Executive Summary
2nd World Conference on Access to Medical Products-
Achieving the SDGs 2030

9-11 October 2018, New Delhi, India

Organised by:

Ministry of Health & Family Welfare, Government of India and World
Health Organization Country Office for India
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 to take forward the recommendations from the 1st World Conference 2017 and build on the work done for access to medical products in the context of SDGs (including trade agreements) in line with GPW 13 of WHO.

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- Ministry of Health and Family Welfare, Government of India
- World Health Organization
- Indian Council of Medical Research
- Translational Health Science and Technology
- Biotechnology Industry Research Assistance Council
- Biotech Consortium India Limited
- Research & Innovation Systems in Developing Countries
- Ministry of Culture, Government of India
**Working Group Members for Conference:**
- Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India - Chairman (Working Group)
- Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights and Trade and Health, WHO SEARO
- Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India
- Dr Sachin Mittal, Director, Ministry of Health and Family Welfare, Government of India
- Mr RG Singh, Under Secretary, Ministry of Health and Family Welfare, Government of India
- Dr Eswara Reddy, Drugs Controller General of India, CDSCO, Government of India

**Conference Secretariat**
- Dr Manisha Shridhar, Regional Advisor, Intellectual Property Rights and Trade and Health, WHO SEARO
- Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India
- Dr Purnima Sharma, CEO, Biotech Consortium India Limited
- Ms Preeti Kharb, Consultant, WHO Country Office for India
- Dr Purnima Sharma, CEO, Biotech Consortium India Limited
- Ms Garima Singh, Consultant, Translational Health Science and Technology Institute
- Ms Kanika Dasan, Consultant, WHO SEARO

**Overall Leadership, Guidance and Useful Inputs**
- Ms Preeti Sudan, Secretary, Ministry of Health and Family Welfare, Government of India
- Dr RK Vats, Additional Secretary, Ministry of Health and Family Welfare, Government of India
- Dr VK Paul, Member, NITI Aayog, Government of India
- Dr Balram Bhargava, Secretary, Department of Health Research, Ministry of Health and Family Welfare, Government of India
- Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India
- Mr Ramesh Abhishek, Secretary, Department Of Industrial Policy & Promotion, Ministry of Commerce and Industry, Government of India
- Dr Arun Panda, Secretary, Ministry of Micro Small and Medium Enterprises, Government of India

**World Health Organization:**
- Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO Headquarters, Geneva
- Dr Henk Bekedam, WHO Representative, WHO Country Office for India
- Ms Payden, Deputy WHO Representative, WHO Country Office for India
- Dr Hilde Renne Susanne De Graeve, Team Leader, Health Systems, WHO Country Office for India
- Ms Phyllida Travis, Director Health Systems Development, WHO SEARO
Dr Sue Hill, Director, Essential Medicines and Health Products, WHO Headquarters, Geneva

Grateful for overall Support:

Ministry of Health and Family Welfare:
- Honourable Mr JP Nadda, Union Minister, Ministry of Health and Family Welfare, Government of India
- Honorable Mr Ashwini Kumar Chaubey, Minister of State, Health & Family Welfare, Government of India
- Honorable Ms Anupriya Patel, Minister of State, Health & Family Welfare, Government of India

Ministry of Science and Technology
- Honorable Dr Harsh Vardhan, Union Minister, Ministry of Science and Technology, Government of India

World Health Organization:
- Dr Tedros Adhanom Ghebreyesus, Director General, World Health Organization
- Dr Soumya Swaminathan Deputy Director General, WHO Headquarters, Geneva
- Dr Poonam Khetrapal Singh, Regional Director, WHO South East Asia Region
Executive Summary

I. Introduction

WHO embarked on 13th Global Programme of Work (GPW13) for strategic direction in Sustainable Development Agenda 2030 (SDG) for health which is vital for the future of our world. The GPW13 states people continue to be susceptible to communicable diseases while the burden of non-communicable diseases is increasing. It is clear that reliable access to effective, safe, quality-assured and affordable medical products (medicines, vaccines, diagnostics, devices) is key to making progress towards Universal Health Coverage (UHC) and the SDGs. The WHO Constitution affirms the health of all people is fundamental to the attainment of peace and security and is dependent on the fullest cooperation of individual and States. GPW 13 is structured around the “triple billion” goal for three interconnected strategic priorities:

- Healthy Lives – 1 billion more people living healthier lives
- Universal health coverage – 1 billion more people with universal health coverage
- Health emergencies – 1 billion more people made safer (making us all safer)

The contribution of India for access to medical products worldwide is well recognized. India is a major manufacturer of medical products and generics. In vaccine manufacturing regulation rebenchmarking by a team of international experts convened by WHO in 2017 reaffirmed that the Indian National Regulatory Authority (NRA) is well equipped to produce and monitor safe, effective and quality vaccines. WHO prequalification of Indian manufacturers, facilitates supply of vaccines through the international procurement system, a major breakthrough for vaccine supplies to low- and middle-income countries. India is engaging in scientific progress and R&D for development of affordable products with supportive technology platforms, network of clinical sites and testing facilities and health technology innovation for meeting critical health needs.

In several recent WHA resolutions it has been recognized that health systems need to promote access to medical products (medicines, vaccines, diagnostics, devices) to ensure universal access to health care, rational use of medical products and the sustainability of health systems. Further, in 2016, the report of the UN Secretary-General’s High-Level Panel on Access to Health Technologies targeted incoherencies between trade and public health objectives. At this year’s World Health Assembly (WHA2018), the WHO Secretariat was tasked with developing a roadmap on access to medicines and medical products, in time for the next Executive Board. Investment in research for new products, especially for health conditions prevalent in low- and middle-income countries, is essential. At the same time, public health needs must be protected. In practice, greater capacity to work within intellectual property and competition rules, and use TRIPs flexibilities would help improve access for Medical products.

WHO policies promote appropriate access to medical products, in line with the WHO’s global strategy and plan of action on public health, innovation and intellectual property, including
policies on: access to generic medicines and innovation; quality-assurance of products through effective regulation and promoting rational use of medical products.

Access to essential medicines has been a priority in the Regional Flagship on UHC since 2014. To improve the quality and safety of medical products India is actively participating to promote regulatory collaboration for access to medical products through the South-East Asia Regulatory Network (SEARN). South-East Asia Region Member States Regional Committee has endorsed ten medicines-related resolutions since 2002, of which four are current.

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 held in New Delhi, 2017 focused substantially on ways to address these challenges. The 1st World Conference 2017 led to 142 recommendations related to national and international policies for Access to medical products agenda (in the framework of globalization and trade agreements). The contribution of partners to the Conference: WHO, Biotechnology Industry Research Assistance Council (BIRAC), a public sector undertaking of the Department of Biotechnology, Translational Health Science and Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science and Technology, Government of India, ICMR, Indian Society for International Law was invaluable. Key ministry(ies) have been identified for implementation of the Recommendations and nodal officers are designated to jointly coordinate for the purpose.

Given the importance of the agenda, the Ministry of Health announced the “2nd World Conference on Access to Medical Products – Achieving the SDGs 2030” during the 2017 Conference itself. The 2nd World Conference 2018 seeks to build on the consensus and deliberations made in the previous Conference. The Agenda of the 2nd World Conference 2018 reflects these priorities.

II. Objective:
The main objective of the 2nd World Conference 2018 is to take forward the recommendations from the 1st World Conference 2017 and build on the work done for access to medical products in the context of SDGs (including trade agreements) in line with GPW 13 of WHO.

III. Specific Objectives were:

1. Take forward recommendations of the 1st World Conference 2017 at national and international levels
2. Promote enabling ecosystem in the context of 13th GPW for access to medical products
3. Foster new approaches in innovation landscape for medical products and health technologies for accelerating research and innovation
4. Identify knowledge, information and policy options on the interface of international trade and health to achieve SDG 2030 goals.

