Department of Pharmaceuticals
Government of India

AFFORDABLE QUALITY HEALTHCARE

'Driving NextGen Pharmaceuticals'

Draft Program: India Pharma 2018 Conference

15-17th February 2018

Bangalore International Exhibition Centre, Bengaluru

DATE / TIME	EVENT
	Day 1 – 15th February 2018, Thursday
0830-0930	**Registration**
0930-1130	**Inaugural Session & Award Ceremony: India Pharma 2018 & India Medical Device 2018**
1130-1200	**Ribbon Cutting of Exhibition & Media Interaction (Tea Open for Conference Delegates)**
1200-1400	**Pharma CEO's Roundtable with Hon'ble Minister (By Invitation)**
1230-1400	**Conference Session: Discovering Innovative Medicines in India: NCE Research – India Perspective**
	Session brief: The Indian pharmaceutical industry is recognized as a global leader in the production of high quality generic drugs and is ranked third in terms of manufacturing pharmaceutical products by volume. Alongside, India drug manufacturers have also steadily developed a healthy pipeline of New Chemical Entities (NCEs) backed by laudable initiatives by BIRAC, CSIR, and DBT. This session aims to take stalk of existing status of Indian drug discovery scenario and discuss strategies to expedite new drug development in India within a 10-year time frame. **Session Moderated by: Dr. Surinder Kher**, Managing Director, Manipal Acunova Ltd. **Session Constituents:** 1. **Dr. Kiran Kalia,** Director, NIPER, Ahmedabad 2. **Dr. Neelima Khairatkar Joshi,** Sr. VP and Head, NCE Discovery Research, Glenmark Pharmaceuticals 3. **Dr. Akhilesh Sharma,** Sr. VP and Global Head of Medical Affairs, Dr. Reddy's Laboratories 4. **Dr. Anand Anandkumar,** CEO & MD, Bugworks Research India Pvt. Ltd. 5. **Shri Ranjit Madan**, CEO, Lifesciences Sector Skill Development Council (LSSSDC) 6. **Dr Luther Gwaza,** Technical Officer, Regulatory Systems Strengthening, Regulation of Medicines and other Health Technologies, WHO Geneva 7. **Ms. Agnes Saint-Raymond**, Head of International Affairs Division, European Medicines Agency **Expected Participation:** Officials from Govt. of India, Clinical research organizations, Industry participants, Regulators – state regulators and DCG, Academia, Trade and Business officials from Embassies / Foreign missions (Seating plan: Dais and Theatre style)
Networking Lunch (14:00 – 15:00)	

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
Day 1 – 15th February 2018, Thursday	
1500-1645	**Conference Session: Opportunities, Challenges and Regulatory Requirements in the Development of Biologics – Domestic Context and Global Scenario**
	Session brief: The Indian biosimilar market is poised for high growth augured by the launch of new products. Indian life science firms are investing in biosimilar development to acquire skill sets, latest manufacturing technologies and to be able to succeed in the complex regulatory environment globally. The sessions aims to discuss: 1. Status of the biosimilars market in India. 2. Highlight success stories of the sector in both domestic as well as global markets. 3. Discuss regulatory requirements for marketing authorization of similar biologics in India. 4. Provide comparative assessment of regulatory requirements/pathways in India and globally. 5. Harmonization of regulatory standards that allow for easier and faster access to export markets. 6. Discuss the Chemistry, Manufacturing & Control (CMC) studies required to gain marketing approval of biosimilars. **7.** Enable application of underlying core principles of biosimilar development, and the lessons learned, into company's biosimilar strategy. **Session Chair: Dr. Surinder Singh,** Director, National Institute of Biologicals **Session Moderated by: Dr. Bobby George,** VP & Head Regulatory Affairs, Reliance Life Sciences **Session Constituents:** 1. **Shri Rajasekar Narayansamy**, ED and CFO, Shantha Biotechnics 2. **Dr Davinder Gill,** CEO, Hilleman Laboratories Ltd 3. **Dr. Rajesh Ullanat**, Vice President, Technical Development, Biologics, Mylan Labs. 4. **Dr. Dhananjay Patankar,** Vice President - Pharmaceutical & Biologics Development - Syngene International Limited 5. **Mr Wondiyfraw Zeleke Worku**, Technical Officer, Prequalification Team, Regulation of Medicines and other Health Technologies, WHO Geneva 6. **Ms. Agnes Saint-Raymond**, Head of International Affairs Division, European Medicines Agency 7. **Mr. Subin Sankarankutty**, Regulatory Consultant, Health Sciences Authority, Singapore **Expected Participation:** 1. Officials from Govt. of India, Industry Participants, Regulators (DCGI and State drug regulators), Export Promotion Agencies, Pharma Associations, Academia and Trade and Business officials from Embassies / Foreign missions (Seating plan: Dais and Theatre style)
Tea Break (16:45 – 17:00)	

