2nd World Conference on Access to Medical Products Achieving the SDGs 2030
9-11 October 2018 | New Delhi, India

Final Report
World Conference on Access to Medical Products -
Achieving the SDGs 2030
9-11 October 2018, New Delhi, India
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<td>NITI</td>
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<td>OECD</td>
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<td>SDG</td>
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<td>USD</td>
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Acknowledgements

Access to medicines is a critical factor for success of the 2030 Sustainable Development Agenda (SDG Agenda) that aims to ensure healthy lives and promote well-being of all people of all ages. The main objective of the Conference is 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.

The World Health Organization would like to thank the following for their support and contribution to the '2nd World Conference on Access to Medical Products-Achieving the SDGs 2030':

- Ministry of Health and Family Welfare, Government of India
- World Health Organization
- Indian Council of Medical Research
- Translational Health Science and Technology Institute
- 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
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- 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

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- Dr Sanchita Chaudhary, Assistant General Manager, 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:**
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- 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:**
- Honorable 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.

<table>
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<td>WHO/ International Organizations</td>
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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 Unipill 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

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<th>Parallel Session 3: Tracking Investments in Medical Products Research &amp; Development</th>
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<tr>
<td><strong>Chair:</strong> Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO, Switzerland</td>
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<td><strong>Co-chair:</strong> Mr PN Ranjit Kumar, Joint Secretary, Ministry of AYUSH, Government of India</td>
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<td>Participants joining from Parallel Session 4</td>
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<td>1. Mr Suresh Chandra, Secretary, Ministry of Law and Justice, Government of India</td>
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<td>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</td>
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<td>3. Mr. Rajeev Sadanandan, Additional Chief Secretary, Department of Health and Family Welfare, Government of Kerala</td>
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<td><strong>Key Note Addresses:</strong></td>
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<tr>
<td>1. Dr Mark Rohrbaugh, Special Adviser-Tech Transfer, National Institutes of Health, USA- The Role of NIH in Development of New Drugs &amp; Vaccines</td>
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<td>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&amp;D and the Portfolio-To-Impact Model</td>
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<td><strong>Panelists:</strong></td>
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<td>1. Mr Niclas Jacobson, Deputy Director-General, Ministry of Health and Social Affairs, Sweden- Improving information in policy making for access to Medical Products</td>
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<td>2. Dr Vipul Chowdhary, Analyst, Policy Cures Research, Australia- Facilitating policy through tracking investments in product R&amp;D</td>
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<td>3. Dr Suman Rijal, Executive Director, Drugs for Neglected Diseases (DNDi), India- Drug development project portfolio: DNDi Experience</td>
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<td>4. Dr Shirshendu Mukherjee, Mission Director, Biotechnology Industry Research Assistance Council, India- Grand Challenges Indian Contribution in Promoting Research &amp; Development</td>
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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.

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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, sUSA- 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
- 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**

**Chairs:** 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
3. Dr Arun Bhardwaj, Director, Central Drugs Laboratory-Kasauli, India-Quality Manufacturing to Meet National and Global Vaccine Needs
4. 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

Parallel Session 7 - Promoting Health and Wellness Through Traditional Medicine

Chair: Mr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India

Co-chair: Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India

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 CDIs & 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

**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
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-
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:

- 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.

**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
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:
   i. Pre competitive inputs:
      a) Sourcing of natural products for screening and novel drug design from biodiverse repositories
      b) Contracted services for pharmacokinetics/pharmacodynamics, toxicology, and so on
   ii. Sharing of Clinical trial data – such as Coalition against Major Diseases pooled control arms of clinical trials on Alzheimer’s disease.
   iii. 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.
   iv. Moving to an End-to-End (drug by drug / company by company) Approach to Ensure Sustainable Access:
      a) Availability: innovation platforms for drug discovery; efficient use of biodiversity resources
      b) Effectiveness: ensuring sustainable production and repurposing older antibiotics
      c) Affordability: Innovative financing
      d) Access: prescription of medicine and diagnostics through diagnostics platforms
2. Collaboration between:
   i. academia and industry through development of incubators/accelerators and partnerships for funding, scaling up innovations and sustainable products
   ii. regulators and patients through promotion of patient access and engaging different stakeholders to address unmet needs
3. Adoption of Multifaceted approach:
   i. Increase awareness about AMR among professionals, politicians and the public
      by Regular information and campaigns
   ii. Conduct National and regional meetings to share experiences and ideas and
catalyse multi-sectoral collaboration
   iii. Involve multiple target groups through education and workshops
   iv. Promote scientific studies and optimize use of old antibiotics
   v. 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

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

- **Sweden**: 25%
- **USA**: 20%
- **UK**: 12%
- **Australia**: 8%
- **Bhutan**: 5%
- **Indonesia**: 5%
- **Belgium**: 3%
- **Singapore**: 5%
- **Switzerland**: 12%
- **Thailand**: 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 Himachal Pradesh
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, 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 Chandershekhar, 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 Guillerme 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
99. Dr Inthira Yamabhai, IHPP, Ministry of Public Health, Thailand
100. Mr James Love, Director, Knowledge Ecology International, USA
101. Dr Anuj Sharma, National Professional Officer-AMR & Labs, WHO India
102. Ms Rachael Crockett, Policy Adviser, Global Policy Team, Wellcome Trust, UK
103. Dr Manica Balasegaram, Director, GARDP, DNDi, Switzerland
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
106. Mr DG Shah, Indian Pharmaceutical Alliance, India- Innovation and IPR in Indian Pharmaceutical Industry
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
109. 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
110. Dr Cha-aim Pachanee, International Health Policy Program, Ministry of Public Health, Thailand
111. Mr KM Gopakumar, Legal Advisor, Third World Network, India
112. Ms Catherina Timmermans, Technical Manager, Intellectual Property, UNITAID, Switzerland
113. Dr Padmini Angela De Silva, Regional Adviser-Nutrition, WHO South-East Asia Regional Office, India
114. Ms Sunita K Sreedharan, Lawyer, SKS Law Associates, India
115. Mr Rajesh Murthy, Business Development Manager-Head of Indian Operations, Medicines Patent Pool, India
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
119. Dr Yashwant D Panwar, Scientist E, Patent Facilitating Centre, India
Main Report

I. Setting the Scene
The “2nd World Conference on Access to Medical Products - Achieving the SDGs 2030” began with highest levels of Ministry of Health, Government of India, Ministry of Health from different states of India and inter-ministerial participation.

Honorable Mr JP Nadda, Union Minister, Health & 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 opened the Conference. The other dignitaries on the dais were Ms Preeti Sudan, Secretary, Health, Ministry of Health and Family Welfare, Government of India, Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region, Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO Geneva, Dr RK Vats, Additional Secretary, Ministry of Health & Family Welfare, Government of India.

There were many Health ministers from various states of India for the conference. Dr R.K. Vats, Additional Secretary, MoHFW, Government of India welcomed the delegates.

The conference was a sequel to 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’ held in 2017 and sought to take forward the recommendations that had emerged from the 1st World Conference. The 2nd World Conference aimed at building on the developments towards and moving forward on the agenda of access to medical products in the context of SDGs. This is in line with the commitment at UN for Universal Health Coverage (UHC) under which Next September’s High-level Meeting of the General Assembly on Universal Health Coverage will be a further milestone in fostering the highest level of political commitment to drive action for health and well-being by 2030.
With the objective of fostering innovative landscape in healthcare and ensuring access and affordability of quality medical products, the conference was designed on three main thematic areas. These are first - 13th Global Program of Work (GPW) of WHO, Innovation and Manufacturing; second - Regulation and Access; and third – Financing, Legal Landscape and Trade-related Aspects of Medical Products. Within the above themes, the Conference included sessions on promoting health and wellness through traditional healthcare; and access in trade issues in non-communicable diseases in greater detail.

The conference was truly an outcome of close collaboration with all the ministries in Government of India. Logistical issues to make the conference proceedings interactive, environment-friendly (through paperless deliberations) and accessible to all through a dedicated website 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 Mariângela Batista Galvão Simão, Assistant Director General for Drug Access, Vaccines and Pharmaceuticals, WHO discussed that in view of advances in technology in recent times, many healthcare solutions have been developed, however, there are still gaps in providing equal access to the medical advances to everyone. She stated that the GPW13 of the WHO approved in May 2018 addresses the gaps with the mission to promote health, keep the world safe, serve the vulnerable towards achieving the SDGs, which aim at leaving no one behind. The target 3.8 - Universal Health Coverage (UHC) includes affordable access to safe quality-assured, effective medicines and vaccines. This requires that the global community, countries, and different stakeholders work together creatively to address the access issues. WHO was mandated by the World Health Assembly to develop an access to medicines and vaccines roadmap that will be presented in the World Health Assembly in 2019. Written comments have been received from 61 countries including India and a new draft will be discussed at the WHO’s Executive Board in January 2019.

Dr Poonam Khetrapal Singh, Regional Director, WHO SEARO congratulated India for hosting the 2nd World Conference and stated that the presence of so many ministers from the Union and State governments; and participation of partnering ministries and stakeholders shows the commitment to this subject which is of extreme importance not only to India but also regionally and globally. She informed that in September, 2018, a ministerial roundtable of South-East Asia region on access to medicines was hosted by the Government of India and ended with a ministerial declaration made by all the ministers who reaffirmed commitment to universal accessibility and affordability of essential medical products in the Delhi Declaration on “Improving Access To Essential Medical Products In The South-East Asia Region And Beyond”. While the Delhi Declaration scope was medicines, vaccines, devices diagnostics, the Access to medicines and vaccines roadmap refers to ‘Health products’.

No child should ever die as the family has no money for medicine, no parent should have to choose between buying food and buying medicine.
WHO South-East Asia Region member states launched the South-East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products. SEARN aims to promote efficiencies and enable availability of affordable and quality medical products through collaboration and reliance among regulators. India has contributed to the information sharing gateway for SEARN by housing the platform free of cost on the Indian Drug Regulators cloud space, and the SEARN information sharing platform gateway is being developed by Centre for Development of Advanced Computing, a scientific society under the Ministry of Electronics & Information Technology, Government of India.

Ms Preeti Sudan, Secretary, Ministry of Health and Family Welfare, Government of India emphasized that with a launch of ‘Ayushman Bharat’, India has demonstrated highest level of critical will to move from policy to implementation in a focused manner. Universal health coverage is the key to sustainable development goals 2030 and the vibrant Indian pharmaceutical sector is contributing in a huge way for universal healthcare in the region and beyond. India provides affordable medical products including medicines, vaccines, diagnostics and devices. Indian manufacturers are also key contributors to the WHO pre-qualification program for medicines and vaccines. India has played a pivotal role in reduction of prices by scaling of the generic medicines. The national regulatory assessment by international experts in WHO global benchmarking tool in vaccines in 2017 reiterated India’s regulatory capabilities. She also shared the different initiatives of the Government of India improving access to essential medical products. These include free medicines and free of cost laboratory and radiology at their public health facilities under the National Health Mission. The WHO’s first Essential Diagnostic List (EDL) unveiled in April, 2018 has provided a strong impetus to India’s endeavour to chart out its own national list of diagnostic procedures, best suited to India’s domestic requirements. There is a push for manufacturing of medicines and devices through the government’s Make in India Campaign to foster public health goals. To foster WHO pre-qualification in micro, small, medium pharmaceutical enterprises that are India’s backbone, there is a special focus on pharma and medical devices parks across the country. The Indian National Regulator, the Central Drug Standard Control Organization (CDSCO) is creating a national digital database for pharmaceuticals. The CDSCO is working towards self-declaration by all drug makers to upload their manufacturing licenses and list of products through an online portal – SUGAM.

The Medical Devices Rules 2017 covering requirements of import manufacture, clinical investigations, sale and distribution of medical devices and in-vitro diagnostics has been made effective from January, 2018. A robust pharmacovigilance is in place in India and 272 adverse drug reaction monitoring centres have been set up in the country. Indian Pharmacopoeia Commission, an autonomous institution of the MoHFW has recently become WHO Collaborating Centre for pharmacovigilance. The pharmacovigilance system set up in India for bedaquiline, using Cohort Event Monitoring for the new anti-TB drug is quite promising.

Ms Anupriya Patel, Minister of State, Health and Family Welfare, Government of India shared her pleasure to note that the recommendations of the 1st World Conference are
leading to tangible outputs. She also highlighted that SDGs are a mantra for a better future for all and SDG3 is a prerequisite for achieving almost all the other SDGs. In the present context, certain international trade issues such as intellectual property, government procurement, competition laws, environment, etc. are becoming critical for decision making on access to medical products. She emphasized that the aspirations for trade with access to medical products like medicines, vaccines, medical technologies as well as diagnostics; and achieving SDG3 need to be considered together, and there is a need to ensure better utilization of scarce resources and optimal use of funds. She stressed upon the commitment of India to the attainment of highest possible levels of health and well-being for all its citizens and reiterated that the National Health Policy, 2017 addresses the current and emerging socio-economic, technological, and epidemiological issues on public health in the country.

Mr. Ashwini Kumar Choubey, Minister of State, Health and Family Welfare, Government of India shared the details of the ambitious health insurance scheme - Aayushman Bharat which provides an insurance cover of INR 5 lakhs to 50 crore poor families annually, and there is no cap on family size and age in the scheme ensuring that nobody is left out. Further, the PM Jan Arogya Yojna (PMJAY) initiative provides medicines at the secondary and tertiary level and ensuring that medicines reach the poor in the country. Mr. Choubey also mentioned that the Ministry of AYUSH was set up in 2014 for strengthening of research and development, maintaining the level of academic standards in Indian medicine practices, and encouraging the use of medicinal plants, with a view to achieve positive public health outcomes. He also briefly mentioned some of the important issues such as AMR, need for increasing investments in R&D, etc. and the need to make available affordable medicines for everyone.

Dr. Tedros Adhanom Ghebreyesus, Director General, WHO shared a video message highlighting UHC as WHO’s top priority and that access to medicines and health products for all is a pillar of UHC. Even developed countries face issues on affordability of medicines for cancer and other chronic conditions requiring long-term treatment. He stated that private sector is an important partner in achieving the SDGs and urged commitment from all stakeholders in making access to safe effective, affordable, quality health products, a reality for everyone, everywhere.

Mr. JP Nadda, Union Health Minister, Government of India, along with dignitaries on dais released the position paper for the ‘2nd World Conference on Access to Medical Products’.
Mr JP Nadda, Union Health Minister, Government of India, and Dr Poonam Khetrapal Singh, Regional Director, SEAR, WHO jointly launched the ‘South East Asia Regulatory Network information sharing platform gateway’. The 11 member states of the WHO, Southeast Asia Region have come together to form the South East Asia Regulatory Network, SEARN. SEARN will promote information sharing, collaboration and convergence of regulatory practices of all medical products that is medicines, vaccines, diagnostics and medical devices in the region.

The Union Health Minister recalled the genesis of the 1st World Conference based on his commitment in the discussions on the United Nations Secretary General’s High Level Panel on Access to Medicines in 2017 in the 70th World Health Assembly in Geneva. He reiterated India’s continued commitment and belief that access to medical products and creating an enabling legal and trade environment for public health are critical to achieve the SDGs and SDGs 2030 agenda. He shared his belief that the health ministry with the active partnership of other ministries of the Government of India - Science and Technology, Chemicals and Fertilizers, Commerce and Industry, Law and Justice, External Affairs, Micro, Small and Medium enterprises, Electronics and Information Technology will move forward in leaps and bounds. He also highlighted that within two weeks since the roll out of the Ayushman Bharat Pradhanmantri Jan Arogya Yojana, more than 50,000 people have already availed the benefits of this scheme.

He apprised that during the recently concluded regional committee meeting, Delhi declaration on improving access to essential medical products in the Southeast Asia Region and beyond was endorsed by 11 member countries. The declaration acknowledged our unique strength with major manufacturers of medical products especially generic medicines. The government is implementing a scheme to strengthen the medical products and drug regulatory systems at the central and state levels. In a period of two years that is from 2019-2020, 412 crore, 56 million US dollars is targeted to be spent to upgrade 31 state laboratories and 38 state drug control offices set up for new drug testing laboratories including mobile drug testing laboratories.

The Union Health Minister also announced that the “Third World Conference on Access to Medical Products’ would be held in India from 19-21 November 2019 and invited all participants in advance.

The inaugural session concluded with Dr Madhur Gupta, Technical Officer, Pharmaceuticals, WHO Country Office for India, giving a vote of thanks to our Honourable ministers, other dignitaries and collaborators for their valuable contributions to the conference.
**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**
3. 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*
4. 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:
1. Contribution of 13th GPW for Access to Medical Products to achieve SDG 2030 Goals
2. Achieving Universal Health Coverage and bringing Healthcare to the People in India through National Health Protection Scheme

The Sustainable Development Goals are the blueprint to achieve a better and more sustainable future for all. They address the global challenges by interconnecting in order to leave no one behind, it is important that we achieve each Goal and target by 2030.  
Sustainable Development Goal 3 of the 2030 Agenda for Sustainable Development is to "*ensure healthy lives and promoting well-being for all at all ages*". The session discussed how the demand side interventions can support accessibility.

Honorable Union Minister, Ministry of Health and Family Welfare, Mr JP Nadda stated that, "India is deeply committed to achieving the sustainable development goals which are the first ever globally agreed for a fairer, safer, and healthier world in 2030."
The SDGs are integrated and indivisible. None can be achieved in isolation and progress on any single goal will spur progress towards others. This is all the more relevant in the health sector while health is represented principally in goal 3, i.e. ensure healthy lives and promote well-being for all at all ages. In pursuing all the 17 SDGs, health goals will be the major focus and outcome.

Under the vision and dynamic leadership of Shri Narendra Modi ji, honorable Prime Minister of India, the Ministry of Health and Family Welfare is successfully working towards providing highest possible standards of healthcare and services for its citizens through preventive and promotive healthcare. Universal access to good quality healthcare without any one having to face financial hardships is our goal. Good health is also the foundation for the sustainable development goals 2030 agenda to which India is firmly committed. To achieve these objectives and demonstrate the commitment, very recently on 23rd September of this year, the honorable Prime Minister, Shri Narendra Modi ji launched Ayushman Bharat Pradhan Mantri Jan Arogya Yojana covering over 10 crores i.e. 100 million poor and vulnerable families, the world’s largest government funded health insurance scheme. It has two goals, one creating a network of health and wellness infrastructure across the nation to deliver comprehensive primary healthcare services and another to provide insurance cover to at least 40% of India’s population for secondary and tertiary healthcare services.

Indian pharmaceutical sector has been providing affordable medical products worldwide. The sector is one of the key 25 sectors identified by Government of India under the ambitious Make In India initiative. This will provide necessary impetus to the sector, supplemented by robust medical products, regulatory system, we should move forward for universal health coverage. A collective and inter-ministerial programs, initiatives and interventions will certainly help to achieve the health goal.

Dr Poonam Khetrapal Singh, Regional Director-Southeast Asia Region, said that there is a need to pursue relentlessly for enhancing the state of health in the countries of Southeast Asia region, which are 11 in number, yet account for one fourth of the world’s population.
Across the region and across the world, too many people do not have access to effective and affordable healthcare. In this context, Government of India is endeavored to hold this conference and also the various initiatives that WHO is proud of and needs to emulate across the region and across the world.

WHO’s work is guided by the sustainable development goals. The sustainable development goals already have been adopted by heads of states and governments across the world with a target date of 2030. The WHO Thirteenth General Programme of Work (GPW13): 2019-2023 is a document which provides vision and goals for the coming 5 years that means from 2019 to 2023.

The GPW defines what all countries want WHO to focus on and is dedicated to three priorities to promote health, to keep the world safe and to serve the vulnerable:

- 1 billion more people enjoying better health
- 1 billion more people benefiting from universal health Coverage
- 1 billion more people better protected from health emergencies

What happens in the Southeast Asia Region matters globally, because 50% of the global deaths from TB occur in this region, 40% of stunted children are in this region, 27% of global mortality due to nature disasters is also in this region and the quarter of the road accidents are in this region, and therefore, Southeast Asia region has a special significance globally and that is what becomes extremely important when we are looking at SDGs and the achievement of SDG goals by 2030. Commitment to UHC is something that all countries of South East Asia region have. WHO SEARO has been pursuing it since 2014 as a regional goal. UHC is the cornerstone of SDG 3.

Equitable access to quality services, financial protection, and leaving no one behind have become the driving principles of our region, and our performance is being judged by that. 3.8.1 and 3.8.2 is what is being monitored globally but definitely in the countries of SEAR. Every year in a governing body regional committee of WHO, SEARO places before its member states the performance of region, the trend that is being taken in achieving UHC. Apart from Ayushman Bharat, India has also taken a decision that at the state levels, there would be an allocation of a minimum of 8% of the budgets to help and having worked at the state level in India.

Ms Preeti Sudan, Secretary, Ministry of Health and Family Welfare said that India as a country, which is almost a subcontinent, is making definite steps towards universal health coverage. In March 2017 India launched the national health policy which sets out a series of ambitious targets to improve the overall health status of the population, reduce the burden of both major infectious disease killers and NCDs and make universal coverage and

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3 http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/
comprehensive health care services a reality. Among the 30 targets are: increasing life expectancy at birth from 6.7 to 70 years by 2025, reducing under 5 mortality from 48 per thousand life birth to 23 by 2025, maternal mortality from 167 per 100,000 at present to 100 by 2020, achieving the global target of 90/90/90 for HIV AIDS by 2020, reaching the elimination status for TB by 2025 a very ambitious target again, and reducing premature mortality from NCDs by 25 percent by the year 2025.

To finance programs and interventions, to reach these targets the policy commits the union government to increase its health spending from 1.5% of GDP to 2.5% by 2025. The policy calls for all the state governments to spend more than 8% of their budget on health by 2020. Ms Preeti Sudan elaborated on the concrete steps the county has made in this direction. India embarked on the world’s largest measles and rubella vaccination campaign targeting more than 400 million children 9 months to 15-year old. In 2017 more than 60 million children in 12 states were reached in the catch-up campaign. Hon’ble Prime Minister Shri Narendra Modi launched the intensified Mission Indradhanush in October 2017 with the goal of reaching 90% full immunization coverage nationwide by the end of 2018. The control of TB has become a top government priority with approval of the new national strategic plan for tuberculosis elimination by the ministry and four-fold increase in the annual TB budget in now a reality. The government reconfirms its commitment to combating AMR resistance and one health approach and endorses the national action plan on AMR at the inter-ministerial meeting in April. The health ministry has launched a new strategic plan to eliminate the malaria by 2027 and to accelerate the control of HIV and sexually transmitted diseases. The government has decided to provide free treatment for hepatitis-C nationwide using generic direct acting anti-virals. India has embarked on the ambitious Ayushman Bharat, a holistic scheme which includes preventive and promotive healthcare. All these initiatives will promote access to medical products.

Health should be considered as the docking station for all SDGs as, out of 17 SDGs, 14 have health-related targets

Dr. Mariangela Simao, Assistant Director General, WHO
WHO Thirteenth General Programme of Work (GPW13): 2019-2023 is a strategy that aligns and articulates WHO responses to the SDGs because it has been approved now and the beauty of GPW is that it provides a framework for accountability and measurements that are based on impact at country level. The three strategic directions—healthy population of one billion people, more people enjoying better health and well-being, one billion people benefiting more from universal health coverage and one billion people more better protected from health and wellness.

Dr Indu Bhushan gave an overview of PM-JAY, its effect on the health sector in terms of the quality of services, accessibility and affordability and a brief snapshot of current status in terms of implementation. PM-JAY (Ayushman Bharat) is the largest public health initiative in the world planning to cover 100 million families across the country. The scheme has two main components: one that envisages the transformation of 1,50,000 primary healthcare

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4 http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/
5 https://www.abnhpm.gov.in/
centres and sub-centres into “wellness centres” that would lay stress on prevention of illness, and second, a health insurance package of ₹5 lakh (approximately 7000 USD) for each of the 100 million families being covered.

The accessibility and universal health coverage, is on three dimensions, how many people you are covering, what kind of benefits you are covering, and how much is the financial cover. This scheme Pradhan Mantri Jan Arogya Yozana (PM-JAY) pushes the boundary on all three dimensions. It increases the cover in terms of number of people and with all states on board, we will have about 17 crore families, about 70% of India covered. Currently, 12.5 crore families, around 62 crore people which is more than half of India’s population covered under this scheme. The benefit packages have been expanded to cover more than 1300 packages and health conditions covering 5 lakhs for each family per year.

Thus a quantum jump in terms of all three dimensions of universal health coverage and as Hon’ble Prime Minister while launching the scheme on 15th of August mentioned that this is only the first step and we will see to expand it once the scheme stabilizes.

A comparison between bottom 40% people in the country and top 40% people in the country based on NSSO 71st round shows that hospitalization rate of top 40% people is almost doubled, actually more than double of the hospitalization rate of bottom 40% people and this is more not because they have better health status or they have a poorer or lower health status and the bottom 40% people actually suffer from more morbidity and despite that their hospitalization rate is half. Of course, there are many reasons but one major reason is that they do not have access and they cannot afford the services. This scheme by providing the access to health care services through financing, to ensure financing to these people, is improving their access to health services and affordability for catastrophic health conditions and to reduce the impoverishment of people because of health services.

PM-JAY is also going to lead expansion of services and improvement of quality of services both in public sector and private sector. The hospitalization of 1.7 crore people with that our projections are that it will lead to about infusion of additional resources of more than 5000 crores in public sector and about more than 7000 crores in private sectors and that is going to help in improving the quality of services both in public sector and private sector. It is also going to increase the availability of services, private hospital in tier-2 and tier-3 cities and in inspirational districts because there will be greater demand for services there and it will also lead to lot of job creation (more than two lakh jobs) based on this scheme both in medical sectors, insurance sectors but also other sectors.

PM-JAY is also going to improve the quality of services due to the following factors:

1. This is the first time that we have given the choice to the patient to choose the provider in the public sector, or private sector.
2. Empanelling only those hospitals which meet some minimum criteria in terms of their human resources and in terms of their infrastructure.
3. Incentive for NABH certification hospitals are going to get more money thus leading to more hospitals undertaking NABH certification.
4. Standard treatment workflows will be developed and enforced in private sector.
5. Seeking beneficiary feedback and looking at the usage pattern and that will help in terms of first quantifying the quality or in terms of objective terms but also providing feedback to providers in terms of improving quality.

In terms of contemplating PM-JAY, so far 32 states have already signed the MOU. One is in process, Kerala, thus covering above 90% of the country right now and hopefully within one year the whole country will be joined together in this scheme under-one country-one scheme-one yojana slogan. In all these states, we have a variety of implementation modes and there is a lot of flexibility that is being provided in terms of implementing the scheme. Eight states have chosen for insurance mode, 17 have chosen for trust mode and eight are in the mixed mode. The scheme is being implemented now for almost two weeks. It was launched and rolled out on 23rd August and more than one lakh cards have been issued and the scheme has benefited more than 50,000 beneficiaries with an amount of about 84 crores.

The important issues which have been highlighted in this session are first, we have been discussing about the multi-sectoral and inter-ministerial approach to intervene for health for all. The universal health coverage is also very necessary to see that we have accessible, affordable and safe medicines and diagnostic facilities and this is also possible when we see that we have robust regulatory mechanism, so that also has to be developed and this is how we are trying to go forward and address these issues.

India has moved from policy to implementation and is an example where in the primary health care and secondary health care free drugs and diagnostic facility is being given. India would like to partner with international organizations along with WHO to make it more robust and meaningful so that the people at the grass root level get these facilities being given by the Government of India and later on share the experiences.