IV. Thematic areas of the Conference

A. GPW 13, Innovation, Manufacturing
   i. 13th GPW for Access to Medical Products to achieve SDG 2030 Goals
   ii. State Health Ministers’ Roundtable Panel on Access to Medical Products
iii. Union Secretaries Roundtable Panel-Progress of 1st World Conference on Access to Medical Products
v. Innovation Policies for Medical Products
vi. High-end Manufacturing of medical products
vii. Tracking of investment into product R&D
viii. Mechanisms for Knowledge Sharing including Licensing Options for Medical Products to Facilitate Health for all

B. Regulation and Access
i. Strengthening Regulatory Networks for Facilitating Access to Quality, Safe and Affordable Medical Products
ii. Standard Setting and Quality Benchmarks for Medical Devices and Diagnostics in National and Global Markets
iii. Medical Diagnostics- Promoting Health for all
iv. Promoting Health and Wellness through Traditional Medicine
v. Developing Efficiencies in Clinical Trials in Global, Regional and National Settings
vi. Access and Affordability of Medical Products-Focus Orphan and Rare Drugs

C. Financing, Legal Landscape & Trade-related Aspects
i. Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards
ii. Legal and Regulatory Issues for Access to Medical Products
iii. Partnering for Access to Medical Products-Bilateral treaties and Regional Agreements
iv. Non Communicable Diseases-Legal Aspects for Prevention and Promotion of Public Health
v. Intellectual Property Rights and Standards in Trade for Medical Products

V. Expected Outcomes
1. Engage with a wide set of stakeholders, on critical issues of innovation, manufacturing, regulation, financing, legal, and trade-related aspects for access to medical products in the context of 13th GPW of WHO
2. Track progress on recommendations of the 1st World Conference 2017 at national and international levels
3. Foster new approaches in innovation landscape for medical products and health technologies for accelerating research and innovation including the interface of international trade and health to achieve SDG 2030 goals

VI. Sessions Details: A total of 18 Sessions were held as follows:
- 6 Plenary sessions
- 12 Parallel sessions
- 1 Wrap-Up session for collating all recommendations
- 17 Chairs, 12 Co-Chairs, Key Note Addresses, and Panelists from various countries and organizations including Ministry Officials, academia, industry, inter-governmental organizations and civil societies.

Subjects covered in Six Plenary Sessions
- Plenary Session 1: Access to Medical Products to achieve SDGs 2030
- Plenary Session 2: Mechanisms for Knowledge Sharing including Licensing Options for Medical Products for Health for all
- Plenary Session 3: Strengthening Regulatory Networks for Facilitating Access to Quality, Safe and Affordable Medical Products
- Plenary Session 4: Global Models for High-end Manufacturing of Medical Products
- Plenary Session 5: Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards
- Plenary Session 6: Legal and Regulatory Issues for Access to Medical Products

**Subjects of Twelve Parallel Sessions**
- Parallel Session 1: Policies to support Innovation for Medical Products (in select countries)
- Parallel Session 2: State Health Ministers’ Roundtable Panel on Access to Medical Products
- Parallel Session 3: Tracking Investments in Medical Products Research & Development
- Parallel Session 4: Union Government Secretaries and Principal Secretaries from States Roundtable Panel-Progress of 1st World Conference on Access to Medical Products and Strengthening Regulation in States
- Parallel Session 5: Standard Setting and Quality Benchmarks for Medical Devices and Diagnostics in National and Global Markets
- Parallel Session 6: Medical Diagnostics- Promoting Health for all
- Parallel Session 7: Promoting Health and Wellness through Traditional Medicine
- Parallel Session 8: Developing Efficiencies in Clinical Trials in Global, Regional and National Settings
- Parallel Session 9: Access and Affordability of Medical Products-Focus Orphan and Rare Drugs
- Parallel Session 10: Partnering for Access to Medical Products-Bilateral Treaties and Regional Agreements
- Parallel Session 11: Non Communicable Diseases-Legal Aspects for Prevention and Promotion of Public Health
- Parallel Session 12: Intellectual Property Rights and Standards in Trade for Medical Products

The detailed summary of each of the Plenary and Parallel sessions follows. The topics covered by each of the Speakers: Chairs, Co-Chairs, Key Note Address Speakers, Panelists is outlined along with the total of 126 recommendations for national governments, WHO and other international organization that emerged from each session.

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<th>Recommendations</th>
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Plenary Session 1: Access to Medical Products to achieve SDG 2030 Goals

Chairs: Mr JP Nadda, Union Minister, Health & Family Welfare, Government of India
Mr Ashwini Kumar Chaubey, Minister of State, Health & Family Welfare, Government of India

Special Addresses:
- Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region
- Ms Preeti Sudan, Secretary, Health, Ministry of Health and Family Welfare, Government of India

Keynote Addresses
1. Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO, Switzerland- Contribution of 13th GPW for Access to Medical Products to achieve SDG 2030 Goals
2. Dr Indu Bhushan, Chief Executive Officer, Ayushman Bharat Programme, Government of India- Universal Health Coverage in India: Bringing Healthcare to the People through National Health Protection Scheme

The objective of the session was to discuss the following:
- Contribution of 13th GPW for Access to Medical Products to achieve SDG 2030 Goals
- Achieving Universal Health Coverage and bringing Healthcare to the People in India through National Health Protection Scheme

Recommendations:

Recommendations for National Governments
1. Engage in UNGA for advocacy in inter-sectoral collaborations

Recommendations for WHO/International Organizations
1. WHO to support industry through prequalification for quality medical products (medicines, vaccines, diagnostics and devices), etc.
   a. WHO prequalification to expand scope to cover additional products on the EML, set up criteria for prioritization, similar biotherapeutic product (SBP) pilot, NCDs (Diabetes/Insulin, Hypertension), IVDs for Cholera, TB, NCDs, NTDs/Dengue
   b. Undertake capacity building and briefing workshops for enabling quality standards by manufacturers and regulators
   c. Promote standardization including through e-governance for market authorization of medical products by national governments of forms and processes
2. Promote competition through multiple manufacturers for increased access to affordable medical products
3. Promote IT in GXP for robust supply chain management
4. Provide assistance to strengthen capacity on Vigilance for medical products capacity in LMICs

Parallel Session 1: Policies to support Innovation for Medical Products (in select countries)
Chair: Dr. Henk Bekedam, WHO Representative to India

Key Note Addresses:
- **Dr. Mariângela Batista Galvão Simão**, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO, Switzerland- *Policy Options Promoting Innovation in Health Technologies- Select MERCOSUR Countries*
- **Dr S Leigh Verbois**, Assistant Commissioner for International Programs, US FDA, USA-*Facilitating Access: The Role of Innovation and Competition*

Panelists:
- **Dr Calvin Ho**, Assistant Professor, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore- *Mainstreaming Medical Ethics in Delivery for Fostering Quality and Safety of Health Services*
- **Dr Alka Sharma**, Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India- *Department of Biotechnology’s Supporting Role in the Innovations Ecosystem in India*
- **Dr Anil Koul**, Director, CSIR-Institute of Microbial Technology, India- *Towards Uni-pill for TB treatment*
- **Dr Pavan Asalapuram**, CEO, EMPE Diagnostics, Sweden- *Developing Rapid Diagnostic Solutions for Infectious Diseases: Focus on antibiotic resistance and Tuberculosis*

The objective of this session was to discuss policy initiatives made by governments to promote innovation in general and healthcare in particular for access to medical products. The following topics were discussed:

- Policy Options Promoting Innovation in Health Technologies- Select MERCOSUR Countries
- Facilitating Access: The Role of Innovation and Competition
- Mainstreaming Medical Ethics in Delivery for Fostering Quality and Safety of Health Services
- Department of Biotechnology’s Supporting Role in the Innovations Ecosystem in India
- Towards Uni-pill for TB treatment
- Developing Rapid Diagnostic Solutions for Infectious Diseases: Focus on antibiotic resistance and Tuberculosis

