appear in the form of commercially successful spin-off companies or patent licensing.

**Globalization and university-industry collaboration**

National innovation systems in most countries are increasingly collaborating with global innovation networks to promote useful research and innovation as well as foster technology. Collaborations between local industry and foreign universities play a critical role in sharing of knowledge between experts from both the sectors and implementing it collectively to achieve desired results. Multinational companies (MNCs) have effectively expanded their global innovation networks, and their aim to collaborate with universities located abroad. These have been defined as platforms for centralization of R&D. Policy makers should strive to stimulate collaboration between multinational subsidiaries and local universities as a mechanism to attract their R&D activity and to enhance local production and technology transfer. This allows universities to globally leverage their reputation, knowledge base, and management practices. Sometimes, their decision to locate in developing countries is driven by generous funding from local governments and international donors.

**Biotechnology Industry Research Assistance Council (BIRAC), a successful example of Industry-Academia Collaboration in India**

BIRAC is a good example of new industry-academia interface in India. It implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally
In the past three years of existence, BIRAC has initiated several schemes, networks and platforms that help to bridge the existing gaps in the industry-academia Innovation research and facilitate novel, high quality affordable products development through cutting edge technologies. BIRAC has initiated partnerships with several national and global partners to collaborate and facilitate fostering of research and innovation.

Its vision is to stimulate, and enhance strategic partnerships to foster research and innovation and strengthen the capabilities of Indian biotech industry mainly startups and Small and Medium Enterprises to ensure that affordable medical products are available to greater sections of the society.

Its key strategies involve:
- Foster innovation and entrepreneurship
- Promote affordable innovation in key social sectors
- Empowerment of start-ups & small and medium enterprises
- Contribute through partners for capability enhancement and diffusion of innovation
- Enable commercialization of discovery
- Ensure global competitiveness of Indian enterprises

The discussants and panelists pointed to the lack of private investments in areas of public health concern such as AMR. There is need for a push-pull strategy. It is important to work along three streams: a) discovery, b) development and c) regulatory approvals. Academia-industry partnerships need to be leveraged for delinking research funding from the price of resulting products. Technology transfer systems need to be improved to motivate scientists and academia to undertake R &D. Public financing of R&D calls for measures of accountability for fair returns on public funds and calculating the social returns. There is also need for transparency in R&D, licensing and pricing of medical products.

Recommendations

The discussions in the session on “Alternative Models of R&D-Industry-Academia Collaborations” led to the following 8 recommendations for National governments and 2 recommendations for WHO/International organizations:

**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

The Parallel Session 5 focused on Achieving SDGs: Use of Information and Communications Technology (ICT) Initiatives including in Trade Agreements. Digital health or e-health, the use of information and communication technology (ICT) to provide health services, has the potential to advance the goal of universal health coverage and improve the quality and efficiency of health services. Key challenges remain in making digital health a successful reality, including fragmentation in digital health solutions, risks to funding continuity and capital expenditure, workforce capacity constraints, and effective collaboration across the health and ICT sectors. It is critical to see that there are still billions of people who have no access to internet. There is an urgent need to look at innovative and functional strategies that can leverage the power of high speed networks to facilitate convenient access to healthcare.
The Fifty-eighth World Health Assembly in May 2005 adopted Resolution WHA58.28 establishing an e-Health strategy for WHO. The resolution urged Member States to plan for appropriate e-Health services in their countries. During the same year, WHO launched the Global Observatory for e-Health (GOe), an initiative dedicated to the study of e-Health—its evolution and impact on health in countries. The Observatory model combines WHO coordination regionally and at headquarters to monitor the development of e-Health worldwide, with an emphasis on individual countries. Recognizing that the field of e-Health is rapidly transforming the delivery of health services and systems around the world, WHO is playing a central role in shaping and monitoring its future, especially in low- and middle-income countries.

The Observatory’s mission is to improve health by providing Member States with strategic information and guidance on effective practices and standards in e-Health.

Its objectives are to:
• provide relevant, timely, and high-quality evidence and information to support national governments and international bodies in improving policy, practice, and management of e-Health;
• increase awareness and commitment of governments and the private sector to invest in, promote, and advance e-Health;
• generate knowledge that will significantly contribute to the improvement of health through the use of ICT; and
• disseminate research findings through publications on key e-Health research topics as a reference for governments and policy-makers.

Resolutions and deliberations of WHO on e-Health

The Executive Board in 2016 considered “m-Health: use of mobile wireless technologies for public health,” reflecting the increasing importance of this resource for health services delivery and public health, given their ease of use, broad reach and wide acceptance. “m-Health” or mobile health has been shown to increase access to health information, services and skills, as well as promote positive changes in health behaviours and manage diseases (Report EB139/8).

The World Health Assembly in 2013 recognized the need for health data standardization to be part of e-Health systems and services, and the importance of proper governance and operation of health-related global top-level Internet domain names, including “health” (Resolution WHA66.24).

The World Health Assembly in 2005 recognized the potential of e-Health to strengthen health systems and improve quality, safety and access to care, and encouraged Member States to take action to incorporate e-Health into health systems and services (Resolution WHA58.28).

The World Health Organization in 1998 recognized the increasing importance of the Internet and its potential to impact health through the advertising and promotion of medical products, in its resolution on “Cross-border advertising, promotion and sale of medical products through the Internet” (101st Executive Board, 1998; Geneva, Switzerland).Resolution EB101.R3

**WHO collaborating centres:** WHO collaborating centres for e-Health, telemedicine and health informatics are institutions around the world that help WHO to fulfill its mandate of e-Health. They act as an important source to enhance WHO’s capacity and expertise in e-Health. WHO initiates and encourages collaborations, networking and knowledge and experience sharing between institutions to strengthen capacity building of institutions. WHO is collaborating with the following institutions to promote e-health:
Another example of WHO’s e-health programme- Target product profiles and priority digital health products for TB: Digital Health in TB Response

- The potential of information and communication technologies to combat TB still remains largely untapped
- Many countries and partners have begun conducting pilot projects to study how e-health and m-health (mobile health) can be used in fighting against TB
- WHO is aiming to maximize the impact of these technologies for people living with TB.
- Financial support as well as functional policy guidance is needed to scale up effective e-health and m-health approaches after due evaluation

The session explored several questions that would help explore the full potential of ICT to meet national health needs in the context of trade agreements. It examined how health care policies can be designed to launch effective e-healthcare platforms that address national needs. The challenges to digital health/e-health were discussed. There was agreement on the need to make national portals more effective to facilitate access to healthcare information/products/services, including the diverse healthcare information that can be disseminated through them. The role of telemedicine serve in ensuring access to doctors and healthcare experts was discussed. Equipping government, healthcare agencies and other stakeholders to fully contribute to the up-gradation and effective functioning of these e-healthcare platforms is also a challenge.

