Department of Pharmaceuticals
Government of India

As on 12 February 2019

Program: India Medical Device Conference -2019
18th – 19th February 2019 | The Lalit Ashok, Bangalore
'Accelerating Growth to Achieve Universal Healthcare'

DATE / TIME	EVENT	
	Day 1: Monday, 18 February 2019	
0930-1130 ***KALINGA -1***	**Inaugural Session & Awards: India Pharma 2019 & India Medical Device 2019**	
	0830-0930	Registration
	0930-1130	Inaugural Session
1130-1200	**Tea Break**	
1200-1330 ***KALINGA-2***	PLENERY SESSION – 1M **DIAGNOSTICS ECOSYSTEM IN INDIA: ENSURING ACCESS, QUALITY & INNOVATION FOR ALL**	
	Session Brief: This session should cover role of IVDs/ IVD industry from Access, Quality and innovation standpoint and how over years access has been increased by stable prices and extended reach to tier2-3 cities through lab networks and robust supply chain ensuring delivery, service and quality to last mile. Since the talk will be on the entire ecosystem – speakers can highlight the intricacies of a diagnostic supply chain and prevailing business models – its uniqueness and how the ecosystem is delicately balanced and prone to getting disturbed by irrational controls.	
	Chair: Mr Lov Verma, Former Secretary – Ministry of Health & Family Welfare, Government of India **Moderator: Mr Vikas Dandekar,** Editor - Pharma and Healthcare, ET Prime	
	Government Panellists: • **Mr Jawaid Akhtar** Principal Secretary - Health and FW Department, Government of Karnataka* • **Dr Mandeep K Bhandari,** Joint Secretary, Ministry of Health & Family Welfare, Government of India • **Ms Ritu Dhillon,** Joint Secretary, Department of Pharmaceuticals; Member Secretary, NPPA, Government of India • **Dr Gaby Vercauteren,** Senior Advisor – Regulatory Systems, WHO Geneva Industry Panellists • **Mr Gerd Hoefner**, Managing Director of Siemens Healthcare Pvt. Ltd • **Mr Saurabh Rajadhyax,** Managing Director - Biomeriuex India Pvt Ltd • **Ms Veena Kohli,** CEO - Vanguard Diagnostics • **Mr Vijay Kumar,** Head – Marketing, Roche Diagnostics India	
1330-1430 ***KALINGA -1***	**Lunch**	
1430-1630 ***LALIT – 3&4***	**INDIA MEDICAL DEVICE 2019 CEO'S ROUNDTABLE *(By Invitation Only)***	

1430-1630 ***KALINGA -2***	PARALLEL SESSION **Workshop on Sensitizing the Medical Device Industry on BIS Standardization**
	Session Brief: BIS has formulated more than 20,000 Indian Standards out of which more than 1240 standards on medical devices are formulated by MHD under its 19 sectional committees through balance of interests among the relevant stakeholders like manufacturers, users, technologists and regulators etc. As per Medical device Rules 2017, the conformance to Indian standards formulated by BIS has been given the first preference for which wherever gap are existing, core groups, sub groups are made for formulation of standards expeditiously on fast track basis. The session will include: • BIS activities on Standardization & Certification • Medical Device Rules 2017 and role of standards therein • Importance of Indian Standards on Medical Devices from user's perspective • An insight into testing facilities envisaged for supporting product certification schemes of BIS. • Standards for the benefits of the Industry and collaborative approach
	Chair : Ms Ritu Dhillon, Joint Secretary, Department of Pharmaceuticals; Member Secretary, NPPA, Government of India
	Session Flow: • **Briefs about BIS** **Dr R K Bajaj,** Sc G & DDG (Standardization), BIS • **Presentation on Standardization** **Mr Prakash Bachani,** HMHD – BIS • **Presentation on Certification schemes of BIS** BIS Officer • **Presentation on Medical Device Rules 2017 and role of standards therein** CDSCO • **Presentation by user on medical devices** AIIMS • **Presentation on Testing Facilities at Kalam Institute of Health technology, (KIHT) Vizag** • **Presentation by Industry representative** **Mr Vibhav Garg,** Vice President-Health Policy & Govt Affairs – GE Healthcare
1630-1645	**Tea Break**