Recommendations

Recommendations for National Government:
1. Strengthen partnership of the federal and provincial regulatory authorities in India with other stringent regulatory authorities
2. Establish an advisory body for regulation of new medical products comprising regulatory agencies and standards control organization, e.g. Bureau of Indian Standards (BIS) for promoting access and local manufacturing
3. Streamline the manufacture and quality control/ assurance of reagents for hematology and biochemical tests in countries
4. Create national repositories of clinical isolates for promoting public health research for diseases of public health relevance
Recommendations for WHO/International Organizations:

1. Assist national governments and international agencies to explore new treatment options for diseases such as Tuberculosis including single pill regimens keeping in mind intellectual property
2. Promote intellectual property management including patent information, facilitation and capacity building for medical products innovations

Parallel Session 3: Tracking Investments in Medical Products Research & Development

Chair: Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO, Switzerland

Co-chair: Mr PN Ranjit Kumar, Joint Secretary, Ministry of AYUSH, Government of India

Participants joining from Parallel Session 4
1. Mr Suresh Chandra, Secretary, Ministry of Law and Justice, Government of India
2. Dr Balram Bhargava, Secretary Department of Health Research and Director General, Indian Council of Medical Research, Ministry of Health and Family Welfare, Government of India
3. Mr. Rajeev Sadanandan, Additional Chief Secretary, Department of Health and Family Welfare, Government of Kerala

Key Note Addresses:
1. Dr Mark Rohrbaugh, Special Adviser-Tech Transfer, National Institutes of Health, USA- The Role of NIH in Development of New Drugs & Vaccines
2. Mr Robert Terry, Manager-Research Policy, The Special Programme for Research and Training in Tropical Diseases, World Health Organization, Switzerland-Funding Global Health Product R&D and the Portfolio-To-Impact Model

Panelists:
1. Mr Niclas Jacobson, Deputy Director-General, Ministry of Health and Social Affairs, Sweden- Improving information in policy making for access to Medical Products
2. Dr Vipul Chowdhary, Analyst, Policy Cures Research, Australia- Facilitating policy through tracking investments in product R&D
3. Dr Suman Rijal, Executive Director, Drugs for Neglected Diseases (DNDi), India- Drug development project portfolio: DNDi Experience
4. Dr Shirshendu Mukherjee, Mission Director, Biotechnology Industry Research Assistance Council, India- Grand Challenges Indian Contribution in Promoting Research & Development

The objective of this session was to have discussions on effective knowledge sharing, collaboration and coordination of the efforts undertaken by different funding agencies globally to support research and innovation in specific areas of healthcare. The mechanisms of sharing experiences through creation of R&D observatories with the involvement of all stakeholders globally were also covered.

The following topics were taken up:

- The Role of NIH in Development of New Drugs & Vaccines
- Funding Global Health Product R&D and the Portfolio-To-Impact Model
Improving information in policy making for access to Medical Products
Facilitating policy through tracking investments in product R&D
Drug development project portfolio: DNDi Experience
Grand Challenges Indian Contribution in Promoting Research & Development

Recommendations

Recommendations for National Government:
1. Consider national-level R&D observatory and explore linkages with data tracking initiatives such as G-FINDER and World RePORT, with WHO Global Observatory on Health R&D.
2. Hold a workshop with NIH on policy initiatives on repurposing of approved drugs effective for new indications

Recommendations for WHO/ International Organizations:
1. Promote robust data tracking initiatives at national levels for addressing gaps in diseases/AMR/Health systems and / or investment tracking to complement G-FINDER and World RePORT.
2. Request workshop design and development support from NIH for clinical research including for repurposing of medical products to promote access.

Plenary Session 2: Mechanisms for Knowledge Sharing including Licensing Options for Medical Products for Health for all

Chair and Opening Remarks: Justice Prathibha M Singh, Judge, Delhi High Court, India
Co-chair: Dr. Manisha Shridhar, Regional Advisor, WHO SEARO, India

Key Note Address:
- Dr Mark Rohrbaugh, Special Advisor-Technology Transfer, National Institute of Health, USA- Intellectual Property Protection and Licensing under the Bayh-Dole Act

Panelists
2. Dr Kavita Singh, Mission Director, Biotechnology Industry Research Assistance Council, India- Enabling Regulatory Ecosystem for Innovation in Health Technologies
3. Dr KS Kardam, Senior Joint Controller Patents and Designs, Indian Patent Office, India- IPR and Public Health: Indian Patent Office Practice
4. Mr Guilherme Cintra, Senior Manager-IP &Trade, International Federation of Pharmaceutical Manufacturers & Association, Sweden- New Licensing Approaches For Access To Medical Products

The objective of the session was to discuss the following:
- Improving Effectiveness, Quality and Efficiency of the Drug Development Process
- Intellectual Property Protection and Licensing under the Bayh-Dole Act
- Accelerated Inclusive Innovation Led Growth- Making Technology Work For Everyone
- National and International Incentives to Promote Market Authorization on Pediatric Medical Products
Enabling Regulatory Ecosystem for Innovation in Health Technologies
Innovative Licensing Mechanisms: The Medicines Patent Pool Perspective
IPR and Public Health: Indian Patent Office Practice

Recommendations

Recommendations for National Government
1. Constitute an all-purpose Group from ministries, departments, regulators, agencies etc. to address Medical Products Policy, legal issues, research, commercialization and monitoring including for intellectual property aspects such as TRIPS flexibilities and patent licensing.
2. Strengthen IP policies at Institutes engaged in medical products research and technology transfer

Recommendations for WHO/International Organisations
1. Provide support to national initiatives for Medical Products Policy including for intellectual property aspects such as TRIPS flexibilities and patent licensing.
2. Support local manufacturing and innovation initiatives in policy making, regulation and IPR for access to medical products

Plenary Session 3: Strengthening Regulatory Networks for Facilitating Access to Quality, Safe and Affordable Medical Products

Chair: Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India;
Mr Ajay Prakash Sawhney, Secretary, Ministry of Electronics and Information Technology, Government of India
Co-chairs: Dr RK Vats, Additional Secretary, Ministry of Health and Family Welfare, Government of India;
Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO, Switzerland

Panelists
1. Dr Eswara Reddy, Drugs Controller General of India, Central Drug Standard Control Organization, India- Strengthening Regulatory Systems for Medical Products in India and for Global Markets including SEARO
2. Dr S Leigh Verbois, Assistant Commissioner for International Programs, US FDA, USA- Strengthening the Supply Chain
3. Dr Manisha Shridhar, Regional Advisor, WHO South-East Asia Regional Office, India- Access to Medical Products: Impact of Regulation, Trade, and Intellectual Property Opportunities for Collaboration
4. Mr Rishi Prakash, Joint Director, e-Governance; Ms Payal Saluja, Principal Technical Office, Centre for Development of Advanced Computing, India- Leveraging Information Sharing Platform for SEARN Countries

The objective of this session was to discuss how to strengthen regulatory networks policy initiatives made by governments to promote innovation in general and healthcare in particular for access to medical products.
The following topics were discussed:
- To create a platform for knowledge sharing and best practices in regulatory systems
strengthening.

- Discuss principles to guide the establishment or evolution of harmonized regulations.
- Harmonized Regulatory pathways in emergencies
- Translation of rare disease research into orphan drug development
- Role of NIH in Development of New Drugs & Vaccines
- USFDA Regulatory Initiatives in public health.
- Strengthening Regulatory Systems for Medical Products in India and for Global Markets including SEARO
- Challenges and Opportunities in an Evolving Regulatory System
- Strengthening the Supply Chain
- Leveraging Information Sharing Platform for SEARN Countries

**Recommendations:**

**Recommendations for National Government:**

- Leverage the strengths of the Region and its role as a major manufacturer of essential medical products especially generic medicines to improve accessibility and affordability

**Recommendations for WHO/ International Organizations:**

- Leverage SEARN to enable product registration for market authorization for HIV/AIDS, Hepatitis C etc.

