Department of Pharmaceuticals
Government of India

INDIA MEDICAL DEVICE 2018™

"Affordable, Accessible Quality Healthcare for All"

15-17 February, 2018 l Bangalore International Exhibition Centre, Bengaluru

Draft Program

As on January 31, 2018

DATE / TIME	EVENT
	Day 1: Thursday, 15 February 2018
0830-0930	**Registration**
0930-1130	**Inaugural Session & Award Ceremony: India Pharma 2018 & India Medical Device 2018**
1130-1200	**Inauguration:** India Pharma & India Medical Device Exhibition. Exhibition will be open from 10 am to 6 pm for Business Visitors. & **Media Interaction**
1200-1330	**Session 1: Innovations and R&D Ecosystem – Making India a part of global supply chain**
	Session brief: As the Medical Device is an innovation driven industry, it is critical to create an innovation ecosystem in the country for the growth and development of the industry. The session will deliberate on the various reforms, initiatives and responsibilities of stakeholders and develop a roadmap for India to become a preferred innovation and R&D destination. **Chair: Shri Dinesh Kapila**, Economic Advisor, Department of Pharmaceuticals, Government of India **Moderator: Mr. Madan R Krishnan**, Vice President, India Medtronic Pvt. Ltd. © **Presentations:** • **Med Tech Research in India** **Mr Vijay Simha,** Advisor, Lemelson Foundation © • **Imperatives for Digital Innovation in India** **Mr Dileep Mangsuli,** Chief Technical Officer, GE Healthcare © **Mr Shashank ND,** Founder & CEO, Practo • **Capital Imperatives** **Mr. Sashi Kumar,** Co-chair**,** FICCI Medical Devices Forum; Managing Director, Phoenix Medical Systems Pvt Ltd © • **Regulatory Imperatives** **Mr NandaKumar Subburaman,** President, Perfint Healthcare Private Limited © **Mr Biten Kathrani**, Director R&D - AMEA & Managing Director Boston Scientific © • **Opportunity & Challenges for Innovative Med Tech Start-ups** **Mr Amit Bhatnagar,** Managing Director, Accuster Technologies Pvt. Ltd. © • **Global Best Practices in Med Tech Research** **Dr Gaby Vercauteren –** Senior Adviser, Regulatory Systems Strengthening, WHO Geneva © **Expected Outcome:** The session will identify the opportunities, gaps, infrastructure required, policy reforms needed and recommend the way forward. (Seating plan: Dais and Theatre style)
1330-1430	**Networking Lunch**

1430-1630	**India Medical Device CEO'S Roundtable**
1630 - 1645	**Tea Break**
1645-1800	**Session 2: Make in India : A sub-sectoral approach**
	Session Brief: Deliberations will focus around opportunities and challenges for "Make in India" to expand the indigenous manufacturing of medical devices. The discussions will be around the sub-sectoral approach based on risk assessment, present capabilities of Med Tech manufacturing and government initiatives on 'Ease of Doing Business' to attract investments. **Chair: Shri Ramesh Abhishek**, Secretary, Department of Industrial Policy & Promotion, Government of India **Moderator: Mr. Probir Das**, Chairman, FICCI Medical Device Forum**;** Managing Director, Terumo India Pvt. Ltd. © **Panelists:** • **Consumable and Disposables** **Mr. Himanshu Baid**, Managing Director, Polymedicure © **Mr. Indranil Mukherje,** Managing Director, B. Braun Medical (India) Pvt. Ltd. © • **Implants** **Mr. Sushobhan Dasgupta,** Managing Director, Johnson & Johnson Medical India © **Mr Gurmit Singh Chugh,** Managing Director, Translumina Therapeutics LLP © • **Medical Equipment** **Mr. Nalinikanth Gollagunta,** President & CEO (India & South Asia), GE Healthcare © **Mr. Krishna Prasad Vajapeyam**, President, Prognosys Medical Systems Pvt. Ltd. © **Mr. Sunil Khurana**, CEO, BPL Medical Technologies Pvt. Ltd. © • **In-Vitro Diagnostics** **Mr. Bivash Chakraborty,** Head- Regulatory, Quality & Customer Care, Biomeriuex India Pvt. Ltd. • **Med-Tech Parks and PSU** **Dr. R.K. Vats**, Chairman and Managing Director, HLL Lifecare Limited **Dr. Jitendar Kumar Sharma,** Managing Director & Chief Executive Officer, Andhra Pradesh Medtech Zone © • **Global Propective** **Dr Gaby Vercauteren** – Senior Adviser, Regulatory Systems Strengthening, WHO Geneva © **Expected Outcome of Session:** The session will suggest a roadmap for Med Tech manufacturing in India. (Seating plan: Dais and Theatre style)