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<td>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</td>
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<td>b. Undertake capacity building and briefing workshops for enabling quality standards by manufacturers and regulators</td>
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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 Unipill 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:
1. Policy Options Promoting Innovation in Health Technologies- Select MERCOSUR Countries
2. Facilitating Access: The Role of Innovation and Competition
3. Mainstreaming Medical Ethics in Delivery for Fostering Quality and Safety of Health Services
4. Department of Biotechnology’s Supporting Role in the Innovations Ecosystem in India
5. Towards Unipill for TB treatment
6. Developing Rapid Diagnostic Solutions for Infectious Diseases: Focus on antibiotic resistance and Tuberculosis

Many governments have taken up policy initiatives to promote innovation in general and in health care in particular. Innovation ecosystem must promote participation of all diverse stakeholders: academic institutions, government, industry and individuals through the creation of new pathways, and programs for medical products and healthcare technologies. It is observed that in spite of continuously increasing R&D investment, output of new drugs has declined and most pharmaceutical innovation has been incremental. As is true in other industries, most pharmaceutical innovation has been incremental, rather than radical. Most such innovation has little or no added therapeutic value over existing treatments.⁶

Affordable medicines and the regulatory environment favoring generic manufactures producing drugs for domestic and international consumption is the need of the hour. The pharmaceutical supply chain has also become more complex and at times, more costly. In long series of middlemen, sometimes, extract premiums for drugs as they pass from manufacturers to patients, adding uncertain value today. Regulatory systems pay a critical role in accessing medicines both in terms of facilitating availability of existing products and stimulating the invention of new products to effectively promote both competition and innovation, regulatory systems must be high quality, efficient and predictable.

FDA has expedited review programs and place for products that would address a medical need in the treatment of serious and life-threatening conditions. The programs are fast-track reviews, accelerated approvals, breakthrough therapy designations and priority reviews FDA issues tentative approvals of generic versions of products that meet all safety, efficacy and manufacturing quality standards for marketing in United States, but they are not yet eligible to serve in the US market. FDA also provides formal guidance to industry on technical issues relevant to application such as how to demonstrate bio-equivalents and generic drug applications. These formal guidances enhance the predictability of FDA reviews and make them more efficient as they make it easier for application sponsors to submit their applications correctly the first time.

The drug price competition in patent term at restoration act of 1984, commonly known as the Hatch-Waxman Act provides the foundation of FDA’s work to improve competition and enhance access to affordable medicines in US market. The goals of this act were to improve innovation in the pharmaceutical research and development space and help generic drugs reach the US market more quickly by providing additional incentives for innovation and also rewards generic applicants that successfully challenge patents in court; Increases transparency through listing patents and other exclusivities in the “Orange Book”, as well as notifying innovators of patent challenges; Promotes resolution of patent disputes prior to marketing of generics.

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. The demography and access to technology changed the world, increased survival and at the same time, low-income countries are facing managing population with NCDs and still have not got rid of the infectious disease or maternal mortality and other more chronic systemic issues. And as chronic diseases rise, so does the financial burden for paying for long term care, either for the governments, insurances or individuals. Clearly access to medicines and health products is a very complex issue.

The Brazilian Health System state that health is the right of all citizens and that the state has the duty to provide it. In 1991, a federal health law was implemented to establish the national health system and it came establishing what were the roles and responsibilities of each level of the government, state, municipal, and federal government. The service provision in Brazil is not only state owned, but also the public can contract private providers. So there was a strong legal framework in the Brazil. The second, the funding for the health system is tripartite arrangement. Their funding in the constitution, there is a constitutional amendment saying, how much money, what percentage of the money budget, has to be allocated on health for the federal government, for the state government and for the city government because at the end of the day, the patient’s health provision is free at the point of the care and the patient should not pay anything
out of pocket. This has huge implications as things progress and new drugs and new technologies are brought into place.

Providing access to novel, high-cost cancer medicines poses ethical challenges in all health systems. Medicines constitute a critical component of achieving the goals of Universal Health Coverage (UHC), namely, securing quality and integrated health services for all people that meet their needs (for prevention, promotion, treatment, rehabilitation and palliation) without exposing them to financial hardship in paying for services. With focus on access to innovative high-cost cancer medicines, to discuss the benefits and limits of an important equity-focused international normative framework underscored by the WHO to guide priority-setting and ethical decision making by its member states as they work towards UHC. This framework is anchored by three considerations (of fair distribution, fair contribution and cost effectiveness), within which certain trade-offs (e.g., between providing access to vaccines versus cancer treatments) are critically evaluated. These considerations play a crucial role in ordering the priority of diseases and treatments, distributing benefits and burdens, and determining the scope of health coverage (through means such as reducing barriers to access and financial risks). In practice, however, these considerations may not suffice.

In the context of pharmaceutical policy decision making the major concern for consideration (1) an explicit appreciation of UHC in terms of equitable access to affordable, and quality use of, medicines; (2) an understanding of equity and fairness in relation to other values like solidarity and individual responsibility; (3) an appreciation of the strengths and limitations of integrating human rights; (4) a recognition of the need to ensure accountability through greater transparency and means such as multi-stakeholders engagement; and (5) suggestions for future research into building resilience and responsiveness in health systems.

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.

India has made a steady progress in unmet public health need with drug like bedaquiline for Tuberculosis which has potential to replace the traditional multiple medicines regimen for treatment of TB.

Bedaquiline was approved in India in 2016 for access program at 6 TB centers across country where bedaquiline was given under conditional access for MDR-TB patients. The next step in terms of tuberculosis innovation is development of vaccines and therapeutics in order to achieve the milestone of Government of India of eradication of TB by 2025.
The discussion over Antimicrobial resistance and moving towards pre-antibiotic era: The emerging antimicrobial resistance is a major concern worldwide. The Government of India has taken up policy initiatives to promote innovation in general and in health care in particular with key focus on early & late translational research and policy formulation to include participation of all diverse stakeholders: academic institutions, government, industry and individuals through the creation of new pathways, and programs for medical products and healthcare technologies. The Atal Innovation Mission (AIM) in India is a flagship initiative set up by the NITI Aayog to promote innovation and entrepreneurship across the length and breadth of the country, based on a detailed study and deliberations on innovation and entrepreneurial needs. AIM is also envisaged as an umbrella innovation organization that would play an instrumental role in alignment of innovation policies between central, state and sectoral innovation schemes incentivizing the establishment and promotion of an ecosystem of innovation and entrepreneurship at various levels - higher secondary schools, science, engineering and higher academic institutions, and SME/MSME industry, corporate and NGO levels.

The key highlights of progress on recent initiatives by NITI Aayog are:

- **Incentivizing manufacturing of medical devices in India:** To streamline and set up pathways for ensuring indigenous manufacturing of standard, quality devices by enabling a cohesive and conducive ecosystem.

- **Universal and Expeditious adoption of current WHO Good Manufacturing Practices (GMP) across the pharmaceutical industry in India:** To be able to ensure that Schedule M-GMP standards are uniformly adopted across entire pharmaceutical industry by 2019.

- **Effective implementation of SUGAM postal in all States:** Self-declaration with respect to the licensed manufacturing units & drugs in SUGAM; Sales and Drugs manufacturing license management across the country through a uniform portal-SUGAM.

- **Ease of Business- Streamlining Drug Regulatory process for Stem cells & Cell based products, Novel & Cutting edge technologies & rare therapies:** Enabling setting up of a ‘facilitation cell’ in the Department of Biotechnology for handholding the Start-ups/ Innovators in the area of Pharma and Medical Devices; a Single window contact for resolving the concerns' at the regulatory end has been initiated at CDSCO; Draft New Drug and Clinical Trial Rules 2018, Guidelines for gene therapy and Immunotherapy are a work in progress; single window and time-bound regulatory pathway are under consideration.

Department of Biotechnology has been instrumental in building and implementation of National Biotechnology Development Strategy 2015-2020 with a focus on Building a skilled workforce and leadership, Building Knowledge Environment, Enhance Research Opportunities, Nurturing innovation & Entrepreneurship

Major initiatives of the National Biotechnology Development Strategy 2015-2020 are:

- Launch four major missions in healthcare, food and nutrition, clean energy and education
- Create a technology development and translation network across India with global partnership, including 5 new clusters, 40 biotech incubators, 150 TTOs, and 20 bio-connect centers
- Ensure strategic and focused investment in building the human capital by setting up a Life Sciences and Biotechnology Education Council

7 [http://www.dbtindia.nic.in/funding-mechanism/competitive-research-grant-scheme/](http://www.dbtindia.nic.in/funding-mechanism/competitive-research-grant-scheme/)
The DBT supported Bio-Design program is inclusive innovation program under which more than 50 prototypes have been developed, 16 technologies have been transferred, 7 medical products have been commercialized, 10 startups have been created. In addition to the initial collaboration with Stanford University other countries including Japan, Australia are now part of the program. As of now 4 bio-design programs have been implemented across the country and there are many technologies which are at various stages of development.

Department of Biotechnology and Kalam Institute of Health Technology have established the Andhra Pradesh Med Tech Zone (AMTZ) as an ecosystem for developing innovation clusters to bring academia, R&D, industries, start-ups, innovations and incubates with supporting mechanism of policy making, venture capital support, regulatory and IPR to scale up the manufacturing. Biotechnology Industry Research Assistance Council (BIRAC), a public sector undertaking of DBT has been setup for promoting public-private partnership model. 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. Some of the on-going programmes include Biotech Ignition Grant Scheme (BIG), Small Business Innovation Research Initiative (SBIRI), Biotech Industry Partnership Programme (BIPP), Contract Research Scheme (CRS), Bio-incubators Support Scheme (BISS), Grand Challenge-India and University Innovation Cluster among others. DBT would partner with BIRAC in Public Private Partnership (PPP) initiatives. A tripartite MoU between KIHT, BIRAC and 'BioCubaFarma' has been signed in the past to facilitate several stakeholders, including industry, R&D Institutes and technology transfer offices and pave the way for technological and industrial progress in health technology sector. Under the aegis of NITI Aayog, the national think tank on policies, the Atal Innovation Centre, known as MediValley and BioValley of BIRAC through Bionest Program are the incubation facilities within a medical device ecosystem.

The Government of India in collaboration with World Bank has launched National Biopharma Mission which is an industry academia collaborative mission for accelerating discovery research to early development for biopharmaceuticals in India. The mission is also called Innovate in India (i3) and being implemented by BIRAC with the initial focus on development of new vaccine, biosimilars, medical devices, implants and diagnostics. Currently, India has only 2.8% share in the global biopharmaceutical market, the program would elevate this to 5% resulting in an additional business opportunity of 16 Billion USD. The Mission will provide a holistic and integrated approach to strengthen and support the entire product development value chain for accelerating the research leads to product development. This will help not only in immediate product development addressing public health needs, but will also help to create an ecosystem which will facilitate development of a continuous pipeline of products.

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<td><strong>Recommendations for National Government:</strong></td>
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<td>1. Strengthen partnership of the federal and provincial regulatory authorities in India with other stringent regulatory authorities</td>
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<td>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</td>
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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:**

- 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
- 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

The Parallel Session 3 focused on Tracking Investments in Medical Products Research & Development. Tracking of investments in R&D of medical products includes assessment of the state of investment, trends and patterns in basic research; discovery; preclinical, clinical development; Phase IV and pharmacovigilance studies; and baseline epidemiological studies.
In the present global health scenario, outbreak of new diseases has become more frequent. For example, infection of Zika and Nipah viruses, and therefore, access to information is required for taking immediate measures for controlling the disease spread as well as for planning the treatment. G-Finder, a survey tracking global public, private, and philanthropic investment into product research and development (R&D) was initiated to carry out this objective specifically for neglected diseases. This annual survey is conducted by Policy Cures, an independent group, through support from Bill and Melinda Gates Foundation. The tool also tracks investment into product R&D for emerging infectious diseases (EIDs) based on the priority pathogens identified in the WHO R&D blueprint. The tool uses the Delphi technique, multi-criteria decision analysis, and expert review to identify relevant diseases and online questionnaires to gather data from participants.

The data available on investments made in the last 10 years as per G-Finder reports indicates that the USA contributed almost two thirds of the total investments on neglected diseases from public and philanthropic sources, followed by the UK. HIV/AIDS received the highest investments, followed by malaria and tuberculosis. Across all diseases, National Institutes of Health (NIH), USA and the Bill & Melinda Gates Foundation (BMGF) have been the top funders. The drug development portfolio of the Drugs for Neglected Diseases initiative (DNDi) is also aligned with the findings of G-Finder.

Several international and national public and non-profit organizations are investing in specific areas of healthcare. Unitaid invests in innovations to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively. Unitaid also works to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C and human papillomavirus (HPV). An entrepreneurial organization, PharmAccess Foundation has a digital agenda dedicated to connecting more people to better healthcare in Africa. Investments in Product Development Partnerships (PDPs) are also being made through initiatives for access to medicines. Further, there are collaborative initiatives such as ‘The Access to Medicine Index’ supported by the BMGF and the UK and Dutch governments, that independently ranks pharmaceutical companies’ efforts to improve access to medicine in developing countries. Grand Challenges initiatives of the BMGF also foster innovation to solve key global health and development problems. In India, Grand Challenges initiatives are being steered by the Department of Biotechnology (DBT) through an umbrella Memorandum of Understanding (MOU) with BMGF for mission-directed research and build Grand Challenges India to support health research and innovation. The MOU aims to support initiatives that could dramatically change the health and development landscape in India and other countries facing similar challenges.

The discussions during the session brought to the fore that different funding organizations across the globe support R&D in healthcare based on their priority areas for access to affordable medical products. It was agreed that effective knowledge sharing, collaboration and coordination of these efforts is needed to improve responses to epidemics and ensure that identified R&D gaps are filled effectively. The involvement of investing organizations, regulators, the private sector, and low- and middle-income countries in defining the scope of the coordination is integral to the success of the investments made. It is also agreed that epidemiological and clinical research should be incorporated under the umbrella of the coordination mechanism, with product R&D before and during public health emergencies.

It was also discussed that challenges to innovation are at all stages of product development – discovery, development and delivery; necessitating improving the quality and breadth of the data available. Further, improving use of data in tracking investments in R&D is required to facilitate devising sustainable approaches of financing for high priority medical products.
In addition, an immediate focus on addressing patient needs through customized short, medium- and long-term approaches is required. Another important aspect that needs to be addressed immediately in this regard is capacity building for streamlining procurement of medical products, which is critical in providing access to affordable healthcare.

### Parallel Session 3: Tracking Investments in Medical Products 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
1. Dr Christer Backman, Senior Expert, International Relations, Medical Products Agency, Sweden- *National and International Incentives to Promote Market Authorization on Pediatric Medical Products*
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
- IPR and Public Health: Indian Patent Office Practice

The access to medicines has two big players in India namely government and the industry. There are numerous statutes that govern Indian legal regime on medical products. The regulatory and the legal mechanism are quite complex to understand and know what are the rules and laws that governs. There needs to be some cohesion in statutory and law making and this needs to be brought under one umbrella.

The act and the rules need to take care of all complexities coming to licensing of patented drugs. The partnership between generic companies and innovator for drug production would

*A good idea to categorize medical products together under one umbrella by WHO.*

*Justice Prathibha M Singh*
be important towards access to medicines. There should be four bodies a regulatory body, an implementation body, education body, and a research body to be set up separately under different departments. India should formulate Medical products Policy to make sure that all the laws, regulations, rules, ministries, departments, etc. are united under one policy and there is one small core group that drafts this policy and looks at the implementation of this policy. Simplification of legal procedures would build into cost effectiveness.

The legal underpinnings in the US that occur between industry and academia where there are different perspectives and missions except they do overlap and come together in wanting new products and services to be brought to the markets and for the fruits of research to reach people, so there is a commonality there as the transfer and collaboration occurs from a research setting to the developmental setting of a company. Therefore, the Bayh-Dole Act in the US underpins the legal structure and regulatory structure for these activities. There is a waiver process in which any net royalties beyond their expenses must be used for scientific research and education. In 2016 numbers with invention disclosures is quite a large output of activity with 800 new products, again all technologies reaching the market and over 1000 start-ups formed.

Impact of Bayh-Dole Act

The Stevenson-Wydler Act governs the activities of the Federal Labs, it is more arm’s length transactions with licensing patents and collaborating in the research and development of technologies. There are 29 FDA approved products that have come out just the internal research program and more than 100 in vitro diagnostics. There are number of licenses issued by NIH in Asia and Africa, licensed technologies to all the major biotech companies, Shantha, Serum Institute, Biological E, Bharat Biotech, Panacea, and Indian Immunologicals. Bayh-Dole Act and Stevenson-Wydler Act have helped many start-ups to come up with new technologies.

The access to care, consists of three major dimensions, one is the institutions for care; second being the personnel or human resources, third is access to Medical products including drugs and diagnostics. The pricing of drugs becomes an important criterion. The essential drugs under a price cap mechanism are fixed by NPPA on a particular formula. For drugs with large amount of profit margins NITI Aayog brought a paper which highlighted that instead of capping prices, it is important to look at regulating trade margins because there is a huge margins in the trade channels and that is something to be addressed.
There is scope for innovation and there is a dire need to have a fund from the government which would enable testing of innovative solutions that could be replicated at scale in India.

Bio-pharma mission is delivering this innovation ecosystem of product development to support bio-pharma, generics, the bio-similars, novel therapeutics and biologicals encompassing vaccines too and specifically addressing the infrastructure needs and the training needs.

**Vision 2025, Unlocking India’s potential for leadership in pharmaceutical innovation**

The access to quality infrastructure to the R&D centers and the industry-small industry, SMEs and larger industries, is essential for innovation. Financing research and making available the medicines to the population is also required. The other essential aspects are high quality, well trained human resource to identify gaps in ecosystem, robust IP legal and regulatory framework with transparent laws. It is essential to find ways of collaborations between the researchers and regulators to have standards of tax credits for innovation system.

Indian patent law is designed to promote innovations, it strikes a balance between the rights of the innovator and the public interests which is instrumental for social economic and technological developments in India. To promote the innovations of start-ups, the government has brought in SIPP Scheme for facilitating start-up and intellectual propriety
protection. The government has introduced this scheme which provides for expedited examination of the applications filed by the start-up companies and the 80% free reductions in the processing of the applications in the patent as well as in the trademark. These start-ups, out of 1134 applications and 47 patents have been issued for start-ups as of applications received on 30th September, 2018. The patent which was granted in shortest time was 93 days, this helps in commercializing the patents at the earliest. Significant efforts are being made to dispose filed patent applications at the earliest.

The research based pharmaceutical industry is a highly technological industry where huge investments are made in R&D. The licenses quite often include not only the right to use IP but also some technology transfer. The amount of bilateral licensing that companies are doing with Indian companies is also very important and not only to supply the Indian market but to supply very large regions, sometimes more than 100 countries; and the market is growing. Recently Patent form was launched which is a tool that allow procurement agencies to have better access to patent information. It is a database where one can have the INN and then see it globally or the Orange Book equivalent of the medicines.

Innovative medicines contribute to better health and more because ‘Today’s innovative medicines are tomorrow’s generics and biosimilars’.

**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
<table>
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<tr>
<th>Chair:</th>
<th>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</th>
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<td>Co-chairs:</td>
<td>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</td>
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**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

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. Expanded access to quality assured medicines and health products and ensure that quality essential medicines and health products are available in sufficient quantities and affordable to the population through functioning regulatory and procurement systems is crucial for achieving universal health coverage (UHC) and in reaching the Sustainable Development Goals (SDG) for health. The SDG3 has specific targets to support research, development and access to essential medicines and vaccines.

Regulators today face a number of challenges related to the wide variety of medical products that they have to deal with (medicines, vaccines, diagnostics, food products and medical devices). In terms of regulation, the bio equivalence and clinical trials, and then the chemistry to biology-based medicines is becoming increasingly complex and in this context there is need of a new strategic regulatory approach to ensure product safety, efficacy, and quality. Greater harmonization—coordination and alignment of regulatory rules—across nations would be beneficial for better public health outcomes and increase access to safe, effective and quality medical products. Regulatory authorities are working more frequently with each other, sharing inspection and safety information, and even conferring over discrete product approvals.

WHO South-East Asia Region member states launched the South-East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products. SEARN aims to promote efficiencies and enable availability of affordable and quality medical products through collaboration and reliance among regulators. The SEARN includes 11 Member States: Bangladesh, Bhutan, Democratic People’s Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste. The Key identified priority areas for SEARN are (1) Quality assurance and standards of medical products, including labs (2) Good regulatory practices including GMP, GDP etc (3) Vigilance for medical products and (4) Information sharing platform and (5) Medical devices and diagnostics. India is actively engaged in the new South East Asia Regulatory Network (SEARN) to promote access to high-quality medical products in WHO Member countries in the South-East Asia Region. CDAC has been entrusted with development and implementation of the information sharing platform for SEARN to share the information, strengthening the overall aspect of sharing the information, the convergence, collaboration and enabling the sustainable goal. One section of the platform is available for the public access. The second one will be available for the regulatory information sharing among the various NRAs and the platform for exchanging the Information is in various formats.

In the context of public health, the supply chain integrity is very crucial. USFDA has addressed this through collaboration and outreach education. The US attempts to maintain integrity from the immediate point of manufacturing from the purchasing of raw ingredients to patients, so identifying who touches the product all the way through to patient, which can be a complex process.

**A progressive regulatory system in India**

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 Government of India has shown commitment and strong political will to strengthen and build capacity of national regulatory authorities. More than INR 1700 Crores have been approved by the Union Cabinet for strengthening the Indian drug regulatory system. The major components are the human resources. In the cabinet note, there is additional creation of 1000 posts for the CDSCO and 2500 additional post for the states. There is a provision for establishment of 6 new labs for CDSCO and for e-governance which is already implemented. There is also a provision for National Drug Regulatory Academy, for time being started at the NIB, Noida and 8 mini labs at the different port offices.

As part of recommendations of the UN Government survey, which states that e-governance has potential to help support 2030 agenda and it helps to achieve 17 sustainable goals also, the ICT-based systems they are very critical to build a platform, the Government of India has taken e-governance steps in order to achieve the goal 3 of SDG. The e-governance portal (Sugam) for drug regulations in India have been implemented which serve as platform for application processing, online sample testing request and reports or post-marketing surveillance, the national databases of manufacturer and manufacturing sites, the APIs and formulations, imported APIs and formulations, foreign manufacturing sites, the clinical trial sites and investigators and the data about NSQ. The e-governance portal has enabled the comprehensive databases for formulations, manufacturers and manufacturing units and clinical trials. Real-time availability of information related to approval of medical products to various stakeholders, easy and instant information exchange between state and central regulatory authorities then enablement of business intelligence and analytics platform to help government for timely decisions.

A key focus area for CDSCO is to harmonize the Indian drug regulations with international standards to the extent feasible and promote the innovation by providing the regulatory support to the innovators. The Government of India has taken steps to improve the quality of the medical products that are manufactured and exported in India. The drugs and cosmetic rules has been amended making it mandatory review of the documents pertaining to formulation development data, which includes excipient compatibility, toxicity data, stability data of API and finished formulation, process validation, analytical method validation for all drugs not only the patent and proprietary medicines before grant of marketing authorization or before grant of product permission by the concerned state drug regulatory authorities. Further it is mandatory for the bio-availability and bio-equivalence data for oral solid dosage forms of drugs of class II and class IV of bio-pharmaceutical classification system and also all the applicants obtaining new drug permissions are mandated to have a Pharmacovigilance System in place.

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. In the last 2 years, joint inspection team has conducted risk-based inspections of almost 184 companies. 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.

CDSCO have established the public relation office and single window system to address all the public grievances and to facilitate/advice the innovators/startup companies for the regulatory pathways for the commercialization of their products. To ensure the enforcement CDSCO has established an intelligence cell at the CDSCO headquarters. The main function is they will gather the information on contraventions under the act and rules. The intelligence cell also will carry over the surprise rights and to investigate the even international quality compliance received from the foreign regulatory agencies.
In order to have more predictable regulations, recently Government of India has approved new clinical trial rules in March 2019, which has a provision for waiver of local clinical trials and the concept of deemed approvals for clinical trials. There is also provision for the pre- and post-submission meeting. The definition of Orphan Drugs has been included in rules along with provision for clinical trial waiver of any orphan drug provided the drug is already approved in any country and also there is a fee waiver.

### 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; 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
Indian Pharmaceutical sector is one of largest provider of generic drugs globally. It supplies over 50% of global demands of various vaccines, 40% of generic demand in U.S. and 25% of all medicines in U.K. India’s pharmaceutical exports stood at US$ 17.27 billion in 2017-18. In 2018-19 these exports are expected to cross US$ 19 billion. Indian companies received 304 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA) in 2017. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US$ 70-80 billion US generics market.

The start-up entrepreneurship has gained momentum in the country in recent years and there are more than 200 SEBI registered funds and 68 incubators, including government supported and private ones. A number of factors promote start-ups in hi-tech manufacturing such as laboratory facilities in the academic institutions and national laboratories for start-ups companies to engage R&D, incentivising select industries to extend their manufacturing facilities to upscale of start-up company products, certification and standardization facilitation, financing of start-up companies and taxation related issues. Further, a platform that champions the cause of the hi-tech manufacturing startups, by continuously disseminates success stories and projects the products that come out of such start-ups. Inter ministerial co-ordination is the key enabler in the ecosystem that has to be in place.

A number of factors promote these startups in high-tech manufacturing such as laboratory facilities in the academic institutions and national laboratory for startup companies to engage in R&D, incentivizing select industries to extend their manufacturing facilities so as to upscale the startup products, certification and standardization facilitation, financing, and taxation-related issues.

In terms of devices or disposables or consumables, 80% of high-end consumables are imported. So, there is a strong need for the high end manufacturing of Medical equipment in the country. It's a huge need of the country to manufacture knee implants, hip implants, stents, catheters, wires, etc which is not happening at present in India.

There is a strong need for revolution in High end manufacturing of Medical equipment industry like Maruti Suzuki Model or collaborations like Indo-US or Indo-European wherein some amount of SOPs have to be provided by the government to facilitate smaller companies to come for manufacturing high end medical products including equipments. The medical equipment includes MRI scanners, CT Scanners and X-rays etc. There is a dire need for change in the mindset of the researchers to move towards innovation and new product development of medical products. Cluster concepts are connecting academia research institutes, expansion of Bio clusters to promote innovation and research is happening across country with the support of grants from Atal Innovation mission, NITI Aayog etc. Atal Innovation Mission is working with IITs and research institutes to have idea generation activities for strengthening new innovations of the country. This is an important initiative to strengthen research and innovation ecosystems in the country.
The discussions also highlighted the need for creation of Biotech parks and Manufacturing parks for large scale production of High end manufacturing in country. India has huge pipeline of innovators and its government and related agencies' responsibility to give them endpoint. BIRAC has a programme -Innovate in India, to take the innovations in India to manufacturing for medical products by need identification in terms of missing links of an ecosystem, be it cell characterization, be it product, be it a lab, or be it a GMP facility or a GLP facility. This is proposed under the Biopharma Mission to create this whole ecosystem which is an end-to-end pipeline, from the institute to the scale-up, facilities available for phase 1 and phase 2, set-up clinical trial networks so it is actually ready to go into manufacturing and then connected with a manufacturer.

WHO needs to provide:

a) The training and capacity building of researchers and startups to be able to undertake the various requirements for product development in terms of clinical research, in terms of regulatory requirements so that India can products compliant with WHO norms such as WHO prequalification.

b) The laboratories will have to be as per the norms which would be recognized for innovation not only for Indian market but for the global market.

WHO study highlighted that the Pharmaceutical enterprises to improve quality standards and to bring micro, small and medium enterprises on board to get quality product. The discussions also highlighted about ISO certification and ministry of MSME handholding for PQ standards for Small and Medium sized Pharmaceutical companies. This session also stated that NITI Aayog has constituted a committee along with Bureau of Indian Standards on lines of FDA and CE which is more simple, faster and robust. Discussions regarding capacity building of MSMEs focused on WHO taking the way forward. A mapping exercise of entire Pharmaceutical and medical device enterprises undertaken to improve Quality standards and compliance approach was discussed.