**Plenary Session 4: Global Models for High-end Manufacturing of Medical Products**

**Chairs:** Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India; Dr Balram Bhargava, Secretary, Department of Health Research, Ministry of Science and Technology, and Director General, Indian Council for Medical Research, Government of India

**Moderated By:** Mr Lav Agarwal, Joint Secretary, Ministry of Health & Family Welfare, Government of India

**Keynote Addresses:**

- Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India- *Ideation to Commercialization of Medical Products-DBT Initiatives*
- Dr Balram Bhargava, Secretary, Department of Health Research, Ministry of Science and Technology, and Director General, Indian Council for Medical Research, Government of India- *High Tech Manufacturing for Local Healthcare Needs- Providing Adaptive Technology Solutions*

**Panelists:**

1. Dr Manisha Shridhar, Regional Advisor, WHO South-East Asia Regional Office, India;
2. Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO India- Fostering Local Production and Technology Transfer for Medical Products
2. Dr Arun Bhardwaj, Director, Central Drugs Laboratory-Kasauli, India-Quality Manufacturing to Meet National and Global Vaccine Needs  
3. Dr Rajiv Nath, Association of Indian Medical Device Industry, India- Accelerating Innovation (Faster Up-Gradation of Existing Technology and Global New Product Innovation)

**The objective of the session** was to discuss the following:
- Ideation to Commercialization of Medical Products-DBT Initiatives
- High Tech Manufacturing for Local Healthcare Needs- Providing Adaptive Technology Solutions
- Policy options to promote Small & Medium Scale Enterprises (MSMEs) manufacturing for world class medical products- Developing enabling eco-system and incentives including financial incentives.
- Industry academia collaboration to stimulate R&D efforts and Technology Transfer for affordable medical products

**Recommendations:**

**Recommendations for National Governments**
1. Engage in joint capacity building and training and regulatory expertise with DBT, WHO and CDSCO for handholding startups and innovators for accelerated manufacture and production of vaccines and other medical products.
2. Promote technical upgradation for manufacture of auto-disposable syringes in MSME clusters.
3. Develop quality benchmarking mechanisms for innovative medical devices and diagnostics for which international quality standards are not available (such as CE/BIS certifications)
4. Conduct capacity building programs with National Bio-Pharma Mission, WHO and CDSCO to build capacity of medical products including vaccine start-ups which are ready for production.
5. Enhance the capacities of the pharmaceutical MSMEs by enabling the targeted enterprises graduate from Schedule M to WHO GMP to WHO pre-qualified for formulations, APIs and medical devices.

**Recommendations for WHO/ International Organizations**
1. Awareness and capacity building on Patent applications, Grants and Sub-Licensing 
2. Engage in capacity building and regulatory expertise for handholding startups and innovators- including for the National Biopharma Mission

**Parallel Session 5: Standard Setting and Quality Benchmarks for Medical Devices and Diagnostics in National and Global Markets**

**Chair:** Ms Surina Rajan, Director General, Bureau of Indian Standards, Government of India  
**Key Note Addresses:**
- Dr VG Somani, Joint Drugs Controller India, Central Drug Standard Control Organization, India- *Regulatory Landscape Reforms for Medical Devices and Diagnostics in India*
- Dr RK Bajaj, Deputy Director General; Bureau of Indian Standards, Government of India;
Dr Prakash Bachani, Head Medical Equipment Planning, Bureau of Indian Standards, Government of India - Promoting Quality through Standards in Medical Products

Panelists:
1. Mr MSR Dixit, Kalam Institute of Health Technology, India - Developing Ecosystem for Quality Diagnostics and Devices
2. Dr Reba Chhabra, Deputy Director-Quality Control Diagnostics & HOO, National Institute of Biologicals, India - Critical Support by Labs for Quality Diagnostics

The objective of this session was to discuss the following:
- International and national standard setting in medical products for quality and safety
- Developing quality benchmark mechanisms for innovative medical devices and diagnostics for which no international quality standards exist (such as CE/ BIS certifications) – the Indian context.
- Regulatory Landscape Reforms for Medical Devices and Diagnostics in India
- Factors necessary for developing Ecosystem for Quality Diagnostics and Devices
- Promoting Quality through Standard setting in Medical Products
- Critical Support by Labs for Quality Diagnostics to promote access

Recommendations:

Recommendations for National Governments
1. Identify and develop national networks of laboratories to share resources, technical expertise & Quality Assurance Programmes.
2. Participate in formation of global standards for medical devices and diagnostics through international committees and provide platform for implementing the latest and globally acceptable guidelines.
3. Develop Collaborative approaches by regulators and government bodies to enhance use of standards by medical device industries, hospitals and users.
4. Examine facilitative ecosystems for medical devices and diagnostics to enable local manufacturing for affordable medical products.

Recommendations for WHO/International Organizations
1. Capacity building, Policy Guidance and Advocacy to indigenous manufacturers / stakeholders in global standards.
2. Capacity building in preparation of Technical Dossiers and evaluation protocols of WHO PQ Programme support cell for In-vitro Diagnostics for further handholding of stakeholders thus promoting them to participate in Global tenders for priority diagnostics.
3. Identify International Laboratories to support in establishment of reference standards such as gold standard Diagnostic Kit for new disease markers.
4. Facilitate the availability of global panels (Population based clinical samples) for Priority & New disease markers.
5. Explore collaboration with comprehensive List of laboratories on WHO website providing EQAS (External Quality Assessment programme) for specific or new disease markers.

Parallel Session 6: Medical Diagnostics- Promoting Health For All
Chair: Dr Balram Bhargava, Secretary, Department of Health Research, Ministry of Science and Technology, and Director General, Indian Council for Medical Research, Government of India
Co-chair: Mr Manoj Jhalani, Additional Secretary, Ministry of Health and Family Welfare, Government of India

Panelists:
1. Dr Ravi Kant Sharma, Deputy Drugs Controller, Central Drug Standard Control Organization, India- Regulatory Updates for Medical Devices and Diagnostics in India
2. Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO India- WHO India Support for National Initiative on Diagnostics and Essential Diagnostics List
3. Dr Kamini Walia, Scientist E, Indian Council of Medical Research, India- Development of First Ever National Diagnostics List: The Indian experience
4. Dr Zachary Katz, Chief Access Officer, FIND-Introduction of New Point Of Care Diagnostics for HIV, Malaria and TB
5. Dr SB Sinha, Advisor Healthcare Technology, National Health Systems Resource Centre, India- Free Diagnostics (and Biomedical Equipment Maintenance) for Universal Health Coverage in India

The objective of this session was to discuss the following:
- Introduction of New Point Of Care Diagnostics for HIV, Malaria and TB
- National diagnostics landscape in India and WHO’s technical assistance
- The Indian experience in development of First Ever National Diagnostics List
- Regulatory Updates for Medical Devices and Diagnostics in India
- Viral Hepatitis Programme of India to Facilitate Diagnostics and Treatment for All
- Free Diagnostics (and Biomedical Equipment Maintenance) for Universal Health Coverage in India

Recommendations:

Recommendations for National Governments
1. Explore provision of high throughput automation for molecular biology platforms like Next Generation Sequencing etc.
2. Promote Essential Diagnostic List to promote the access to quality and affordable diagnostics
3. Promote integration of laboratory services for disease programs on multiple platforms to enable optimization of resources at facility levels (e.g. GeneXpert, Roche, Abbott). Integration with existing diagnostics initiatives and national health programmes so that all designated tests are available at all facilities.
4. Promote Evidence-based and rational prescription of tests for making informed decisions for treatment protocols using standard treatment guidelines and Standard Diagnostics Workflows
5. Promote digital initiatives including Artificial intelligence through telemedicine and remote monitoring for improved health outcomes and integrated disease surveillance