The discussions brought to the fore need for full-fledged digital strategy to operationalize policies. For instance, National Digital Health Authority (NDHA) proposed in National Health Policy 2017 of India need to develop a robust National Digital Health Strategy for realization of India’s National Health Policy and smooth adoption of digital health throughout India. Interoperability of health data such as basic patients data among private players via platform operators was also discussed.

In India, CDSCO started an online portal, Sugam, in 2015 for online licensing of sales and manufacturing. There is need to scale up the reach of the e-Health startups and recognize health informatics as an academic discipline to build a cadre of professionally qualified health informaticians.

Recommendations

The discussions in the session on “Achieving SDGs: Use of Information and Communications Technology (ICT) Initiatives including in Trade Agreements” led to the following 6 recommendations for National governments and 3 recommendations for WHO/ International organizations:

- Health is Local, and Health is Individual! Technology needs to capture, analyse and adjust for variances in local conditions.
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.
V. The third of the three thematic areas of the conference i.e. Role of trade agreements such as WTO and Intellectual Property Rights focused on the following:

- TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products
- Patents, Intellectual Property, Price Control and Competition Law in Access to Medicines
- WTO Trade Agreements influencing Health Products – Context SDGs
- Achieving SDGs: Regional Agreements, Challenges (TRIPS plus Agreements) and Access to Medical Products

### 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*


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*

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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
The Plenary Session 4 focused on TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products. Intellectual Property systems operate by providing limited rights to exclude certain defined third-party use of protected material. Their protection is generally intended to strengthen market based incentives for private-sector stakeholders to invest resources in product development and the marketing of new technologies.

The rationale for having patents is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in the patent application is accessible to society. Among others, the obligation of patent owners to publicly disclose their inventions enables society to know, and eventually use, the knowledge contained in patent documents. However, the use of the exclusive right can itself contribute to a market distortion and can lead to a situation characterized by inefficiencies, high prices and the under provision of goods.

The UN HLP has stressed the Delinking the costs of Research and Development from end product: Patents allow developers to recoup the costs and make profits by charging a price which is in excess of the costs of production. The principle of delinking is based on the concept that costs and risks associated with R&D of medical products should be rewarded, and incentives for R&D provided, other than through the price of the product. Delinking can be facilitated by push mechanisms and by pull mechanisms. Push mechanisms are upfront grants and other contributions including incentives that include such initiatives as grant funding and tax credits for investment in the most expensive parts of R&D. Pull mechanisms offer financial rewards for the final outcome of R&D of certain products, basically when the objective is achieved.

The TRIPS multilateral standards for each form of intellectual property (IP) are minimum standards, thus leaving considerable scope for policy-makers to decide on their implementation in a way that supports public health objectives. The latter is an important policy space for all countries.

The session noted that while TRIPS limited the scope for government supply of health care, the HLP report has reiterated the use of TRIPS flexibilities to meet those needs. Governments should utilize this fully to establish legal and administrative infrastructure for compulsory licensing of essential medicines, adopt its patentability criteria (such as innovation, industrial applicability, curtailing ever greening of patents) and require open access approach to publicly funded R&D. At the same time, countries need to avoid TRIPS plus restrictions on IPRs in emerging trade agreements and revisiting those that have already incorporated such provisions such as the Central American Free Trade Agreement. There is urgent need for WHO, WIPO and WTO to jointly build the capacity of patent examiners and help delink the price of R &D from drug pricing.

The investment clause in bilateral trade agreements, such as the Transpacific Trade Partnership agreement are intended to protect the rights of foreign investors and allow private foreign investor companies dispute decisions of countries to protect their people in international dispute settlement bodies such as Investor-state dispute settlement (ISDS) Tribunal. The investment clause typically ensures fair and equitable treatment of foreign investors and freedom from expropriation and prohibition from performance requirements.
In the first major case of Eli Lilly Vs Canada at the International Centre for Settlement of Investment Disputes, the company sued the government for 0.5 B Canadian Dollars for invalidating two of its medicines patents and frustrating its profits. The tribunal ruled upholding Canada’s “promise doctrine” requiring performance requirements from patents. Similarly, Ukraine and Colombia have been challenged in ISDS Tribunal. Countries like India, Brazil and South Africa have taken steps to safeguard against such challenges.

Trade agreements with TRIPS Plus provisions can hamper access to medicines in developing countries. African countries could adopt a regional approach for collective bargaining, including for PDPs. Public interest should stay at the heart of IPR management. Additionally, it is important to leverage, PDPs to promote technology transfer and build manufacturing capacity in LICs.

The Medicines Patent Pool (MPP), set up by UNITAID in 2010 to accelerate availability of HIV drugs presents another approach to drug development and improving access to medicines. Its mandate has since been expanded to include drugs for malaria and TB. MPP does not set prices, which is left to market determination. IP holders are attracted to the MPP for reasons as varied as management efficiency to visibility and high ratings in Access to Medicines Index. The pool currently has thirteen HIV medicines, and enabled the development of Fixed Dose Combination for HIV treatment. It also runs MedsPAL providing information on patents. A feasibility study examining the scope to expand the pool to include essential medicines for NCDs such as Cancers, Diabetes is underway.

World Health Organization- South East Asia Regional Office has the experience of developing and implementing the Pandemic Influenza Preparedness Framework. The framework, adopted in 2011, aimed to increase preparedness for bird flue and achieve predictable and equitable access to life-saving medicines. The initiative is supported through annual payments to WHO to support in country preparedness.

Active discussion took place on the merits and demerits of compulsory and voluntary licensing. Colombia’s compulsory licensing of a cancer drug attracted legal threats from an aggrieved pharmaceutical company and pressures from another government. Similarly, Ukraine was threatened by a company with investment arbitration and forced to deregister its generic products.

In the case of Hepatitis C drug, Indian companies have not attempted innovation as they are engaged in manufacturing the patented drug for the patent company’s voluntary licensing agreement.

Government involvement is critical in pricing, bilateral investment agreements, developing patenting policies, including flexibilities in IPR laws, initiating R&D on alternative products and appeal to the philanthropic sense of the pharmaceutical industry. It also needs to set up regulatory bodies such as competition commissions and anti-trust bodies.

Recommendations

The discussions in the session on “TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products” led to the following 4 recommendations for National governments and 6 recommendations for WHO/ International organizations:

**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.


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

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

The Parallel Session 6 focused on Patents, Intellectual Property, Price Control and Competition Law in Access to Medicines. The Patent policy predominantly plays a twofold role: firstly, it promotes innovation, through research and development which is practically useful to the society at large and secondly, by requiring the inventors to disclose their invention to the public authority in lieu of time bound protection, helps in the dissemination and accessibility of the useful innovation after its expiry, thus, ensuring transparency and equitable availability of the innovation. Therefore, time bound protection of inventions has facilitated the right holders to generate revenues, significant part of which is being directed towards R&D of medicines, vaccines and diagnostics tools, thereby advancing the goal of ensuring healthy lives to all.