There was discussion in this session on Standard guidelines formed by Bureau of Indian Standards that NITI Aayog has constituted a committee with the Bureau of Indian Standards to have something on the lines of CE and FDA which is more simple, more robust, and faster for approvals. Also discussed about need of to scale up existing ecosystem in high end medical equipment sector. The session mentioned and stressed about Capacity building for human resources to handle equipped infrastructure resources for development of High-end medical equipment sector.

The Indian Pharmaceutical Industry is endowed with significant potential to transform the public healthcare system. The Indian industry supplies nearly 20% of global generic medicines making it the largest supplier in the world. Based on a survey undertaken with the support of WHO during 2014-2017 to study the capacities of Indian pharmaceutical enterprises, it has been felt that the Indian Micro, Small and Medium Enterprise (MSME) sector has significant potential to upscale the manufacture of medical products; and enable India to contribute to the global agenda of access to affordable medical products. It has also been discussed that requisite hand-holding is required in order to leverage the true potential of the Indian MSME sector for facilitating access to quality pharmaceuticals. The objectives were to profile the pharmaceutical based industries and investigate what the factors which will promote technology access to them and the status of any intellectual property rights in these industries, what is it that will help them to adopt more R&D and to adopt suitable policy interventions for greater innovation. The report of survey clearly stated that there were many agencies and regulatory approvals that are needed for the cost which add to cost of the final product. This is one of the very strong recommendations, which was outlined and all the industry said that can we have simplification of systems.
WHO prequalification came into being in 2001 because the global fund wanted to actually supply drugs for HIV-AIDS, malaria and TB and we wanted to make sure that we were getting quality supply under the global fund and the Doha Declaration and the aspects of access to public health came in 2001, so a lot of activities which have been done together have actually led to the access conundrum.

The inspections approach which the regulators take can be moved to the compliance approach and the entire band of the WHO PQ of IVD, medicines, vaccines, and vector control products, can be considered instead of focusing only on medicines or only on vaccines. Following this inter-ministerial collaboration and cooperation and discussion inter-ministerially within the Government of India started happening and the Ministry of Health, and the Department of Pharmaceuticals had discussions with each other and the overall approach of how the overall regulatory approach could move from being an approach of regulator or an inspector to more a facilitator and more an enabler for the industry and this is both at the central levels and at the state levels of the Government of India, regulatory authorities.

Subsequent to the above, some discussions have further happened on how further a short listing of medical sector enterprises be done based on the result of this MSME survey which was done by WHO also identify initiatives and schemes of the central ministries or departments that could support the small and medium pharma enterprises for enhancing their capacities towards facilitating access to medical products and this is what has been done, taking 2 criteria which is very transparent criteria of employment and investment in plant and machinery. A short listing of a few enterprises which span across the APIs, formulations, devices, and diagnostics has been done. The next discussion is that the Ministry of MSME, Ministry of Commerce and DIPP, Department of Pharmaceuticals, Department of Biotechnology, the BIRAC, Department of Science and Technology, would all consider the short listed enterprises and the mapped schemes and a roadmap or the next steps could be developed and jointly looking at the map and enterprises and this has also been at the level of the NITI Aayog, leading to a roadmap for local production and fostering local production, channeling financial support for procurement of raw material, infrastructure development, technology upgradation, tax incentive, subsidies, etc. thus enabling the targeted pharma as well as medical device enterprises to graduate from schedule M to WHO GMP, also a work in the work in progress at the NITI Aayog level in the Government of India. The next steps also include promoting the enterprises identified by the Ministry of MSME in
the Government of India in the 10 pharma for setting up of common facility centers under the cluster development program for assistance by WHO or for assistance by other associations, etc., and also engaging with the various government ministries providing support to the small and medium pharma enterprises through the schemes and other initiatives, etc.

As per the SDG 2030, malaria, dengue, tuberculosis, and AIDS are the vaccines which need further consideration and action in the country. The vaccines need improvement in safety, efficacy and low cost vaccines. There is a need for efficient delivery to the persons who are in need. Reduction and management of adverse side effects is another issue with the vaccines and implementing effective AEFI reporting by the regulatory system were also discussed in this session. CDL Kasauli is testing the efficacy and safety, release capacity in terms of vaccine for all as per one of the criteria of SDG. This lab is NABL accredited, WHO prequalified and has a maturity level of 4 as per the last inspection of WHO in February 2017.

Central Drug Laboratory plays an important role in ensuring global vaccine needs, as it is part of regular inspections of the manufacturers. It reviews the dossiers of the experimental batches and for marketing authorization, review of post-approval changes, and technical advice to manufacturers as well as NRA. Training of drug inspectors is a recent incorporation in CDL by the NRA for training the newly inducted drug inspectors in aspect of quality control of the vaccines. Central Drug Laboratory is also a WHO approved lot release training center and it has already trained during the last 8-10 years, regulators from the 16 countries in lot release system by the CDL; thus, helping the other NCLs also to come up and control the vaccines part especially in their countries.

Central Drug Laboratory, Kasauli has a malaria vaccine, which is being reviewed; dengue vaccine against the all 4 parts of the DN antigen, this is also under the clinical trial in India. Then our national goals for vaccine reach eradication of disease by 2030 as per SDG are tuberculosis, malaria, and hepatitis B. WHO qualified, measles vaccine is another classical example of role of Indian manufacture in global vaccination. All vaccines to be used safely during immunization schedule.

Profits are important to grow, profiteering is not, especially when it comes to public healthcare and innovation in healthcare. Increasing role of incubators, accelerators and the government also has from NITI Aayog form a fund of funds. Mentors have a very strong role in taking innovation forwards and now they are beginning to realize that they were placed in the ecosystem. These mentors can be themselves angel funds or they can just be mentors alone but here again, the ecosystem is changing and 20 years back or 30 years back, we would not be having this luxury which is available now to the new startups and entrepreneurs. The World Bank and the International Financial Corporation have been pushing at India and taking the step forward so even organizations like Andhra Med Tech Zone has been able to access funding from IFC and see that it is going to be well utilized for driving manufacturing forwards. Additionally, there has been a big push from WHO, Gates Foundation, John Hopkins Path and seeing that innovative products come forwards especially in public healthcare sector.

The role of BIS is commendable who is now really fast tracking the product standards required both vertical and horizontal to manufacture these products. Quality Council of India has done a great work in helping to make quality assurance, certification system, the Indian certification system for medical devices which is very much required for startups; and startup convince the surgeon to use its product on a live patient. Manufactures also now have access to proper accredited certification from NABCB and IF accredited certification bodies.
All India Institute of Medical Sciences started an interface of IPR and technology transfer and is providing handholding type of projects through PPP. There is a portal through which medical device manufacturers can have a faculty from All India Institute of Medical Sciences to take their innovation forward. AIIMS is now trying to take this forward to set-up a bio park along with IIT in 2 years to give a bigger interface to the industry, this kind of support is required for the industries to take forward their innovation further.

The session had a rich discussion on various aspects of the mechanisms for providing Adaptive Technology Solutions of High Tech Manufacturing for Local Healthcare Needs. There is a need for policy options to promote Small & Medium Scale Enterprises (MSMEs) manufacturing for world class medical products- Developing enabling eco-system and incentives including financial incentives. There is also a need to foster Industry academia collaboration to stimulate R&D efforts and Technology Transfer for affordable medical products. There is a high priority need of inter-sectoral and inter-ministerial conversions which is going to be key to success, focusing on developing the human resource capital, and creating the required value proposition for the industry as well as consumer. There is an opportunity to look at models internationally for facilitating scientific cooperation, coordination of activities, information exchange, exchange of expertise and implementation of joint projects.

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

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:

3. Mr MSR Dixit, Kalam Institute of Health Technology, India- Developing Ecosystem for Quality Diagnostics and Devices
4. 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

Medical devices contribute to the attainment of the highest standards of health for individuals. Medical devices are health technologies that include: in vitro diagnostics, any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease, or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices and providing information by means of in-vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Medical devices are required to achieve SDG3: universal health coverage, including financial risk protection, access to quality essential healthcare services. The National Health policy 2017 recommends strengthening regulation of medical devices and establishing a

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8 http://www.who.int/medical_devices/full_definition/en/
9 http://164.100.158.44/showfile.php?id=4275
regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India.

The understanding of standards systems, the standards development process and their use in conformity assessment has become essential in establishing medical device regulations. Bureau of Indian Standards, the national standards body of India function in a range of sectors in the country and there are 14 divisions and medical devices falls under hospital equipment department, one of the major divisions focusing on standardization for medical equipment, medical devices. Standards are basically specifications for products, processes and services. These could be prescriptive in nature, for example with respect to medical device, it could oblige for certain product characteristics, device dimensions, bio materials, tests or calibration procedures or definition of terms and terminologies to be sure that what every specification means when the specification are decided. Apart from prescriptive, there are other standards like design standards-the usage conditions, the room specifications, other medical system which will support any medical device; performance standards performance on repeated usage; management standards- the quality management systems where the medical device is being manufactured or utilized.

If we see historically in the western world, as the technology and the manufacturing has evolved, people have gone from product standard to process standard, design standard to finally the quality management standards. Globally there are 2 international organizations, which are into standardization and which address the medical device standardization space that is International Organization for Standardization (ISO) \ and international electro-technical commission which have basically representation from majority of the countries of the globe and the international standards developed by them are considered to be internationally accepted specifications. Once the Bureau of Indian Standard adopts a standard, it is called a national standard or an Indian standard and it gives a level of credibility to the user in terms of its safety, its quality, and its performance. So, when standardization of medical devices is considered, there is a need to address the entire range of product from product to managements standards of the entire space, which will finally help use in having medical devices, which are fit for usage, which are fit for consumption from both quality and safety angle and one big rationale for standardization is that it creates specifications.
Once the standards are adopted by some kind of act for implementation, it becomes regulation. The regulation of medical device came in 1989, but only hypodermic syringes, needles, perfusion sets, and in vitro diagnostic services were regulated. In 2005, there was a court case between Medisciences versus Government of India following which notified 10 other devices, which are more or less cardiac stent, drug-eluting stent, internal prosthetic and then in 2016, ablation devices were also notified. Notified means it gets all the machinery protection and the system which are available in Drugs and Cosmetic Act for its implementation. The standards, its manufacturing, its sale, its distribution, its clinical trial or clinical investigation, its performance testing, everything gets a legal platform through which it is processed, so following products are notified as a drug but under MDR 2017, they are regulated as a medical device.

The Medical Device Rules 2017\(^{10}\) are effective from 1\(^{st}\) day of January, 2018. India with introduction of Medical Device Rules (MDR), 2017 has introduced a risk based classification system in line with WHO and GHTF recommendations. They have been harmonised with the international regulatory practices. Two Support Cells have been launched for WHO PQS for IVDs in India for providing guidance to the Indian manufacturers for the WHO Prequalification of In Vitro Diagnostics Programme in India i.e. National Institute of Biologicals in North India and Andhra Med-tech Zone in south India.

\(^{10}\) [http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E(1).pdf](http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E(1).pdf)
The entire regulatory landscape and how the ecosystem is developing was explained specifically the standard laid down by the BIS or as may be notified by the central government from time to time and if some standards are not available, ISO-IEC standard and even ISO-IEC standards are not available then the manufacturers validated standard which are approved by regulatory authority can be followed. So, regulatory landscape strengthening started with changing the regulation then there are certain thought, talks about the change in the duty exemption, structure, infrastructure boost is also going on and other favorable initiatives are also being taken. In the BIS, there are 16 technical committees of the BIS which are working so fast now-a-days that you get a lot of standards being developed for various medical devices. Compilation of rules, standards and FAQ is being done. WHO collaborating centers for materiovigilance and pharmacovigilance is established at the IPC. More steps are being taken for implementing online processing establishment of laboratories, capacity building training, simplification and convergence and what are the new which are being taken into the regulations. DTAB has already passed all implantable devices then equipments like MRI, PET, CT, x-ray, ultrasound, dialyzers, cell separator, glucometer, nebulizer, blood monitoring system and all those things will be taken into the regulations.

Some aspects of how the standards and startup are collaborating and how BIS is building a good quality ecosystem for medical devices vis-à-vis facilitating the innovation in the medical devices sector were discussed. BIS is also participating and representing the country in the international standard setting bodies, which are the ISO and the ISE primarily. BIS is fast tracking the system of covering all the gamut of the products which need to be standardized and is developing the standards on the fast pace and in the last 2-3 months more than 25 standards have been prepared. BIS is engaging with start-ups also in stabilizing their products and making the standards both at the national level as well as recommend the same to be taken up at the international level for development of the ISO or IEC standards. BIS Act 2016 has been recently passed and which allows us to go for various kind of the certifications systems, the product certification system, the management system certification and combination of the both also. BIS has a provision whereby integration of both, the product as well as the management system certification. BIS is working on to develop IVD standards also on a fast track basis. For regulation BIS has a self declaration of conformity system which is similar to the CE system which is also primarily dependent on the self declaration of conformity for say class A and class B at least.
For promoting quality through standards in medical products, BIS in addition to product certification standard formulation, has got compulsory registration scheme also, foreign manufacturer certification scheme, hallmarking scheme, laboratory services, laboratory recognition scheme and online purchase of sale of standards is also available on the portal itself. The training services are provided through National Institute of Training in Standardization, Noida at national as well as international level. Whatever designs we are giving in our standard in products, those should be interchangeable, variety control is also established, safety production of the environment as well as product protection. These are various requirements, which should be fulfilled for achieving the quality of particular product or requirement. Various stakeholders in terms of manufacturers, users from laboratory and various minds are involved, but the goal is common by means of same goal we achieve through consensus principle. There is a Japanese proverb called Itai Doshin means many in body, one in mind, so there are various stakeholders, various manufacturers and users, but the common goal is achieved through consensus principle and harmonization with international standardization organization also like ISO and IEC.

BIS has 19 sectional committees under which about 1200 standards are formulated by medical equipment and hospital planning department. These standards are in the form of anesthesia, cardiovascular, dental, gynecological, obstetrics and neurosurgery, hospital devices and so many other standards are available under these 19 sectional committees.

The standards which are falling under various sectional committees like MHD19 has got 27 standards MHD17 for Health Informatics has got 33 standards, hospital planning got 23 standards. Anyone who wants to participate in these committees, they can send BIS their request with their company background and about their technical backgrounds and they can very much participate in these various committees for which the standards are formatted. There are 52 standards which are under BIS certification and a total number of licenses about 215 and mandatory certification, there are 3 standards which are under mandatory certification (those products cannot be sold in the market, cannot stored in the market or cannot be purchased without BIS standard mark and this is IS3055 part 1 for solid stem type clinical thermometer, IS3055 part 2 is for enclosed scale type clinical thermometer and 7520 part 1 is for x-ray machines) and other types of standards are voluntary in nature.

![National Standards on Medical Devices]

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Once standards are formulated, they should be implemented also so that quality is ensured and BIS has three certification schemes - product certification, compulsory registration scheme and foreign manufacturer certification scheme under which these can be registered.

Kalam Institute of Health Technology is the nodal point for all the incubation centers in the country and all the startups and providing a platform which is providing all kinds of support to startups in their new technological development and device development. A perspective from the point of view of startups and incubators as to what is it that they look for in terms of support for standardization and certification of their products which can guide the work on the site of regulation and standardization that is required to accelerate standards, especially in the startups.

One is to allay the fears of the standards and regulations. A CE standard will not suffice the substandardness of the products that are created out of our country, so we have to enforce that we need to get the device specific particular standards in the terminology of standards that is something which is the need and at war footing, those standards have to be there because of CE specifically talks about particular standards again. CE is more of a horizontal standard. Until unless we have this particular standards defined for this 80+ odd products which are predominantly we are import dependent, we will not be able to really solve the problem at hand.

National Institute of Biologicals which is under the Ministry of Health and Family Welfare, Government of India, was set up in 1992 as an apex autonomous institute and it is under the administrative control of the Ministry of Health and Family Welfare, Government of India, for promoting and protecting human health through various activities assigned to it. The mandate of NIB and its various activities related to standards development and validation for quality control testing procedures for biological and immunobiological products were discussed.

In terms of regulatory space, another issue which was addressed is how do we regulate the devices which are covered under the medical devices rules today considering the regulatory innovation which has happened in India. Under BIS Act, a provision has been made, anything in interest of human safety, plant safety, environmental safety, if government, any department of central government feels it is essential to regulate, they can use the platform of BIS Act where, if country feels it is essential for regulation, it can be introduced without any further legislations.

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

**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

Essential diagnostics are defined as diagnostics that satisfy the priority health-care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy and comparative cost effectiveness. The initiative to develop a List of Essential In-Vitro Diagnostics (EDL) to improve access to diagnostics including In-Vitro diagnostics (IVDs) and to guide safe and rationale use of medicines in concurrence with National List of Essential Medicines\(^1\). In vitro diagnostics are defined as devices which, whether used alone or in combination, are intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. It includes reagents, calibrators, control material, test kits, etc\(^2\).

Diagnostic tests are a key component of health care, an essential human right, creating evidence for the practice of medicine for both diagnosis and prognosis. Access to good quality, affordable and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations-the three strategic priorities of the World Health Organization (WHO) Thirteenth General Programme

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of Work 2019–2023. Without access to *In-vitro* diagnostics (IVDs), health providers cannot diagnose patients effectively and promptly or provide appropriate treatments\(^\text{13}\).

In a path breaking development, 40 years after publishing the first Essential Medicines List, the World Health Organization (WHO) just published the first Essential Diagnostics List\(^\text{14}\). The WHO EDL will prove invaluable as a guide for countries to establish national EDLs\(^\text{15}\). EDL will provide a robust evidence base for improved health care delivery through improved patient care, greater capacity to diagnose diseases during outbreaks, increased affordability of tests, improved regulation and quality of diagnostic tests and strengthened capabilities of national laboratories.

EDL requires an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems\(^\text{16}\). EDL will be a driver for innovations for diagnostics in India. With the upsurge of “Make in India”, this list will help sensitize the R&D sector of the country to develop quality Point of Care tests for the primary healthcare settings. EDL should be accompanied by the target product profile for tests in the EDL for various settings in Indian healthcare settings.

The Ministry of Health and Family Welfare, Government of India under the aegis of National Health Mission launched the Free Diagnostics Scheme in July 2015. Under this initiative, the National Health Mission is supporting all States to provide essential diagnostics – Laboratory and Radiology at their public health facilities, free of cost. Different States are adopting different models for implementing this initiative. India is the first country to ever begin the process of developing a National diagnostic list and this is a huge step in the direction of improving Indian Healthcare system.

Essential diagnostic list is intended to complement the essential medicine’s list to improve the patient’s care and also could be a potential to increase affordability of tests thereby reducing out of pocket expenses for tests, improving the regulatory landscape, the existing regulatory frameworks of how diagnostics are regulated in countries, strengthening the accreditation systems present in counties and the quality of laboratories, these upscaling and strengthening of the in-house laboratories in member states with the support of the other stakeholders, may be through the private public sector, improving the entire supply

\(^{13}\) http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_3-en.pdf

\(^{14}\) http://www.who.int/medical_devices/diagnostics/EDL_ExecutiveSummary_15may.pdf

\(^{15}\) http://www.who.int/medical_devices/diagnostics/WHO_EDL_2018.pdf

chain of diagnostics moving in the health system in the public sector and guiding the research and development of new diagnostic tools.

Essential Diagnostics list of WHO was discussed in details with all its aspects. For primary healthcare the list which is divided into 2 subtypes- for primary healthcare and the second part is for those tests, which required sophisticated laboratories. The difference in the India approach from the WHO's approach or how is it different from the WHO EDL would be that the India EDL will include not only IVDs, but it will also include other diagnostics like the radiology, etc. It would provide in a much more expanded basket of test based on the disease burden of India as a country. Pathology tests like histopathology and cytology tests for common diseases, which are prevalent in the Indian setting as well as in the South-East Asian Region setting like typhoid, endemic diseases like kala-azar, Japanese encephalitis, tests for local epidemics like dengue, chikungunya, and tests for disease surveillance like measles and diphtheria. This list based on the India’s epidemiological disease burden, which was actually inspired or derived from the ICMR’s latest study on disease burden in India, which has got the latest statistics state-wise of the disease burden, and what are the different tests needed to engage to match the disease burden. So this provides us a list of tests for each type of health facility, health and wellness center, the sub-center, the primary health center which is below the district level hospitals in India.

Recommendations highlighted included developing an essential diagnostic list with extremely high political and administrative commitment and leadership for the budgetary allocations by the governments to have the availability of all the designated tests at all facilities and also the integration of existing diagnostic initiatives with the national health programs for requisite equipment and technology, human resources, procurement supply chain issues. These are looked at ensuring robust monitoring mechanism, quality assurance for diagnostic services and advocacy and awareness generation about availability of test and ensuring quality of test and for WHO and international organizations would be to support the development and implementation of that essential diagnostic list in countries in this case in India and the intertwined aspects such as a regulatory framework of medical diagnostic equipment, consumables which also includes reagents for example. A lot of reagents at this point in time are being imported into the country, which then build into the cost of the final test price. So consumables indeed should be a part of EDL.

Indian public health standards in the context of Ayushman Bharat are being revised. So all these parallel or already setup in place, the integration with them and leveraging their presence on the ground and learning from that were taken to cognizance and there was a specific session designed on leveraging existing initiatives, which are ongoing, which are underway such as free diagnostics initiative, the revision of IPHA standards, which prescribes what could be for the public health facilities, the various services which are going, what are the different things like diagnostics which would be required. Standard treatment workflows, are being developed for 150 conditions so that the first choice of the test is clear at all the levels in the system- primary healthcare, secondary, and the tertiary.

There is a lack of good diagnostics to properly diagnose and treat the non-communicable diseases, which are now increasing in India. Based on a global burden of disease study, which was published last year in the Lancet, which actually identified that many of our states are in a transition epidemiological-type communicable diseases burden to the non-communicable diseases burden with increasing diseases because of the air pollution, injuries. So, in light of this changing epidemiological transition, there is need to strengthen the diagnostics as well as the treatment at different levels of healthcare, so that we are able to deal with them better.

National health policy was revised in 2017. Then, there are Indian public health standards, which are currently under revision and there is a free diagnostic initiative by national health
mission. Indian public health standards, are currently under revision, they create guidelines for what kind of the infrastructure, what kind of human resource should be available at different labs and different levels of healthcare. The free diagnostic initiative is one of the latest initiatives to ensure the availability of minimum set of diagnostics to reduce the out of pocket expenditure and able to initiate pre-treatment, use of appropriate diagnostics to screen patients for chronic conditions as well as improve the overall quality of healthcare and the patient’s experience. It is being currently rolled out in 29 states and Government of India has a very flexible approach around this where some of the states are actually being supported by funds from the Ministry of Health while others are entering into different kind of arrangements and there are public private partnerships, which are also being encouraged in this initiative and states also have the freedom to add to this list based on their epidemiological considerations and the available financial resources.

Regulation of medical devices and diagnostic kits including initiative taken by CDSCO, what are the challenges we are going to face and medical device innovation in the India.

Prospective on the pipelines for HIV, malaria, and TB for point of care diagnostics, to improve care, especially at the periphery, experience in the introduction of point of care was discussed. Point of care in itself has great potential because you can move towards at test and act approach rather than wait for sample transportation and result return, which often results in lost to follow up. Examples related to Malaria, TB and HIV were discussed specifically with respect to Indian settings, such as the tests with respect to special populations such as HIV, Pediatric and geriatric populations, which are non-invasive and an easier way to collect samples to ease the burden of screening. The capacity for multiplex testing and for cost effectiveness, there is a need to breakdown vertical silos of programs, established sample transportation networks and return networks in place.
Discussions on consideration of access across the pipeline from R&D took place.

The framework approach to access with need to holistic solution while investing in a new product in order to have holistic solution was discussed. For eg: TB pediatric project where full solution that could be taken up either by states or by the ministry and which has now been included into the global fund where data was used as a way where services should be. The investment in point of care diagnostics highlighted the need for innovative ways to monitor action at the periphery. The importance of holistic solution was highlighted as a multiplex across disease areas. There are benefits across the vertical programs to share...
infrastructure, share HR, pull volumes to get a better deal and how the monitoring of decentralized testing and diagnosis using data and data-driven approaches be leveraged.

A case study relevant to universal health coverage was discussed which showed that there is a need to have tele-consultation and in one cycle only the patient should be diagnosed using the diagnostics, and the medicine should be provided. The same can be implemented by the clinical decision support system in the primary level, through artificial intelligence, integrated in lieu of free diagnostic initiative program as well.

India lacks a national laboratory policy. Most of the countries in the Southeast Asia region have a national laboratory policy, which actually prioritizes laboratories within the health system and this is coming from the bioregional strategy for Southeast Asia region and the Western Pacific. There is a bioregional strategy for Asia-specific strategy for strengthening health laboratory services, which talks of 6 or 7 key thing policy. Second critical thing that India lacks is having a dedicated laboratory focal point in the ministry of health to ensure that there is a co-ordination. The accreditation which is very important point, but currently is still voluntary, and needs to be mandatory and the strong quality assurance in systems which are modular in nature. Current quality assurance, especially external quality assessment schemes are one size fits all, which are being driven by the process of accreditation, which the private sector is sort of doing, but they do not take into account the needs of the labs. The same sort of panel of EQAS should be available to a tertiary care, medical college, or center of excellence and the same for standalone private labs. So there is a need to have
EQAS systems, which sort of tailored for the laboratory services that they deliver and the lab should have the facility to pick and choose. As these tests are being done on regular basis, basic, intermediate and advanced EQAS for diseases needs to be done.

Ministry of Health has established the coordination of the entire lab network whether it is under IDSP or the HIV or the TB labs. In ICMR surveillance and AMR surveillance network the quality assurance, EQAS. Is being piloted initially limited to the ICMR network only and later it will be taken forward. A combination of affordability and sustainability should be considered while developing the EDL.

### Parallel Session 6: Medical Diagnostics- Promoting Health For All

**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
Parallel Session 7: Promoting Health and Wellness Through Traditional Medicine

Chair: Mr Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH, Government of India
Co-chair: Mr Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare, Government of India

Panelists
1. Dr DC Katoch, Adviser, Ministry of AYUSH, Government of India - Integrating Traditional Medicine With Modern System Of Medicine For Achieving Public Health Goals
2. 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
3. Dr Vijay Laxmi Asthana, Senior Scientist, CSIR-National Institute of Science Communication and Information Resources, India - Traditional Knowledge Digital Library (TKDL)
4. 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
5. 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
6. Dr Kim Sungchol, Regional Adviser- Traditional Medicine, WHO South-East Asia Regional Office, India - WHO South East Asia Regional Perspective on Traditional Medicine
7. Dr Jing Xu, Deputy Director, National Administration of Traditional Chinese Medicine, China - Ensuring Quality and Standards In Traditional Medicines In China

The objectives of the session were:
- 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

The session highlighted that traditional medicine had taken care of the health of general population and allopathy is only few centuries old and has some constraints and drawbacks whereas the traditional medicine has some areas of strength, especially in promoting health and wellness. It is the traditional medicine with the promotive aspects of healthcare in India, there are various streams of AYUSH Ayurveda Yoga Unani Siddha Homeopathy which works in terms to promote health and Wellness for everyone.
WHO developed global traditional medicine in 2014 which has two main goals, one is to harnessing potential contribution over traditional medicines to health relief and people sent to healthcare and to promote safe and effective use over traditional medicines through research, regulation, and integration. To achieve these two goals, global strategy clearly defined its three strategic objective and directions. Objective one is building knowledge base for active management of traditional medicine through appropriate national policy and second objective is to strengthen quality assurance, safety, and national use of traditional medicine through regulation. The core of Universal health coverage is to ensure everybody access good quality of service when they need, but without any financial problems.