Recommendations for WHO/International Organizations
1. Support the development and implementation of Essential Diagnostics List and the intertwined aspects such as regulatory framework of medical diagnostics; diagnostic formulary and standard diagnostic guidelines.
2. Provide assistance for diagnostic formulary and standard diagnostic guidelines, as is
done for medicines as standard treatment guidelines - linkage with clinical education
3. Foster and leverage EDL as a tool to spur R&D, innovation and enterprise in diagnostics
4. Recommend/advise on quality assurance systems for new products put in use

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<th>Parallel Session 7 - Promoting Health and Wellness Through Traditional Medicine</th>
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<tbody>
<tr>
<td><strong>Chair:</strong> Mr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India</td>
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<td><strong>Co-chair:</strong> Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India</td>
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**Panelists**
1. Dr Ishwar V Basavaraddi, Director, Morarji Desai National Institute of Yoga, Ministry of AYUSH, Government of India - The Role Of Traditional Medicine Practice In Prevention Of Non-Communicable Diseases
2. Dr Vijay Laxmi Asthana, Senior Scientist, CSIR-National Institute of Science Communication and Information Resources, India-Traditional Knowledge Digital Library (TKDL)
3. Dr. N Shrikant, Deputy Director General, Central Council For Research In Ayurvedic Sciences, Ministry of AYUSH, Government of India - Strengthening The Evidence Base Of Medical Products Through Research In Ayurvedic Medicine Systems
4. Dr Asim Ali Khan, Director General, Central Council for Research in Unani Medicine, Ministry of AYUSH, Government of India - Integration Of Traditional Medicines Into The Health Systems: The Unani Council Experience
5. Dr Kim Sungchol, Regional Adviser - Traditional Medicine, WHO South-East Asia Regional Office, India - WHO South East Asia Regional Perspective on Traditional Medicine
6. Dr Jing Xu, Deputy Director, National Administration of Traditional Chinese Medicine, China - Ensuring Quality and Standards In Traditional Medicines In China

**The objective of the session** was to discuss:
- Role of TM in health & wellness for prevention CDs & NCDs- next steps to TKDL
- Strengthening the evidence base for innovation & safety in TM
- Integrating traditional medicine with modern system of medicine for achieving public health goals
- The role of traditional medicine practice in prevention of Non-Communicable Diseases
- Strengthening the Evidence Base of medical products through research In Ayurvedic Medicine systems
- Integration of Traditional Medicines Into The Health Systems: The Unani Council Experience
- WHO South East Asia Regional Perspective on Traditional Medicine
- Ensuring quality and standards in Traditional medicines in China

**Recommendations:**

**Recommendations for National Government**
1. Promote Legal protection of traditional knowledge and associated genetic resources
2. Promote research and strengthen evidence base for quality, safety, and efficacy of traditional medicine
3. Strengthen pharmacovigilance systems for safety monitoring of traditional medicine products

**Recommendations for WHO/International Organizations**
1. Support research and strengthen evidence base for quality, safety, and efficacy of traditional medicine
2. Support strengthening pharmacovigilance systems for safety monitoring of traditional medicine products

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**Parallel Session 8: Developing Efficiencies in Clinical Trials in Global, Regional and National Settings**

**Chair:** Dr VK Paul, Member, NITI Aayog, Government of India

**Co-chair:** Dr BD Athani, Former Director General Health Services; Principal Consultant, Ministry of Health and Family Welfare, Government of India

**Key Note Addresses: Best Practices in Clinical Trials**
1. Dr Balram Bhargava, Secretary, Department of Health Research, and Director General, Indian Council for Medical Research, Ministry of Health and Family Welfare, Government of India
2. Dr Preetha Rajaraman, India Health Attaché, US Department of Health, US Embassy

**Panelists**
1. **Dr P Paul Kumaran**, Scientist E, National Institute for Research in Tuberculosis, India- *Ethical and Regulatory considerations in Clinical Trials in India*
2. **Lt Gen Velu Nair**, Group Technical Head, Cluster of Comprehensive Blood and Cancer Centres, USA & Former DG-Medical Services (Army), India- *Accreditation of Ethics Committees in the Context of Clinical Trials: The India Experience*
3. **Dr M Vishnu Vardhana Rao**, Scientist G & Director, NIMS, Indian Council for Medical Research, India- *Disclosure of Clinical Trials Results by Stakeholders: Clinical Trial Registry of India Experience*
4. Dr Sunder Raman, Head-Global Regulatory Affairs, Biocon, India- *Strategies to Accelerate Access to High Quality Biosimilars for Global Patients*

The objective of this session was to discuss policy options adopted by national governments for making medical products affordable, with particular reference to orphan and rare drugs. Different initiatives for fostering industry to take up R&D on orphan drugs, drugs for rare diseases and neglected tropical diseases (NTDs) and were also discussed.

The following topics were taken up:
- Ethical and Regulatory considerations in Clinical Trials in India
- Accreditation of Ethics Committees in the Context of Clinical Trials: The India Experience
- Disclosure of Clinical Trials Results by Stakeholders: Clinical Trial Registry of India Experience
- Strategies to Accelerate Access to High Quality Biosimilars for Global Patients
### Recommendations:

#### Recommendations for National Government:

1. Examine the ways clinical trials are conducted nationally and internationally to shorten timelines and foster access to medical products; leverage multiregional clinical trials for faster clinical trials; streamlined pathways for antibiotics for drug resistant infections.
2. Explore provision of high throughput automation for molecular biology platforms like Next Generation Sequencing etc.
3. Identify and develop national networks of laboratories to share resources, technical expertise & Quality Assurance Programmes

#### Recommendations for WHO/International Organizations:

1. Develop collaborative efforts with NRAs for training of investigators in good clinical practices and biomedical research ethics
2. Strengthen the international mechanism of WHO Clinical Trials Registry Platform with appropriate national interventions.

### Parallel Session 9: Access and Affordability of Medical Products-Focus Orphan and Rare Drugs

**Chair:** Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO, Switzerland

**Co-Chair:** Mr. Navdeep Rinwa, Joint Secretary Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India;
**Dr Chandershekhar,** Additional Director General, Indian Council for Medical Research, India

**Panelists:**

1. **Dr S Leigh Verbois**, Assistant Commissioner for International Programs, US FDA, USA- *FDA Role in Facilitating Access of Medical Products for Orphan and Rare Diseases*
2. **Dr Yannis Natsis**, Policy Manager, Universal Access and Affordable Medicines, European Public Health Alliance, Belgium- *European Public Health Alliance Contribution for Universal Access and Affordable Medicines*
3. **Dr Calvin Ho**, Assistant Professor, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore- *Timely Access to Innovative Drugs but with Affordable Prices*
4. **Dr Inthira Yamabhai**, IHPP, Ministry of Public Health, Thailand- *Pricing Policy and Local Manufacturing for Affordable Medicines*
5. **Mr James Love**, Director, Knowledge Ecology International, USA- *Orphan Drugs Tax Credits and Cost of Clinical Trials*
6. **Dr Anuj Sharma**, National Professional Officer-AMR & Labs, WHO India- *Development of Indian Priority Pathogen List (IPPL) of Antibiotic-Resistant Bacteria to Guide Research, Discovery and Development of New Antibiotics*

The objective of this session was to discuss policy options adopted by national governments for making medical products affordable, with particular reference to orphan and rare drugs. Different initiatives for fostering industry to take up R&D on orphan drugs, drugs for rare diseases and neglected tropical diseases (NTDs) and were also discussed.