The creation of sound, competitive market structures through competition law has an important role to play in enhancing access to medical technology and fostering innovation in the pharmaceutical sector. Unwarranted restrictions on competition, resulting from the abuse of intellectual property rights (IPRs), can be addressed on a case-by-case basis through competition law enforcement. Competition policy promotes effective innovation and helps shape the conditions for access. Competition policy is relevant to all stages in the process of supplying medical technology to patients, from their development to their sale and delivery. It can serve as a corrective tool if and when IP rights hinder competition and thus constitute a potential barrier to innovation and access. Competition authorities in several jurisdictions have taken action to address anticompetitive practices in the pharmaceutical sector, including some patent settlements, certain licensing practices and pricing policies. Competition policy also has an important role to play in preventing collusion among suppliers of medical technology participating in procurement processes.

In 2016 report of Untangling the Web of Antiretroviral Price Reductions published by MSF, the report found that prices of older HIV drugs continue to decline, while newer drugs remain largely priced out of reach of the patients. Presently, the lowest available price for a quality-assured, WHO-recommended first-line one-pill-a-day combination is US$100 per person per year (tenofovir/emtricitabine/efavirenz). This is a decrease of 26 percent since MSF last recorded the lowest price for first-line treatment at $136 in 2014. For a WHO-recommended second-line regimen, the lowest available price is now $286 per person per year (zidovudine/lamivudine + atazanavir/ritonavir), 11 percent decrease from $322 two years ago.

These prices continue to fall as a result of robust competition among generics manufacturers in key producing countries, primarily India. But the prices of newer drugs, or important treatments are needed for people who have run out of other HIV treatment options. These remain high, largely because of patent monopolies held by big pharmaceutical corporations. The lowest price for salvage treatment is $1,859 per person per year (raltegravir+daranavir/ritonavir + etravirine). This is more than 18 times the price of first-line therapy, and more than six times the price of today’s most affordable second-line combination. The price for this combination has come down only by seven percent, from $2,006 per year in 2014. These are the lowest global prices, but many countries, especially ‘middle-income’ countries, pay much higher prices for these medicines.
In accordance with the scientific, technological and developmental level of a State, it is highly desirable that the patent policy should not unnecessarily hinder the development of a State thereof; patent protection should be devised in such a manner so as to achieve an appropriate balance between public costs and private benefits. Keeping these aspirations in mind, TRIPS agreement requires member States to adhere to the minimum standards and the inbuilt flexibilities allows the member States a considerable degree of freedom in implementation of the patent policy.

In an economic sense, competition is conducive to freedom of choice, low prices and good value for money in addition to being an important driver of innovation and productivity improvement. Therefore, among the plethora of policy instruments available to governments in addressing public health concerns, competition policy has a crucial role to play in ensuring access to medical technology and fostering innovation in the pharmaceutical sector.

In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the needs of the general public. Therefore, proper and effective utilization of intellectual property flexibilities and other policy tools can help in achieving the required stability between profit-driven innovation models and public health priorities.

The session discussed ways to analyse the cost structure of medicines and use the data to negotiate prices. Anti-trust authorities need to play an active role in prosecuting agreements such as “pay for delay”. Such agreements offer limited technology and innovation transfer to developing countries.

The role of price caps in ensuring access to medicines and ways to balance the cost of production and price of products was discussed. In the case of essential drugs, it is particularly challenging when companies decide against entering certain markets where they are needed. Compulsory licensing can be used as a tool by governments if a company is not willing to enter the market and drug is of essential use. There was agreement on the need for governments to play an active role and develop proper procedures for price negotiations. All the same, it is important to allow companies to have a window to recover costs, a need to define fair amount of profits and due protection of innovation. There should be transparency in cost structures, rate of return analysis and bargaining procedures.

Increasing and sustain public R&D funding offer another route to access to affordable medicines. Open innovation approaches that promote data and knowledge sharing, fosters collaboration to reduce innovation costs, avoid duplication and improve R&D productivity needs to be promoted.

Recommendations

The discussions in the session on “Patents, Intellectual Property, Price Control and Competition Law in Access to Medicines” led to the following 3 recommendations for National governments and 6 recommendations for WHO/ International organizations:

**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. Strengthen the capacity of countries to negotiate for drug prices.
2. Support countries in implementing price caps and other mechanisms to control drug prices.
3. Promote research and development in low-income countries.
4. Enhance transparency in pricing and cost structures.
5. Develop guidelines for the use of compulsory licensing.
6. Support international cooperation and knowledge sharing on drug pricing.
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:
4. Dr Gregory Messenger, Lecturer in Law, School of Law and Social Justice, University of Liverpool, UK- Sustainable Development Goals, subsidies and trade
5. Dr Reji K Joseph, Associate Professor, , Institute for Studies in Industrial Development, India- Measures to reduce import dependence on bulk drugs
6. 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
The Parallel Session 7 focused on WTO Trade Agreements influencing Health Products— Context SDGs. A number of WTO agreements have legal provisions for protection of human health. For example, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states Members (i.e. the countries signatories to the WTO Agreement) may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health. Similarly, the Agreement on Technical Barriers to Trade (TBT) considers public health as a legitimate objective in the application of regulations. Again the preamble to the Agreement on the application of Sanitary and Phytosanitary Measures states “no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health…”. WTO agreements aim to promote trade and that is why pursuit of ‘health’ is given as an exception in the legal texts. Thus many WTO agreements have a clause that aims to protect public health. However in spite of these provisions in WTO law, often the application of the agreements comes in conflict with health objectives.

With the rise of Non Communicable Diseases there is an increasing need to deal with the interface on issues of trade, health and safety. The SPS Agreement deals with specific risks to health and stipulates explicit rules for member countries to restrict trade to ensure food safety and the protection of human life from plant- or animal-carried diseases. The TBT Agreement deals with the technical regulations and standards characteristics of a product therefore, the rights and obligations entailed under SPS and TBT Agreements are different in scope with regards to the assessment of health risks.

With the advent of globalization and opening of economies, there has been a major boost to trade and thereof an increasing need to deal with the issues of health and safety has arisen. To address these issues in SPS Agreement and the TBT Agreement) public health aspects have been introduced. The main aim of these agreements is to assess as to when health and safety standards should be considered as compatible or incompatible with trade rules. Both these Agreements allow the countries to restrict trade for lawful reasons, including health, provided these reasons should not unnecessarily inhibit legitimate trade. National and international health standards have important implications on trade. To promote health and nutrition labeling and packaging information on foods according to international standards such as Codex Alimentarius in the framework of TBT and SPS Agreements is important.

General international law provides choices to all countries, the law has needs to be applied with rigor in international treaty making. International trade agreements such as TRIPS and TBT of WTO pose challenges to public health. There are emerging concerns of data protection from TRIPS Plus provisions. Large number of International Investment Agreements include restrictive clauses impacting public health. International trade and investment treaties tend to be inequitable when being negotiated by unequal partners.