1700-1900	**Joint Closed-Door Session: International Regulators Interaction with CEOs**
1700 - 1800	**Pharmaceuticals Industry CEOs and Regulatory Head**
1800 - 1900	**Medical Devices Industry CEOs and Regulatory Head**
	Session brief: The session aims to provide a platform for Med-tech CEOs to place their views on evolving international regulatory scenario. This is to enable Indian manufacturers faster access to international markets while at the same time allow international markets to harness the growth and export potential of Indian manufacturers. **Chair: Smt. Anupriya Patel**, Hon'ble Minister of State, Health & Family Welfare, Government of India **Moderator:** *To be Decided* **Proposed Dignitaries from Government of India:** • **Smt. Rita Teaotia,** Secretary, Ministry of Commerce, Government of India • **Shri Amitabh Kant,** CEO, NITI Aayog, Government of India • **Shri Ramesh Abhishek,** Secretary, Department of Industrial Policy and Promotion, Government of India © • **Mr. Rajendra Gupta,** Chair, Personal Connected Health Alliance (PCHA) © • **Shri Bhupendra Singh**, Chairman, National Pharmaceutical Pricing Authority, Government of India © • **Shri Sudhansh Pant,** Joint Secretary, Department of Pharmaceuticals, Government of India © • **Shri Rajneesh Tingal**, Joint Secretary, Department of Pharmaceuticals, Government of India © • **Shri Dinesh Kapila**, Economic Advisor, Department of Pharmaceuticals, Government of India © • **Dr. R.K. Vats**, Additional Secretary, MoHFW, Government of India • **Shri Sudhanshu Pandey**, Joint Secretary, Department of Commerce, Government of India • **Shri J.V. Patil**, Additional Director, Directorate General of Foreign Trade, Government of India • **Shri Ravi Shankar Prasad**, Joint Secretary, Ministry of Environment, Forest and Climate Change, Government of India • **Shri Rakesh Ranjan**, Member Secretary, National Pharmaceutical Pricing Authority, Government of India **Session Constituents: On Regulators Head Table:** • Central Drugs Standard Control Organization (CDSCO) • US Food and Drug Administration (US FDA) • Pharmaceutical and Medical Device Agency (PMDA) - Japan • Representatives of regulators from EU, UK, Australia, Singapore, Russia, Kenya, Mexico, Brazil, Saudi Arabia, Indonesia, Vietnam, Myanmar, Ghana and Malaysia • Representatives from WHO headed by Ms Emer Cooke – Head, Regulation of Health Technologies (Team Leader), WHO Geneva
1915 Onwards	**Networking Dinner**

Day 2 : Friday, 16th February, 2018	
0930 – 1130	**Joint Regulators Meet: Sharing International Best Practices and Ensuring Quality in line with Global Standards** Pharmaceuticals & Medical Device sector
	Session Moderated by: *Knowledge partner* **Session Constituents:** **1. Indian Regulators** a. **Dr. G.N. Singh**, Drug Controller General of India, CDSCO, MohFW, GoI b. **Dr. V.G. Somani,** Joint Drug Controller, CDSCO, MoHFW, GoI c. **Dr. Eswara Reddy**, Joint Drug Controller, CDSCO, MoHFW, GoI d. **Dr. A. Ramkishan,** Deputy Drug Controller, CDSCO, MoHFW, GoI **e. Mr. Aseem Sahu,** Deputy Drug Controller, CDSCO, MoHFW, GoI **2. International Regulators invited:** Representatives of regulators from USFDA, PMDA Japan, EU, UK, Australia, Singapore, Russia, Kenya, Mexico, Brazil, Saudi Arabia, Indonesia, Vietnam, Myanmar, Ghana and Malaysia **3. WHO** • **Ms Emer Cooke – Head, Regulation of Health Technologies (Team Leader), WHO Geneva** • **Dr Madhur Gupta,** Technical Officer- Pharmaceuticals, WHO India Country Office • **Dr Manisha Shridhar**, Regional Advisor, WHO South East Asia Regional Office • **Mr Wondiyfraw Zeleke Worku**, PQT-Medicine Assessment Group – Prequalification Team, WHO Geneva **Expected participation:** **4.** Industry Members comprising Regulatory Affairs, Quality Assurance etc. **5.** Government Officials **6.** Regulators – CDSCO and State Drug regulators **7.** Trade and Business officials from Embassies / Foreign missions Seating plan: Dais and Theatre style
1130 – 1145	**TEA BREAK**
1145 – 1345	**Workshop by WHO: Regulatory System Strengthening and Prequalification updated by WHO**
1345 - 1430	**Lunch**