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
Day 1 – 15th February 2018, Thursday	
1700-1800	**Closed-Door Session: International Regulators Interaction with CEOs**
	Session brief: The session aims to provide a platform for Pharma 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. **Session Chair: Shri Jai Priye Prakash,** Secretary, Department of Pharmaceuticals, Government of India © **Convener of the Session:** Knowledge Partner **Dignitaries from Government of India:** 1. **Shri Amitabh Kant,** CEO, NITI Aayog, GoI 2. **Smt. Rita Teaotia,** Secretary, Ministry of Commerce, Government of India 3. **Shri Ramesh Abhishek,** Secretary, Department of Industrial Policy and Promotion, GoI 4. **Dr. R.K. Vats**, Additional Secretary, MoHFW, GoI 5. **Shri D.V. Prasad,** Additional Chief Secretary - Industries, Govt. of Karnataka 6. **Dr. Ajay Seth,** Additional Chief Secretary - Industries, Govt. of Karnataka 7. **Shri Bhupendra Singh**, Chairman, National Pharmaceutical Pricing Authority, GoI 8. **Dr. G.N. Singh**, Drug Controller General (India), CDSCO 9. **Shri Sudhansh Pant,** Joint Secretary, Department of Pharmaceuticals, GoI 10. **Shri Rajiv Aggarwal,** Joint Secretary, Department of Industrial Policy & Promotion, Government of India 11. **Shri Shyamal Misra**, Joint Secretary, Department of Commerce, GoI 12. **Shri Rajneesh Tingal,** Joint Secretary, Department of Pharmaceuticals, GoI 13. **Sri Solomon Arokia Raj,** Principal Secretary, Industries, Govt. of Andhra Pradesh 14. **Shri Sudhir Rajpal,** Principal Secretary, Industries, Govt. of Haryana 15. **Shri Rakesh Ranjan**, Member Secretary, National Pharmaceutical Pricing Authority, Government of India 16. **Dr. Dinesh Arora,** Director, NITI Aayog 17. **Shri Ravi Uday Bhaskar,** Director General, Pharmexcil **Session Constituents: On Regulators Head Table ©:** 1. Central Drugs Standard Control Organization (CDSCO) 2. US FDA, EMA Europe, HSA Singapore, COFEPRIS Mexico, Russia, Indonesia and Ghana 3. State Drug Controllers from 15 states 4. Ms Emer Cooke, Head, Regulation of Medicines and other Health Technologies, WHO Geneva 5. Dr Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India Country Office **Industry CEOs and Regulatory Heads from:** Zydus Cadila, Glenmark, Pfizer, Lupin, Cipla, Sun Pharma, Sanofi, GSK, Novartis, Roche, MSD, Abbott, Mylan, Reliance Life Sciences, Micro Labs etc.