1645-1745 ***KALINGA -2***	PLENERY SESSION – 2M **PROMOTING MAKE IN INDIA: REVITALIZING EASE OF DOING BUSINESS**
	Session Brief: Track 1 - Strengthening Policy Framework for Med - Tech Sector Discussion on the immediate need for a separate Act and policy governing medical devices sector in order to streamline regulation on various fronts and pricing mechanisms. Predictable evidence based policy environment a key for growth of the sector. Track 2- Ensuring Global Harmonization of Regulatory Standards and Regimen Discuss on the need for global harmonization of regulatory standards and implementation of policies that promote access to world class standards compliant devices while tackling duplicity of testing requirements Track 3- Making Innovation the Cornerstone of Improving Healthcare Discussion on challenges in access to innovative medical technologies in the country today and recommend approaches to address the conundrum between pricing and quality, me-too products and cutting -edge technology and why innovation needs to be at the centre of improving healthcare access and achieving UHC targets
	Chair: Ms Surina Rajan, Director General, Bureau of Indian Standards **Moderator: Mr Madan Rohini Krishnan,** Vice President, India Medtronic
	Government Panellists: • **Ms Ritu Dhillon,** Joint Secretary, Department of Pharmaceuticals; Member Secretary, NPPA, Government of India • **Mr Rajiv Aggarwal,** Joint Secretary, , Department for Promotion of Industry and Internal Trade, Government of India • **Dr Mandeep K Bhandari,** Joint Secretary, Ministry of Health & Family Welfare, Government of India Industry Panellists: • **Mr Sashi Kumar V,** Co-Chair-FICCI Medical Device Committee; MD - Phoenix Medical Systems • **Mr Probir Das,** Regional Representative - India and Asia Pacific & Chairman, Terumo Asia Holding • **Mr Himanshu Baid,** Managing Director, Poly Medicure Ltd • **Mr Nalinikanth Gollagunta**, President & CEO, GE Healthcare & MD, Wipro GE Healthcare • **Mr Prabal Chakraborty,** Vice President & Managing Director, Boston Scientific India • **Mr Ajay Durrani**, Managing Director, Covestro India Pvt
1745-1800	**Tea Break**
1800-1930 **SIDDHARTHA**	**JOINT CLOSED-DOOR SESSION: INTERNATIONAL REGULATORS INTERACTION WITH CEO'S OF PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY (By Invitation Only)**
	Session Brief: The session aims to provide a platform for Pharmaceutical and 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.
1930 ***POOL SIDE***	**Dinner Hosted by Department of Pharmaceuticals, Government of India**

Day 2: Tuesday, 19th February, 2019	
1000 -1130 SIDDHARTHA	**SESSION by WHO** **WHO Regulatory Systems Strengthening and Prequalification Programme of Medical Products- Recent Updates**
	Session Brief The session will cover WHO activities and plans related to the regulation of health technologies including regulatory systems support and the prequalification of finished pharmaceutical products, active pharmaceutical ingredients, vaccines, and in vitro diagnostic products. The session will also provide participants with information on important developments and updates of the prequalification program, and the various ongoing and planned health product regulatory oversight strengthening, work-sharing and capacity building activities that can inform their development strategies. The session will also provide details on available expertise and technical assistance to achieve prequalification.
	Speakers • **Mr Deus Mubangizi,** Coordinator, Prequalification team, WHO Geneva- Update on WHO-PQ and supportive activities and update on WHO Collaborative procedure • **Dr Manisha Shridhar**, Regional Advisor, WHO South East Asia Regional Office- South East Asia Regulatory Network Updates • **Dr Madhur Gupta,** Technical Officer- Pharmaceuticals, WHO India Country Office- India Updates in India on the regulatory landscape and access to medical products. • **Dr Gaby Vercauteren** – Senior Adviser, Regulatory Systems Strengthening, WHO Geneva- Update on RSS – Technical assistance, Capacity building, harmonisation and GBT
1130 -1145	**Tea Break**
1145-1300 *SIDDHARTHA*	JOINT SESSION: 3MP **DECODING APPLICATIONS OF ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRY**
	Session Brief: Artificial intelligence (AI) is a growing technology that is finding applications in all aspects of life and industry: within the smart assistants found within the latest smartphones, and in the smart factories that use AI to enhance their efficiency. Likewise, the healthcare industry especially pharmaceutical and med-tech industry are finding new and innovative ways to use this powerful technology to not only help solve some of the biggest problems facing them today but also suggesting the newer opportunities in the ways they offer their products. In this session, the panellists will throw more light on various ways and avenues, where AI will contribute to better access to medical products and contributing to growth of these industries. **Key Points of Discussion:** • Use of AI in drug discovery & distribution– generating novel drug candidates, understanding disease mechanisms, analysing pre-clinical data, improving drug distribution and supply chain • Case studies on how deployment on AI tools are helping companies improve quality in manufacturing both in Pharma & Medtech • Use of AI in medical technologies - management of chronic diseases, improving medical imaging and integration with IoT to better monitor patient adherence to treatment protocols