National health policy 2017, have focused objective for AYUSH, ensuring the access to AYUSH services, introduction of yoga in schools and work places for health promotion and building research and public health skills for preventive and promotive healthcare. AYUSH orientation to grass root health workers and village health sanitations and nutrition committees and bridge courses for midlevel healthcare providers, certification mechanism from traditional community health providers. In India has a established system of Unani, there are almost 50,000 registered practitioners with 265 almost hospitals, 1511 dispensaries, 3500 in government hospitals. Around 54-55 colleges which provides UGE teachings and almost 11 colleges provide the postgraduate teaching. There are certain departments in colleges which are conducting researches in Unani system of medicine.

Traditional knowledge Digital Library is a collaborative project between AYUSH and CSIR which started with the turmeric patent that was granted at the USPTO. TKDL is a prior art database which is a defensive protection mechanism. The access is restricted only to patent officers and searchable database. It contains content for Siddha formulations and Yoga practices and have published manuscripts on traditional medicines. It is unique database which have Unani, Siddha and Ayurveda in same platform. The robust and stringent policies for sustainable use of traditional plants, awareness and incentivizing research and traditional medicine at grass root level because this information lies there and sharing mechanism using combination of regulatory and local level governing bodies.
Traditional Integrative approach in Patients Care

Yoga has been preventive medicine from the ancient time, but in present days it is found very useful in the management of lifestyle disorders and non-communicable diseases. The Yoga is useful in the treatment of almost all disorders of body. The Yogic practices improves steadiness, stamina, flexibility, endurance and helps to strengthen the bones and prevent age related weakening. It improves bone density and help in prevention of Osteoporosis by improving metabolism and maintaining hemostasis. The practice of Yoga reduced oxidative stress in diabetes and improves glycemic parameters, utilization of antioxidants present in our body.

Parallel Session 7- Promoting Health and Wellness Through Traditional Medicine

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
**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

The Parallel Session 8 focused on Developing Efficiencies in Clinical Trials in Global, Regional and National Settings. Clinical trials are required to assure the safety and efficacy of the health-related products. Clinical trials are also the biggest R&D expense. Clinical trial sponsors and scientists are guided by national laws and non-binding professional ethical standards for research involving human subjects but trials are not only conducted in the country where the product is discovered or developed and the health technologies are used around the world. The uncertainties related to trial outcome with added complexity of regulatory procedures and lack of economic incentives push back the clinical trial on rare diseases and orphan drugs specially in developing markets. Information on the clinical trials is not available to all stakeholders and details on how the trial was conducted, on how many subjects they have been conducted and what were the results and what were side effects, need to be made available for developing efficiencies in the processes.
The United States Food and Drug Administration (FDA) in 2004 have introduced a strategic path Initiative to modify the way drugs are made and introduced into the market. This initiative encompasses the implementation of adaptive design clinical trials. Also, since the design allows investigators to assess results on a real-time basis, changes can be easily made to enhance the probability of a positive result. USFDA guidance also discusses the way of estimating trial operating characteristics which is to simulate large numbers of clinical trials and observe their outcomes. Modeling and simulation efforts utilize information from prior clinical trials, such as dose response, disease change over the likely duration of the trial, effects in the placebo group including time-course, and patient baseline data. Typical sources of information included literature, previous trials within the organization, and publicly available databases. Clinical trial simulations are conducted to evaluate the adequacy of the proposed trial design and alternatives with respect to the predicted probability that the trial would successfully discriminate the treated groups from the control groups (e.g., placebo).

WHO has developed the International Clinical Trials Registry Platform (ICTRP) network of Primary Registers, to ensure that a complete view of research is accessible to all those involved in health care decision making. The ICTRP in itself is not a Registry, but collects data (details of registered trials) from its Primary Registers and displays them from a single search portal. Thus the ICTRP serves as a one-stop search portal for clinical trials that may be registered in diverse Primary Registers of the world.

The Clinical Trials Registry- India (CTRI), hosted at the ICMRs National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched in 2007 (www.ctri.nic.in). Initiated as a voluntary measure, with the support of WHO India in 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India). Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHOs search portal, the ICTRP as well as from the CTRI. CTRI is developing a platform for results disclosure which would strengthen the process of transparency accountability and accessibility of clinical trials and their results.17 CTRI is a primary registry of WHO’s 16 registries available in the WHO and ours is the third biggest clinical trial registry. The trials registered in the CTRI are part of the global pool of a trial data. There are 24,000 registered users and total submissions so far are 21,687 trials and total registered as of now is 15,868 trials in the database are available and there are some trials which have been sent back for want of information around 5000 and there are 655 trials who got registered.

The Ministry of Health and Family Welfare of Government of India has released draft Clinical Trial (CT) Rules 2018, the new rules will be applicable to all new drugs, investigational new drugs for human use, clinical trials, bioequivalence study, bioavailability study and Ethics Committees. The proposed draft clinical trial rules cover the full spectrum of clinical trial activities, from ethics committees and manufacturing permissions to inspections and injury compensation. Publication of the draft rules marks an important step in India’s attempts to codify its approach towards clinical trials.

In the last few decades, there has been an increasing flow of capital information, goods across borders and this has been largely driven by the rise of emerging markets. At the same time researchers have been facing intense pressure to lower the cost and improve productivity and as a result, this quest for efficiency has led to the globalization of clinical research and increasing outsource into third parties. There has been a tremendous growth in both the scale and scope of clinical trials worldwide. These studies have increased in

complexity with additions of new biomarkers and surrogate end points that are taken into account. There has been rapid inclusion and expansion of technology within these clinical trials and finally the quest for expanded markets for new products also means that for any given clinical trial, there are a number of regulatory authorities with oversight over that trial. For a good quality of clinical trial, need to protect the right safety and welfare of humans participating in research to assure quality, reliability and integrity of the data collected, standards and guidelines to ensure safe and effective products.

Multi-regional clinical trials (MRCT) have also emerged as a tool to achieve the objective of reducing the time lag of launch in various markets and improve patient access to new and innovative treatments. The rise of multi-regional clinical trials (MRCTs) has led to several harmonization initiatives between ICH (International Conference on Harmonization) member countries and non-ICH member countries to streamline the trial process. The ICH E17 guideline defines the factors that must be considered in planning, designing, and executing MRCTs. Guidelines for multicentric clinical trials, guidelines are being prepared and issues such as ethical standards, honoring compensation, ancillary care and post-trial access for clinical trial patients need to be adequately addressed therein.

The 21st Century Cures Act, 2016 US, aims at encouraging biomedical research investment and to facilitate innovation. Under this Act, the US FDA provides assistance to countries in design and conduct of trials and best practices for approvals. One of the most crucial roles in overall ethical conduct of clinical trial is played by Institutional Ethics Committee (IEC). The basic responsibility of the IEC is to protect the dignity, safety and the wellbeing of the subject and countries must adhere to universal ethical values and stick to international scientific standards to assist in the developing education of the whole research community as a whole. The registrations of ethics committee was made mandatory with the CDSCO and currently 322 such ECs have been registered with CDSCO.

In view of the changing scenario witnessing Government support for developing a strong regulatory apparatus and conduct of clinical trials, innovative mechanisms to implement the changes are required to create a conducive ecosystem for CTs in India. Further, it is important to have a rational and evidence based regulatory framework, and foster collaborations that would lead to adherence to best practices for global standards.

With the advent of globalization, it is important to adhere to global standards and best practices, collaborative work should be promoted and regulatory framework must be rational and evidence based.
## Parallel Session 8- Developing Efficiencies in Clinical Trials in Global, Regional and National Settings

### 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.

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

The Parallel Session 9 focused on Access and Affordability of Medical Products—Focus Orphan and Rare Drugs. Neglected tropical diseases (NTDs) are a diverse group of communicable diseases that prevail in tropical and subtropical conditions in 149 countries, affect more than one billion people and cost developing economies billions of dollars every year. Populations living in poverty, without adequate sanitation and in close contact with infectious vectors and domestic animals and livestock are those worst affected. At present, the WHO NTD portfolio includes 20 diseases including dengue, chikungunya, leprosy and leishmaniasis. India experiences the world’s largest absolute burden of at least 11 major NTDs and also leads the world in terms of the total number of cases for each of the major NTDs, as defined by WHO. The WHO NTD Roadmap on neglected tropical diseases (2012),
sets forth several targets and implementation of appropriate measures aims at elimination of many NTDs and the eradication of at least two by 2020.

Drugs for Neglected Diseases initiative (DNDi), a collaborative, patients’ needs-driven, non-profit drug research and development (R&D) organization is developing new treatments for neglected diseases. DNDi has been working with the objectives of developing treatments for people suffering from NTDs, influencing the R&D landscape for NTDs and strengthening research capacity in low- and middle-income countries.

In addition to NTDs, a separate category of health disorders – Rare Diseases also need consideration with respect to access and affordability of their treatment regime. The definition of rare diseases varies across jurisdictions and typically considers disease prevalence, severity and existence of alternative therapeutic options. ‘Rare disorders’ is the name given to the diseases, of very varied aetiology, whose common denominator is that they are low-prevalence diseases, and for the majority of which there is no treatment available. Orphan product is a drug, biologic, device or medical food that is used for the prevention, diagnosis, or treatment of a rare disease.

Regardless of the need and importance of access to orphan drugs, there is a paucity of available treatments for rare diseases. Further, rare diseases which have available treatments are highly cost intensive and out of reach of common man, particularly in the low and middle-income countries. Less than one in ten patients with rare diseases receives disease-specific treatment.

The common issues faced during the drug development process of rare diseases are less understood pathophysiology, lack of validated preclinical models, less research, and lack of standard comparator drugs. Clinical issues pertain to limitations in conducting clinical trials for orphan drugs and include lack of information about natural history of the disease, poorly defined endpoints, poor trial designs and inadequate sample size, recruitment problems, lack of well-defined diagnostic criteria, and other issues such as non-existent comparator drug and funding problems.

The discussions during the session highlighted that in order to streamline the regulatory system, transparency in function and regular interactions with all the stakeholders, i.e. industry and patients are required. The challenges of regulatory systems in regulating new and innovative drugs and therapies were also stated. It was also shared that in 2017, the Center for Drug Evaluation and Research, USA granted 192 designations for orphan and rare diseases. Forging intergovernmental collaborations, such as Beneluxa is also considered an important mechanism for providing access to affordable medical products for all.

India has also been actively working towards devising strategies to make drugs for orphan and rare diseases accessible and affordable to the populations at large through stakeholder consultations. Efforts are underway to explore possibility of providing separate pricing mechanism, custom duty exemption and cheaper medicines for patients with rare diseases, and to have revised timelines for orphan drug approvals. Indian Council of Medical research (ICMR) has initiated two programmes viz. The National Initiative for Rare Diseases (NIRD) and disease for supporting programmes on rare diseases; and “Indian rare disease registry” launched in 2017 to cover all rare and ultra-rare diseases prevalent in India. The objectives of the registry are identification of the rare disease patients; use that data for policy framing and to guide future research.

The discussions in the session also brought to the fore the issue of Antimicrobial Resistance (AMR), a national priority for India harbouring high burden and spectrum of infectious diseases. In this regard, an Indian Priority Pathogen List (IPPL) aligned with the WHO
Global Priority Pathogen List of antibiotic-resistant bacteria (2017) is under preparation to guide the prioritization of incentives and funding, help align R&D priorities with Indian public health needs and support India’s containment of antibiotic resistant bacteria.

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

#### 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**

- Explore feasibility study of delinking R&D incentives for diseases of public health importance from prices of treatments.
## 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:
- 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

At every stage from bench to bedside, important efforts to reengineer how we finance the development, delivery and access to health technologies give us hope of a future where the needs of all patients requiring treatment will be met.

The model of pharmaceutical innovation banks on public sector support of the basic sciences and the training of a scientific workforce, but leaves it to the private sector to bring new drugs to market. Public funding has been structured to reinforce this division of duties. The European Union’s Innovative Medicines Initiative focuses on precompetitive inputs to R&D. The US NIH’s National Center for Advancing Translational Sciences is limited, by statute, in how it may support phase 3 clinical trials. The market failures suggest though the need to bridge gaps in these arrangements.

Over the past couple decades, product development partnerships have begun to show how these entities funded by public sector monies can shepherd treatments for neglected and orphan diseases to market. These efforts are still fledgling and have sometimes built upon products already on the market or under development. Still PDPs have demonstrated that R&D costs can be significantly lower than in the private sector. The Open Source Drug Discovery Initiative for TB, led by India’s CSIR, also sought to forge an alternative pathway...
for bringing drugs to market. In the United States, concerns even over generic drug pricing have recently prompted four large health care systems to announce efforts to create their own generic drug company.

Upfront investments, such as push incentives that pay for inputs of R&D, assume greater upfront risk by the public sector, but later investments, such as pull incentives that pay for outputs of R&D, include all those costs, plus discounting. Put in perspective, discounting can so significantly erode the value of what the public sector invests that a push incentive can be 95% smaller than a pull incentive like extended exclusivity, but still have a greater impact on present value in a financial model.

The financial model by which we bring new drugs to market needs to be revisited. How should capital for R&D be sourced, and where might it be best deployed to make a catalytic difference in bringing drugs to market that meet public health priorities. We There is a need to examining the 3Rs—sharing resources, sharing risks and sharing rewards. Each of these suggest operating principles by which benchmarking of potential solutions can be done on how to financially reengineer the way we bring new drugs to market.

In sharing resources, how innovation platforms could be constructed was discussed. An open science platform might lower the barriers to entry to a diverse range of potential contributors to pharmaceutical R&D. Such platforms might enrich compound libraries with natural products from the rich biodiversity and traditional knowledge found in low- and middle-income countries; support benefit sharing arrangements and pooled intellectual property to enable access to the building blocks of knowledge; and create the enabling environment for sharing information more freely in developing new drugs. From the Structural Genomics Consortium to the work of PDPs like Drugs for Neglected Diseases Initiative, case studies might suggest how to reshape pharmaceutical R&D.

In sharing risks, whether the equity financing that drug companies rely upon really commands such high discount rates was discussed. The work of patient disease foundations for orphan diseases and product development partnerships for neglected diseases can help us understand what is the true opportunity cost of capital.

In sharing rewards, how best to prioritize and lay down bets with public sector funding was explored. A diversified portfolio—with a mix of high-risk and low-risk candidates—can average out to a risk level that draws in non-traditional funders of pharmaceutical R&D. We could unpack the proposals of those who would have the public sector buy options in these
companies to those who have proposed a mega-fund to pursue a diverse portfolio of drug candidates. Collectively, the 3Rs have the potential to transform how we innovate, bring new drugs to market, and ensure that public health priorities are met with affordable end-products.

A new analysis has found that many of the products critically needed to fight some of the world’s most prevalent infectious diseases are not likely to be developed based on current candidates in the research & development (R&D) pipeline, and reveals significant gaps in funding for health innovation. Global health R&D analysis reveals major gaps in critical tools and funding.

Researchers report that about 500 products already in development are estimated to cost about US$ 16.3 billion to complete, with three-quarters of those costs coming in the first five years, and would result in about 128 expected product launches. The study also identifies 18 high-priority missing products in the pipeline, including vaccines against HIV, tuberculosis (TB), malaria and hepatitis C; a combined vaccine against multiple diarrheal diseases; and, new drugs for TB and 12 of the most neglected tropical diseases.

Open policy discussions to unkey pharmaceutical issues critical to innovation and access to medicines with regards to genesis in policy concerns over innovation and access that stretched a couple of decades back was discussed.

| Pre-competitive inputs | • Sourcing of natural products for screening and novel drug design from biodiverse repositories  
| Clinical trial data | • 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.  

**Invest in Changing the Innovation Ecosystem**

The discussions in the session also brought to the fore the issue of innovation ecosystem as current financed can sustainably innovate and deliver what public health demands. Over the past couple of decades, public sector funding mechanisms such as push and pull mechanisms come to picture. Pushing standards pay for the inputs of R&D, decreasing the red zone and there by de-risking the pipeline. Pushing standards can take many forms such as grants, tax credits, or publically funded support for product development partnerships in the R&D process. By contrast pull mechanisms paid for the outburst of R&D and ensure returns on investment. They can take of course a number of forms for interactive incentives and prices to market commitments. Now, low middle income countries and civil societies working on access to medicines issues have argued who the red zone should relate to the

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green zone in these diagrams and particularly that we will focus on a concept of De-linkage. Now much of the understanding of De-linkage in the Global Health Community, comes from actually the work of the WHO’s consultative expert working group a few years ago as a defined De-linking as a means of divorcing the funding of R&D from the way in which it is actually priced. When the consultative expert working group describes the idea, they envisioned the generic competition would bring pricing close to marginal cost. Now more recently, De-linkage, has been discussed and circles involved in the innovation of antibiotics and here De-linkage seeks to divorce return on investment from sales volume or reimbursement; in other words, price times quantity and in tackling antibiotic resistance quantity matters.

The antibiotic innovation as a case study for considering how might engineering financing of delivery and access in health technology products should be considered.
A global research fund upstream and R&D push, global development fund to support clinical trial testing push, a global launcher reward that will help ensure a returns on investment pull. In composite their recommendations give shape to oppose Pulse Initiative, a Global Union for Antibiotic Research and Development and GARDP.

The Consultative Expert Working Group (CEWG) on Research and Development had also 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 delinking 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. In the case of developing countries, the market failure which intellectual property rights try to correct is compounded by a lack of reliable demand for the products generated by research and development (R&D). Thus the incentive offered by intellectual property rights fails to be effective in correcting the market failure.19

Product Development Partnerships like DNDi and corporate target product profiles, which they described as “I proprietary planning to use in industry to guide product development and to inform regulatory body and investors.” Now, target product profiles also have been using the public sector to shape the specifications of products like the pneumococcal vaccine. In the hands of Product Development Partnerships like DNDi affordability of a product is often one specification.

19 http://www.who.int/phi/CEWG_Report_5_April_2012.pdf
Boston Consultant Group, however, separated this out from their use of target product profiles and by so doing they open the door to what they called differentiated pricing and access requirements for new drugs in all funding contracts entered into with guard. The differentiated pricing approach allowed for partial Delinkage approach, where the return on investments is divorced from pricing quantity of drugs sold, but only in certain markets such as low and middle income country markets. In the industrialized country markets, the de-linkage required may not apply, raising some very important questions of double standards, such as why should we be more concerned about stewardship and low or middle income country markets when, we do such as spectacular job of overusing antibiotics in the United States.

The increase in antibiotic resistance and the dearth of novel antibiotics have become a growing concern among policy-makers. A combination of financial, scientific, and regulatory challenges poses barriers to antibiotic innovation. However, each of these three challenges provides an opportunity to develop pathways for new business models to bring novel antibiotics to market. Pull-incentives that pay for the outputs of research and development (R&D) and push-incentives that pay for the inputs of R&D can be used to increase innovation for antibiotics. Financial incentives might be structured to promote delinkage of a company’s return on investment from revenues of antibiotics. This delinkage strategy might not only increase innovation, but also reinforce rational use of antibiotics. Regulatory
approval, however, should not and need not compromise safety and efficacy standards to bring antibiotics with novel mechanisms of action to market. Instead regulatory agencies could encourage development of companion diagnostics, test antibiotic combinations in parallel, and pool and make transparent clinical trial data to lower R&D costs. A tax on non-human use of antibiotics might also create a disincentive for non-therapeutic use of these drugs. Finally, the new business model for antibiotic innovation should apply the 3Rs strategy for encouraging collaborative approaches to R&D in innovating novel antibiotics: sharing resources, risks, and rewards.

Sharing resources, risks, and rewards should each suggest operating principals against which to benchmark potential solutions. Sharing resources might ensure the availability of research inputs from new sources of potential drug candidates to platforms for greater collaboration and savings in R&D cost. Sharing this, would involve targeting public moneys in ways that help lower the risk of drug developers pursuing new novel classes of antibiotics and sharing rewards should help us de-link financial returns from sales of the product and ensure fair returns and affordability to those in need.

Reengineering R&D Value Chain

So every stage of essentially the process from bench to bedside, we might ask how do we actually ensure the overarching goal of sustainable access to better serve the patients, does a target product profile ensures affordability of the end product, is the process of innovation not just for those disease in developed countries but by those disease in developed countries. How sustainable is the production of the drug and is there enabling regulatory environment of the data of the drug that actually is brought to market publically shared and the invention and use of platforms not exclusively licensed, is the financed delinked, is the scaling of the drug at the pricing affordable and fair.

Through an end-to-end approach, we are beginning to envision how making an intervention in one part of supply chain might have acuity impact on another. Best part of actually being responsible public steward; however, the money is actually that the public actually pays into the pharmaceutical R&D process. Both during the R&D process and as we buy these drugs for the healthcare delivery system, it means moving beyond bed by bed, company by company, drug by drug approach to actually thinking about the innovation ecosystem where resources, risks, and rewards are shared between the public and private sector and now in the area of antibiotic innovation, potential infrastructure.
For example, a procurement facility is actually very important potentially within this mix of infrastructure we need and the global drug facility has been a one stop shop, has become a one stop shop for TB medicines, diagnostics and supplies and through these efforts to pull procurement for these commodities has help ensure forecast this table, forecast demand for suppliers, has been enabling a prerequisite for keeping the suppliers in the relatively small markets for treatments for multidrug-resistant infections and at the same time to negotiate concessionary prices from those manufacturers. The global drug facility is playing a key part in procuring bedaquiline and delamanid, child friendly formulations are treating drugs for TB, adding of the expert system cartridges for diagnosis of drug-resistant TB.
Moving to an End-to-End Approach to Ensure Sustainable Access

Considering better incentives for patented drugs by putting them on a quicker path for regulatory approval rather than consuming too much time and some kind of hoops can be given within the regulatory network to mechanism to skip phase I and phase II trials and go to straight phase III trials before product is approved by the FDA or the European medical agency etc and controlling the dispensation of antibiotics. The need for coordination between the center and the state FDAs under the Drugs and Cosmetic Act, and a coordinated approach between the Pharmacist’s Act, the Pharmacy Counsel, the Center FDA, and the State FDA.

GARDP, the Global Antibiotic R&D Partnership is not for profit R&D entity that’s really focusing on Global Public Health Needs in the space of antimicrobial resistance focused on drug resistance, bacterial infections that have been designated as priorities by the WHO. Discussed the challenges in sustainable access in the field of antimicrobial resistance such as lack of development, quality, distribution, inappropriate use, regulatory strategies that are pursued, lack of commercial interest and pricing. R&D requires sustainable funding in a long-term approach and that is why, GARDP takes portfolio approach building collaborative global partnerships with both the public and private sector supporting end-to-end public health driven R&D with very strong scientific and project management team that really works with our partners to drive the project, thus working, conducting, and sponsoring complex R&D with partners from preclinical to clinical studies, chemistry, manufacturing and control, regulatory processes, manufacturing, and supply.
The work flow and details of the word of GARDP were discussed. During surveillance state to determine one of the R&D and access needs and priorities, the countries that are mostly affected, where to target focus is thought of. One example is that by 2023 the first business plan is to register a new drug for gonorrhea and its integration into relevant policies and guidelines and initiate its implementation with suitable consolation and access strategy. With license of the drive for 168 countries to drive with the FDA and to decide the sublicense in terms and conditions including all quality, manufacturing, environmental standards, and target markets.

Affordability clauses were discussed with respect to availability in high income countries as well as low and middle income countries. Some high income countries may be high burden, but actually represent a very small market. Prioritizing registration linked back with surveillance data and this is where the link with WHO is extremely important.

A big investment in the pharmaceutical development to support work in drug development as well as to conduct relevant public health studies for hard to be generate evidence to guide policy and use, which is essential for stewardship. GARDP mentioned there drug development program on fosfomycin, which is a repurposed antibiotic and on pediatrics on a repurposed drug and intending to build up a clinical trial network both for neonatal sepsis and pediatrics. The public sector needs to drive and set the agenda to be done at international and national level and R&D strategies and TPPs are very important. Access and stewardship is a critical component, it involves a broad range of actors in addition to just to the product developers and public investment requires a public return and there is a need to balance this with the fair contractual partnership to ensure with a private sector entity to ensure registration access and appropriate use. Sweden for instance has published a very interesting report and how one could look at economic compensation storage distribution models for both old and new antibiotics.

Rational use of antibiotics implemented through the Swedish Strategic Program for antibiotic resistance was discussed. The rationales why optimizing use of antimicrobial agents, is one
of the five strategic objectives in the WHO global action plan, which was endorsed by the World Health Assembly in 2015 and supported by the UN Fruit and Agriculture Organization and World Organization for Animal Health as well. In line with this strategic use of antimicrobial agents in health and amounts of food is also included in the Indian National Action Plan and antimicrobial resistance and in the Swedish Strategy to combat antibiotic resistance, there is a point for responsible use of antibiotics.

**Strama’s role in the Swedish work to contain AMR**

The Swedish Strategic Program against antibiotic resistance, way of doing antimicrobial stewardship, which is actually an acting body comes into picture and the antibiotics available outside hospitals are by prescription only from licensed pharmacist and there is a mandatory standardized reporting systems or say some prescriptions to national registers and these prescribed drugs are financed by Universal Insurance and only drugs with proven value for public health are covered. Strama have 21 regions and have a full remit and financing from the regional healthcare providers and has 2 overall aims, the first one to give the best available treatment to the patient. It’s not only about decreasing use, but to have appropriate use when it makes a difference for the patient. Sometimes antibiotics are the best treatment and it needs to preserve the affecting antibiotics and prevent emergence and spread of resistant bacteria. The basis for the stroma work is to make a local regional situation analysis to collect data on antimicrobial consumption and use from surveillance based on the national registries and antibiotic use.

The role of funders in ensuring access to the healthcare interventions that result from funding was discussed. Welcome Trust funds primarily basic early stage medical research and spends about a billion pounds every year supporting researchers all over the world. The primary focus is on basic science but we are also committing to a few priority areas, you may have heard our work on AMR or drug-resistant infections that we call it or our vaccines priority areas to develop one in mental health. So, ideas that we kind of support these ideas
in terms of kind of targeted approaches, targeted amount of money, put a lot of weight of the organization behind it, advocacy, public engagement and with other organizations, other funders to fund new approaches such as CEPI is the Coalition for Epidemic Preparedness Innovations, CARB-X, vaccines for development for epidemic potential and CARB-X or antimicrobials,

Providing funding to make sure products does exist, but are affordable and accessible, innovating ways of revenue sharing, trying new and innovative models, open research. The intellectual property and commercial reward have a rule in developing and delivering interventions but the health benefit should be the absolute priority that shouldn’t come at the expense of that. There is no one size fits all approach, so research funders and pharmaceutical companies and everyone working together should use practices like voluntary licensing, patent pooling, equitable pricing and of particular interest where funding the medicines patent pool to explore further their expansion into conditions that are not just HIV, TB, Hep C where they have historically focused before but see what role an organization likely medicines patent prove and volunteer licensing can play unexpanded conditions.Public-private partnership can span both PDPs, Product Development Partnerships, which are more focused on the R&D system and broader downstream public-private partnerships that are focused more on the delivery system, leading to an example of integration of both ends of R&D and manage delivery system.