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
Day 1 - 15 February 2018, Friday	
1815 – 1915	**Roundtable Session: Moving towards API Self-sufficiency**
	Session brief: Today India is dependent on basic drugs like Penicillin or Paracetamol or Ciprofloxacin. After achieving self-reliance in the 1980s, we are back to 1960s wherein we are importing Penicillin-G, 6-APA, 7-ACA, Thioc, etc. Import of APIs & Intermediates during FY 2016-17 was approx. USD 3.2 Bn, 65% of which is imported from One Single Country. A lot of policy discussions have already been carried out in various quarters of the government to kick start the process towards API self- sufficiency. The session will aim to discuss policy decisions that have been taken so far and aim to facilitate interaction between policy makers and industry stakeholders to identify best way forward **Session Chair: Shri Jai Priye Prakash,** Secretary, Department of Pharmaceuticals, GoI **Dignitaries from Government of India:** 1. **Shri Amitabh Kant,** CEO, NITI Aayog, GoI 2. **Smt. Rita Teaotia,** Secretary, Ministry of Commerce, Government of India 3. **Shri Ramesh Abhishek,** Secretary, Department of Industrial Policy and Promotion, GoI 4. **Dr. R.K. Vats**, Additional Secretary, MoHFW, GoI 5. **Shri D.V. Prasad,** Additional Chief Secretary - Industries, Govt. of Karnataka 6. **Dr. Ajay Seth,** Additional Chief Secretary - Industries, Govt. of Karnataka 7. **Shri Bhupendra Singh**, Chairman, National Pharmaceutical Pricing Authority, GoI 8. **Dr. G.N. Singh**, Drug Controller General (India), CDSCO 9. **Shri Sudhansh Pant,** Joint Secretary, Department of Pharmaceuticals, GoI 10. **Shri Rajiv Aggarwal,** Joint Secretary, Department of Industrial Policy & Promotion, Government of India 11. **Shri Shyamal Misra**, Joint Secretary, Department of Commerce, GoI 12. **Shri Rajneesh Tingal,** Joint Secretary, Department of Pharmaceuticals, GoI **13. Sri Solomon Arokia Raj,** Principal Secretary, Industries, Govt. of Andhra Pradesh 14. **Shri Sudhir Rajpal**, Principal Secretary, Industries, Govt. of Haryana 15. **Shri Rakesh Ranjan**, Member Secretary, National Pharmaceutical Pricing Authority, Government of India 16. **Dr. Dinesh Arora,** Director, NITI Aayog 17. **Shri Ravi Uday Bhaskar,** Director General, Pharmexcil 18. **Shri Lanka Srinivas,** Advisor - Pharmexcil **Special Invitee:** **Dr Manisha Shridhar**, Regional Advisor, WHO South East Asia Regional Office **Dr Madhur Gupta**, Technical Officer- Pharmaceuticals, WHO India Country Office **Partner industry associations:** Mr. D.G. Shah, Secretary General, Indian Pharmaceutical Alliance Mr. Deepnath Roy Chowdhury , National President, IDMA - Indian Drug Manufacturers' Association Mr. Daara B. Patel, Secretary-General , IDMA - Indian Drug Manufacturers' Association Mr. S.M. Mudda, Chairman, IDMA – KSB Mr. V.V. Krishnareddy, National President, BDMA Ms. T.K. Kanchana, Director General, OPPI Ms. Ivy Louis, President, PDA India Chapter **Industry representatives from:** Zydus Cadila, Glenmark, Pfizer, Lupin, Cipla, Sun Pharma, Sanofi, GSK, Novartis, Roche, MSD, Abbott, Mylan, Reliance Life Sciences, Micro Labs etc.
Reception and Business Networking Dinner	