1430 - 1600	**Session 3: – National List for Priority Medical Devices & Healthcare Technology Assessment**
	Session brief: Session will facilitate the discussion on the above areas, to be able to create an appropriate pricing and reimbursement framework. Discussion will be done on trade margin rationalization, cost of healthcare, need for NLEMD, Out of Pocket Spending for patients. **Chair: Dr. V. K. Paul,** Member, NITI Aayog, Government of India **Moderator: Mr Amit Mookim**, Managing Director, South Asia, IQVIA © **Panelists:** • **Shri Bhupendra Singh**, Chairman, National Pharmaceutical Pricing Authority • **Shri V.K. Gauba**, Joint Secretary, Department of Health Research (DHR), Ministry of Health & Family Welfare (MoH&FW), Government of India • **Mr. Sripen Tantivess**, Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand - HTA prospective from Thailand • **Dr. Nandakumar Jairam,** Chairman, CEO & Group Medical Director, Columbia Asia Hospitals India © • **Mr. Sushobhan Dasgupta**, Managing Director, Johnson & Johnson Medical India © • **Mr. Girish Rao, Charman,** Chair, FICCI Health Insurance Committee, Chairman & Managing Director, Vidal Healthcare Services © • **Mr Vibhav Garg,** Vice President-Health Policy & Govt Affairs, GE Healthcare © • **Mr. Mohammad Ameel**, National Health Systems Resource Centre (NHSRC) • **WHO Representative** **Expected Outcome:** The session will focus its discussion on exploring the pathways which lie ahead for India to adopt health technology assessment for decision makers. (Seating plan: Dais and Theatre style)
1600 – 1615	**TEA BREAK**

1615 – 1745	**Session 4: Standards, Quality & Testing**
	Session Brief: Deliberations will be on the way forward to adapt to new Medical Devices Rules, 2018, Quality Testing and role of Notified Bodies in transition to new rules. The session will also focus on changing healthcare delivery mechanisms in light of inter-operability of medical devices and safe, effective use of information exchange. **Chair: Shri S. A. Bhardwaj**, Chairman, Atomic Energy Regulatory Board **Co-Chair**: **Shri Rajendra Pratap Gupta**, Chair, Personal Connected Health Alliance (PCHA) © **Moderator**: **Mr. Suresh Sugavanam**, Vice President Managing Director, South Asia, UL India Pvt Ltd © **Panelists:** • **Dr G N Singh**, DCGI, Central Drugs Standard Control Organization, MoHFW, GoI • **Dr Harish Nadkarni**, CEO, NABH • **Mr Rajesh Saigal**, Executive Vice President, South & South East Asia, Intertek • **Mr. Manish Bhuptani**, Managing Director, TUV Rheinland India • **Mr Michael H Scholla**, Global Director – DuPont • **Mr Sudhakar Mairpadi,** Director-Q&R (Health Care & Consumer Life Style sector), Philips India Limited © • **Ms Kirti Arora,Director –** Regulatory Affairs, Boston Scientific © • **Bureau of Indian Standards** **Expected Outcome of Session:** The session will help in bringing in clarity on the role and responsibilities for Notified and accreditation bodies and expected industry co-operation (Seating plan: Dais and Theatre style)

Day 3 : Saturday, 17th February, 2018	
1000-1100	**IQVIA Workshop on EU & APAC medical device REGULATIONS**
	Brief: The workshop will highlight the recent changes in the EU & APAC medical device regulations. The presenters will share the impact of these changes on the India Device companies having business outside India and also to harmonize Indian Standards with global changes **Presenters:** **20 Mins** • **Qi Li,** Senior Director, Regulatory Affairs – MedTech (Asia), IQVIA © • **Caroline Freeman,** Principal Consultant – MedTech Regulatory, IQVIA © **Participation:** Regulatory Heads of leading Med-Tech Companies **Expected Outcome:** Session will bring about awareness to the India Device Companies on the global regulatory changes. (Seating Plan: Roundtable Sitting)
1100-1300	**Workshop on Medical Device Rules 2018**
	Brief: The discussion will be focused on Start – Stop – Continue approach, to come out with an industry relevant Devices Rules. **Chair: Dr G N Singh**, DCGI, Central Drugs Standard Control Organization, MoHFW, GoI **Moderator**: **Mr. Sanjay Arudi**, Senior Director Regulatory Affairs - SHS (Africa, ASEAN & South Asia), GE Healthcare © **CDSCO Representatives:** • **Dr. V.G. Somani,** Joint Drug Controller, CDSCO, MoHFW, GoI • **Dr. A. Ramkishan,** Deputy Drug Controller, CDSCO, MoHFW, GoI • **Mr. Aseem Sahu,** Deputy Drug Controller, CDSCO, MoHFW, GoI • **Mr. Somnath Basu,** Asst. Drugs Controller, CDSCO, MoHFW, GoI **Participation:** Regulatory Heads of leading Med-Tech Companies, WHO Representatives. **Expected Outcome:** Participants will develop clarity on the new rules that will go into effect from January 2018. (Seating Plan: Roundtable Sitting)