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

Recommendations:

Recommendations for National Governments

1. Discuss for changing the Innovation Ecosystem (lead by ICMR/DBT) through:
   i. Pre competitive inputs:
      a) Sourcing of natural products for screening and novel drug design from biodiverse repositories
      b) Contracted services for pharmacokinetics/pharmacodynamics, toxicology, and so on
   ii. Sharing of Clinical trial data – such as Coalition against Major Diseases pooled control arms of clinical trials on Alzheimer’s disease.
   iii. 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.
   iv. Moving to an End-to-End (drug by drug / company by company) Approach to Ensure Sustainable Access:
      a) Availability: innovation platforms for drug discovery; efficient use of biodiversity resources
      b) Effectiveness: ensuring sustainable production and repurposing older antibiotics
      c) Affordability: Innovative financing
      d) Access: prescription of medicine and diagnostics through diagnostics platforms

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

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

The session focused on legal and regulatory issues for access to medical products.

The Lancet commission identified five areas that are crucial to essential medicines policies: paying for a basket of essential medicines, making essential medicines affordable, assuring the quality and safety of medicines, promoting quality use of medicines, and developing missing essential medicines. The Commission located essential medicines policies within the context of current global debates about balancing trade and intellectual property policies with human rights, assuring health security, strengthening people-centred health systems, and advancing access to essential technologies. In all policy areas, particular attention was paid to furthering equity in access, strengthening relevant institutions, and creating accountability. For each policy area, the Commission made actionable recommendations,
thereby reaffirming essential medicines policies as a central pillar of the global health and development agenda

The designing innovative approaches to improving antimicrobial stewardship regulation. Regulatory approach remains one most important tool in addressing the challenge of antimicrobial stewardship and some of these approaches may lie in the hands of the drug regulator but depending on the country’s government, others will rely on collaborating across agencies with authority of healthcare services or the regulation of hospital facilities.

The problems of access but not excess highlight the concern over underuse, not just overuse of antibiotics. It is estimated that 5.7 million people die from treatable infections annually because they lack access to the right antibiotic when needed and an estimated 700,000 deaths result from antibiotic resistant infections, so many more today die of underuse than overuse, even though tomorrow that gap will not only narrow but reverse as the toll from drug resistant infections rises but drug resistant infections can result in increased morbidity and mortality, diminished market life for effective antibiotics, higher economic and health cost of second-line therapy as well as prolonged hospitalizations with greater associated cost.

There is need to curb antibiotic use for growth promotion and preventative indications. Antibiotics are used both in humans and in food animals, drug-resistant infections, particularly foodborne outbreaks are spreading from our food system to healthcare delivery system. Therefore, drug regulatory agencies to ensure that antibiotics are used appropriately for treating diseased animals to conserve their effectiveness for both healthcare delivery system and food production systems.

There was focus on the regulatory aspects of developing an antibiotic and registering a new antibiotic and the issues and challenges faced. It is essential to streamline regulatory pathways for antibiotic development for unmet needs and focus on priority pathogens and there are some specific indication pathways, for instance for STIs, urinary tract infections, hospital-acquired pneumonia, intra-abdominal infections etc. There is a whole raft of other indications that are probably not well covered and one needs to balance the time to market versus appropriately assessing risk-benefits; therefore, it is important to streamline pathways, there has to be a requirement for additional data and that requirement needs to be fulfilled and this is important to guide policy in use as well as continuing to assess particularly safety. There is a need to facilitate global clinical trials and run parallel registration, to have a level of coordinative thinking among regulators.

### GARDP – a not-for-profit R&D organization

**Focus:**
- Drug-resistant bacterial infections for which adequate treatment is not available.
- Address global health priorities that reflect the realities of clinical practice.

**Global scope:**
Low-, middle- and high-income countries

**Joint initiative:**
- World Health Organization
- Drugs for Neglected Diseases initiative

**Priorities:**
- Neonatal sepsis
- Paediatric antibiotics
- Sexually transmitted infections
- Memory recovery and exploratory
It is fundamental to achieve the sustainable development goals, to address the issue of health and importance of good health for everyone. The problem has been largely connected with role of patent and the monopoly created by patent. In 2015, the United Nation Secretary General constituted a high-level panel to assess and reveal proposals and recommendations on how to balance the legitimate interest of inventors, intellectual property, the interest of manufacturers and international human right law as well as trade rules and various policies in the access in context of adaptability, affordability and availability. It was noted that the major international treaties contain sufficient flexibilities to address the challenge and interpreting these flexibilities in a manner that would promote a balance of right and obligations in a manner conducive to social economic interest of countries at various levels of development. The human rights jurisprudence provides a strong basis for ensuring the utilization of TRIPS flexibilities and which is underutilized and efforts should be made to use the human rights framework to address the access challenge.

Global Antibiotic Research and Development Partnership (GARDP), a non-profit entity, is a joint initiative by the Drugs for Neglected Diseases initiative and World Health Organisation\(^20\). The aim is to develop novel antibiotics, focusing on R&D gaps as well as to promote their responsible use and ensure equitable access. The global community now recognises the seriousness and growing threat of AMR. There is minimal overreaching guidance and coordination across the active R&D initiatives which have become the key reason behind the significant gaps in the incentive structure and unaddressed public health priorities. At a national level, countries need to adjust their funding commitment to spurping antibiotic innovation in a way that more accurately reflects the unrelenting global emergency of AMR\(^21\).

The TRIPS agreement sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals has ensured that patent protections do not become barriers to access to medicines in developing countries.

It is important for Indian Drug Regulatory system, to build a capacity building of drug regulatory system, strengthening the testing laboratories, research and development funding in innovative products supported by the government and medical products R&D facilitation center should be created in the nation. There must be regulatory convergence of ICH and interventional performers like ICMR and ICDRA, regulatory harmonization to promote the exchange of information to establish dialect and cooperation between nations to exchange of best practices between the nations and to participate in scientific meetings, symposium, seminars and to strengthen the relationship between the different regulatory authorities.

Indian Pharmaceutical Alliance represents 60% of total turnover of Indian Pharmaceutical Industry, which is about $32 billion. In Novel Drug Delivery System, India has made mark for eliminating or reducing the burden, dose of drug and better treatment.

Incubation is nurturing the small companies. There are 31 incubators supported by BIRAC and most of the activity is in the south and west of the country with cluster in and around Delhi and within these, the major cities are Chennai, Bangalore, Hyderabad and Pune, which have the biggest clusters. The challenge faced by incubators are the difficulty to find financial sustainability and lack of funding for young tech companies which affects their income either as rentals or even through equity. The whole ecosystem is rather young and

\(^{21}\) [https://www.nature.com/articles/ja2017124]
raw and evolving. Efforts are made to increase funding of the incubators through recognitions, winning various kinds of competitions, some products or services are reaching the market, milestones in product development and tie-ups.

Plenary Session 6- Legal and Regulatory Issues 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**

*Chairs:* 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 was:**

- Develop systems and approaches 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.

The session focused on partnering for access to medical products-bilateral treaties and regional agreements. There is a need to protect the TRIPS flexibility, the compulsory license and the grounds for issuing patent. Governments must avoid any commitment for enforcing intellectual property under a TRIPS Plus agreement, all trade and investment agreements must not go beyond TRIPS. Any dispute concerning quality and counterfeit should be settled in court under national jurisdiction. In terms of approaches to the agreements, the first and important thing is transparency on negotiation and it is essential to do impact assessment before signing an agreement on the provisions of the agreement on public health and on access to medicine. To monitor the implementation, allow for a review, allow the techs to include for reviewing the implementation and amending any problems are important tools to ensure the access to medicines under the trade agreements.
It is important to leverage the TRIPS Flexibilities and should not give up on issue of TRIPS Plus and the rising impact of FTA. Regional cooperation is not only important for exercising these flexibilities but also providing greater ideas like open innovation and principles, health system strengthening, respect for equal human right, sustainable financing, scientific research, monitoring and evaluation.

The policy coherence between the trade and health are the essential factors to strengthen protection of pharmaceutical patents. To focus on the national policy making process it is important to ensure that international trade policies are coherent with the national objectives of public healthcare22. With growing expansion of social, economic and political determinants of health, health diplomacy becomes focused on coherence between different sectors, which makes the multisectoral dimension as an integral element of multilateral negotiations for health.

For capacity building, both capacity for the trade and the health is needed for people to understand the implication. There must be enough capacity to understand the subject and to generate evidence to support the concern because providing recommendation with evidence is to convince the policy level. Thailand is engaged in multisectoral collaboration, networking involved in both health sector and non-health sector concerning trade issue, exchange evidence and research filing. Building trust between the trade sector and the health sector is very important because with trust, understanding fosters aiming at policy coherence on trade and health, mutually benefitting the country with less impact on the population.

**Thailand – Trade agreements**

The IP provisions in Bilateral and Regional Agreements should respect the following principles:

1. Provisions demanding strong IP protection should be sufficiently flexible to take into account the socio-economic condition and needs of both parties which is imperative where legal norms from the domestic system of the IP-demanding country are included in the agreement.

2. The public interest-related flexibilities included in TRIPS should not be undermined as these norms provide policy space in domestic implementation or limit IP protection through so called "ceilings". A ceiling provides a (binding) maximum level of protection that countries can offer in their national law.

3. Examples are contained in the limitation of the scope of protected subject matter (Art. 9.1 of the TRIPS that excludes ideas from copyright protection), (mandatory) exceptions to exclusive rights (Art. 10.1 of the Berne Convention makes it an obligation to make quotations permissible) or indirect limitations of right holders' rights by granting a right of coexistence to other signs (trade mark holders in the EU sui generis GI system must accept a limitation of their rights).

The licensing mechanisms and TRIPS Flexibilities can be effective to overcome patent barriers which will result in lower prices, savings and treating more people. They may alleviate supply constraints and increase negotiation with originator companies. The issue of trade agreements that contain clauses that can undermine or limit the options to use TRIPS Flexibilities and it is important for governments to take these issues into account to be aware of them and it is important for international organizations like WHO to help government in understanding these issues and being aware of them.

**Estimated (projected) impact – voluntary licensing**

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<thead>
<tr>
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<th>Period</th>
<th>Countries</th>
<th>Budget difference (US$)</th>
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<tr>
<td>11 HIV medicines</td>
<td>2015-2028</td>
<td>100-127 countries*</td>
<td>1.39-2.04 billion</td>
</tr>
<tr>
<td>2 new TB medicines</td>
<td>2015-2035</td>
<td>116 countries* with + 65% of the global MDR-TB burden</td>
<td>184 million</td>
</tr>
<tr>
<td>1 hepatitis C medicine</td>
<td>2015-2030</td>
<td>108-114 countries*</td>
<td>1.29-1.70 billion</td>
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**Estimated (projected) impact – using TRIPS flexibilities**

<table>
<thead>
<tr>
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<th>Period</th>
<th>Countries</th>
<th>Budget difference (US$)</th>
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<tbody>
<tr>
<td>4-6 HIV medicines</td>
<td>2015-2028</td>
<td>4 countries</td>
<td>678-942 million</td>
</tr>
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</table>
The trilateral cooperation between WHO-WTO-WIPO has focused on access to medicines and encouragement of research and development for availability of new medical technologies. It ensures accessibility of medicines and health products involves affordable prices, properly designed health systems, suitable financing in the developing countries. The cooperation responds to an increased demand in developing countries for strengthening capacity of informed policy making in areas of intersection between health, trade and IP focusing on access to innovation of medicines and related technologies.

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

**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
The session highlighted the legal aspects for promotion of public health and prevention of non-communicable diseases. The law follows technology and innovations, most of the legal experts, are aware of the relief or directions safeguarded by the Supreme Court of India under Article 32 and by the various High Courts of India under Article 226 by incorporating the fundamental rights and including right to health under guaranteed Article 21 of the Constitution.

The paediatric regulations in Europe and the European Registration Procedures have common legal framework in Europe for issues related to NCDs. The regulation standards and licensing are pathways to approval in different parts of world. The Europe has common legal framework in form of regulations that are immediately applicable in all member states and there are directives which must be implanted in the national laws. India is part of International Coalition of Medicines Regulatory Authorities that discuss issues on Pharmacovigilance, on falsified medicine and access and communication between the member states.

The trade and dietary environment that surrounds nutrition and people, WHO has developed and advocating evidence based dietary to reduce non-communicable diseases. The high rate of mortality contributes due to non-communicable diseases WHO has provided several guidance for dealing with non-communicable diseases. Childhood Obesity and importance of the dietary environment in reducing Non-Communicable diseases WHO emphasized the importance of physical activity as a risk reduction factors essential for countries to make Sustainable Development Goals, especially target on nutrition, the Zero Hunger target and promote good health and wellbeing. The WHO focuses on regulatory population-based interventions to be implemented by countries to change food environment.
There is lot of processed pre-packaged foods which are high in salt, sugar and fat and less of healthier foods. Countries are advocating to set standards for healthy foods in public institutions like schools wherein, cafeteria policies ensure that children are not exposed to unhealthy foods, labeling becomes a very important aspect of preprocessed package foods especially what referred to front of pack labels are being promoted so that people are aware about what they are buying and of course another type of regulatory intervention being promoted is to restrict the use of unhealthy foods, for example transfats which cause a lot of heart disease.

One of the biggest problems is that different government sectors have a different priority to public health obligation, policy coordination between trade, commerce and health is required to implement regulations and developing implementing policy around dietary environment such as tobacco since, there is a lack of capacity which is a big problem, lack of monitoring and evaluation, lack of public awareness, all these cause many issues that need to be addressed. Policy development process must be transparent, led by government so that public interest is the main key objective. Industry and other stakeholders need to be consulted but the process must be laid by government. Civil society support, public support is essential to accompany to have behaviour change communication among people. There are lot of issues to be addressed like lack of awareness, capacity building, lack of monitoring and lack of policy development process. It is crucial for government to come out with a policy for prevention of noncommunicable diseases and the legislations to be put together in place to have something that connects with what is already present because there are numerous legislations, for instance, India has about 71 legislations. Interministerial communication must be setup to see that transparency and accountability.

Medicine Patent Pool’s (MPP) vision is basically a world in which people who are in need, especially in the lower- and middle-income countries to have rapid access to effective and affordable medical treatments and health technologies and our mission is something which is basically practice on an everyday basis that is to increase access to, and facilitate the development of, life-saving medicines for LMICs through an innovative approach to voluntary licensing and patent pooling. It is implemented by working out with a range of stakeholders, industry, patient groups and governments. MPP has ensured that 17 million patient years of treatments and around 6.2 billion doses of medicines delivered through generic partners with an actual savings of 553 million USD through international community through licenses funded by UNITAID.
NCDs are commonly due to bad food habits, lack of physical activity and drug abuse etc. The Supreme Court of India has issued directions under National Health guidelines concerning Health policies. It was recommended that there is need to make collaborative efforts by different departments/ministries like health, agriculture, environmental, narcotics department require to come up with some strong policies to prevent the population from these NCDs. It is essential to spread awareness in low-middle income group regarding their fundamental rights with respect to have access to good health and good food. To follow the supreme court guidelines issued on these fundamental rights government should formulate such policies for young children to avoid bad habits like outside foods, tobacco etc. in order to prevent NCDs.

**Parallel Session 11 - Non Communicable Diseases-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 this session was to discuss the role Intellectual Property Rights (IPR) and standards in the access and affordability of medical products. The challenges in striking a balance between promoting innovation through IPR and facilitating access to medicines for all were also discussed in the context of trade agreements.

The following topics were taken up:
- New Initiatives in PDPs for Access to Affordable Medical Products
- Bringing First Generation Entrepreneurs to the Market Place for Medical Devices
- Health Technology Transfer
- Patents as a Tool for Innovation- Challenges in the NCD Medical Products Pipeline

The Parallel Session 12 focused on Intellectual Property Rights and Standards in Trade for Medical Products. The TRIPS Agreement recognizes the significance of the IP system for innovation, providing (in Article 7) 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”. The national IP systems play a significant role in helping the innovators gain and retain an innovation-based advantage through IPR protection. This has high relevance in the healthcare domain wherein technological basic or fundamental innovations produce new markets for a new medical product; and incremental innovations lead to improved products. The main benefit claimed for strong IPR protection is that by allowing innovators to appropriate a share of the benefits of their creative activities, R&D is encouraged, which leads to innovation and higher long-run growth. Further, it has been observed that IPR protection can encourage domestic innovation in countries that have significant domestic capacity for innovation, but that it has little impact on innovation in countries with a small innovative capacity. This essentially signifies that IPR protection is a potential driver promoting innovation and needs to be leveraged for drug discovery and product development of medical products.

IP rights provide the holder with several opportunities, which facilitates successful completion of the life cycle of an innovation. Such opportunities include technology transfer, sale, licensing, and various types of strategic partnerships or alliances in commercializing it. The provisions under TRIPS Agreement also advocate that one of the purposes of protecting IP is to promote innovation and technology transfer, and it requires developed countries’ governments to provide incentives for their companies to transfer technology to least-developed countries.
The criteria that need to be satisfied to obtain a patent are set out in the national legislations on Intellectual Property and may differ from one country to another in respect of inclusions and exclusions. On one hand, IP system is market driven and is considered to neglect the needs of developing countries and their populations. Therefore, it is thought that driving up levels of innovation through IP may sometimes not serve public health objectives. The developed countries of the world, being front-runners in technology development, obtain IP protection on platform technologies in healthcare which creates barriers for access to the technologies by developing countries. The monopolies created through IP protection of such technologies also leads to manifold increase in their cost and therefore, affects their affordability to the developing world. The role of national governments on grant/ rejection of IP becomes crucial in such cases, keeping in view the unmet need for the medical products under consideration. A landmark decision of the Government of India in this regard was to uphold the rejection of Gleevec (imatinib mesylate) patent assigned to Novartis and disallow evergreening in public interest.

Since the healthcare needs are of prime importance for human kind across the globe, there is an imminent need to increase the capability of developing countries to manufacture high quality medical products, which would facilitate their access and make them affordable. This would also discourage monopolies and have multiple industry players develop and market lost cost generic quality medical products. The issue of access to medicines for MDR-TB in India was emphasized citing the existing IP barriers for making affordable the only effective drugs - Bedaquiline and Delaminid.
The discussions during the session also highlighted that Product Development Partnerships (PDPs) are an important tool to bring together industry resources that are actually required for the development of new drugs and funding support from government and philanthropic organizations. DNDi, one of the leading PDPs in healthcare established in 2003 focuses on healthcare needs for neglected tropical diseases. DNDi, with support from WHO has also launched the Global Antibiotic Research and Development Partnership (GARD-P) to address drug-resistant bacterial infections and other infections that do not have adequate treatments available. Innovative Medicines Initiative (IMI), a PDP established by the European Commission in conjunction with European Federation of Pharmaceutical Industries and Associations (EFPIA) has over 50 projects covering various diseases including cancer, diabetes, ABR infections and tuberculosis.

A balanced and effective intellectual property system is recognized as an integral element of the policy framework that supports innovation; and for facilitating access to medical products for populations of the country from healthcare perspective. National commitments under free trade agreements also play an important role in taking decisions on patent exclusivity and other aspects that have a critical impact on access to affordable medicines.

The National IPR Policy of India, 2016 also highlights access to medicines as one of the salient features as access to affordable medicines and other healthcare solutions is becoming a challenge for all countries. The Policy aims to enhance access by (a) encouraging cross-sector partnerships between public sector, private sector, universities and NGOs; (b) promoting novel licensing models, and (c) developing novel technology platforms. India has taken several initiatives to promote innovation such as creation of National Healthcare Innovation Portal under the Ministry of Health and Family Welfare; and Health technology Assessment Scheme of Department of Health Research to assess innovation potential of technologies developed by local entrepreneurs. Capacity building, mentoring and hand-holding of stakeholders in bringing technologies from ideation to market is also a priority for different government initiatives.
### Parallel Session 12: Intellectual Property Rights and Standards in Trade for Medical Products

#### Recommendations:

**Recommendations for National Governments**

2. 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**

2. Foster regional networks for using PDPs to provide access to medicines
Annex I: Session Briefs

Session Brief Plenary Session 1: Access to Medical Products to achieve SDG 2030 Goals

The Sustainable Development Goals are the blueprint to achieve a better and more sustainable future for all. They address the global challenges by interconnecting in order to leave no one behind, it is important that we achieve each Goal and target by 2030.

Sustainable Development Goal 3 of the 2030 Agenda for Sustainable Development is to “ensure healthy lives and promoting well-being for all at all ages”. The associated targets aim to reduce the global maternal mortality ratio; end preventable deaths of newborns and children; end the epidemics of AIDS, tuberculosis, malaria and other communicable diseases; reduce mortality from non-communicable diseases; strengthen the prevention and treatment of substance abuse; halve the number of deaths and injuries from road traffic accidents; ensure universal access to sexual and reproductive health-care services; achieve universal health coverage; and reduce the number of deaths and illnesses from hazardous chemicals and pollution.

The UN General Assembly (UNGA) adopted a resolution calling for all people to have equal access to health services, and agreeing to hold a high-level meeting on universal health coverage in 2019. Another UNGA resolution establishes 12 December as ‘Universal Health Coverage Day.’ In the resolution titled, ‘Global health and foreign policy: addressing the health of the most vulnerable for an inclusive society’ (A/72/L.28), UNGA reaffirms the Sustainable Development Goals (SDGs) and several other international goals and agreements, including the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) promoting access to medicines for all. In the resolution, Member States agree that a high-level meeting on universal health coverage will take place in 2019, and request the UN Secretary-General and Director-General of the World Health Organization (WHO) to report to the next session of UNGA on steps taken towards improving international coordination and cooperation on the SDGs. Thus, reaffirming the 2030 Agenda for Sustainable Development’s commitment to “leave no one behind”.

The WHO Thirteenth General Programme of Work (GPW13): 2019-2023

Access to good quality, affordable and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations—the three strategic priorities of the World Health Organization (WHO) Thirteenth General Programme of Work 2019–2023. GPW 13 is based on the SDGs and is relevant to all countries – low, middle and high income. Health is fundamental to the SDGs and, in an interconnected world, WHO’s role in providing global public goods that help to ensure health for all people within and across national boundaries has never been more relevant.

The “triple billion” goal is a joint effort of Member States, WHO and other partners. WHO has a catalytic role to play in reaching the goals in GPW 13 i.e. ensuring healthy lives and promoting well-being for all at all ages by: Achieving universal health coverage – 1 billion more people benefitting from universal health coverage Addressing health emergencies – 1

24 https://www.un.org/sustainabledevelopment/health/
26 http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/
billion more people better protected from health emergencies Promoting healthier populations – 1 billion more people enjoying better health and well-being

The Government of India is strongly committed to the 2030 Agenda, including the SDGs, as evidenced by the statements of the Prime Minister and other senior Ministers at national and international meetings. India’s national development goals and its “sab ka saath, sab ka vikas” or “development with all, and for all,” policy initiatives for inclusive development converge well with the SDGs, and India will play a leading role in determining the success of the SDGs, globally. As Prime Minister Narendra Modi noted, “These goals reflect our evolving understanding of the social, economic and environmental linkages that define our lives.”

National Action on the SDGs in India

NITI Aayog, the Government of India’s premier think tank, has been entrusted with the task of coordinating the SDGs. NITI Aayog has undertaken a mapping of schemes as they relate to the SDGs and their targets, and has identified lead and supporting ministries for each target. They have adopted a government-wide approach to sustainable development, emphasising the interconnected nature of the SDGs across economic, social and environmental pillars. States have been advised to undertake a similar mapping of their schemes, including centrally sponsored schemes.

State Governments are a crucial driving force for SDG progress

State governments are key to India’s progress on the SDG Agenda as they are best placed to ‘put people first’ and to ensuring that ‘no one is left behind’. Many of the Government’s flagship programmes such as Swachh Bharat, Make in India, Skill India, and Digital India are at the core of the SDGs. State and local governments play a pivotal role in many of these programmes. The role of local governments is equally important; 15 of the 17 SDGs directly relate to activities undertaken by local governments in the country. State governments are paying keen attention to visioning, planning, budgeting, and developing implementation and monitoring systems for the SDGs.

India and Goal 3 to ensure healthy lives and promote wellbeing for all at all ages

India has made significant strides in improving various health indicators. The Infant Mortality Rate has declined from 57 in 2005-06 to 41 in 2015-16. Similarly, Under-5 Mortality Rate has fallen from 74 to 50 over the same period. This has been enabled, at least partially, by a significant improvement in vaccination coverage for children between 12-23 months of age. Moreover, institutional deliveries have increased from 38.7% in 2005-06 to 78.9% in 2015-16. The country’s strategy in health is focused on providing essential services to the entire population, with a special emphasis on the poor and vulnerable groups.

The National Health Policy, 2017 has specified targets for universalising primary health care, achieving further reductions in infant and under-5 mortality, preventing premature deaths due to non-communicable diseases as well as increasing government expenditure on health. A composite index is being used to monitor and incentivise improvements in health services delivery across states in the country. The government is aiming to immunize all unimmunized and partially immunized children against vaccine preventable diseases by 2020. Towards achieving universal health coverage, a health insurance cover of INR 100,000 (USD 1,563) is being extended to all poor families.

27 http://niti.gov.in/india-s-commitment-to-the-sdgs
28 http://niti.gov.in/content/overview-sustainable-development-goals
29 http://niti.gov.in/content/mapping-ministries-goals-and-targets
30 http://niti.gov.in/content/states
31 https://mohfw.gov.in/sites/default/files/9147562941489753121.pdf
Ayushman Bharat is arguably the largest public health initiative in the world planning to cover 100 million families across the country. The scheme has two main components: one that envisages the transformation of 1,50,000 primary healthcare centres and sub-centres into “wellness centres” that would lay stress on prevention of illness, and second, a health insurance package of ₹5 lakh (approximately 7000 USD) for each of the 100 million families being covered.

The objective of the session is to discuss the following:

3. Contribution of 13th GPW for Access to Medical Products to achieve SDG 2030 Goals
4. Health focus in 2019 UN General Assembly-UHC, NCDs and TB
5. Achieving Universal Health Coverage and bringing Healthcare to the People in India through National Health Protection Scheme

Questions to spur thinking

1. How intergovernmental collaborations including at the UN general assembly and with other stakeholders lead to attainment of SDG3?
2. Will WHO’s first ever investment case in the organization for the achievement of 13 GPW provide greater impetus for national and international donors to invest for public health?
3. How will the Ayushman Bharat Programme-National Health Protection Scheme accelerate the achievement of Universal Health Coverage in India?

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32 https://www.abnhpm.gov.in/
Session Brief Parallel Session 1 - Policies to support Innovation for Medical Products (in select countries)

Many governments have taken up policy initiatives to promote innovation in general and in health care in particular. Innovation ecosystem must promote participation of all diverse stakeholders: academic institutions, government, industry and individuals through the creation of new pathways, and programs for medical products and healthcare technologies.

Recently in India, the Atal Innovation Mission (AIM) in India is a flagship initiative set up by the NITI Aayog to promote innovation and entrepreneurship across the length and breadth of the country, based on a detailed study and deliberations on innovation and entrepreneurial needs. AIM is also envisaged as an umbrella innovation organization that would play an instrumental role in alignment of innovation policies between central, state and sectoral innovation schemes incentivizing the establishment and promotion of an ecosystem of innovation and entrepreneurship at various levels - higher secondary schools, science, engineering and higher academic institutions, and SME/MSME industry, corporate and NGO levels.

In India, in the area of R&D, the Indian Council of Medical Research (ICMR, Biotechnology Industry Research Assistance Council (BIRAC) and Translation Health Science and Technology Institute (THSTI) are playing an important role. BIRAC aims to create an ecosystem that will facilitate innovation and development of specific products through shared infrastructure, strengthened skills and technology transfer capabilities. More research programs are currently being funded by BIRAC. All the research institutes of ICMR have played an important role in their assigned area of research. There are 14 divisions at ICMR Headquarters that deals with different areas of medical research. Kalam Institute of Health technology was conceived as a research facilitation institution by former Principal Scientific Advisor (PSA) to the Government of India. It ushers in focused research on critical components pertaining to medical devices with support from various stakeholder institutions.