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
Day 2 - 16 February 2018, Friday	
0930-1130	**Joint Regulators Meet: Sharing International Best Practices and Ensuring Quality in line with Global Standards**
	Session brief: A special session to focus on the best regulatory practices from around the globe. This adds to the bilateral convergence in these sectors and helps in creating special corridors of understanding and adopting best trade/ regulatory / manufacturing practices from across the globe. With theme of global knowledge sharing at the centre of the session, it also aims at long term harmonization between trading nations in the sector. **Session Moderated by:** *Knowledge partner* **Session Chair:** Shri Jai Priye Prakash, Secretary, Department of Pharmaceuticals, Government of India **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. K. Bangarurajan,** Joint Drug Controller, CDSCO, MoHFW, GoI e. **Dr. A. Ramkishan,** Deputy Drug Controller, CDSCO, MoHFW, GoI **2. International Regulators ©:** Regulatory experts from USFDA, EMA EU, Singapore, Russia, Mexico, Indonesia and Ghana **3. WHO ©** a. **Ms Emer Cooke –** Head, Regulation of Medicines and other Health Technologies, WHO Geneva **b. Dr Madhur Gupta,** Technical Officer- Pharmaceuticals, WHO India Country Office c. **Dr Manisha Shridhar,** Regional Advisor, WHO South East Asia Regional Office **d. Dr Gaby Vercauteren –** Senior Adviser, Regulatory Systems Strengthening, Regulation of Medicines and other Health Technologies, WHO Geneva **Expected participation:** 1. Industry Members comprising Regulatory Affairs, Quality Assurance etc. 2. Government Officials 3. Regulators – CDSCO and State Drug regulators 4. Quality Council of India 5. Trade and Business officials from Embassies / Foreign missions (Seating plan: Dais and Theatre style)
Tea Break (11:30 – 11:45)	

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
Day 2 - 16 February 2018, Friday	
1145-1345	**Workshop by WHO: Regulatory Systems Strengthening and Prequalification updates by WHO**
	Session Chair: Shri Jai Priye Prakash, Secretary, Department of Pharmaceuticals, GoI **Session Co-chair**: Dr. R.K. Vats, Additional Secretary, MoHFW, GoI **Session Moderator**: Shri Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals, GoI; Dr GN Singh, Drugs Controller General (India) **Speakers** • **Ms Emer Cooke –** Head, Regulation of Medicines and other Health Technologies, WHO Geneva • Dr Manisha Shridhar, Regional Advisor, WHO South East Asia Regional Office • **Dr Madhur Gupta, Technical Officer-** Pharmaceuticals, WHO India Country Office • **Mr Wondiyfraw Zeleke Worku,** Technical Officer, Prequalification team, Regulation of Medicines and other Health Technologies, WHO Geneva • **Dr Gaby Vercauteren –** Senior Adviser, Regulatory Systems Strengthening, Regulation of Medicines and other Health Technologies, WHO Geneva • **Dr Luther Gwaza –** Technical Officer, Regulatory Systems Strengthening, Regulation of Medicines and other Health Technologies, WHO Geneva **Scope of the workshop:** 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 opportunities that are expected to result from the expansion and evolution of the prequalification program, starting with a pilot on biosimilars, as well as the intention to promote greater reliance on mature regulatory authorities in the prequalification process. Participants will be provided with information on the various ongoing and planned health product regulatory oversight strengthening, work-sharing and capacity building activities that can inform their development strategies. Within the purview of prequalification, the session will also provide an overview of what products are eligible for evaluation, the application processes (including the type and extent of information that must be submitted) and the components of evaluation. The session will also provide details on available expertise and technical assistance to achieve prequalification. **Objectives:** • To provide information, insight and available opportunities from various regional harmonization initiatives for regulation and accelerated/facilitated approval of health products. • To provide an update on WHO's collaborative registration procedure (CRP): the achievements to date and plans for extending those achievements other products. • To introduce manufacturers who are unfamiliar with WHO prequalification and/or are considering submission of an application for evaluation for prequalification. • To introduce recent product additions to the prequalification scheme i.e. products for vector control and the pilot project for prequalification of biosimilars for cancer treatment • To provide technical updates for the different prequalification product streams: contraceptive devices, IVDs, medicines, vaccines and vector control products. • To provide details for advice and technical expertise and assistance to potential manufacturers. **An opportunity for one-on-one sessions by appointment with interested companies. These would likely be in parallel to sessions that our team members are not actively involved**.
Networking Lunch (13:45 – 14:30)	