	Chair: Dr Vijay Raghavan, Principle Scientific Advisor, Government of India ***** **Moderator: Mr Abhijit Varma**, Partner and Head of Data and Analytics, KPMG India
	Industry Panellists: • **Dr Vivek Ahuja,** Head Pharmacovigilance, Sun Pharma • **Mr Debashish Banerjee**, Head- Innovation and Strategy, Novartis • **Mr Rama Chandra Dash**, Delivery Leader, APAC & Greater China Group, GHHS, IBM Watson Health, IBM • **Mr Partha Sarathi Guha Patra**, Co-Founder and Director, SafetyKart.com • **Mr Dileep Mangsuli**, Chief Technology Officer, GE Healthcare • **Mr Rahul Shingrani**, Founder, ten3T
1300-1400	**Lunch**
1400-1515 ***GRAND BALLROOM***	PLENERY SESSION – 4M **ROAD TO UNIVERSAL HEALTHCARE THROUGH HEALTH TECHNOLOGY ASSESSMENT (HTA)**
	Session Brief: Track 1: Road to Universal Health Coverage in India: HTA as a Value Assessment Tool • How is HTA in India different than other LMICs? What are the learnings which could be applied in India? • Will HTA help in value assessment or also deciding a price point for a product? • How HTA is connected to equity and benefits various strata of society at large? Track 2: Universal Health Coverage and HTA: Healthcare Provider's perspective • How does local HTA fit into the decision-making process at a local level? • How would a hospital prioritize a list of the products, which would need local/hospital HTA as an addition to the national HTA findings of that product? Track 3: Universal Health Coverage and HTA: Healthcare Regulator's perspective • How does a product undergo a pan India evaluation in terms of data availability and quantitative assessment? How does real world evidence from India shape HTAIn evaluations?
	Chair: Dr Dinesh Arora, Deputy CEO, National Health Authority, Government of India **Moderator: Mr Pavan Choudary**, Managing Director, Vygon India
	Government Panellists: • **Ms Ritu Dhillon,** Joint Secretary, Department of Pharmaceuticals; Member Secretary, NPPA, Government of India • **Mr V K Gauba**, Joint Secretary - Department of Health Research (DHR), Ministry of Health & Family Welfare, Government of India * • **Mr Rajneesh Tingal, ,** Joint Secretary, Department of Pharmaceuticals, Government of India • **Mr Suresh Mathur**, Executive Director – IRDAI* • **Dr Mohammad Ameel**, Senior Consultant - National Health Systems Resource Centre (NHSRC) Panellists: • **Mr Sanjay Bhutani,** Managing Director – India & SAARC, Bausch & Lomb • **Dr Pinaki Ghosh,** Manager - Market Access & Health Economics, BBraun
1515-1530	**Tea**

1530 -1545 ***SIDDHARTHA***	**Keynote Address on Ayushman Bharat** **Dr Indu Bhushan,** CEO - National Health Agency; Secretary – Government of India
1545 – 1715 ***SIDDHARTHA***	JOINT SESSION – 5 MP **MED-TECH & PHARMACEUTICALS: GEARING UP FOR AYUSHMAN BHARAT**
	Session Brief: Track 1: The session would revolve around Ayushman Bharat, and how the entire ecosystem can move together towards Universal Healthcare. • Role of Medical Technology & Pharmaceutical Industry • Learnings from AB-PMJAY and road ahead for gearing up to serve a population of 500 Million. • Role to be played by med tech and pharma sector in skilling and capacity building of healthcare professionals, doctors, physicians, nurses, technicians etc. and institutionalizing this initiative for constant up-skilling of capabilities in the healthcare system • Steps towards a more inclusive Universal Healthcare coverage—International best practices Track 2: Enabling Med-Tech & Pharmaceuticals to Efficiently Serve Ayushman Bharat Ayushman Bharat's roll out makes a promising start to expand the market size and fill the longstanding demand side gaps in the medical device industry. The next BIG question arises on the supply side preparedness to meet this rising demand. In this evolving backdrop, this session aims at deliberating the short/medium/ long term structural/ operational changes required to enable this industry to serve this most aspirational health scheme rolled out by GoI.
	Chair: Dr Indu Bhushan, CEO - National Health Authority, Government of India **Moderator: Mr Parijat Ghosh,** Partner – Bain & Company *
	Government Panellists: • **Ms Shubhra Singh,** Chairperson, NPPA • **Mr Jawaid Akhtar,** Principal Secretary - Health and FW Department, Government of Karnataka* • **Mr Arun Singhal,** Additional Secretary, Ministry of Health & Family Welfare, Government of India; Chairman & Managing Director, HLL Life Care Limited* • **Mr Navdeep Rinwa,** Joint Secretary – Department of Pharmaceuticals, Government of India Industry Panellists: • **Mr Badhri Iyenger,** Chair - FICCI Medical Device Committee; Managing Director - South Asia & South East Asia, Smith & Nephew Healthcare Ltd. • **Mr S Sridhar,** Chair – FICCI Pharma Committee; Managing Director, Pfizer India Ltd • **Dr Alok Roy,** Co-Chair – FICCI Health Services Committee; Chairman, Medica Hospitals • **Mr Vivek Kamath**, Managing Director, MSD Pharma • **Mr Rakesh Chitkara**, Senior Director, Global Government Affairs, Abbott India
1715	**Close**

**Awaiting Confirmation*