In Brazil, the federal government is the main actor in the Brazilian health science and innovation scenario because it sets priorities, provides funding for research, fosters collaborations between public laboratories and private companies for technology transfer and manufacturing of strategic products, and purchases a wide range of health technologies.

The objective of the session is to discuss policy initiatives made by governments to promote innovation in general and in healthcare in particular for access to medical products:

7. Policy Options Promoting Innovation in Health Technologies- Select MERCOSUR Countries
8. Facilitating Access: The Role of Innovation and Competition
9. Policy Initiatives to Promote Medical Devices and Diagnostics
10. Mainstreaming Medical Ethics in Delivery for Fostering Quality and Safety of Health Services
11. Department of Biotechnology’s Supporting Role in the Innovations Ecosystem in India
12. Towards Unipill for TB treatment
13. Developing Rapid Diagnostic Solutions for Infectious Diseases: Focus on antibiotic resistance and Tuberculosis & Sexually Transmitted Infections

Questions to spur thinking

1. What are the policy options before developing countries to encourage medical products innovations for public health needs?
2. How to promote cooperation between private and public sectors on research and development?
3. What are the steps needed to leverage global and regional networking for innovation for NCDs?
4. How to hand hold the innovators, start-ups, small and medium enterprises and bring the product on to the market?
5. How do diagnostics assist in appropriate and timely rational use of medical products?
Efforts are underway across the world to support R&D in healthcare for access to affordable medical products. However, effective knowledge sharing, collaboration and coordination of these efforts is needed to improve responses to epidemics and ensure that identified R&D gaps are filled effectively. The involvement of investing organizations, regulators, the private sector, and low- and middle-income countries in defining the scope of the coordination is integral to the success of the investments made. It is also agreed that epidemiological and clinical research should be incorporated under the umbrella of the coordination mechanism, with product R&D before and during public health emergencies33.

The data available on investments put up by WHO as made in last 10 years as per G-Finder reports indicates that the USA contributed almost two thirds of the total investments on neglected diseases from public and philanthropic sources, followed by the UK. HIV/AIDS received the highest investments, followed by malaria and tuberculosis. Across all diseases, National Institutes of Health (NIH), USA and the Bill & Melinda Gates Foundation (BMGF) have been the top funders34. The drug development portfolio of the Drugs for Neglected Diseases initiative (DNDi) is also aligned with the findings of G-Finder35.

Several international and national public and non-profit organizations are investing in specific areas of healthcare. UNITAID invests in innovations to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively36. An entrepreneurial organization, PharmAccess Foundation has a digital agenda dedicated to connecting more people to better healthcare in Africa37. Investments in Product Development Partnerships (PDPs) are also being made through initiatives for access to medicines38.

There are collaborative initiatives such as 'The Access to Medicine Index' supported by the BMGF and the UK and Dutch governments, that independently ranks pharmaceutical companies’ efforts to improve access to medicine in developing countries39. Grand Challenges initiatives of the BMGF also foster innovation to solve key global health and development problems40. In India, Grand Challenges initiatives are being steered by the Department of Biotechnology (DBT) through an umbrella Memorandum of Understanding (MOU) with BMGF for mission-directed research and build Grand Challenges India to support health research and innovation. The MOU aims to support initiatives that could dramatically change the health and development landscape in India and other countries facing similar challenges41.

**The objective of the session** is to discuss:

- Tracking investments in research and development in medical products for facilitating policy initiatives to promote access in different tools such as G-Finder etc

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33 [https://www.chathamhouse.org/sites/default/files/events/2016-11-10-Global-Coordination-Meeting-Summary.pdf](https://www.chathamhouse.org/sites/default/files/events/2016-11-10-Global-Coordination-Meeting-Summary.pdf)
36 [https://unitaid.org/about-us/#en](https://unitaid.org/about-us/#en)
37 [https://www.pharmaccess.org/](https://www.pharmaccess.org/)
39 [https://accesstomedicineindex.org/](https://accesstomedicineindex.org/)
40 [https://gcgh.grandchallenges.org/](https://gcgh.grandchallenges.org/)
• The facilitatory landscape role of NIH in promoting new drug Development including for medical technologies and biologicals
• To present and discuss next steps to Global health R&D analysis revealing major gaps in critical tools and funding outlined in 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
• Priority Targets for Global Health R&D
• Grand Challenges Indian Contribution in Promoting Research & Development

Questions to spur thinking

1. What could be different mechanisms to track outcome of investments made to enable devising policy initiatives and suitable interventions for priority diseases?
2. Could the localization of G-Finder approach yield better data and policy options for national governments?
3. What outcomes does the recent product R&D mapping exercise by TDR with a focus on the poverty related neglected diseases bring out?
Session Brief Plenary Session 2: Mechanisms for Knowledge Sharing including Licensing Options for Medical Products to Facilitate Health for all

Sharing of Knowledge, data, and research materials is needed to gain a better understanding of which biological aspects of the disease to target and with what combination of therapies. Sharing of costs and risks is needed to keep the many private sector participants that are needed engaged in development efforts 42.

Technology transfer related to health encompasses transfer of technical information, know-how, performance skills, licensing agreements, technical materials and equipment jointly or as individual elements, with the intent of enhancing the technological capacity of the recipients43. Such transfer can take place in several forms including public and private, institutional and individual, formal and informal, through partnerships and joint ventures and within and across national borders. There are multilateral and national issue in technology transfer which needs to be addressed at these dual levels. The discussions on technology are in synchrony with trade and IPR issues44.

Certain attempts have been made in bilateral provisions on technology transfer. They have however, not being specific enough and merely including soft obligations, for example, the exchange of views, the sharing of information and using language such as "promoting" partnerships for research and development activities and "facilitating" support for technical assistance45.

As a developing country, policies should favour not only tilt towards the reasonable expectation of the public, but also foster domestic industry by technology transfer and technical co-operation46. It also implies that the pharmaceutical industry, aiming to reduce public health risks, a patent holder is expected to endeavour to work a patent to its fullest extent to maximise access to affordable medicines.

Public health and Intellectual Property rights go hand in hand in terms of innovation in treatments and development of medications. The legal structures such as patents are designed in a way to encourage innovation and to offer a system which ensures the benefits accessible to the society47. The expensive brand medicines and no legal production of generics can add up the catastrophic costs as well as the morbidity and mortality due to low access of medicines in lower income countries. The policymakers in developing countries consider the greatest benefit in ensuring access in two senses: ensuring financial affordability and securing the physical availability of medicines48.

Voluntary licensing (VL) authorizes a generic manufacturer to distribute a patented medicine in certain countries and it is a strategy to increase access to medicines by facilitating low-cost production of medicines for low-income populations. The VL provides a balance between intellectual property rights protection and public health concerns and ensures that

42 48 U.C. Davis L. Rev. 1509
45 IIC 2017, 48(7), 760-783: Do developing countries have a say? Bilateral and regional intellectual property negotiations with the EU
46 TRIPS arts 7, 8 and 67.
47 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/ : IPR: An overview and implications in pharmaceutical industry
one does not have to infringe upon the other’s right. A patent pool is an agreement between different patent owners to pool their patents and license them, collectively, to each other or to third parties. These pools can be an important form of voluntary licensing, offering the benefits of scale and uniformity for generic companies seeking voluntary licenses for multiple compounds. They can help facilitate the development of combination and second-line treatments by making multiple patents available to generic firms through a single license, thereby minimizing transaction costs.

**Objectives of the session to be discussed:**

- 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
- Public Health: Indian Patent Office Practice

**Questions to spur thinking**

1. To what extent is academia industry collaboration through licensing options important for bringing medical products into the market?
2. Do new licensing mechanism models by MNCs such as in Hepatitis C hold promise for affordable medical products?
3. Do patent pooling mechanisms bring timely access to medical products for developing countries?
4. Can TRIPS flexibilities be used in conjunction with and addition to other licensing options for promoting access to medical products to address TB and NCDs and achieve the UHCs as mentioned in UNGA?

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51 24 Geo. J. on Poverty L. & Pol’y 161: Expanding Access To Medicines And Promoting Innovation: A Practical Approach
Session Brief-Plenary Session 3: Strengthening Regulatory Networks for Facilitating Access to Quality, Safe and Affordable Medical Products

In the recent years scientific knowledge and the scope of the pharmaceutical industry have increased and regulatory authorities and their laws and regulations have grown in number, breadth, and complexity in almost every nation in the world. Access to quality medical products is crucial for achieving universal health coverage (UHC) and in reaching the Sustainable Development Goals (SDG) for health. Regulators face a number of challenges today and these are related to the wide variety of medical products that they have to deal with (medicines, vaccines, diagnostics and medical devices). In this context there is need of a new strategic regulatory approach to ensure product safety, efficacy, and quality. Greater harmonization—coordination and alignment of regulatory rules—across nations would be beneficial for better public health outcomes and increase access to safe, effective and quality medical products. Regulatory authorities are working more frequently with each other, sharing inspection and safety information, and even conferring over discrete product approvals. Various bilateral and multilateral arrangements seek to enhance collaboration, learning, and sharing of best practices as well as efforts to strengthen the regulatory science that underlies regulation and oversight.

WHO South-East Asia Region member states launched the South-East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products. SEARN aims to promote efficiencies and enable availability of affordable and quality medical products through collaboration and reliance among regulators. The SEARN includes 11 Member States: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste. The Key identified priority areas for SEARN are (1) Quality assurance and standards of medical products, including labs (2) Good regulatory practices including GMP, GDP etc (3) Vigilance for medical products and (4) Information sharing platform. India is actively engaged in the SEARN in a move to increase access to high-quality medical products in WHO Member countries in the South-East Asia Region.

The African Vaccine Regulatory Forum (AVAREF) is a regional regulatory network founded by WHO in 2006, at a time when the focus on clinical trials of vaccines began to shift from developed countries to developing countries, including those in sub-Saharan Africa. Developing Countries Vaccine Regulatory Network (DCVRN) provide an avenue for the increasing number of multi-regional or global trials.52

The AMRH Program is a partnership initiative formalized in 2009 and launched throughout the East African community in 2012 (Tanzania, Uganda, Kenya, Burundi, Rwanda). The main objective of the AMRH program is to create regulatory mechanisms that are effective, efficient and transparent to achieve faster approval and subsequent availability of the products in various African markets.

The WHO Collaborative procedure is collaboration between the WHO Prequalification of Medicines Program (WHO/PQP) and interested NMRAs. This procedure can be used for the assessment and accelerated national registration of WHO prequalified pharmaceutical products. Applicants interested in registration in two or more EAC Member States can submit product registration dossiers through the EAC Joint Assessment Procedure. This

procedure entails joint assessment of selected medicinal products and joint inspection of their respective manufacturing site(s) by designated assessors.\textsuperscript{53}

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use became an association under Swiss Law upon the finalization of the Articles of Association in year 2015.\textsuperscript{54}

**The objective of the session is 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:
- 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

**Questions to spur thinking**

1. How can increased efficiencies in the national regulatory authorities lead to improved access to medical products?
2. What should the national regulatory authorities do to increase efficiencies for improved access to medical products?
3. What role should the regulatory networks play to ensure access to medical products nationally and internationally?
4. What aspects need to be put in place by national regulatory authorities for world class standards?

\textsuperscript{53} \url{http://apps.who.int/medicinedocs/documents/s20130en/s20130en.pdf}
\textsuperscript{54} \url{http://www.ich.org/home.html}
Session Brief- Plenary Session 4: Global Models for High-end Manufacturing of Medical Products

The Indian pharmaceutical industry is a world leader in bringing generic drugs to the market in a cost-effective way. More recently, Indian pharma companies have demonstrated the capability to develop bio-similars for global healthcare markets. The start-up culture has gained a lot of momentum in the country in recent couple of years. The country has more than 200 SEBI registered funds and 68 incubators, including government supported and private ones. The start-ups companies backed up with intellectual knowledge generated through sustained R&D efforts are now picking up in India. Inter ministerial co-ordination is the key enabler in the ecosystem that has to be in place.56.

The Government through Department of Biotechnology is investing substantially on collaborative programmes like Stanford India Biodesign programme (SIB) and School of International Biodesign to boost medical technology innovation in the country. These programmes are creating medical technology innovators, multiple innovative medical device technologies and start-ups which are making huge impact.

Atal Innovation Mission (AIM) is Government of India’s endeavour to promote a culture of innovation and entrepreneurship. NITI Aayog supports creation of incubators for promoting start-ups and aspiring innovators in various sectors through funding to Atal Incubation centers created under AIM.

BIRAC through its various programs is already facilitating research and innovation and to complete the 360 degree start-up facilitation, setting up of First Hub is envisaged. BIRAC is also facilitating “Testing and Standardisation of Medical Devices” in collaboration with KIHT. National Capital Region-Biotech Science Cluster (NCR-BSC) where Translational Health Science and Technology Institute (THSTI) is a partner in the National Institute of Immunology (NII), National Brain Research Centre (NBRC), National Institute of Plant Genome research (NIPGR), Regional Centre for Biotechnology (RCB). There is clustering for multi-disciplinary integration-domain knowledge in biosciences to products, Pooling of resources and facilities, Operational connectivity and synergy where biotech sciences are exploited for accelerated technology and product development to nurture and promote innovation for world class—innovation, translational capacity, entrepreneurship.

Kalam Institute of Health Technology (KIHT) aims to facilitate focused research on critical components pertaining to medical devices by supporting institutions involved with R&D, industry, policy makers and knowledge repositories. The mandate and work of KIHT cuts across different departments of the GoI. More than 65% of MSMEs have in-house R&D set-up, however their vision and landscape is limited.

Regulatory Context is different in different Medical Products. Medicines are relatively well established, vaccines are well established ‘closed’ system, diagnostics and devices are developing. Promoting local production of high quality medical products is an immediate requirement for India and other developing countries from a public health perspective.57

The Indian Pharmaceutical Industry is endowed with significant potential to transform the public healthcare system and to make country the leader in ‘Global Generics’. The Indian

55 http://psa.gov.in/high-tech-manufacturing-startups
56 http://psa.gov.in/recommendations
57 http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf
industry supplies nearly 20% of global generic medicines making it the largest supplier in the world. Based on a survey undertaken with the support of WHO during 2014-2017 to study the capacities of Indian pharmaceutical enterprises, it has been felt that the Indian Micro, Small and Medium Enterprise (MSME) sector has significant potential to upscale the manufacture of medical products; and enable India to contribute to the global agenda of access to affordable medical products. It has also been discussed that requisite hand-holding is required in order to leverage the true potential of the Indian MSME sector for facilitating access to quality pharmaceuticals.

The objective of the session is 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

Questions to spur thinking

1. What kind of knowledge networks can be promoted for facilitating scientific cooperation, coordination of activities, information exchange, exchange of expertise and implementation of joint projects?
2. What are the different kind of mechanism and models including e-Auction platform/repositories in scope for transfering medical device technical knowledge from research institutes, start-ups, innovators to industries and establishing good connections with health technology stakeholders?
Session Brief-Parallel Session 5: Standard Setting and Quality Benchmarks for Medical Devices and Diagnostics in National and Global Markets

Medical devices contribute to the attainment of the highest standards of health for individuals. Medical devices are health technologies that include: in vitro diagnostics, any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease, or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices and providing information by means of in-vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means\textsuperscript{58}.

Medical devices are required to achieve SDG3: universal health coverage, including financial risk protection, access to quality essential healthcare services. The National Health policy 2017\textsuperscript{59} clearly recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India.

WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices\textsuperscript{60} recommends guiding principles, harmonized definitions and specifies progressive, or stepwise, approach to regulating the quality, safety and performance of medical devices. The understanding of standards systems, the standards development process and their use in conformity assessment has become essential in establishing medical device regulations.

The Medical Device Rules 2017\textsuperscript{61} are effective from 1\textsuperscript{st} day of January, 2018. India with introduction of Medical Device Rules (MDR), 2017 has introduced a risk based classification system in line with WHO and GHTF recommendations. They have been harmonised with the international regulatory practices. Two Support Cells have been launched for WHO PQS for IVDs in India for providing guidance to the Indian manufacturers for the WHO Prequalification of In Vitro Diagnostics Programme in India i.e. National Institute of Biologicals in North India and Andhra Med-tech Zone in south India.

The objective of the session is to discuss the following:
1. International and national standard setting in medical products for quality and safety
2. 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.
3. Regulatory Landscape Reforms for Medical Devices and Diagnostics in India
4. Factors necessary for developing Ecosystem for Quality Diagnostics and Devices
5. Promoting Quality through Standard setting in Medical Products
6. Critical Support by Labs for Quality Diagnostics to promote access

\textsuperscript{58} http://www.who.int/medical_devices/full_deffinition/en/
\textsuperscript{59} http://164.100.158.44/showfile.php?lid=4275
\textsuperscript{60} http://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/
\textsuperscript{61} http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E(1).pdf
Questions to spur thinking

1. What are the factors necessary for developing Ecosystem for Quality Diagnostics and Devices?
2. How to Develop quality benchmark mechanisms for innovative medical devices and diagnostics for which no international quality standards exist (such as CE/ BIS certifications) for access in global markets?
3. How to leverage provisions of the BIS Act, 2016 in conjunction with the Drugs and Cosmetics Act, 1940?
4. How to facilitate industry specific quality standards and benchmarks in consonance with national and international best practices?
5. How “Centers of Excellence” for product development, validation, and design improvement lead to improving access to medical device industry and establishing technical and financial frameworks for such initiatives?
Session Brief-Parallel Session 6: Medical Diagnostics- Promoting Health For All

Essential diagnostics are defined as diagnostics that satisfy the priority health-care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy and comparative cost effectiveness. The initiative to develop a List of Essential In-Vitro Diagnostics (EDL) to improve access to diagnostics including In-Vitro diagnostics (IVDs) and to guide safe and rationale use of medicines in concurrence with National List of Essential Medicines. In vitro diagnostics are defined as devices which, whether used alone or in combination, are intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. It includes reagents, calibrators, control material, test kits, etc.

Diagnostic tests are a key component of health care, an essential human right, creating evidence for the practice of medicine for both diagnosis and prognosis. Access to good quality, affordable and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations-the three strategic priorities of the World Health Organization (WHO) Thirteenth General Programme of Work 2019–2023. Without access to In-vitro diagnostics (IVDs), health providers cannot diagnose patients effectively and promptly or provide appropriate treatments.

In a path breaking development, 40 years after publishing the first Essential Medicines List, the World Health Organization (WHO) just published the first Essential Diagnostics List. The WHO EDL will prove invaluable as a guide for countries to establish national EDLs. EDL will provide a robust evidence base for improved health care delivery through improved patient care, greater capacity to diagnose diseases during outbreaks, increased affordability of tests, improved regulation and quality of diagnostic tests and strengthened capabilities of national laboratories.

EDL requires an integrated, connected, tiered laboratory system, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems.

The Ministry of Health and Family Welfare, Government of India under the aegis of National Health Mission launched the Free Diagnostics Scheme in July 2015. Under this initiative, the National Health Mission is supporting all States to provide essential diagnostics – Laboratory and Radiology at their public health facilities, free of cost. Different States are adopting different models for implementing this initiative. India is the first country to ever begin the process of developing a National diagnostic list and this is a huge step in the direction of improving Indian Healthcare system.

EDL will be a driver for innovations for diagnostics in India. With the upsurge of “Make in India”, this list will help sensitize the R&D sector of the country to develop quality Point of Care tests for the primary healthcare settings. EDL should be accompanied by the target product profile for tests in the EDL for various settings in Indian healthcare settings.

63 2 Global Harmonization Task Force (2012). Definition of the terms medical device and in vitro diagnostic (IVD)
medical device (http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-ofterms-120516.pdf#search)
64 http://apps.who.int/ebwha/pdf_files/EB142/B142_3-en.pdf
65 http://www.who.int/medical_devices/diagnostics/EDL_ExecutiveSummary_15may.pdf
The objective of the session is to discuss on:

- 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

Questions to spur thinking

1. Will having the Essential Diagnostic Lists in countries promote the access to quality and affordable diagnostics?
2. Should there be standard diagnostic workflows to guide appropriate diagnosis and timely and targeted treatment guided from diagnostics?
3. How can the information sharing platform of SEARN be leveraged for collaboration and exchange of best practices at national and international levels?
4. Develop network for collaboration of labs through SEARN for quality diagnostics
5. Promote innovative approaches for collaborated research on diagnostics: the CSIR; ICMR; IMTECH; NIPER experience
Session Brief- Parallel Session 7: Promoting Health and Wellness through Traditional Medicine

Traditional medicine (TM) is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness$^{68}$. TM is used interchangeably with “complementary medicine” or “alternative medicine” in some countries, which refers to a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system$^{69}$.

Realizing the worldwide importance of TM for public health, the WHO TM Strategy 2002–2005$^{70}$ was developed for the Member States with four key objectives: (i) policy - integrate TM within national health care systems, where feasible, by developing and implementing national TM policies and programmes; (ii) safety, efficacy and quality - promote the safety, efficacy and quality of TM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards; (iii) access - increase the availability and affordability of TM, with an emphasis on access for poor populations; and rational use - promote therapeutically sound use of appropriate TM by practitioners and consumers. The 62nd World Health Assembly WHA62.13 Resolution on TM (2014) requested the WHO to update the WHO TM strategy 2002–2005 based on countries' progress and current new challenges in the field of TM$^{71}$. In response to the resolution, the WHO TM Strategy 2014-2023 was developed with the goals of supporting Member States in harnessing the potential contribution of TM to health, wellness and people-centred health care; and promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems$^{72}$.

It is important that medical health care providers increase their awareness and understanding of TM and its use on chronic diseases, especially regarding interactions of specific herbal remedies with conventional medicines$^{73}$. Accumulating evidence supports to further consolidate TM’s scientific base so as to play a bigger part in forging future medicines$^{74}$.

Objectives to be discussed:

1. Role of TM in health & wellness for prevention CDs & NCDs- next steps to TKDL
2. Strengthening the evidence base for innovation & safety in TM
3. Integrating traditional medicine with modern system of medicine for achieving public health goals
4. The role of traditional medicine practice in prevention of Non-Communicable Diseases
5. Strengthening The Evidence Base of medical products through research In Ayurvedic Medicine systems
6. Integration Of Traditional Medicines Into The Health Systems: The Unani Council Experience

$^{68}$ http://www.who.int/traditional-complementary-integrative-medicine/about/en/
$^{69}$ http://www.who.int/global_health_histories/seminars/Dr_Zhangs_Presentation_GHHSeminar_86.pdf
$^{71}$ http://apps.who.int/medicinedocs/en/d/Js21477en/
$^{72}$ http://www.searo.who.int/entity/health_situation_trends/who_trm_strategy_2014-2023.pdf?ua=1
Questions to spur thinking

1) What is the Role of TM in health & wellness for prevention CDs & NCDs
2) How to strengthen the evidence base for innovation & safety in TM
3) How can the modern system of medicine be integrated with traditional medicine for achieving public health goals?
4) To what extent traditional medicine practices play a role in prevention of Non-Communicable Diseases?
5) Is there a need of cross disciplinary standardization and propagation of traditional medicine systems globally?
6) How to strengthen relevant policy and regulations for TM products, practices and practitioners?
Session Brief Parallel Session 8: Developing Efficiencies in Clinical Trials in Global, Regional and National Settings

Clinical trials are required to assure the safety and efficacy of the health-related products. Clinical trials are also the biggest R&D expense. Clinical trial sponsors and scientists are guided by national laws and non-binding professional ethical standards for research involving human subjects but trials are not only conducted in the country where the product is discovered or developed and the health technologies are used around the world. The Ministry of Health and Family Welfare of Government of India has released draft Clinical Trial (CT) Rules 2018, the new rule will be applicable to all new drugs, investigational new drugs for human use, clinical trial, bioequivalence study, bioavailability study and ethics Committee. The proposed draft clinical trial rules cover the full spectrum of clinical trial activities, from ethics committees and manufacturing permissions to inspections and injury compensation. Publication of the draft rules marks an important step in India’s attempts to codify its approach towards clinical trials.75

The United States Food and Drug Administration (FDA) in 2004 have introduced a strategic path Initiative modify the way drugs are made and introduced into the market. This initiative encompasses the implementation of adaptive design clinical trials. The design allows investigators to assess results on a real-time basis, changes can be easily made to enhance the probability of a positive result.76

The ICTRP is a network of Primary Registers, which has been developed by the WHO. The mission of the WHO's ICTRP is to ensure that a complete view of research is accessible to all those involved in health care decision making. The Clinical Trials Registry- India (CTRI), hosted at the ICMMRs National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched in 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India). Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHOs search portal, the ICTRP as well as from the CTRI.77

Multi-regional clinical trials (MRCT) have emerged as a tool to achieve the objective of reducing the time lag of launch in various markets and improve patient access to new and innovative treatments. The rise of multi-regional clinical trials (MRCTs) has led to several harmonization initiatives between ICH (International Conference on Harmonization) member countries and non-ICH member countries to streamline the trial process78.

The Clinical Trials Transformation Initiative (CTTI) co-founded by the USFDA and Duke University has been instrumental in working on incorporating patients as partners in clinical trials and new technologies for future clinical trials.79

The objective of the session is to discuss-

75 http://cdsco.nic.in/writereaddata/GSR%2020104(E)20dated%2001_02_2018_New%20Drugs%20&%20Clinical%20Trial%20Rules,%202018.pdf
76 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2422839/
77 http://www.who.int/ictrp/search/en/
79 https://www.ctti-clinicaltrials.org/
1. Regulatory framework efficiency and Best Practices in Clinical Trials
2. Ethical and Regulatory considerations in Clinical Trials
3. Newer trials methodologies and Promoting the Use of Innovative Designs in Clinical Trials
4. Accreditation of Ethics Committees in the Context of Clinical Trials: The India Experience
5. Quality Manufacturing to Meet National and Global Vaccine Needs
6. Disclosure of Clinical Trials Results by Stakeholders: Clinical Trial Registry of India Experience
7. Strategies to Accelerate Access to High Quality Bio-similars for Global Patients

**Questions to spur thinking**

1. What innovative trial designs could be explored to advance drug development?
2. What could be the expedited regulatory review pathway for trial approvals in case of emergencies, rare disease and orphan drugs?
3. Is there a need for the paradigm changes in the ways clinical trials are conducted nationally and internationally to shorten timelines and foster access to medical products?
4. How can the multiregional clinical trials be leveraged for faster clinical trials?
5. Identify methods for medical technologies for quicker access in markets with a targeted post approval safety monitoring?
6. What are the Ethical and Regulatory considerations in Clinical Trials and what aspects should be considered during Accreditation of Ethics Committees?
7. Can shorter clinical trials promote faster entry of medical products in the market with strong post market vigilance system in place?
Neglected tropical diseases (NTDs) are a diverse group of communicable diseases that prevail in tropical and subtropical conditions in 149 countries, affect more than one billion people and cost developing economies billions of dollars every year. Populations living in poverty, without adequate sanitation and in close contact with infectious vectors and domestic animals and livestock are those worst affected. At present, the WHO NTD portfolio includes 20 diseases including dengue, chikungunya, leprosy and leishmaniasis. Global Burden of Disease (GBD), a tool to quantify health loss has revealed a geopolitical dimension of the major NTDs. India experiences the world’s largest absolute burden of at least 11 major NTDs and also leads the world in terms of the total number of cases for each of the major NTDs, as defined by WHO. The WHO NTD Roadmap on neglected tropical diseases (2012), sets forth several targets and implementation of appropriate measures aims at elimination of many NTDs and the eradication of at least two by 2020.

Drugs for Neglected Diseases initiative (DNDi) is a collaborative, patients' needs-driven, non-profit drug research and development (R&D) organization founded in 2003 and is developing new treatments for neglected diseases. DNDi has been working with the objectives of developing treatments for people suffering from NTDs, influencing the R&D landscape for NTDs and strengthening research capacity in low- and middle-income countries.