Recommendations

The discussions in the session on “WTO Trade Agreements influencing Health Products— Context SDGs” led to the following 2 recommendations for National governments and 4 recommendations for WHO/ International organizations:

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
The Parallel Session 8 focused on Achieving SDGs: Regional Agreements, Challenges (TRIPS plus Agreements) and Access to Medical Products. In recent times, the protection granted to intellectual property (IP) has been considerably expanded by the introduction of stricter IP obligations referred to as TRIPS-Plus that goes beyond the minimum requirements of TRIPS agreement. TRIPS-Plus provisions limit the policy space to the developing countries for fulfilling their developmental needs. The specific provisions in trade agreements and investment treaties includes data exclusivity provisions, restriction on parallel importation, linkage between drug registration and patent protection, more restrictive conditions for issuing compulsory licenses, expanded subject matter requirements and patent term extensions.

Bilateral and regional agreements have shaped the framework for access and innovation in many countries. They are not limited to setting IPR standards, but also include rules on tariffs on pharmaceutical products.

One of the main recommendations of United Nations Secretary-General’s High-Level Panel on Access to Medicines on Intellectual Property Laws and Access to Health Technologies was that “Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfill the right to health.” In the UN Sustainable Development Goals (SDGs), States are under an obligation to make informed policy choices with targeted strategies to attain its citizens’ healthy lives by 2030. Therefore, it is essential that the policy space and operational flexibility for achieving SDGs is ensured.

Encouraging the engagement and participation of relevant stakeholders in national actions and thereby fostering ownership and leadership of those efforts will enable progress. For this purpose technical and scientific cooperation, such as North-South, South-South and triangular, regional and international cooperation on and access to science, technology, innovation and knowledge-sharing is important.

The factors shaping access transcend borders and demand collaboration to comprehensively address the interaction between economics, trade, and intellectual property rights, Youth Commission on Essential Medicines Policies, Lancet Commissions, The Lancet Commissions, January 2017. In the UN Sustainable Development Goals (SDGs), States are under an obligation to make informed policy choices with targeted strategies to attain its citizens’ healthy lives by 2030.

The session deliberated on global governance and IP for public health. The TRIPS-Plus provisions in trade and investment agreements come in the way of access to medical products. Concerns were expressed about the impact of TPP and EU FTAs on TRIPS flexibilities. Building regional trade blocks reflective of the needs of developing countries can yield better bargaining power.

Voluntary Licensing could be explored collectively for regions such as Africa, where over 50% are low income countries. A single license through collective bargaining could make medicines readily available and affordable to all countries in the region. This needs to be augmented through enabling legislative environment in countries for IP to work for global health. Agreements with academic institutions and research centres need to be explored to make R&D information accessible at affordable prices.

Recommendations
The discussions in the session on “Achieving SDGs: Regional Agreements, Challenges (TRIPS plus Agreements) and Access to Medical Products” led to the following 3 recommendations for National governments and 3 recommendations for WHO/International organizations:

**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.
VI. 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 7: Country wise distribution of International Participants
VII. Conclusion

India invited experts from across the world for “1st 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” to explore next steps for access to medical products. The conference saw participation of experts from across the world. Co-Chair of the UN HLP Dr Ruth Dreifuss and other members highlighted the timeliness and importance of the Government of India initiative.

The conference brought together diverse stakeholders for the agenda of access to medical products: participation from many governments, academia, industry representatives and civil society groups. The conference was a result of close collaboration with many ministries in the Government of India. The Science and Technology Ministries, ICMR, Ministry of Chemicals and Fertilizers, Ministry of Commerce and Industry, Ministry of Law and Justice, Ministry of External Affairs, Ministry of MSME, Ministry of Electronics & Information Technology and Ministry of Health brought their expertise and ideas for tangible actions.

Detail deliberations were held on many facets for access to medical products. The impact of trade and intellectual property rights, regulatory aspects, affordability and fair pricing were focus areas of discussions. The experts shared their views on the essential role of innovation including R&D models and information communication technologies for bringing medical products within reach of all populations. The requirement to increase transparency and coordination between the National Regulatory Authorities and pharmaceutical sector to enable launch and registration of new health technologies is important. Innovative thinking is also needed to keep invaluable antibiotics effective. The dialogue on the role of competition in competitive pricing and discussion on related WTO agreements influencing health, led to recommendations on many policy options for governments and WHO/International organizations.

The broad three thematic areas: first, Access to Medical Products, second, Innovation and Research & Development and third, trade agreements such as WTO and Intellectual Property Rights were taken up for discussion in the following sub themes:

i. Regulatory Pathways for safe, quality, efficacious and affordable medical products including in emergencies to achieve SDG goals

ii. Affordability and Fair Pricing of Medical Products

iii. Role of Innovation, Research and Development for Medical Products

iv. Fostering Local Production, Technology Transfer and Market Entry Barriers for Medical Products

v. Infectious Disease Control: What are the Pathways to Technology Development and Access to Medical Products

vi. Alternative Models of R&D-Industry-Academia Collaborations

vii. Achieving SDGs: Use of Information and Communications Technology (ICT) Initiatives including in Trade Agreements

viii. TRIPS, UN High Level Panel Report and Benefit sharing for access to medical products

ix. WTO Trade Agreements influencing Health Products– Context SDGs/Achieving SDGs: Regional Agreements, Challenges (TRIPS plus Agreements) and Access to Medical products

Many recommendations came up more than once in the sessions and therefore, were not repeated in the session outcomes. The conference resulted in a total of 142 recommendations for national governments, WHO and other international organization. There are 70 recommendations for national governments, 68 recommendations for WHO/International organizations and 4 for the United Nations. The overall summary of the recommendations is as follows:
It is hoped that the recommendations will promote new thinking and forge alliances for access to medical products and better health for everyone and make SDG2030 goals real for all.

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Annex I: Media Release

Press Information Bureau

Government of India
Ministry of Health and Family Welfare
21-November-2017 15:28 IST

Shri J P Nadda inaugurates ‘1st World Conference on Access to Medical Products and International Laws for Trade and Health’

India is deeply committed nationally and globally to achieving all public health goals: J P Nadda

“India is deeply committed nationally and globally to achieving all public health goals and also focusing on developing India as a hub for affordable medical devices.” This was stated by Shri J P Nadda, Union Minister of Health and Family Welfare at the inauguration of ‘1st World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development’, here today. The Health Minister further stated that there is a need for promoting industry and academia collaboration for developing affordable medical products such that innovations and advances in medical sector reach a vast population.

Smt. Anupriya Patel, Minister of State (HFW), Dr. V.K. Paul, Member, NITI Aayog, Govt. of India, Smt Preeti Sudan, Secretary (Health), Dr. Soumya Swaminathan, Secretary, Dept. of Health & Research (DHR) and DG, ICMR and Dr. Jagdish Prasad, Director General Health Services also graced the occasion.