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
Day 2 – 16th February 2018, Friday	
1430-1600	**Technical Session: Opportunities & Challenges for Stem Cells and Regenerative Medicine**
	Session Brief: Stem cells and regenerative medicine has emerged as a new and most exciting field of life science in view of its potential clinical applications. In 2013, taking note of the increasing use of cell and cell based therapies in India, the CDSCO set-up an expert committee and released draft guidance document in conformity with Drugs and Cosmetics Act and Rules thereunder and GCP guidelines of India for submission of clinical trial application. Also, in 2013, the Indian Council of Medical Research (ICMR), Department of Health Research (DHR) and Department of Biotechnology (DBT) jointly released a guidance document titled "National Guidelines on Stem Cell Research" to monitor and regulate research activities in Stem Cells. ICMR and DBT have also formed the "National Apex Committee for Stem Cell Research and Therapy" (NAC – SCRT). This session aims to: **1.** Provide a status update/ market potential for such therapies in both domestic as well as export markets **2.** Showcase challenges and mitigation strategies for gaining marketing approval in India **3.** Discuss case stories of pipeline treatment options **4.** Provide regulators view point and clarify any approvals related queries **5.** Highlight the roles and responsibilities of ICMR and DBT in governing research in stem cell therapy **6.** Clarify any ambiguities with respect to the ambit of NAC – SCRT **Session Chair: Dr. VG Somani**, Joint Drug Controller, CDSCO, GoI **Session Moderated By: Shri Mayur Abhaya,** MD & CEO, LifeCell International Pvt. Ltd **Session Constituents:** **1.** **Dr. Geeta Jotwani,** Scientist 'F', Indian Council of Medical Research (ICMR) **2.** **Dr. B.N.Manohar**, MD, Stempeutics Research Pvt. Ltd. **3.** **Dr. K.M.Cherian**, Chairman & CEO, International Centre for Cardio Thoracic & Vascular Diseases **4.** **Dr. Taslimarif Saiyed,** CEO and Director, Centre for Cellular and Molecular Platforms **5.** **Mr**. **Brendan Cuddy**, Head of Manufacturing and Quality Compliance - European Medicines Agency **Expected Participation:** Industry Members, Government Officials, Regulators – CDSCO and State Drug regulators, Trade and Business officials from Embassies / Foreign missions (Seating plan: Dais and Theatre style)
Tea Break (16:00 – 16:15)	

Department of Pharmaceuticals
Government of India

DATE / TIME	EVENT
	Day 2 – 16th February 2018, Friday
1615-1800	**Conference Session: Emerging global trends in self-care and relevance of OTC regulatory framework for Indian public healthcare system**
	Session brief: The Global market for OTC drugs is valued at USD 120 billion and estimated to scale up to USD 133.25 billion by the end of 2016. Currently the Indian Consumer Healthcare Market is estimated to be approximately INR 222,135.4 million with a compound annual growth rate (CAGR) of 12.7% for the years 2011-16. Despite this evidence showing that OTC medications play a significant role in supporting the public health, OTC medicines currently have no legal recognition in the Drugs and Cosmetics Act and Rules of India. Instead, all drugs that are not included in the list of 'prescription drugs' are currently considered non-prescription drugs (or "deemed" OTC drugs). In order to remove ambiguity and to empower the consumer, as well as the pharmacist to assist in making the choice of correct medication, it is required that clear processes are laid out for approval, marketing and distribution of OTC drugs in the country. The session will debate and explore views from Industry, academia, regulators, health care practitioners, experts on self-care and OTC framework for India. Self-care is the treatment of common health problems with medicines especially designed and labelled for use without medical supervision and approved as safe and effective for such use. Access-Affordability-Trust-Empowerment, these four attributes epitomize the value over-the-counter (OTC) medicines provide to consumers and our nation's healthcare system. **Key Note Address: Shri Martin Koehring**, Managing Editor & Global Healthcare Lead, Thought Leadership, The Economist Intelligence Unit © **Session Moderated by**: **Shri Arun Mishra**, Executive Vice President (Regulatory Affairs), GSK Consumer Healthcare, India © **Session Constituents:** 1. **Shri Sudhansh Pant,** Joint Secretary, Department of Pharmaceuticals, GoI © 2. **Dr. GN Singh,** Drug Controller General (India), Central Drug Standards Control Organization, GoI 3. **Shri Navneet Saluja,** Managing Director, GSK Consumer Healthcare Ltd © 4. **Ms Emer Cooke**, Head, Regulation of Medicines and other Health Technologies, WHO Geneva 5. **Shri Kedar Rajadnye**, Chief Operating Officer, Consumer Products Division, Piramal Enterprises Ltd. © 6. **Shri Venu Ambati**, Managing Director, Abbott India Ltd. © 7. **Dr Madhur Gupta**, Technical Officer- Pharmaceuticals, WHO India Country Office 8. **Dr Kiran Kalia,** Director, NIPER Ahmedabad © 9. **Mr. Subin Sankarankutty,** Regulatory Consultant, Health Products Regulation Group, Health Sciences Authority, Singapore © **Expected Participation**: Industry Members, Government Officials, Regulators – CDSCO and State Drug regulators, Trade and Business officials from Embassies / Foreign missions (Seating plan: Dais and Theatre style)