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The following topics were taken up:

- USA- FDA Role in Facilitating Access of Medical Products for Orphan and Rare Diseases
- European Public Health Alliance Contribution for Universal Access and Affordable Medicines
- Timely Access to Innovative Drugs but with Affordable Prices
- Orphan Drugs Tax Credits and Cost of Clinical Trials
- Development of Indian Priority Pathogen List (IPPL) of Antibiotic-Resistant Bacteria to Guide Research, Discovery and Development of New Antibiotics

**Recommendations:**

**Recommendations for National Governments**
1. Study Intellectual Property protection of orphan drugs keeping in view its implications on their affordability for LMICs.
2. Foster collaboration between national government agencies and international players on delinking the costs of R&D for diseases of public health importance from price of treatment.
3. Explore communication methodologies during early drug development for improved transparency between the regulators and the industry to enable decisions (explore US CDER (Center for Drug and Evaluation and Research) model).

**Recommendations for WHO/International Organizations**
1. Explore feasibility study of delinking R&D incentives for diseases of public health importance from prices of treatments.

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**Plenary Session 5: Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards**

**Chair:** Justice Prathibha M Singh, Judge, Delhi Court, India  
**Co-chair:** Dr K Vijay Raghavan, Principal Scientific Adviser to the Government of India; Dr 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, USA

**Keynote Address:**
1. Dr 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, USA- **Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards**

**Panelists:**
1. Ms Rachael Crockett, Policy Adviser, Global Policy Team, Wellcome Trust, UK- **Approach To Equitable Access To Healthcare Interventions**
2. Dr Manica Balasegaram, Director, GARDP, DNDi, Switzerland- **Role of Product Development Partnerships for Access to Health Technologies**
3. Dr Johan Lennart Struwe, Public Health Agency of Sweden, Sweden- **Rational Use of**
**Antibiotics Implemented though the Swedish Strategic Programme for Antibiotic Resistance**

**The objective of the session** was to discuss the following:
- Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards
- Approach To Equitable Access To Healthcare Interventions
- Role of Product Development Partnerships for Access to Health Technologies
- Rational Use of Antibiotics Implemented though the Swedish Strategic Programme for Antibiotic Resistance

**Recommendations:**

**Recommendations for National Governments**

1. Discuss for changing the Innovation Ecosystem (lead by ICMR/ DBT) through:
   - Pre competitive inputs:
     - Sourcing of natural products for screening and novel drug design from biodiverse repositories
     - Contracted services for pharmacokinetics/pharmacodynamics, toxicology, and so on
   - Sharing of Clinical trial data – such as Coalition against Major Diseases pooled control arms of clinical trials on Alzheimer’s disease.
   - Combination treatments - Global Alliance for TB Drug Development, Gates Foundation and the Critical Path Institute work to shave years off the regulatory approval of TB combination regimens.
   - Moving to an End-to-End (drug by drug / company by company) Approach to Ensure Sustainable Access:
     - Availability: innovation platforms for drug discovery; efficient use of biodiversity resources
     - Effectiveness: ensuring sustainable production and repurposing older antibiotics
     - Affordability: Innovative financing
     - Access: prescription of medicine and diagnostics through diagnostics platforms

2. Collaboration between:
   - academia and industry through development of incubators/accelerators and partnerships for funding, scaling up innovations and sustainable products
   - regulators and patients through promotion of patient access and engaging different stakeholders to address unmet needs

3. Adoption of Multifaceted approach:
   - Increase awareness about AMR among professionals, politicians and the public by Regular information and campaigns
   - Conduct National and regional meetings to share experiences and ideas and catalyse multi-sectoral collaboration
   - Involve multiple target groups through education and workshops
   - Promote scientific studies and optimize use of old antibiotics
   - Monitor the international scientific literature and media

4. A global public-private partnership such as coalition for epidemic preparedness model, where global philanthropy as well as governments come together to fund the market failure gap, but that should also reserved in capacity building in area such as India rather substantially.

5. Secure databases ranging from product and disease registry, hospital information
management system (HIMS), electronic health records, etc. for efficient decision making in healthcare.

**Recommendations for WHO/ International Organizations**

1. Support Accelerated introduction of new tools for TB diagnosis and treatment
2. Examine Reengineering of R & D value chain through: sharing of resources, risks and rewards at different stages
3. Promote Access and Stewardship to tackle health priorities in India and other developing countries, as well as partnering with Indian actors to deliver programs on R & D, clinical evaluation, sustainable access and funding.
4. Focus on optimal use of antimicrobial agents to address issues of AMR by:
   i. Harmonizing evidence-based/ consensus guidelines for treatment and diagnosis
   ii. Deploying models for prevention of disease as well as prevention of bacterial spread
   iii. Encouraging antimicrobial stewardship efforts through need defined resources

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**Plenary Session 6- Legal and Regulatory Issues for Access to Medical Products**

*Chair:* Mr Suresh Chandra, Secretary, Ministry of Law and Justice, Government of India

*Key Note Address:*
Dr 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, USA- *Designing Innovative Approaches to Improving Antimicrobial Stewardship through Drug Regulation*

*Panelists:*
1. Dr Manica Balasegaram, Director, GARDP, DNDi, Switzerland- New Global Initiatives for Innovation of Medical Products- Global Antibiotic R&D Partnership (GARD-P)
2. Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia- Intellectual Property, Access to Medicines and Universal Health Coverage Through a Health Rights Lens
3. Dr K Bangarurajan, Joint Drugs Controller India, Central Drug Standard Control Organization, Government of India- Regulatory Updates to Foster an Enabling Landscape for Access to Medical Products
4. Mr DG Shah, Indian Pharmaceutical Alliance, India- Innovation and IPR in Indian Pharmaceutical Industry
5. Dr Gayatri Saberwal, Scientist and Dean, Institute of Bioinformatics and Applied Biotechnology, India- Bio-incubation Clusters and Initiatives in India for Health Technologies

*The objectives of this session were:*
- Designing Innovative Approaches to Improving Antimicrobial Stewardship through Drug Regulation
- New Global Initiatives for Innovation of Medical Products- Global Antibiotic R&D Partnership (GARD-P)
- Intellectual property, access to medicines and universal health coverage through a health rights lens
- Innovations and IPR in Indian pharmaceutical industry
- Bio-incubation Clusters and Initiatives in India for Health Technologies
• Access & Stewardship: How do Companies Address the Affordability of Antibiotics
• Regulatory Updates to Foster an Enabling Landscape for Access to Medical Products

Recommendations:

Recommendations for National Government
1. Simplify the regulatory requirements to strike a balance between the extent of unmet need vs the amount of efficacy and safety required for registration.

Recommendations for WHO/International Organizations
1. Enhance the scope and greater resources dedicated for WHO Prequalification program that assesses medical products for quality and safety.
2. Facilitate registration for new drugs through regional and global networks.
3. Promote paediatric development and Pharmacokinetics and safety to support streamlined paediatric development.
4. Facilitate ability to conduct global clinical trials and run parallel registration.

Parallel Session 10- Partnering for Access to Medical Products-Bilateral Treaties and Regional Agreements

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

Panelists
1. Dr Mohga Kamal Yanni, Senior Health and HIV Policy Adviser, Oxfam GB, UK- Developing systems and approaches for Access to Medical products in Free Trade Agreements
2. Dr Cha-aim Pachanee, International Health Policy Program, Ministry of Public Health, Thailand- Thailand’s Engagement for Public Health in Bilateral and Regional Agreements
3. Mr DG Shah, Indian Pharmaceutical Alliance, India- Partnering for Access to Medical Products in Bilateral Treaties and Regional Agreements
4. Dr Sachin Chaturvedi, Director General, Research & Information System for Developing Countries, India- Achieving the Sustainable Development Goals (SDGs): Strengthening Regional Cooperation and Resources for the SDGs
5. Mr KM Gopakumar, Legal Advisor, Third World Network, India- Progress on TRIPS Flexibilities since Doha Declaration since 2001

The objective of this session:
• Develop systems and approaches to track for Access to Medical products in Free Trade Agreements
• Progress on TRIPS Flexibilities since Doha Declaration since 2001
• Engagement of countries to achieve public health goals in Bilateral and Regional Agreements
• Partnering for Access to Medical Products in Bilateral and Regional Agreements
• Overcoming Patent Barriers: Options and Impact
- Strengthen the partnerships between international trade and health policy for access to medical products.