Highlighting the importance of transparency between regulatory authorities and pharma sector, Shri Nadda stated that the coordination between the National Regulatory Authorities and pharmaceutical sector will enable launch and registration of new health technologies. He further said that the dialogue on role of competition in competitive pricing and discussion on related WTO agreements influencing health should lead to a larger umbrella of suggested policy options for the government.

Shri Nadda stated that the 2015 National Medical Device Policy will enable local manufacture in the multiproduct, multidisciplinary industry. “In India, nearly 150 thousand orthopaedic knee procedures are done every day. More investments and more players in the medical devices sector will lead to lowering down of prices and access to medical products as most of the governments are sensitive to access and pricing of medical products,” he added.

Addressing the conference via video link, Shri Ashwini Kumar Choubey, Minister of State (HFW) said that research and development in public health should focus on two main aspects. To enable safe, effective and quality medical products for the diseases and rolling out the innovations and inventions along with the learning’s from the field to the people. He further stated that the research and development should focus on making the cost of medical devices/products affordable to the people and highlighted the issue of Anti-microbial Resistance (AMR).

Speaking at the function, Smt Anupriya Patel, Minister of State (HFW), stated that India is committed to attainment of the highest possible standards of health for its citizens. She further said that at the national level, access to medical products (medicines, vaccines, medical devices & diagnostics) is an important facet in the health system as a whole and at the international level, access to medical products is a critical factor for the success of the
2030 sustainable development goals agenda that aims to ensure healthy lives and to promote well-being of people of all ages.

Dr. V.K. Paul, Member, NITI Aayog, Govt. of India stated that there is a need for investment in medical products for preventive therapy and treatment and highlighted the importance of affordability, quality, domestic production capacity and to create an eco-system of policy and innovation for greater accessibility of affordable medical drugs and devices. Dr V K Paul further said that technology is an integral block for strengthening medical systems in any country and must also ensure timely maintenance of medical equipment by suppliers in remote and rural areas such that equipment functions effectively.

Smt Preeti Sudan, Secretary (Health) spoke about the issues of access of medicines and medical products. She said that safe medical products should be available at affordable prices. She further reiterated that the Health Ministry is committed to robust regulatory systems for ensuring safety, quality and efficacy of drugs.

Dr. Soumya Swaminathan, Secretary (DHR) and DG, ICMR highlighted issues such as how to use TRIPs flexibilities; alternative models for affordable medicines and devices such as voluntary licensing; clear predictable regulatory pathways; more investment in R&D and publicly funded R&D; innovative healthcare service delivery models; anti-biotic stewardship; and collaboration between the public and private sectors including academia to reduce cost of production and delivery.

The Conference is being organized by the Ministry of Health & Family Welfare with the support of WHO Country Office for India and in partnership with Indian Society of International Law. The objective of the Conference is 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.

Also present at the event were, Dr. R.K. Vats, Addl. Secretary, Ministry of Health & Family Welfare; Dr. Henk Bekedam, WHO Representative to India; and Dr. EMS Natchiappan, President, Indian Society of International Law, India along with other senior officers of the Ministry, delegates from various countries and representatives of development organizations.
Annex II: Address by Dignitaries

His Excellency Minister Health and Family Mr JP Nadda

Distinguished Ladies and Gentlemen,

I am happy to welcome you to New Delhi to participate in the “1st World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development”. I am sure we will have positive results from the Conference jointly organized by the Ministry of Health, Government of India, WHO, and the Indian Society for International Law.

Many of you would recall that on 24 May 2017 during the 70th World Health Assembly in Geneva, India had jointly, with certain like-minded Member states, organized a side event to discuss the Recommendations of United Nations Secretary-General's High-Level Panel on Access to Medicines in the Context of the SDG goals. At that event I had briefly indicated that India will be organizing a Conference to discuss the issues in greater detail. I am happy that we have kept our word.

As has been widely affirmed, access to medical products: medicines, vaccines, diagnostics and devices is critical for achieving SDG2030. I am delighted to see the detailed three day agenda. The proposed discussions on existing scenarios of intellectual property and trade, regulatory aspects, affordability and fair pricing are well-timed. Discussions on innovation including in research and development models and information communication technologies, I hope, will unveil new ideas for bringing medical products at the doorstep of the most vulnerable groups. The dialogue on role of competition in competitive pricing and discussion on related WTO agreements influencing health should lead to a larger umbrella of suggested policy options for government. It is heartening to note that the Conference is a result of close collaboration with many ministries in the Government. The contribution of Science and Technology Ministries, 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 will bring concerted action on the access agenda for health for all. We will work closely together for successful results.

India is deeply committed nationally and globally to achieving all public health goals. Our National Health Policy 2017 addresses national current and emerging socio-economic, technological and epidemiological issues of public health for the country. Globally, the Indian pharmaceutical industry’s role in providing affordable quality medicines is well known. The Government of India is also focusing on developing India as a hub for affordable medical devices. The 2015 National Medical Device Policy will enable local manufacture in the multiproduct, multidisciplinary industry. In India, nearly 150 thousand orthopaedic knee procedures are done every day. More investments and more players in the Medical Devices sector will lead to lowering down of prices and access to medical products as most of the governments are sensitive to access and pricing of medical products.

We are committed to strengthening the drug regulatory system in the country for which the government has approved investment of more than USD 275 million. In addition,
India has actively contributed to the formation and provided support for the new South East Asia Regulatory Network (SEARN). SEARN will promote collaboration among the countries of the South East Asia Region.

I am happy to note that many of the best minds and experts have found time to participate here in New Delhi. While we have the deliberations, I hope you will come up with useful suggestions on issues of importance.

Specifically, I hope to hear from you on policy coherence between trade, intellectual property rights and health policies to effectively manage the interface between health and trade aspects. In addition, promoting industry academia collaboration in R&D of medical products, from lab to field, harnessing small and medium enterprises to contribute fundamentally for affordable healthcare product development. Further, the steps to increase transparency and coordination between the National Regulatory Authorities and pharmaceutical sector will enable launch and registration of new health technologies. Innovative thinking is also needed to keep invaluable antibiotics effective and tackle antimicrobial resistance.

The UN Secretary-General High-Level Panel Report on Access to Medicines advocates that the world must take bold new approaches to both health technology innovation and ensuring access so that all people can benefit from the medical advances. The Sustainable Development Goals (SDGs) agenda prioritizes equity and human rights-based approaches with an emphasis in health, on universal health coverage. I am confident that the discussions in the next three days will go a long way to advance concerted action for all stakeholders for these global goals. I wish you a successful conference and look forward to the recommendations from the meeting. We look forward to welcome you all again during the second world conference next year from 9-11 October 2018 at New Delhi, India.
Distinguished Ladies and Gentlemen,

I welcome you to the “1st World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development”. I am happy to be here for the Conference jointly organized by the Ministry of Health, Indian Society for International Law and WHO on issues of great contemporary importance. Access to medical products and achieving SDG goals are closely intertwined. I am also happy to see that India will take the discussion forward for next steps to the 2016 United Nations Secretary-General High-Level Panel (HLP) report.