Department of Pharmaceuticals
Government of India

<table>
<tr><th>DATE / TIME</th><th>EVENT</th></tr>
<tr><td colspan="2">Day 3 – 17th February 2018, Saturday</td></tr>
<tr><td>1100-1315</td><td>Conference Session by NASSCOM: Digital Transformation through Innovation in Pharmaceutical, Medical Devices and Healthcare Industries</td></tr>
<tr><td></td><td>
Session brief: Internet of Things (IoT) and other emerging technologies are revolutionizing the way the businesses are conducted. The rate of adoption of newer technologies such as Big Data, Analytics, Artificial Intelligence, Machine Learning, Augmented Reality, Virtual Reality, Robotics etc. has been on the rise in the last few years, and it's going to grow exponentially in the coming years.
The Indian Life Sciences industry, with a leading role in global economy, is not the one to be left behind in this race. Several start-ups and matured organisations are continuously churning out newer and better solutions based on these technologies.

Pharmaceuticals, Medical Devices and Healthcare industries are thriving extensively to adopt these newer technologies for efficiency gains, reduction in cycle times, improvised quality and optimizing the costs.
Session Agenda:
<table>
<tr><td>Welcome Address (11:00 AM to 11:10 AM)</td><td>Sanjeev Malhotra – CEO, NASSCOM Center of Excellence - IoT</td></tr>
<tr><td>Key Note 1 – Technology Adoption and Trends in Pharmaceutical Industry (11:10 AM to 11:30 AM)</td><td>Naveen Kashyap – Managing Director, Yokogawa IA Technologies India Ltd.</td></tr>
<tr><td>Key Note 2 –Growth of Wearables & its impact on Life Sciences Industry (11:30 AM to 11:50 AM)</td><td>Ramaswamy Narayanan – Director, Global IT & Center Leader, Medtronic</td></tr>
<tr><td>Start-up Show Case – (11:50AM to 12:20PM)</td><td>Innovator 1 - Geetha Manjunath, Co-founder and CEO, NIRAMAI

Innovator 2 - Dr. Ashim Roy, Founder, CardioTrack

Innovator 3 – Vikram Rastogi, Founder, Hack Lab</td></tr>
<tr><td>Panel Discussion - "Digital Transformation – Enablers & Challenges: Role of Start-up eco-system in India" (12:20 PM to 01:00 PM)</td><td>Moderator: Annie Mathew - Senior Director, Evangelism, Commercial Software Engineering

Panellist 1 – Phani Mitra, Vice President – Analytics & Strategy, Dr. Reddy Labs

Panellist 2: Vamsi Chandra Kajjivala, Co-Founder & CEO at Enlightiks (Acquired by Practo)

Panellist 3: Shyam Harinath - Innovation Lead, Philips HealthWorks

Panellist 4: Dr.Anup Karnik, Lead (COE) – Life Sciences and Healthcare, Capgemini</td></tr>
</table>
</td></tr>
</table>