**Recommendations:**

**Recommendations for National Governments**
1. Promote capacity building for the health and Non-health officials to understand impact of international trade on health
2. Develop Multi-sectoral collaboration, networking involved in both health sector and non-health sectors on trade issues, exchange evidence and research.

**Recommendations for WHO/International Organizations**
1. Promote Capacity building, Policy Guidance and Advocacy to indigenous manufacturers / stakeholders about standards.
2. Support adoption of a model list of medicines, medical devices including diagnostic and other equipment to optimize the treatment for the achievement of SDG
3. Build capacity through international organizations (e.g. WTO-WHO workshop on trade and public health)
4. Assess potential impact of FTAs provisions on public health and Access to medical / health products and suggest concurrent review of agreements

**Parallel Session 11- Non Communicable Diseases-Legal Aspects for Prevention and Promotion of Public Health**

**Chair:** Dr Suresh Chandra, Secretary, Ministry of Law and Justice, Government of India  
**Co-chair:** Dr. Mohd. Shaukat, Advisor(NCD), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India

**Panelists**
1. Dr Padmini Angela De Silva, Regional Adviser-Nutrition, WHO South-East Asia Regional Office, India- Nutrition and NCDs
2. Dr Christer Backman, Senior Expert, International Relations, Medical Products Agency, Sweden- Regulations, Standards and Licensing of Medical Products
3. Ms Sunita K Sreedharan, Lawyer, SKS Law Associates, India-Legal Regulations Preventing Non-Communicable Diseases Governance with Special Reference to India

**The objective of the session was to**
- Nutrition and NCDs
- Regulations, Standards and Licensing of Medical Products to address NCDs
- Research Institutions Licensing Practices for Prioritizing Public Health
- Licensing Approaches for Newer Anti-Cancer and Anti-Diabetic Medicines
- Internationalization of research & development for healthcare in emerging economies
- Legal regulations in non communicable diseases governance in public health
- Legal aspects for prevention and promotion of public health
Recommendations:

Recommendations for National Governments:
1. Build a robust framework for licensing health technologies taking into account needs, access gaps and likelihood of licenses resulting in impact
2. Provide opportunities to patent holders for In-licensing, development support and performance impact such as the procedures adopted as in Medicines Patent Pool
3. Bring synergies for public health outcomes by engaging in technical barriers to trade agreement and standard setting for food and nutrition products for NCDs
4. Explore quicker access to medicines through alternate models like PRIME, Breakthrough, SAKIGAKE, etc.

Recommendations for WHO/International Organizations:
1. Support public health impacts of technical barriers to trade agreement and standard setting for Codex for food and nutrition products for NCDs

Parallel Session 12: Intellectual Property Rights and Standards in Trade for Medical Products

Chair: Mr Sudhanshu Pandey, Additional Secretary- Trade Policy Division, Ministry of Commerce and Industry, Government of India

Panelists:
1. Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia- New Initiatives in PDPs for Access to Affordable Medical Products
2. Dr Purnima Sharma, Managing Director, Biotech Consortium India Limited, India- Bringing First Generation Entrepreneurs to the Market Place For Medical Devices
3. Dr H Purshottam, Chairman and Managing Director, National Research Development Corporation, India- Health Technology Transfer
4. Ms Leena Menghaney, Head-South Asia, Access Campaign, Medecins Sans Frontieres, India- Patents as a Tool for Innovation- Challenges in the NCD Medical Products Pipeline

The objective of the session is to discuss:
- IPR standards and promoting innovation and technology transfer
- Balancing Intellectual Property Rights and research and development and innovation in traditional medicine
- National IP policies and their role in innovation and facilitating access to affordable medical products.

Recommendations:

Recommendations for National Governments
1. Facilitate robust innovation ecosystem for enabling startups in healthcare to deliver affordable medical products accessible to all through mentoring and financial support

Recommendations for WHO/International Organizations
1. Foster regional networks for using PDPs to provide access to medicines

VII. Participants in the Conference
Approximately 300 participants attended, coming from 10 countries including India and from many intergovernmental organizations. The attendees came from all six WHO regions. The countries which participated other than India were Australia, Belgium, Bhutan, Singapore, Sweden, Switzerland, Thailand, United Kingdom, United States of America. Attendees represented a variety of organizations, with the largest numbers from the government or public agencies and academic sectors.

The participation was also from State Health Ministries, partner agencies, academia and WHO South-East Asia Region countries, civil society organizations and private sector including Pharmaceutical and Medical device associations.

International participants

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

International Participants

- USA: 20%
- Sweden: 25%
- Switzerland: 12%
- Bhutan: 5%
- Belgium: 3%
- Indonesia: 5%
- Australia: 8%
- UK: 12%
- Thailand: 5%
- Singapore: 5%
Dignitaries in the Conference, Chairs, Co-chairs, Key Note Speakers and Panelists