R&D in public health has to address two major factors: to enable safe, effective quality medical products for diseases of all populations and a fast roll out from academia, labs and field. Many medical products are still missing e.g. specific medicines for children. More work is also needed for adults on the interplay of various medicines when taken together for a multitude of medical problems. Safety is the key. The roll out of medical products goes through a rigorous process of clinical trials. The trials are a must to make sure the new molecules address what they are expected to. However, the cost of R&D and bringing medical products to the market is becoming daunting. An ‘affordable and fair’ price that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country is desirable. The WHO R&D strategy to bring medical products quickly to the affected populations in the wake of emergencies is critical for access to happen.

Antibiotics are the miracle drugs of modern medicine. However, antimicrobial resistance threatens the efficacy of these drugs. Many factors contribute to AMR such as the over/under/inappropriate use of antibiotics either in people or humans, environmental or health issues, lack of access to clean water that promote infectious disease and overuse of antibiotics. I am glad that AMR issues are also being discussed. New research and development models are needed to address lack of adequate investment in the antibiotics. Sustained long term solutions are needed for insufficient financial return or lack of incentive for the private sector to develop new antibiotics.

I am glad that the conference is discussing these important aspects and that all relevant Ministries are here to select the best course options.

In India, in the area of Research and Development, the Indian Council of Medical Research (ICMR) and institutions such as Biotechnology Industry Research Assistance Council (BIRAC) and Translational Health Science and Technology Institute (THSTI) are playing an important role. They do so in their own capacity as well as in collaboration with international stakeholders. New initiatives such as the Biopharma Mission in India by BIRAC, also named as ‘Innovate in India’, promise to accelerate India’s biopharma hub through focused programs on vaccines as well as medical technology including devices and diagnostics. The institutions facilitate research for the development of vaccines, maternal and child health, point-of-care diagnostics, metabolic diseases and nutrition, and provide training in clinical and product development to improve public health.
I hope the Conference will discuss how research discoveries can be quickly transformed into drugs, treatments, or methods for prevention. There is a need to develop new partnerships of research to expedite the process with complete safety and focus on the diseases of importance to large populations. In this context both communicable diseases that get immediate attention and the non-communicable diseases – which are becoming silent killers, diabetes, hypertension, etc. should be addressed. E-health and mobile phone technologies have promise to reach vast populations concurrently; more work needs to be done to harness the new medium available to us.

I wish the Conference all success and I look forward to the outcomes of the deliberations.
Her Excellency Minister of State Ms Anupriya Patel

Distinguished Ladies and Gentlemen,

Good morning. It is a great pleasure for me to see the galaxy of international experts from all over the world who have joined us today for participation in the 1st World conference in India, jointly organized by the Ministry of Health, Indian Society for International Law and WHO. We welcome all of you here - knowledge opinion leaders in this area from all over the world.

WHO constitution clearly states that Health is a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity. Health is a basic human right that can't be guaranteed (due to factors like genetically inherited diseases, aging, etc.) but access to health services can be. Providing good health to all citizens is a key role for government.

At the national level, access to medicines is an important facet in health systems as a whole. The other aspects of importance are adequate human resources for health care delivery, procurement and supply chain management, health management information systems, service availability and accessibility and financial management.

At an international level, globalization and increase in regional and bilateral trade is a phenomenon where international measures are becoming critical in national decision making for public health. Certain international trade issues such as intellectual property, government procurement, competition laws, environment, etc. are becoming critical for decision making. The aspirations for trade with access to medical products (medicines, vaccines, medical technologies, diagnostics) and the Sustainable Development Goal 3 on Health are to be considered together to balance for trade and health benefits. In this process, there is need to ensure better utilization of scarce resources and optimal use of funds.

The Union Cabinet in India recently approved the National Health Policy 2017 of Government of India. The Health Ministry has formulated the Policy under the guidance of the Hon. Prime Minister Shri Narendra Modi updating the previous 2002 policy. The Government of India adopted a highly participative and consultative approach in policy formulation process. The policy aims for attainment of the highest possible level of health and well-being for all at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face financial hardship as a consequence.

This would be achieved through increasing access, improving quality and lowering the cost of healthcare delivery. The policy also looks at reforms in the existing regulatory systems both for easing manufacturing of drugs and devices, to promote Make in India, as also for seeking to align other policies for medical devices and equipment with public health goals. The 2017 policy will address current and emerging challenges necessitated by the changing socio-economic, technological and epidemiological landscape.

We look forward to the outcomes and recommendations from all the sessions, which have been carefully chosen in this debate in India, to contribute in a meaningful manner to the global agenda on access to medical products, intertwined with research, innovation and intellectual property issues.
I hope the deliberations of global experts from all over the world leads to strategies and thinking to promote innovation and access for the 2030 Agenda for Sustainable Development and identify linkages between international trade and health policy to achieve SDGs, for access to medical products.

I wish you all very fruitful deliberations during the conference and a very pleasant stay in India.
Address by Secretary Health and Family Welfare: Ms Preeti Sudan

I join all previous speakers to welcome you in the Conference jointly organized by the Ministry of Health, WHO, and Indian Society for International Law.

The Sustainable Development Goals are the first ever globally-agreed development plan for a fairer, safer and healthier world by 2030. The Health goals in the SDGs build on the unfinished business of the MDG (Millennium Development Goal) era (such as on HIV, tuberculosis and malaria). The SDGs add new targets, such as non-communicable diseases and universal health coverage. Of the 17 SDGs, Good health and well-being finds direct mention in Goal 3. Goal 3, however, is a prerequisite for achieving almost all other SDG goals.

The SDG3 has specific targets to support research, development and access to essential medicines and vaccines.

**Goal 3 states: Ensure healthy lives and promote wellbeing for all at all ages. The goal 3b within goal 3 is particularly focused on the theme of the conference. That is, to support the research and development, R&D of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health.**

As we know, the 2016 United Nations Secretary-General High Level Panel (HLP) report addressed four major areas:

- *Health Technology Innovation and Access*
- *Intellectual Property Laws and Access to Health Technologies*
- *New Incentives for Research and Development of Health Technologies*
- *Governance, Accountability and Transparency*

It is pertinent that “1st World Conference on Access to Medical Products and International Laws for Trade and Health in the Context of the 2030 Agenda for Sustainable Development” is taking place here in New Delhi.

India’s pharmaceutical industry’s contribution for affordable health care products in both developed and developing countries is well recognized. The total size of the Indian pharmaceutical industry is about US$ 33 billion, of which exports accounted for about 55%. Indian manufacturers are the key contributors to the WHO Prequalification Programme (PQP) for medicines and vaccines. Out of 538 finished pharmaceutical products, 345 i.e. 64% of Finished Pharmaceutical Products are from India. Good-quality Active Pharmaceutical Ingredients (APIs) are fundamental for the production of good-quality medicines. Of WHO prequalified Active Pharmaceutical Ingredients 59% are from Indian manufacturers in the segments of HIV/AIDS, Tuberculosis, Malaria, Reproductive Health, etc.