In addition to NTDs, a separate category of health disorders – Rare Diseases also need consideration with respect to access and affordability of their treatment regime. The definition of rare diseases varies across jurisdictions and typically considers disease prevalence, severity and existence of alternative therapeutic options. 'Rare disorders' is the name given to the diseases, of very varied aetiology, whose common denominator is that they are low-prevalence diseases, and for the majority of which there is no treatment available. Orphan product is a drug, biologic, device or medical food that is used for the prevention, diagnosis, or treatment of a rare disease.

Regardless of the need and importance of access to orphan drugs, there is a paucity of available treatments for rare diseases. Further, rare diseases which have available treatments are highly cost intensive and out of reach of common man, particularly in the low and middle-income countries. Less than one in ten patients with rare diseases receives disease-specific treatment.

The common issues faced during the drug development process of rare diseases are less understood pathophysiology, lack of validated preclinical models, less research, and lack of standard comparator drugs. Clinical issues pertain to limitations in conducting clinical trials for orphan drugs and include lack of information about natural history of the disease, poorly defined endpoints, poor trial designs and inadequate sample size, recruitment problems,
lack of well-defined diagnostic criteria, and other issues such as non-existent comparator drug and funding problems.\(^\text{89}\)

India has also been actively working towards devising strategies to make drugs for orphan and rare diseases accessible and affordable to the populations at large through stakeholder consultations. Efforts are underway to explore possibility of providing separate pricing mechanism, custom duty exemption and cheaper medicines for patients with rare diseases, and to have revised timelines for orphan drug approvals.\(^\text{90}\) Indian Council of Medical research (ICMR) has initiated two programmes viz. The National Initiative for Rare Diseases (NIRD) and disease for supporting programmes on rare diseases; and “Indian rare disease registry” launched in 2017 to cover all rare and ultra-rare diseases prevalent in India. The objectives of the registry are identification of the rare disease patients; use that data for policy framing and to guide future research.\(^\text{91}\)

**The objective of this session is to discuss:**

1) FDA Role in Facilitating Access of Medical Products for Orphan and Rare Diseases
2) Provide an update of the work being undertaken by agencies such as DNDi for NTDs – the challenges and their redressal.
3) European Public Health Alliance Contribution for Universal Access and Affordable Medicines
4) Timely Access to Innovative Drugs but with Affordable Prices
5) Pricing Policy and Local Manufacturing for Affordable Medicines
6) Orphan Drugs Tax Credits and Cost of Clinical Trials
7) Development of Indian Priority Pathogen List (IPPL) of Antibiotic-Resistant Bacteria to Guide Research, Discovery and Development of New Antibiotics

**Questions to spur thinking**

1. What has been the contribution of public health alliances in access to affordable medicines, with focus on neglected and rare diseases?
2. What are different national regulation initiatives for orphan and rare drugs?
3. How could industries be encouraged to undertake R&D and production of orphan drugs?
4. What are the existing policy initiatives that aim at delinking the costs of R&D for neglected and rare diseases?

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\(^{89}\) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5754932/

\(^{90}\) http://www.ijp-online.com/article.asp?issn=0253-7613;year=2017;volume=49;issue=4;spage=267;epage=269;aulast=Kumar

\(^{91}\) http://bmi.icmr.org.in/irdr/index.php
Session Brief-Plenary Session 5: Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards

From treatments for neglected and orphan diseases to antibiotic innovation, the failings of today’s pharmaceutical R&D system are often characterized as market failures. These market failures result, we are told, from the imbalance of risk and reward. The solutions typically call for more funding that would ensure greater returns, and therefore incentive, to industry.

Such an approach relies on the traditional model of pharmaceutical innovation. This model banks on public sector support of the basic sciences and the training of a scientific workforce, but leaves it to the private sector to bring new drugs to market. Public funding has been structured to reinforce this division of duties. The European Union’s Innovative Medicines Initiative focuses on precompetitive inputs to R&D. The US NIH’s National Center for Advancing Translational Sciences is limited, by statute, in how it may support phase 3 clinical trials. The market failures suggest though the need to bridge gaps in these arrangements.

Over the past couple decades, product development partnerships have begun to show how these entities funded by public sector monies can shepherd treatments for neglected and orphan diseases to market. These efforts are still fledgling and have sometimes built upon products already on the market or under development. Still PDPs have demonstrated that R&D costs can be significantly lower than in the private sector. The Open Source Drug Discovery Initiative for TB, led by India’s CSIR, also sought to forge an alternative pathway for bringing drugs to market. In the United States, concerns even over generic drug pricing have recently prompted four large health care systems to announce efforts to create their own generic drug company.

Private sector R&D costs to bring a new drug to market have climbed, most recently to $2.6 billion. Just under half of this figure is the cost of capital, assessed at 10.6% per year, compounded over the 10-15 years of drug development. Purportedly, drug companies depend primarily on equity financing, but questions have arisen as to why other sources of capital at lower discount rates might not be substituted. In the end, the public pays every dollar of drugs purchased. The strategic question is whether we should pay now or pay more later. Upfront investments, such as push incentives that pay for inputs of R&D, assume greater upfront risk by the public sector, but later investments, such as pull incentives that pay for outputs of R&D, include all those costs, plus discounting. Put in perspective, discounting can so significantly erode the value of what the public sector invests that a push incentive can be 95% smaller than a pull incentive like extended exclusivity, but still have a greater impact on present value in a financial model.

The financial model by which we bring new drugs to market needs to be revisited. As a theme for the Second World Conference on Access to Medical Products, it provides a strategic organizing focus for discussions. How should capital for R&D be sourced, and where might it be best deployed to make a catalytic difference in bringing drugs to market that meet public health priorities? How can we ensure that the innovation ecosystem focuses on these priorities? How can the process of innovation supported be not only for disease-endemic countries, but also by disease-endemic countries? How can life-saving medicines be affordable to those in need, and how can we insist on fair returns on publicly funded research?
We might begin these discussions by examining the 3Rs—sharing resources, sharing risks and sharing rewards. Each of these suggest operating principles by which we might benchmark potential solutions as we consider how to financially reengineer the way we bring new drugs to market.

In sharing resources, the conference might discuss how innovation platforms could be constructed. An open science platform might lower the barriers to entry to a diverse range of potential contributors to pharmaceutical R&D. Such platforms might enrich compound libraries with natural products from the rich biodiversity and traditional knowledge found in low- and middle-income countries; support benefit sharing arrangements and pooled intellectual property to enable access to the building blocks of knowledge; and create the enabling environment for sharing information more freely in developing new drugs. From the Structural Genomics Consortium to the work of PDPs like Drugs for Neglected Diseases Initiative, case studies might suggest how to reshape pharmaceutical R&D. The conference could also invite select speakers to float new proposals for doing this.

In sharing risks, the conference might explore whether the equity financing that drug companies rely upon really commands such high discount rates. How might capital from sources like pension funds commanding much lower interest rates be accessed? Importantly, how could public sector investments change the risk of return on such capital, and in so doing, help to lower the need for high-priced drugs as a source of that return for companies? Could alternative sources of capital de-risk the R&D process? The work of patient disease foundations for orphan diseases and product development partnerships for neglected diseases can help us understand what is the true opportunity cost of capital. The conference could invite experts to share what this financial reengineering of the pharmaceutical R&D system might look.

In sharing rewards, we could explore how best to prioritize and lay down bets with public sector funding. In so doing, how might a portfolio approach be followed to limit the risks taken by any single investor in bringing a new drug to market? In what ways can public sector monies broaden the range of bets we might place, and at the same time, improve the likelihood of returns? A diversified portfolio—with a mix of high-risk and low-risk candidates—can average out to a risk level that draws in non-traditional funders of pharmaceutical R&D. We could unpack the proposals of those who would have the public sector buy options in these companies to those who have proposed a mega-fund to pursue a diverse portfolio of drug candidates.

Each of these areas suggests a potential work stream that might culminate in productive discussions on Access to Medical Products. Collectively, the 3Rs have the potential to transform how we innovate, bring new drugs to market, and ensure that public health priorities are met with affordable end-products.

A new analysis has found that many of the products critically needed to fight some of the world’s most prevalent infectious diseases are not likely to be developed based on current candidates in the research & development (R&D) pipeline, and reveals significant gaps in funding for health innovation. Global health R&D analysis reveals major gaps in critical tools and funding.

Researchers report that about 500 products already in development are estimated to cost about US$ 16.3 billion to complete, with three-quarters of those costs coming in the first five years, and would result in about 128 expected product launches.
The study also identifies 18 high-priority missing products in the pipeline, including vaccines against HIV, tuberculosis (TB), malaria and hepatitis C; a combined vaccine against multiple diarrheal diseases; and, new drugs for TB and 12 of the most neglected tropical diseases.92

The Consultative Expert Working Group (CEWG) on Research and Development had also 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. In the case of developing countries, the market failure which intellectual property rights try to correct is compounded by a lack of reliable demand for the products generated by research and development (R&D). Thus the incentive offered by intellectual property rights fails to be effective in correcting the market failure.93

At every stage from bench to bedside, important efforts to reengineer how we finance the development, delivery and access to health technologies give us hope of a future where the needs of all patients requiring treatment will be met.

The objective of this session is to discuss the following:

1) Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards
2) Approach To Equitable Access To Healthcare Interventions
3) Role of Product Development Partnerships for Access to Health Technologies
4) Rational Use of Antibiotics Implemented though the Swedish Strategic Programme for Antibiotic Resistance
5) Bringing Better Healthcare To People In India-Role Of Health Technology Assessment

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93 http://www.who.int/phi/CEWG_Report_5_April_2012.pdf
The Lancet commission located essential medicines policies within the context of current global debates about balancing trade and intellectual property policies with human rights, assuring health security, strengthening people-centred health systems, and advancing access to essential technologies\(^94\). There is a need for MNCs to invest in R&D activities of domestic pharmaceutical companies engaged in producing generic drugs; the quality of such drugs must be high to meet demand from domestic and foreign consumers. In order to produce such high quality products, domestic firms should be more innovative and must invest more on R&D activities to increase their productivity levels. The government incentives such as tax benefits and grants help in promoting R&D activities\(^95\).

The Bayh--Dole Act encourages private-sector investment to turn basic government-funded biomedical research into tested and approved products, which requires these products to be manufactured domestically and ensures royalties for universities to further advance basic research and education\(^96\). The Bayh--Dole Act was passed in 1980 to accelerate the dissemination and commercialization of new knowledge produced in universities\(^97\). One of the major concerns posed is that patents may drive prices of essential medical products out of reach for some consumers in the developing world\(^98\). For instance, patients in sub-Saharan Africa pay higher prices for a first-generation HIV treatment patented by Yale\(^99\).

New partnerships are emerging such as Global Antibiotic Research and Development Partnership (GARDP), a non profit entity, a joint initiative by the Drugs for Neglected Diseases initiative and World Health Organisation\(^100\). The aim is to develop novel antibiotics, focusing on R&D gaps as well as to promote their responsible use and ensure equitable access. The global community now recognises the seriousness and growing threat of AMR. There is minimal overreaching guidance and coordination across the active R&D initiatives which have become the key reason behind the significant gaps in the incentive structure and unaddressed public health priorities. At a national level, countries need to adjust their funding commitment to spurring antibiotic innovation in a way that more accurately reflects the unrelenting global emergency of AMR\(^101\).

India has initiated steps, to promote biotechnology industry by taking initiatives aimed at providing facilities for accelerated commercial development of Biotechnology. With large number of multinational and bio-pharma companies initiating their R&D and manufacturing operations in India, the demand of biotech incubators has increased. Both Central and State Governments are making their earnest efforts to promote biotechnology activities in the country by setting up biotechnology parks, incubators through public private partnership. DBT has supported the following biotechnology parks and incubation centres located in different states for the promotion of Biotech start-up companies and the promotion of Public Private Partnerships\(^102\).

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\(^95\) [https://mpra.ub.uni-muenchen.de/75925/1/MPRA_paper_75925.pdf](https://mpra.ub.uni-muenchen.de/75925/1/MPRA_paper_75925.pdf)  
\(^96\) [https://www.bio.org/sites/default/files/BIO_Bayh_Dole.pdf](https://www.bio.org/sites/default/files/BIO_Bayh_Dole.pdf)  
\(^97\) 35 U.S.C. §§ 200-212  
\(^99\) [https://academic.oup.com/jlb/article/4/2/282/3778309#97294700](https://academic.oup.com/jlb/article/4/2/282/3778309#97294700)  
\(^101\) [https://www.nature.com/articles/ja2017124](https://www.nature.com/articles/ja2017124)  
Objectives to be discussed:

- 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

Questions to spur thinking

1. How often do research institutions seek patent protection for their inventions on medical products?
2. How to engage with different stakeholders to achieve the common objective of promoting public health?
3. What are effective measures to address AMR in developing countries?
4. How to develop and build strong implementation strategies to promote innovation and promote health technologies in developing countries?
Session Brief-Parallel Session 10: Partnering for Access to Medical Products-
Bilateral treaties and Regional Agreements

The policy coherence between the trade and health are important to achieve national objectives of public healthcare\textsuperscript{103}. The developed country partners in Bilateral and Regional trade agreements mostly with developing countries, with the idea of same IP law as they were having; such laws are beneficial to a developed country since the national legislations are based on its techno economic development. The access to the markets of the developed countries is the driving force behind bilateral Free Trade Agreements for developing and least developed countries\textsuperscript{104}. It is crucial to leverage the power of partnerships to promote global health for a focused health systems to strengthen population health. These collaborations can be achieved through strategic alignment among stakeholders at all levels of the health partners for improving population’s health globally\textsuperscript{105}.

Certain bilateral and regional trade agreements encourage flexibility in the protection of pharmaceutical patents which enables the government to ensure drug affordability. Multilateral trading rules, GATS and TRIPS are relevant to the health care services as they regulate health related services as well as the trade and production of medicines\textsuperscript{106}. With growing expansion of social, economic and political determinants of health, health diplomacy becomes focused on coherence between different sectors, which makes the multisectoral dimension as an integral element of multilateral negotiations for health\textsuperscript{107}.

The IP provisions in Bilateral and Regional Agreements should be sufficiently flexible to consider the socio-economic condition and needs of both parties which is imperative where legal norms from the domestic system of the IP-demanding country are included in the agreement. The public interest-related flexibilities included in TRIPS should not be undermined as these norms provide policy space in domestic implementation\textsuperscript{108}.

TRIPS flexibility ensures access to affordable essential medicine. Thailand in its Global Health Strategy has signed 12 regional and bilateral free trade agreements and is in the process of negotiating for more agreements to maximize health benefits. The main aim is to focus on key issue:

- Ensuring inclusive and stronger collaboration for balanced trade policy where the health concerns are taken into account when developing trade policy trade; hence a need for trade and health policy coherence
- Generating timely and concrete evidence to support the formulation of trade policy taking into account health aspects and concerns
- Supporting the role of agencies such as MoPH in the International Economic Policy Committee, the International Trade Development Committee and for public education

The impact has been evidence based related to policy decisions and trade negotiations towards trade and health policies for better health outcomes\textsuperscript{109}.

\textsuperscript{104} https://www.scidev.net/global/policy-brief/trips-and-its-impact-on-developing-countries.html \textsuperscript{: TRIPs and its impact on developing countries}
\textsuperscript{105} https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0366-5
\textsuperscript{106} https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122739
\textsuperscript{107} https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5759719/
\textsuperscript{108} IIC 2017, 48(7), 760-783: Do developing countries have a say? Bilateral and regional intellectual property negotiations with the EU
\textsuperscript{109} http://www.searo.who.int/thailand/areas/ghd/en/
The trilateral cooperation between WHO-WTO-WIPO has focused on access to medicines and encouragement of research and development for availability of new medical technologies\(^{110}\). It ensures accessibility of medicines and health products involves affordable prices, properly designed health systems, suitable financing in the developing countries. The cooperation responds to an increased demand in developing countries for strengthening capacity of informed policy making in areas of intersection between health, trade and IP focussing on access to innovation of medicines and related technologies. Each country should resort to informed policy choices with targeted strategies. The fair and equitable interpretation and implementation of trade agreements is needed to address intellectual property and public health\(^{111}\).

**Objectives to be discussed:**
- Develop systems and approaches for Access to Medical products in Free Trade Agreements
- TRIPS Flexibilities since Doha Declaration since 2001
- Engagements 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.

**Questions to spur thinking**
1. How to improve the policy coherence on trade, health and intellectual property for access to medical products?
2. How to ensure better health outcomes in FTA agreements?
3. What are the measures to build synchrony between the national trade and IP policy to facilitate affordable access to medical products?


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

The pandemics of non communicable disease (NCD) require an urgent attention; it accounts 41 million deaths every year posing an imminent threat which is sweeping the entire globe. Around 85% of premature deaths occur due to the predominance of non communicable diseases more in low and middle income countries, the prolonged condition will lead to burdened health systems and hindrance to the nation building112.

The NCD are posed with governance challenges, the factors are affected population and its effective actions required by multi sectorial cooperation. Such approach to health needs to create a synergy across regulating agencies and requires a whole-of-government action. Flexible partnerships across government and non-government actors at both the national and international level have been incommensurate to the growing threat of NCD113.

The law needs to influence risk factors for NCDs by the following ways: health infrastructure and governance; shaping the informational environment; creating economic incentives and subsidies; designing or altering the built environment; addressing health inequalities through economic policies; and command and control regulation, i.e. directly regulating persons, professionals, businesses and other organisations114.

On a national level these challenges could be safeguarded by including stricter food labelling laws, guidelines on food advertisements, tax incentives for healthy lifestyle choices, stringent regulations on food and drinks producers115. These interventions rely on legal and regulatory reforms which are either on fiscal policies and their implementation will depend upon law or statutory instruments and requires government agencies to play a key role in monitoring and enforcement. Besides the legal governance controlling NCDs, a comprehensive approach to healthier lifestyle includes community-based programs on health promotion and its remedial measures in the primary healthcare centres116.

To address the growing health disparities, support on R&D for improving health in developing countries is urgently required. The consultative expert working group (CEWG) on R&D Financing and Coordination at WHO suggested the need for alternative models to fund and incentivize R&D, supported by a global normative R&D framework that would deliver both innovation and access, underpinned by certain key principles and a pooled R&D fund117.

India became one of the first countries in the world to adapt the UN mission to prevent and control the non communicable disease118. Government of India has taken initiatives lead and steered by Ministry of Health through various missions and programmes. The Ministry of Health and Family Welfare of Government of India through National Health Mission organized Universal Health Coverage in 2017 to discuss about aspects of financing the health and strengthen the primary healthcare facilities in India119.

112 http://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases
113 22 Annals Health L. 224
114 https://www.rsph.org.uk/uploads/assets/uploaded/18165127-73a3-4c7a-8eb01fd5b791e5b1.pdf
116 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4077679/
117 http://www.who.int/phi/CEWG_Report_5_April_2012.pdf?ua=1
118 http://www.who.int/CEWG_Report_5_April_2012.pdf?ua=1
119 www.nhm.gov.in
Objectives to be discussed:

- 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

Questions to spur thinking

1. What legislative measures may promote nutrition standards for preventive action for NCDs?
2. What policy actions are necessary for promoting licensing for newer anti-cancer and anti-diabetic medicines?
3. What are the legal interventions to ensure affordable and availability of access to medical products in NCDs?
4. What are the methods to strengthen implementation and enforcement of global research collaboration to promote public health against the pandemics of NCDs?
The TRIPS Agreement recognizes the significance of the IP system for innovation, providing (in Article 7) 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”120. The national IP systems play a significant role in helping the innovators gain and retain an innovation-based advantage through IPR protection. This has high relevance in the healthcare domain wherein technological basic or fundamental innovations produce new markets for a new medical product; and incremental innovations lead to improved products121. The main benefit claimed for strong IPR protection is that by allowing innovators to appropriate a share of the benefits of their creative activities, R&D is encouraged, which leads to innovation and higher long-run growth. Further, it has been observed that IPR protection can encourage domestic innovation in countries that have significant domestic capacity for innovation, but that it has little impact on innovation in countries with a small innovative capacity122. This essentially signifies that IPR protection is a potential driver promoting innovation and needs to be leveraged for drug discovery and product development of medical products.

IP rights provide the holder with several opportunities, which facilitates successful completion of the life cycle of an innovation. Such opportunities include technology transfer, sale, licensing, and various types of strategic partnerships or alliances in commercializing it123. The provisions under TRIPS Agreement also advocate that one of the purposes of protecting IP is to promote innovation and technology transfer, and it requires developed countries’ governments to provide incentives for their companies to transfer technology to least-developed countries124. While IPR are incentives for investment and innovation, Competition Law aims at promoting economic efficiency; and preserving the competitive framework as the most appropriate means to ensure the efficient allocation of economic resources125.

While IPR protection promotes innovation, technology transfer and collaborations for facilitating access to quality medical products for all, one of the healthcare sectors – traditional medicine needs to be discussed in light of its geographical, cultural and ethnic aspects. Traditional medicine (TM) is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness126. TM is based on genetic resources which exist in nature and are not creations of the human mind, they cannot be directly protected as IPR127. TM is also subject to access and benefit-sharing regulations under international agreements128. The World Intellectual Property Organization (WIPO) is primarily concerned with “protection” of traditional medical knowledge through different tools of IPR for protection against unauthorized use by third parties129. Negotiations currently

120 https://www.wto.org/english/tratop_e/trips_e/innovationpolicytrips_e.htm
124 https://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm
126 http://www.who.int/traditional-complementary-integrative-medicine/about/en/
128 https://www.cbd.int/abs/
underway in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) seek to develop an international legal instrument that would provide effective protection of traditional medical knowledge, and address the IP aspects of access to and benefit-sharing of genetic resources\textsuperscript{130}.

The criteria that need to be satisfied to obtain a patent are set out in the national legislations on Intellectual Property and may differ from one country to another in respect of inclusions and exclusions\textsuperscript{131}. The developed countries of the world, being front-runners in technology development, obtain IP protection on platform technologies in healthcare which creates barriers for access to the technologies by developing countries. The IP protection of such technologies also leads to manifold increase in their cost and therefore, affects their affordability to the developing world. Since the healthcare needs are of prime importance for human kind across the globe, there is an imminent need to increase the capability of developing countries to manufacture high quality medical products, which would facilitate their access and make them affordable. A balanced and effective intellectual property system is recognized as an integral element of the policy framework that supports innovation\textsuperscript{132}; and for facilitating access to medical products for populations of the country from healthcare perspective. The National IPR Policy of India, 2016 also highlights access to medicines as one of the salient features as access to affordable medicines and other healthcare solutions is becoming a challenge for all countries\textsuperscript{133}. The Policy aims to enhance access by (a) encouraging cross-sector partnerships between public sector, private sector, universities and NGOs; (b) promoting novel licensing models, and (c) developing novel technology platforms.

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.

Questions to spur thinking

1. What role does national IPR policy play in facilitating access to medical products?
2. How does IPR act as a facilitator in promoting innovation in R&D of medical products, technology transfer and collaborations?
3. What are the different mechanisms to foster technology transfer of innovative medical products?
4. How are innovations in traditional medicine protected through IPR and what are the associated challenges?
5. What are the aspects of convergence between IPR and Competition Law?

\textsuperscript{130} http://www.wipo.int/tk/en/
\textsuperscript{131} http://www.wipo.int/ip-outreach/en/ipday/2017/innovation_and_intellectual_property.html
\textsuperscript{132} https://www.wto.org/english/tratop_e/trips_e/innovationpolicytrips_e.htm
\textsuperscript{133} http://dipp.nic.in/policies-rules-and-acts/policies/national-ipr-policy
Annex II: Media Release

Ministry of Health and Family Welfare
Shri J P Nadda inaugurates ‘2nd World Conference on Access to Medical Products: Achieving the SDGs 2030’

India is committed to achieving all public health goals: J P Nadda

“India is deeply committed nationally and globally to achieving all public health goals. Together we are working towards providing highest possible standards of health care for our citizens. Universal health coverage is key to the Sustainable Development Goals 2030 agenda and to which India is firmly committed.” This was stated by Shri J P Nadda, Union Minister of Health and Family Welfare during his address at the inauguration of ‘2nd World Conference on Access to Medical Products: Achieving the SDGs 2030’, here today.

At the function, Shri J P Nadda released the Position Paper and launched the Information Sharing Platform Gateway for South-East Asia Regulatory Network (SEARN) developed by Centre for Development of Advanced Computing, which will promote regulatory and health collaboration among the countries of the South-East Asia Region.

Shri Ashwini Kumar Choubey, Minister of State (HFW), Smt. Anupriya Patel, Minister of State (HFW), Smt Preeti Sudan, Secretary (Health), Dr. Balram Bhargava, Secretary, Dept. of Health & Research (DHR) and DG, ICMR, Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO Geneva, Dr. Poonam Khetrapal Singh, Regional Director, WHO SEARO, Dr RK Vats, Additional Secretary, Health Ministry, and Dr. Henk Bekedam, WHO Representative to India, also graced the occasion. State Health Ministers and Principal Secretaries from several states in India were also present.

Speaking at the function, Shri Nadda said that the National Health Policy 2017 is dedicated to the highest possible standards of health for the country. “The Government has launched Ayushman Bharat, a National Health Protection Scheme, which envisions health assurance of 5 lakh rupees (6815 USD) per family per year, will benefit over 50 crore (i.e. 500 million) people, and is the world's biggest health assurance scheme. He further added that since its launch on 23rd September, 2018, more than 50,000 people have availed of services under the scheme. The Union Health Minister stated that access to medical products and creating an enabling legal and trade environment for public health are critical to achieving the Sustainable Development Goals 2030 Agenda. “These issues require continuous engagement and dialogue. I believe that the Health Ministry with active partnership of other ministries in Government of India will move forward in leaps and bounds,” he said. The Union Health Minister further added that India is actively contributing and providing support for the South-East Asia Regulatory Network (SEARN) to guarantee access to high-quality medical products.

Shri Ashwini Kumar Choubey, Minister of State for Health and Family Welfare highlighted the importance of traditional medical system in achieving the health goals. He stated that strengthening R&D and upholding education standards in the Indian Systems of Medicines, promoting the cultivation of medicinal plants used, and working on Pharmacopoeia standards are areas with positive public health potential outcomes. “The diagnosis of modern medicine combined with the treatment modalities of the Ayurveda, Yoga, Homeopathy and other systems of AYUSH will help in giving a holistic approach to treatment,” Shri Choubey said.
Smt Anupriya Patel, Minister of State for Health and Family Welfare said that Sustainable Development Goals are the mantra for a better future for all and access to medicines is a critical factor for success of the SDG Agenda that aims to ensure healthy lives and promote well-being of all people of all ages. “Universal Health Coverage and access to medicines is also one of the regional flagship priorities for countries in the WHO South-East Asia region,” she added. She stated that India is committed to attainment of the highest possible standards of health for its citizens.

Dr Tedros Adhanom Ghebreyesus, Director General, World Health Organization through his video address stated that WHO has embarked on the 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. GPW 13 is structured around the “triple billion” goal for three interconnected strategic priorities of Healthy Lives, Universal Health Coverage and health emergencies. ‘Reliable access to effective, safe, quality-assured and affordable medical products are keys to making progress towards Universal Health Coverage (UHC) and the SDGs,’ he said.

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, foster new approaches in innovation landscape for medical products and health technologies for accelerating research and innovation and identify knowledge, information and policy options on the interface of international trade and health to achieve SDG 2030 goals.

Posted On: 09 OCT 2018 3:30PM by PIB Delhi
Annex III: Address by Dignitaries

His Excellency Minister Health and Family Mr JP Nadda

Distinguished Ladies and Gentlemen,

I am happy to welcome you all to the “2nd World Conference on Access to Medical Products – Achieving the SDGs 2030”. I also extend a warm welcome my Ministerial colleagues from the various State governments in India. I welcome all the representatives from the Ministries in Government of India, international and national experts, civil society organizations and WHO participants who gather here today for the important deliberations.