1. Honorable Mr JP Nadda, Union Minister, Health & Family Welfare, Government of India
2. Honorable Mr Ashwini Kumar Chaubey, Minister of State, Health & Family Welfare, Government of India
3. Honorable Ms Anupriya Patel, Minister of State, Health & Family Welfare, Government of India
4. Mr Vipin Singh Parmar, Minister of Health & Family Welfare, Revenue & Law, Government of Himachal Pradesh
5. Mr Shivananda S Patil, Hon'ble Minister for Health and Family Welfare, Government of Karnataka
6. Mr Ramchandra Chandravanshi, Minister of Health & Family Welfare and Medical Education, Government of Jharkhand
7. Mr Firarooq Khan, IPS, Administrator, Union Territory of Lakshadweep
8. Mr Malladi Krishna Rao, Minister of Health & Family Welfare, Government of Puducherry
9. Mr Devendra Kumar Joshi, Governor-Andaman & Nicobar
10. Mr Brahm Mohindra, Minister of Health & Family Welfare, Government of Punjab
11. Mr Satyendar Jain, Minister of Health, Government of NCT of Delhi
12. Dr C Vijaya Baskar, Minister of Health & Family Welfare, Medical Education Government of Tamil Nadu
13. Mr Siddharth Nath Singh, Minister of Medical & Health, Government of Uttar Pradesh
14. Mr Pangnyu Phom, Minister of Health & Family Welfare, Government of Nagaland
15. Dr VK Paul, Member, NITI Aayog, Government of India
16. Justice Prathibha M Singh, Judge, Delhi High Court, India
17. Dr K Vijay Raghavan, Principal Scientific Adviser to the Government of India
18. Ms Preeti Sudan, Secretary, Health, Ministry of Health and Family Welfare, Government of India
19. Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region
20. Dr Balram Bhargava, Secretary, Department of Health Research, Ministry of Health and Family Welfare, Government of India
21. Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India
22. Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO Geneva
23. Dr Indu Bhushan, Chief Executive Officer, Ayushman Bharat Programme, Government of India
24. Ms Surina Rajan, Director General, Bureau of Indian Standards, Government of India
25. Mr Ajay Prakash Sawhney, Secretary, Ministry of Electronics and Information Technology, Government of India
26. Mr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India
27. Mr Suresh Chandra, Secretary, Ministry of Law and Justice, Government of India
28. Dr RK Vats, Additional Secretary, Ministry of Health & Family Welfare, Government of India
29. Mr Manoj Jhalani, Additional Secretary, Ministry of Health and Family Welfare, Government of India
30. Dr Henk Bekedam, WHO Representative to India
31. Dr BD Athani, Former Director General Health Services; Principal Consultant, Ministry of Health and Family Welfare, Government of India
32. Mr Alok Kumar, Adviser, NITI Aayog, Government of India
33. Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India
34. Mr Sudhansh Pant, Joint Secretary, Ministry of Health and Family Welfare, Government of India
35. Mr Lav Agarwal, Joint Secretary, Ministry of Health & Family Welfare, Government of India
36. Mr Sudhanshu Pandey, Additional Secretary- Trade Policy Division, Ministry of Commerce and Industry, Government of India
37. Mr Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India
38. Mr Rajiv Aggarwal, Joint Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India
39. Mr PN Ranjit Kumar, Joint Secretary, Ministry of AYUSH, Government of India
40. Dr J Radha Krishnan, Principal Secretary, Health, Government of Tamil Nadu
41. Mr Rajeev Sadanandan, Additional Chief Secretary (Health), Department of Health & Family Welfare, Government of Kerala
42. Mr V Vumlunmang, Principal Secretary (Health & FW) Department of Health & Family Welfare, Government of Manipur
43. Mr Satish Chandra, Additional Chief Secretary (Health & FW), Department of Health & Family Welfare, Government of Punjab
44. Mr Vivek Pandey, Secretary (Health), UT of Lakshadweep
45. Mr Ajay Seth, Additional Chief Secretary (H&FW), Health and FW Department, Government of Karnataka
46. Mr Jawaid Akhtar, IAS, Principal Secretary to Government, Health and Family Welfare Department, Government of Karnataka, Bengaluru
47. Mr Prashant Trivedi, Principal Secretary, Department of Health & Family Welfare, Government of Uttar Pradesh
48. Mr I Himato Zhimomi, Principal Secretary (Health), Department of Health & Family Welfare, Government of Nagaland
49. Dr Jayanti S Ravi, Commissioner (Health) & Principal Secretary (Public Health & Family Welfare), Government of Gujarat
50. Mr Roop Ram Jowel, Additional Chief Secretary (Health), Department of Health & Family Welfare, Government of Haryana
51. Mr KR Meena, Principal Secretary (Health), Department of Health & Family Welfare, Government of Andaman & Nicobar
52. Dr Chandershkekar, Additional Director General, Indian Council for Medical Research, India
53. Dr 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, USA
54. Mr Nilambuj, Adviser, Ministry of Health and Family Welfare, Government of India
55. Dr Eswara Reddy, Drugs Controller General of India, Central Drug Standard Control Organization, India
56. Dr RK Bajaj, Deputy Director General; Bureau of Indian Standards, Government of India
57. Dr Prakash Bachani, Head Medical Equipment Planning, Bureau of Indian Standards, Government of India
58. Dr VG Somani, Joint Drugs Controller India, Central Drug Standard Control Organization, India
59. Dr K Bangarurajan, Joint Drugs Controller India, Central Drug Standard Control Organization, Government of India
60. Dr S Leigh Verbois, Assistant Commissioner for International Programs, US FDA, USA
61. Dr Calvin Ho, Assistant Professor, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore
62. Dr Alka Sharma, Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India
63. Dr Anil Koul, Director, CSIR-Institute of Microbial Technology, India
64. Dr Pavan Asalapuram, CEO, EMPE Diagnostics, Sweden
65. Dr Mark Rohrbaugh, Special Adviser-Tech Transfer, National Institutes of Health, USA
66. Mr Robert Terry, Manager-Research Policy, The Special Programme for Research and Training in Tropical Diseases, World Health Organization, Switzerland
67. Mr Niclas Jacobson, Deputy Director-General, Ministry of Health and Social Affairs, Sweden
68. Dr Vipul Chowdhary, Analyst, Policy Cures Research, Australia
69. Dr Suman Rijal, Executive Director, Drugs for Neglected Diseases (DNDi), India
70. Dr Shirshendu Mukherjee, Mission Director, Biotechnology Industry Research Assistance Council, India
71. Dr Christer Backman, Senior Expert, International Relations, Medical Products Agency, Sweden
72. Dr Kavita Singh, Mission Director, Biotechnology Industry Research Assistance Council, India
73. Dr KS Kardam, Senior Joint Controller Patents and Designs, Indian Patent Office, India
74. Dr Manisha Shridhar, Regional Advisor, WHO South-East Asia Regional Office, India
75. Dr Madhur Gupta, Technical Officer-Pharmaceuticals, WHO India
76. Dr Arun Bhardwaj, Director, Central Drugs Laboratory-Kasauli, India
77. Dr Ravi Kant Sharma, Deputy Drugs Controller, Central Drug Standard Control Organization, India
78. Dr Kamini Walia, Scientist E, Indian Council of Medical Research, India
79. Dr Zachary Katz, Chief Access Officer, FIND
80. Dr SB Sinha, Advisor Healthcare Technology, National Health Systems Resource Centre, India
81. Dr MSR Dixit, Kalam Institute of Health Technology, India
82. Dr Reba Chhabra, Deputy Director-Quality Control Diagnostics & HOO, National Institute of Biologicals, India
83. Dr Rajiv Nath, Association of Indian Medical Device Industry, India
84. Mr Guilherme Cintra, Senior Manager-IP &Trade, International Federation of Pharmaceutical Manufacturers & Association, Sweden
85. Mr Rishi Prakash, Joint Director, e-Governance, Centre for Development of Advanced Computing, India
86. Ms Payal Saluja, Principal Technical Office, Centre for Development of Advanced Computing, India
87. Dr Ishwar V Basavaraddi, Director, Morarji Desai National Institute of Yoga, Ministry of AYUSH, Government of India
88. Dr Vijay Laxmi Asthana, Senior Scientist, CSIR-National Institute of Science Communication and Information Resources, India
89. Dr KS Dhiman, Director General, Central Council For Research In Ayurvedic Sciences, Ministry of AYUSH, Government of India
90. Dr Asim Ali Khan, Director General, Central Council for Research in Unani Medicine, Ministry of AYUSH, Government of India
91. Dr Kim Sungchol, Regional Adviser- Traditional Medicine, WHO South-East Asia Regional Office, India
92. Dr Jing Xu, Deputy Director, National Administration of Traditional Chinese Medicine, China
93. Dr Preetha Rajaraman, India Health Attaché, US Department of Health, US Embassy

94. Dr P Paul Kumaran, Scientist E, National Institute for Research in Tuberculosis, India
95. Lt Gen Velu Nair, Group Technical Head, Cluster of Comprehensive Blood and Cancer Centres, USA & Former DG-Medical Services (Army), India
96. Dr M Vishnu Vardhana Rao, Scientist G & Director, NIMS, Indian Council for Medical Research, India
97. Dr Sunder Raman, Head-Global Regulatory Affairs, Biocon, India- Strategies to Accelerate Access to High Quality Biosimilars for Global Patients
98. Dr Yannis Natsis, Policy Manager, Universal Access and Affordable Medicines, European Public Health Alliance, Belgium
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102. Ms Rachael Crockett, Policy Adviser, Global Policy Team, Wellcome Trust, UK
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104. Dr Johan Lennart Struwe, Public Health Agency of Sweden, Sweden
105. Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia
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107. Dr Gayatri Saberwal, Scientist and Dean, Institute of Bioinformatics and Applied Biotechnology, India
108. Dr Sachin Chaturvedi, Director General, Research & Information System for Developing Countries, India
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116. Dr Purnima Sharma, Managing Director, Biotech Consortium India Limited, India
117. Dr H Purshottam, Chairman and Managing Director, National Research Development Corporation, India
118. Ms Leena Menghaney, Head-South Asia, Access Campaign, Medecins Sans Frontieres, India
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