Further, 8 out of 10 people on antiretroviral therapy across the globe are treated with WHO PQP generic medicines and 19 out of 26 i.e. 73% antiretroviral therapy WHO PQP generic medicines are from India. There is also a push for manufacturing of medicines and devices also through the Government’s Make in India campaign to foster public health goals.
India is committed to a robust drug regulatory system. The Central Drugs Standard Control Organization (CDSCO) in collaboration with State Drug Regulatory Authorities prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country. To strengthen and build capacity of the National and State (provincial) Regulatory Authorities (NRAs) manpower is being scaled up and new labs are being installed. The E-Governance portal (SUGAM portal) set up at the central regulatory authority is being linked to the state regulatory authorities. As a result, there is greater transparency and dissemination of information for all. India has also scaled up the Risk Based Inspections for medicines and Active Pharmaceutical Ingredients (APIs) amongst manufacturers in the states jointly with state regulatory authorities. The benchmarks comprise the regulations and norms of national GMP (Good Manufacturing Practices), WHO/ PIC(Pharmaceutical Inspection Cooperation)/ ICH(International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use) etc. The enforcement offices of CDSCO are ISO accredited and the central laboratories are NABL accredited.

The Indian NRA competencies were reiterated when WHO led team of international experts made a comprehensive review for vaccines from 13-17 February 2017 with WHO Global Benchmarking Tool. India has 21 vaccine manufacturing facilities. Vaccines are supplied for the national and international market (150 countries) which makes India a major vaccine supplier across the globe. Furthermore, India supplies several vaccines to many UN agencies {UNICEF, WHO and PAHO(Pan American Health Organization)}. We hope the assessment will enable a greater number of Indian manufacturers to apply for WHO vaccine prequalification and thus provide the world with more affordable vaccines.

There have been dynamic changes in the regulatory landscape of the country. The recently released Rules for Medical Devices and in-vitro diagnostics released in the public domain is one such example. The 4th WHO Global Forum on Medical Devices is likely to be hosted in October 2018 at New Delhi, India and I take this opportunity to invite each one of you for this important event.

Additionally, a robust Pharmacovigilance Programme is in place in India and 250( likely to be increased to 375) Adverse Drug Reaction Monitoring Centres have been set up in the country. Indian Pharmacopoeia Commission (IPC), an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India recently became the WHO Collaborating Centre for pharmacovigilance. The pharmacovigilance systems set up in India for Bedaquiline using cohort event monitoring for the new anti-TB drug is promising.

The new South-East Asia Regulatory Network (SEARN) has the potential to enhance South-south collaboration and guarantee access to high-quality medical products in the WHO South-East Asia Region Member countries. UN High-Level Panel on Access to Medicines has indicated: to “Build on the Consultative Expert Working Group (CEWG) process and other discussions at the World Health Organization and “initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies.”

I wish the Conference all success and eagerly await the outcomes.
Address by Additional Secretary Ministry of Health and Family Welfare Dr RK Vats

Distinguished participants, ladies and Gentlemen,

On behalf of the Ministry of Health & Family Welfare and on my own behalf I am delighted to welcome you today. The “1st World Conference on Access to Medical Products and International Laws for Trade and Health, in the Context of the 2030 Agenda for Sustainable Development” is being organized in partnership with Indian Society of International Law and WHO.

As you have seen in the Conference brochure, the main objective of the Conference is 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. We will discuss next steps to the recommendations of the UN High Level Panel Report on Access to medicines. We hope that India’s initiative and these deliberations would be useful and contribute to the discussions at WHO Executive Board in Geneva in 2018.

The Specific Objectives of the Conference are to
1. Engage with a wide set of stakeholders for access to medicines and medical products for upcoming international discussions in the context of SDGs.
2. Promote pragmatic responses to contemporary policy issues on research and innovation landscape for medical products and health technologies.
3. Provide recommendations for possible policy coherence on international trade laws and health, including intellectual property aspects for access to medical products.

It has been my privilege to be actively involved in the design of the Conference. I acknowledge and thank Indian Council of Medical Research and Dr Soumya Swaminathan for her advice and guidance and the contribution of Translational Health Science and Technology Institute, THSTI and Biotechnology Industry Research Assistance Council, BIRAC. The conference is thus truly a result of close collaboration with all Ministries.

I thought I will share with you the design of the conference and the hard work put in by the Conference Secretariat over the past 6-7 months.

1. The Conference has been uniquely designed as a closed set of deliberations among experts selected on the three main thematic areas. These are first, Access to Medical Products, second, Innovation and Research & Development and third, trade agreements such as WTO and Intellectual Property Rights. The sessions are designed to move the global agenda forward on access to medical products, including the discussion on the UN High Level Panel Report. Each session is hoped to come up with doable set of options/outcomes.

2. A Position paper developed highlights key issues on the topic of discussions. We hope the paper will enable more meaningfully outcomes for moving the access to medicines agenda forward.
3. We have been fortunate that each of the Experts present have provided a one / two page concept paper and lead questions which in his his/her view are the key issues to be discussed. These papers are all on the conference website and I hope you would access them.

4. A number of logistic issues were addressed. A dedicated website has been made for the conference. As a result, the entire visa process is paper free. As you would have seen, the invitation letters, visa letters are downloadable from the website. The website is a one stop portal for all information related to the Conference. All the documents, the position paper and concept papers developed by experts are uploaded on the website for easy access by all. The suggested resources and reading materials for each session are also on the website. I hope you have found them useful.

5. Dedicated Sessions Briefs, on key issues in each session are on the web and also printed day wise, for your reference.

6. A mobile app for the conference has been developed to facilitate background resource material in an easy to read mode on an android/smart phone, for ease of accessing documents. It is also envisaged you will find the mobile app useful in intra-venue navigation here in the hotel, from other hotels to this hotel. Certain features are available to enable taking down points and views which may not be possible to cover through discussion and question and answer sessions. Thus, polling, live voting in sessions, chat with conference secretariat etc. has been made possible. I hope the mobile app would enable greater interaction and proves to be useful.

To conclude, the journey of last several months has been enriching and rewarding in itself. The length and breadth of preparations to design these deliberations made us think out of the box many times. We hope we will meet your expectations and those we set for ourselves from this world conference. I thank the entire secretariat of WHO – Dr Manisha Shridhar and Dr Madhur Gupta as focal persons from WHO for this conference, and their teams, and our team at MOH and at Indian Society of International Law- our co-partners.

We hope for deep discussions and a developing a holistic view on access to medical products: medicines, vaccines, devices, diagnostics. We look forward to the guidance from experts and specific recommendations leading to tangible solutions. I hope we will do well and see progress when we move to the 2nd World Conference next year.
Address by WHO Representative to India Dr Henk Bekedam

Distinguished participants, colleagues, ladies and gentlemen,

Good Morning and a very warm welcome!