As we know, the Conference is a sequel to the “1st World Conference held last year on 21-23 November 2017. The 1st Conference as you may recall was the result of my commitment in the discussions on the United Nations Secretary-General's High-Level Panel on Access to Medicines in 2017 in the 70th World Health Assembly in Geneva. We are continuing our engagement on the very important agenda.

I believe Access to Medical Products and creating an enabling legal and trade environment for public health are critical to achieve the Sustainable Development Goals 2030 Agenda. These issues require continuous engagement and dialogue. I believe that the Health ministry with active partnership of other ministries in Government of India - Science and Technology, Chemicals and Fertilizers, Commerce and Industry, Law and Justice, External Affairs, MSME, Electronics & Information Technology will move forward in leaps and bounds. I congratulate all the ministries on taking the many recommendations from the 1st World Conference forward. I thank all the Ministries for giving a high priority to health goals.

I am sure the 2nd World Conference 2018 will bring further collaborations. The three-day agenda this year will is taking into account the WHO’s 13 Global Programme of Work and the captivating ‘triple billion’ goal announced by the Director General WHO. This is the first time that WHO has population goals in health achievements. India is a country with 1.4 billion people. The Indian people should benefit from the WHO ‘triple billion’ focus. The State Health Ministers’ will also have an opportunity to discuss and consider new ways to bring health outcomes to their people.

I am also happy to see the wide spectrum of issues being taken up in the technical agenda. Strengthening Regulatory networks are critical for facilitating access to quality, safe and affordable medical products. ‘Standard setting and quality benchmarks for medical devices and diagnostics are necessary to make the Essential Diagnostics List (EDL) useful for dosage and delivery of medicines. I am also happy to see new approaches for R&D being discussed such as in ‘Reengineering how we finance delivery and access to medical products: The 3Rs of Sharing Resources, Risks and Rewards’. Given the rising Non-Communicable Diseases worldwide, discussions on the ‘Legal aspects for prevention and promotion of public health’ are well-timed. Discussion on topics such as ‘Mechanisms for knowledge sharing including licensing options for medical products to facilitate health for all’ should enable new approaches for the triple billion targets.

In the year that India celebrates the 150th birth anniversary of Mahatma Gandhi, we reiterate our commitment nationally and globally to achieving public health goals. During the recent UN General Assembly in September in New York I had said that India plans to end TB epidemic by
2025, 5 years ahead of the SDG goal. I stated “Equitable access to medicines, diagnostic tools and technologies remains a concern. We must address all barriers to access to medicines and to new technologies, including through use of flexibility provisions in WTO TRIPS Agreement and the Doha Declaration. The launch of the BRICS TB Research Network is also a promising opportunity”. These aspirations were echoed in the recommendations of the 1st World Conference on Access to Medical Products held last year in 2017 at New Delhi, India.

Our National Health Policy 2017 led by Shri Narendra Modi Ji, Honourable Prime Minister of India, is dedicated to the highest possible standards of health for the country. The Government has launched Ayushman Bharat, a National Health Protection Scheme, which envisions health assurance of 5 lakh rupees (6815 USD) per family per year, will benefit over 50 crore (i.e. 500 million) people, and is the world’s biggest health assurance scheme.

Globally, the Indian pharmaceutical industry’s role in providing affordable quality medicines is well known. During the recently concluded Regional Committee meeting in September a Delhi Declaration on “Improving Access to Essential Medical Products in the South-East Asia Region and Beyond” was endorsed by the 11 Member countries. The Declaration acknowledged our unique strength with major manufacturers of medical products, especially generic medicines.

To strengthen the medical products and drug regulatory system at the Central and in the State levels Rs. 1,750 crores (238 million USD) are committed in the government budget. In a period of two years viz, up to 2019-20 Rs.412 crores (56 million USD) will be spent to upgrade 31 State Labs, 38 State Drug Control Offices, setup 10 New Drug Testing labs and 20 mobile drugs testing labs. An additional component of giving incentives to States/UTs to support the functional labs/human resources based on performance is included. Seven new drugs/medical devices/cosmetics testing Central labs and 8 Mini labs at Airports and Seaports for assuring the safety, efficacy and quality of drugs, cosmetics and medical devices are being set up. A National Academy for training Drug Regulators has been envisaged.

In the South-East Asia region in WHO, India is actively contributing and provided support for the South-East Asia Regulatory Network (SEARN) to guarantee access to high-quality medical products. My Ministry has engaged closely, also with Centre for development of Advanced Computing, CDAC, an autonomous body in the Ministry of Information Technology to develop and Information Sharing Platform Gateway for SEARN. SEARN will promote regulatory and health collaboration among the countries of the South-East Asia Region.

I am sure the Conference will result in positive outcomes. I hope the outcomes will inform the Access to Medicines and Vaccines roadmap at WHO. I am very happy to note that the 2nd World Conference continues the close collaboration with the ministries in the Government. The contribution of ICMR, the ministries of Science and Technology Chemicals and Fertilizers, Commerce and Industry, Law and Justice, External Affairs, MSME, Electronics & Information Technology will bring concerted action on the access agenda for health for all is welcome. The contribution of international government and academic would yield fresh ideas. Together we work closely for successful results. I am confident that the discussions in the next three days will advance concerted action from all.

I also take this opportunity to invite you all to another important event being hosted in India by my Ministry, the 4th Global Medical Device Forum of WHO at Vishakhapatnam from 13-15th December 2018.
I see the Conference as an important forum for all bringing innovative thinking on contemporary public health issues. Therefore, I am happy to also announce that next year’s conference will be held here in New Delhi on 19-21 November 2019. I wish you a successful conference and I look forward to the recommendations from the meeting.
Distinguished Ladies and Gentlemen,

I am happy to join you and welcome you for the “2nd World Conference on Access to Medical Products – Achieving the SDGs 2030”. I am happy to welcome my Ministerial colleagues from the various State governments in India.

I remember in the 1st World Conference 2017, I could not come at the last minute and I addressed you through a live video link. I am happy to be here in person today. I see you have many issues to discuss and many ministries of the government participating as also international experts from many different countries. This forum will thus enable a cross fertilization of ideas for public health goals for access to medical products.

On 23 September, this year the Honourable Prime Minister Modi announced the Ayushman Bharat scheme. This is an ambitious health insurance by the government. There is a provision for a cover of Rs. 5 Lakhs per family per year for secondary and tertiary care. There is no restriction on family size, age or gender. No money needs to be paid by the family for treatment in case of hospitalization. All pre-existing conditions are covered from day one of the policy. The benefit cover will include pre-& post hospitalization, A person can go to public or empanelled private hospitals across the country and get free treatment.

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, half of which are exports. However, a lot more needs to be done for affordable health care for the citizens.

In this regard, the role of traditional medicine is important and I am happy to see that the Conference addresses this area too. Since November 2014, the Department of AYUSH is no more under Ministry of Health & Family Welfare, it has been elevated as separate Ministry. The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) deals with alternative medicine systems. Now ‘Sowa-Rigpa’ the Tibetan medicine system also has been added in AYUSH. Strengthening R&D and upholding education standards in the Indian Systems of Medicines, promoting the cultivation of medicinal plants used, and working on Pharmacopoeia standards are areas with positive public health potential outcomes.

The traditional medicine R&D initiatives may also inform modern medicine. In this context, the contribution of traditional medicine to develop new drugs such as artemisinin for malaria cannot be over emphasized. The search for recipes that had been used to treat fever found that certain individual plant names had high frequencies of appearance in the recipes. A plant called *Artemisia annua* was one of the plants that appeared frequently leading to the discovery. Artemisinin represents a new class of antimalarial drugs, which led to a change from quinoline-based antimalarial drugs to artemisinin-based therapies due to the emergence of parasites resistant to quinoline drugs. The role of AYUSH systems in prevention for non-communicable diseases – which are becoming silent killers, diabetes, hypertension, etc. should be explored.

Another set are the antibiotics, the miracle drugs of modern medicine. 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.

In India, in Research and Development, the Indian Council of Medical Research (ICMR) and institutions such as Biotechnology Industry Research Assistance Council (BIRAC) with the Department of Biotechnology and Translational Health Science and Technology Institute (THSTI) are playing an important role. The institutions are moving ahead in 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 am glad that the conference is discussing these important aspects and that all partnering Ministries are here to explore new options.

I hope the Conference will discuss greater collaboration for drugs, treatments, or methods for prevention.

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 and it is a great pleasure for me to see that experts from all the world have joined us today for the 2nd World Conference on Access to Medical Products- Achieving the SDGs 2030 in India!

I am pleased that the Ministry of Health & Family Welfare with the support of WHO and in partnership with other Ministries is moving forward. I am also happy to learn that the recommendations from last year are leading to tangible outcomes- this is refreshing as we see progress emerge from the deliberations.

The Sustainable Development Goals are the mantra for a better future for all. 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.

Dr Antonio Guterres, the UN Secretary General as recently as on 26 September 2018 stated: Health is both an outcome and a driver of progress. The commitment at UN for Universal Health Coverage is reiterated. The UN Secretary General said that Next September’s High-level Meeting of the General Assembly on Universal Health Coverage will be a further milestone in fostering the highest level of political commitment to drive action for health and well-being by 2030.

Access to medicines is a critical factor for success of the SDG Agenda that aims to ensure healthy lives and promote well-being of all people of all ages.

Universal health coverage and access to medicines is also one of the regional flagship priorities for countries in the WHO South-East Asia Region.

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.

These aspects are particularly important as new international challenges emerge for global political and trading systems.

India is committed to attainment of the highest possible standards of health for its citizens. The National Health Policy 2017 addresses national current and emerging socio-economic, technological and epidemiological issues on public health for the country. 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 2nd World Conference is unique in many ways. The conference theme for discussions and the resource persons/global experts have been invited relating to the various themes of Access to Medical Products, Innovation and Research & Development and Intellectual Property Rights and trade, for providing specific recommendations leading to possible policy interventions. The objective of the discussions in the conference are to build on the recommendations made in the 2017 Conference. I also appreciate the Ministry of Health and partnering ministries have worked in the interim on the previous recommendations to move forward.

Furthermore, I understand there is participation from officials and experts from the government sectors nationally and internationally. Ministry of Public Health, Ministry of Commerce, UN agencies, university academicians, related civil societies and private will all contribute to the discussions. We look forward to the outcomes and recommendations from all sessions, to contribute in a meaningful manner to the national and global agendas on access to medical products, intertwined with research, innovation and intellectual property issues.

I am happy to see the enthusiasm for the 2nd World Conference and the Ministry would do well to continue to engage for discussion and collaboration on the agenda in the coming years.

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 warmly welcome you to the “2nd World Conference on Access to Medical Products – Achieving the SDGs 2030”. The title is quite a handful and gives an idea of the vast set of issues that form part of the deliberations. We continue to take the work forward from the 1st World Conference held last year, together with the ministries and all stakeholders for better health outcomes for our people.

Universal health coverage is key to the Sustainable Development Goals 2030 and the vibrant Indian pharmaceutical sector is contributing in a big way for universal health care, in the Region and beyond. India provides affordable medical products worldwide. These include primarily medicines and vaccines but also diagnostics and devices.

The vibrant Indian pharmaceutical sector is contributing in a big way for universal health care, in the Region and beyond. India provides affordable medical products worldwide. Indian manufacturers are the key contributors to the WHO Prequalification Programme for medicines and vaccines. It is seen that 64% of finished pharmaceutical products are from India. In the segments of HIV-AIDS, Tuberculosis, Malaria, Reproductive Health WHO prequalified active pharmaceutical ingredients, which are a pre-requisite for all drug formulations, find that 59% are from Indian manufacturers.

India is a major vaccine producer that has 21 major vaccine manufacturing facilities. These vaccines support health care in over 150 countries. 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. The National Regulatory Assessment by international experts in the WHO Global Benchmarking Tool in vaccines in 2017, reiterated India’s regulatory capabilities. The government has committed an expenditure of Rs. 1,750 crores for regulatory strengthening to ensure quality, safe and efficacious medical products.

Universal health coverage and the interlinked agenda of access to medicines, is one of the regional flagship priorities for the countries in the WHO South East Asia Region and India is one of the main contributors to this agenda by strengthening the regulatory system. India is actively contributing and providing support for the South-East Asia Regulatory Network SEARN in a move to guarantee access to high-quality medical products. India is contributing to the Information sharing platform gateway for SEARN by housing the platform free of cost on the Indian drug regulator’s cloud space. Further, the SEARN Information Sharing Platform Gateway is being developed by Centre for Development of Advance Computing (CDAC) – a scientific society of the Ministry of Electronics and Information Technology, Government of India. The ISP will promote collaboration and convergence among the regulatory authorities in the region. The ISP Gateway will enable better communication between regulatory agencies in the Region to ensure access to quality medical products.

The Government of India and the state governments have made a lot of progress. Many measures are in place for improving access to essential medical products. The provision of free medicines for all under the Free Medicines Schemes and the support to states under the National Health Mission for providing free drugs to all is one such measure. Prices of around 850 essential drugs are capped by the government. The drug price regulator National Pharmaceutical Pricing Authority (NPPA) revises these prices annually based on the wholesale price index. In February 2018, the prices for coronary stents were also notified. To improve access to quality generic medicines and devices to the population, the Prime Minister is considering continued subsidy to the Jan Aushadi scheme.
The Ministry of Health and Family Welfare under the aegis of National Health Mission launched the Free Diagnostics Scheme in July 2015 to address the urgent need for accessible and quality diagnostics in public health facilities. Under this initiative, the National Health Mission is supporting all States to provide essential diagnostics – Laboratory and Radiology at their public health facilities, free of cost.

India’s move to craft the essential diagnostics list is being led by the Ministry of Health & Family Welfare and Indian Council of Medical Research (ICMR), the research wing of the health ministry. The WHO first essential diagnostics list which is a catalogue of tests for detecting common morbid conditions and priority diseases, provides a strong impetus to India’s endeavour to chart out its own national list of diagnostic procedures. The essential diagnostics list, unveiled by WHO on April 15, concentrates on in vitro tests. It contains 113 items - 58 tests are listed for detection and diagnosis of a wide range of common conditions, providing an essential package that can form the basis for screening and management of patients. The remaining 55 tests are designed for the detection, diagnosis and monitoring of ‘priority’ diseases such as HIV, TB, malaria, hepatitis B & C, human papillomavirus and syphilis. The ministry is taking this up as base and designing an EDL that is best suited to its own requirements.

There is a push for manufacturing of medicines and devices also through the Government’s “Make in India” campaign to foster public health goals. To foster WHO prequalification with special focus on Indian MSME sector- special packages for the micro, small and medium pharmaceutical enterprises (MSME) industry in the pharma parks and medical device parks have been taken up and discussions on further stimulus are being held.

The Indian national regulator, the Central Drugs Standard Control Organisation’s (CDSCO) is attempting to create India’s first national digital database for pharmaceuticals. The Ministry is working on a creation of database of manufacturing facilities, wholesale and retail sale licenses where data to be uploaded by the manufacturers and authenticated by the State Drugs Controllers. The CDSCO is working to make it mandatory for all drug makers to upload the details of their manufacturing licenses and list of products on ‘Sugam’, an online portal developed by the health ministry. The state licensing authorities can easily verify it by checking the inputs on the site. Once it is made mandatory, all the manufacturers will be putting details of their facilities and products regularly in the database. The database will promote quality medical products not only within the country but also internationally to all countries sourcing their products from India. As part of this exercise, for continuous monitoring of quality of drugs, CDSCO has recently initiated Risk Based Inspections of Pharmaceutical manufacturing facilities based on the risk they pose with regards to the quality of drugs manufactured by them.

Many of the Government’s policies and interventions are contributing to good health outcomes. The Clinical Trial (CT) Rules 2018 have been notified. MOH also acted swiftly, curbing the manufacture and sale of the drug Oxytocin, on reported misuse in the public domain. Medical Devices Rules, 2017 on requirements for import, manufacture, clinical investigation, sale and distribution of Medical Devices and In-Vitro Diagnostics have been effective from 1st January 2018.

Vigilance measures ensure that post marketing surveillance is carried out and appropriate steps taken on any signal alerts. A robust Pharmacovigilance Programme is in place in India and 250 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 MaterioVigilance Programme of India (MvPI) has put 10 exclusive centers under it to collect and disseminate reporting of adverse events due to medical devices at the point of care besides the 250 adverse drug reaction monitoring centers (AMCs) across the country. I hope further steps to increase affordable and appropriate medical devices use will be discussed in the 4th WHO Global Forum on Medical Devices will be hosted by Government of India on 13-15 December 2018 at New Delhi.

I am also pleased to report that all the partnering ministries have taken measures to follow up on the recommendations made last year in the 2017 Conference. On consultation with the Ministries the 2017 recommendations have been grouped based on the key Ministry(ies) and partnering Ministry(ies) responsible for taking action towards implementation. I am also happy to report that progress made has been taken note of through the identified nodal officers from the Ministries.

I am encouraged to see the diverse program outlined for the Conference. I thank all my colleagues from the partnering ministries for their advice and support. I look forward to further collaboration on health agenda for our people.

I wish the Conference all success and eagerly await the outcomes.
Address by Regional Director- South East Asia Region- Dr Poonam Khetrapal Singh

Excellencies', Honourable Health Minister, Shri J.P Nadda, Ministers of State, Distinguished participants, Ladies and Gentlemen,

I congratulate the Ministry of Health and all partnering ministries in Government of India that have followed up on the important initiative of the 1st World Conference held last year.

Every country in the world is deeply committed to the Sustainable Development Goals agenda. In the 17 SDGs, Good health and well-being finds direct mention in Goal 3. The latter however, is a prerequisite for achieving all the other SDG goals. Access to medicines and medical products is a critical factor in the pursuit of health for all goals. Access to medical products is reflected in SDG target 3.8 (achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all). These aspirations are presently being echoed in the WHO's Draft thirteenth general programme of work 2019–2023.

Policies that promote access to health products, and access to generic medicines and innovation are critical for achieving public health goals. Medical products are "accessible" only if they are paid for in such a way that they actually reach the people who need them the most. In WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHO has intensified its collaboration with other relevant international organizations, including UNCTAD, WIPO and WTO. The Trilateral Cooperation with WIPO and WTO is fostering a better understanding of the linkage between public health and intellectual property policies and enhance mutually supportive implementation of those policies. The objective is to promote medical research and development, innovation and increased access to medicines, vaccines, diagnostics and related health technologies to improve the health and wellbeing of all, according to the Sustainable Development Goal 3.

The requirement before us is to strengthen coordination in research and development efforts based on a realistic assessment of the health needs to provide medical and health products for treatment of diseases for all populations, rich and poor. To achieve these aims we must achieve greater consensus among Member States for which WHO is presently engaged in developing a Roadmap for 2019-2023 on ‘Addressing the global shortage of, and access to, medicines and vaccines’.

In this context, I must mention that ensuring efficient regulatory processes are vital to achieving Universal Health Coverage and health goals. Indeed, effective regulation guarantees quality of health and medical products such as medicines, diagnostics, medical devices and vaccines. To promote information sharing and collaboration of regulatory practices across the Region, Member states in the Region have come together to form South-East Asia Regulatory Network – SEARN. Presently in this initiative there is a Steering group of five Member Countries in the South-East Asia Region – three permanent members- India, Indonesia, Thailand, with two revolving members – presently Bangladesh and Maldives. Five working , 5 Working Groups are working on the following areas: Quality assurance and standards of medical products, including labs, Regulatory Practices including GMP, GDP, etc., Vigilance for medical products, Information Sharing Platform and Medical devices and diagnostics. This laudable initiative is being supported by WHO.
In our Region, nearly 65 million people are impoverished on account of out-of-pocket health spending, much of which is on medicines. We need to explore innovative strategies to improve information sharing on a range of factors such as prices, quality and performance and to dedicate resources to build, institutionalise and strengthen platforms and networks for such an open exchange of information. It is necessary to find effective mechanism to support countries with small markets and limited purchasing power which requires a high degree of reliance on imported medical products. Universal health coverage and access to medical products, is one of the regional flagship priorities in the WHO South East Asia Region and WHO Country Cooperation Strategies refer to Universal Health Coverage.

World over it is recognized that India’s pharma industry has made substantial contribution for providing quality generic drugs and vaccines. It is no surprise that India is hosting the meeting of the Global Forum on Medical Devices during 13-15 December 2018 at Visakhapatam, Andhra Pradesh. WHO lauds India’s commitment to a robust drug regulatory system amply demonstrated in the February 2017 re-benchmarking of the Indian National Regulatory Authority. WHO had scaled up its technical support to the India’s national regulatory authority over the past several years. Making medical products accessible and affordable is a key WHO priority, in India and globally. The challenge is to ensure that access to high-quality affordable medical products becomes a reality and meets the needs of the vast majority.

Concerted and simultaneous actions on various fronts towards this objective are called for to make significant progress by 2030. The whole gamut of National Health and Pharmaceutical systems need to be further strengthened with a sharp focus on attaining the objective of Universal Health Coverage which is possible only with easy and quality access to health products and services. I hope the conference will yield important policy outcomes on the related critical areas for access such as law and governance, innovation, research and development, manufacturing and trade, affordability, Quality assurance and regulation.

I wish you all have fruitful discussions and a productive meeting leading to a clear defining of outcomes and strategies we need to collectively pursue.

I thank you for having given me this opportunity to interact with you and I wish you all the very best.
Address by Assistant Director General, World Health Organization - Dr Marianagela Simao

Distinguished authorities, colleagues, friends, distinguished participants.

Let me say, I am glad I was able to come here this year. I was invited last year but I had just joined WHO so it was one week after so it was not possible for me to come but I see that this event is already a success because it is coming back again this year with a very important agenda. I would like to say a few reflections as we start this conference and the first is that we live in interesting times, not in the sense of the Chinese curse but in the sense that we never in the past have our knowledge and the possibilities to prevent and treat all manners of disease so great, so I feel privileged living in times like this. The penicillin, vaccines, discovery of DNA to name just a few concrete advances, life expectancy has increased by 25 a year since 1950 globally, it is in part because of the advances in technology, not everything is about technology but a large part. New drugs for diseases like hepatitis C, some new drugs for cancer transforming people’s lives but we know that why we have advances not everyone has equal access to these medical advances. For example, childhood cancer survival is about around 80% in high income countries and as low as 20% in low income countries. Five-year survival rates for breast cancer 2% in my home country which is Brazil by the way 58% and in Gambia is 12% so these inequalities, they are unjust and they are preventable.

We have more imperative to address this gaps and in many ways, WHO New Global Program Of Work which has translated into WHO’s new strategy and it was approved last May addresses this issue when it puts as a mission, promote health, keep the world safe, and serve the vulnerable and linking this to the challenge of the sustainable development goals which is to leave no one behind, we have a target 3.8 which is universal health coverage which, by the way, the sustainable development goals were adopted by all member states in the General Assembly in 2016, 3.8 includes affordable access to safe quality-assured, effective medicines and vaccines. This requires that the global community, countries, the different stakeholders to work together creatively to address the access issues. We know technologists exist that can save lives, how do we ensure that people will get actual benefit for it. Because a medicine that sits on the shelf, because it is unaffordable, has no value. It has no value for the patient. It has no value for the manufacturer. Even access to existing off-patent medicines remains unaffordable in many countries and in developing countries up to 90% of the populations to purchase medicines through out of pocket.

The director general, Dr. Tedros said recently that no family should endure financial hardship for out-of-pocket payments for the purchase of medicines to treat their loved ones and no men, women or child should die simply because they cannot access the life saving medicines. For this and for many other reasons, WHO was mandated by the World Health Assembly last May to develop an access to medicines and vaccines roadmap that will be presented in the World Health Assembly next year. We have received written comments including from India from 61 countries and we will be discussing a new draft at the WHO’s Executive Board in January of this year. We have also continued with what we call the fair pricing for which happened last year in Amsterdam and we will be very glad to involve the government of India present its experiences in industry, in generic industry in India to come and this is to happen early in 2019 in South Africa. We are acutely aware that increasing access to vaccines, medicines, health technology in general is not a job WHO can do single handed or member states can do single handed. We need all stakeholders stake on this and I truly hope that the experiences from this conference
will help and form a global agenda. I wish you all a very productive conference and look forward to hearing about its outcomes. Thank you very much for inviting me to the conference.
Address by Additional Secretary Ministry of Health and Family Welfare Dr RK Vats

On behalf of the Ministry of Health & Family Welfare and on my own behalf I am delighted to welcome you to the “2nd World Conference on Access to Medical Products- Achieving the SDGs 2030, 9th-11th October 2018. The Conference is organized in partnership with many ministries in Government of India, WHO and international experts.

As you have seen in the Conference brochure, 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. The Ministry of Health and all the partnering ministries have actively followed up on the 1st World Conference 2017 recommendations. After nominating focal points for each ministry, progress meetings have been held and I am happy to share that all Ministries are working in tandem to take health agenda forward.

The 2nd World Conference takes next steps on the access to medical products in the context of SDGs (including trade agreements). We hope that India’s initiative will enable discussions at WHO on the Access to medicines and vaccines roadmap in Geneva in 2018. The objective is to foster new approaches in innovation landscape for medical products and health technologies for accelerating research and innovation.

I share with you the design of the conference and the hard work put in by the Conference Secretariat over the past months. The three days program cover the themes of

Firstly, Innovation and Manufacturing. We look at the 13th Global Program of Work of WHO for Access to Medical Products to achieve SDG 2030 Goals. This year we have invited the State Health Ministers as well to participate in a Roundtable Panel on Access to Medical Products. The Secretaries including from the states will also discuss progress on last year's recommendations.

The second Day’s theme is Regulation and Access. The discussions cover strengthening Regulatory Networks for Facilitating Access to Quality, Safe and Affordable Medical Products. Standard setting and Quality Benchmarks for Medical Devices and Diagnostics in National and Global Markets, Developing Efficiencies in Clinical Trials in Global, Regional and National Settings, Access and Affordability of Medical Products-Focus Orphan and Rare Drugs etc. For this year’s Conference, we have also invited the AYUSH and have a session on promoting Health and Wellness through Traditional Medicine.

The 3rd Day’s theme is on Financing, Legal Landscape & Trade-related Aspects which looks at Reengineering How We Finance Delivery and Access to Medical Products: The 3Rs of Sharing Resources, Risks and Rewards, Legal and Regulatory Issues for Access to Medical Products, Partnering for Access to Medical Products-Bilateral treaties and Regional Agreements and Intellectual Property Rights and Standards in Trade for Medical Products. In this 2nd Conference we cover access and trade issues in Non-Communicable Diseases in greater detail. As was the case last year each session is hoped to come up with doable set of options/outcomes.

My colleagues and I have been actively involved in the design of the Conference. I acknowledge and thank Indian Council of Medical Research, Department of Biotechnology in the Ministry of Science and Technology, the Translational Health Science and Technology Institute, THSTI and
Biotechnology Industry Research Assistance Council, BIRAC for their contribution in the design of the Conference. The Conference is truly a result of close collaboration with all Ministries in the Government of India.

1. A Position paper has been prepared which 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. We have been fortunate that many experts have provided a one / two-page concept paper and lead questions which in his his/her view are the key issues to be discussed.

2. A number of logistic issues are 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 information is 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.

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

4. 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. 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.

We commenced in 2017 and have made progress in 2018. We are encouraged by the support and enthusiasm of our partners and collaborators – the ministries, international organizations, pharmaceutical industry, civil society, foreign governments on the important agenda on access to medical products 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.

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 3rd World Conference in 2019 next year.
### Annex IV: List of Participants

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