It is a great pleasure to have with us experts of great eminence from across the world on this special occasion.

I congratulate the Ministry of Health & Family Welfare for its leadership and vision in organizing this timely meeting. I would also like to thank the Indian Society of International Law for collaborating with the government in this excellent initiative.

I would like to specially acknowledge and thank the Indian Council of Medical Research and Dr Soumya Swaminathan for her advice and guidance and the contribution of Translational Health Science and Technology Institute, Biotechnology Industry Research Assistance Council and Research & Innovation Systems in Developing Countries in putting together this conference.

I am proud to say that India is playing a vital role on the global pharma platform. It is also the host to this first ever World Conference on Access to Medical Products and International Laws for Trade and Health. And it is for a good reason.

India is the considered the pharmacy of the world and spreading its wings beyond producing generic drugs into manufacturing medical products. For this, the leadership of the Health Ministry must be commended.

It is no surprise that India is hosting the meeting of the Global Forum on Medical Devices next year.

In my address, I will touch upon the key themes, which are pertinent to the outcome of the conference:

• SDGs – the context
• Access to medical products
• Strengthening the regulatory systems
• Ensuring quality
• Innovation and Research & Development
• Intellectual Property Rights and Trade for SDGs

SDGs – the context

• The Sustainable Development Goals are the world’s to-do list for a fairer, safer and healthier world by 2030. Universal health coverage and access to medicines is also one of the regional flagship priorities for countries in the WHO South-East Asia Region.

• The need to expand access to medicines and health products is highlighted in the SDGs, specifically in two targets and more broadly in at least seven other targets under SDG3.
Promoting affordable and cost-effective interventions is central to the achievement of universal health coverage within the mandate of Sustainable Development Goal 3. This is more true for the developing countries that are faced with a double burden of disease – from communicable diseases such as tuberculosis and malaria and non-communicable diseases such as diabetes, cancer and hypertension.

Access to medical products

- There is a clear link to Universal Health Coverage, the underlying theme being access to affordable and quality medical devices.

- Allow me to use an example related to the World Hepatitis Day 2016 in the context of access to high quality and safe medical devices.

- India has also played a pivotal role in the reduction of prices of Hepatitis C medicines by scaling up the generic medicines, which are otherwise unaffordable.


- Establishing this fair pricing model, therefore, is urgent, as many currently available new products, such as those for cancer and Hep C are unaffordable, even for high-income countries.

- India can also make the medical devices more affordable and accessible. Again not only for India, but also globally.

- On the 2016 World Hepatitis Day, the Government of India also committed to eliminating unsafe injections and switch to Re-Use Prevention syringes as part of prevention of blood borne infection, like hepatitis B and C.

- We look at India to produce these devices, and to ensure in future the safety of 5 billion injections per year in the country.

- Establishing this fair pricing model, therefore, is urgent, as many currently available new products, such as those for cancer and Hep C are unaffordable even for high-income countries.

- In May this year, The Netherlands Ministry of Health, Welfare and Sport, in partnership with WHO conceived a Fair Pricing Forum to facilitate discussion on strategies that could lead to a fairer price setting and a pricing system that is sustainable for health systems and for innovation, identifies research gaps, including the need for transparency of research and development costs, and profit margins.

- Medical devices sector is one of the 25 focus sectors identified by the Indian government and is supported by a proposed robust regulatory framework as outlined in the National Health Policy 2017.

Strengthening the regulatory system

- The issue of safety and quality is paramount for medical products.
• In 2014, the World Health Assembly adopted a resolution on regulatory system strengthening for medical products.

• WHO plays a pivotal role in supporting countries in strengthening their regulatory systems, and promoting equitable access to quality, safe, efficacious, and affordable medical products and health products.

• WHO Regulatory System Strengthening programme is not restricted to vaccines alone; it extends to other medical products and health technologies, including medicines, medical devices and diagnostics.

• India has shown continued commitment and a strong political will to strengthen and build capacity of the National Regulatory Authorities (NRA).

• The effective regulatory oversight of vaccines is especially crucial for India as it is a major vaccine producer and also supplier across the globe.

Ensuring quality
• As you are aware, WHO has a Prequalification Programme for promoting and facilitating access to safe, appropriate and affordable medical devices of good quality.

• WHO will continue to foster the global role being played by India in the space of pharmaceuticals and vaccines and its contribution to the WHO Prequalification Programme of Medicines and Vaccines for ensuring continued global supply of quality medical products.

• Indian manufacturers are the key contributors to the WHO Prequalification Programme (PQP) for medicines and vaccines. India supplies vaccines to 150 countries, making it a major vaccine supplier across the globe. 340 out of 533 finished pharmaceutical products i.e. 63% of Finished Pharmaceutical Products are from India.

• WHO works with partners to ensure that principles used in the selection of medicines are applied to all products including diagnostic tests, devices and assistive products.

Innovation and R&D
• Medicines pricing has been the subject of global debate for some years, calling in question current pricing strategies as well as predominant research and development financing models.

• The balance between national aspirations and technological advancements in R&D, ICT, production and manufacturing practices could lead to collective and collaborative efforts for global solutions.

• The need for innovation to make medical devices more affordable has been highlighted across the board.

• India is ideally placed to do so.
• I am confident that in the years to come, on the lines of being a pharmacy of the world, India will emerge as a global player in manufacturing accessible, affordable and quality medical devices and also be known as ‘medical device hub of the world’.

Intellectual Property Rights and Trade for SDGs in the context of Access to Medical Products

• The aspirations for trade with access to medical products - medicines, vaccines, medical technologies, diagnostics - and the Sustainable Development Goal 3 on Health are to be considered together to balance for trade and health benefits.

• Making health technology accessible and affordable is a key WHO priority, in India and globally. The challenge is to ensure that access to high-quality affordable health products becomes a reality and meets the needs of the vast majority. WHO is committed to supporting Member States in this endeavour.

• India has actively contributed to the formation and provided support for the new South East Asia Regulatory Network (SEARN) amongst the South East Asian countries.

• This move will enhance South-south collaboration and guarantee access to high-quality medical products in the WHO South-East Asia Region Member countries.

Ladies and gentlemen, we look forward to the outcomes and recommendations, which I am confident, will contribute to the global agenda on access to medical products, intertwined with research, innovation and intellectual property issues.

I am equally confident that the deliberations will promote innovation and access for the 2030 Agenda for Sustainable Development and identify linkages between international trade and health policy to achieve SDGs, for access to medical products.

I may also add that a major reason that the outcome of this deliberation is important is that during the World Health Assembly 2017 discussions on the UN High Level Report on access to medicines, it was decided by all Member States to bring up the matter in the Executive Board of WHO, to inform the proposed special session UN discussions in 2018. The proceedings of this meeting would, therefore, be an important input for the Executive Board of WHO.

I wish you all fruitful and productive deliberations and a very pleasant stay in India.

Thank you
Annex III: List of Participants

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