Confederation of Indian Industry

CII PHARMA Driving Competitive & Quality Pharmaceuticals

14th National Pharmaceutical Conclave 2017

Maximizing the Pharmaceutical Opportunity for India
Vision and Roadmap- 2025
20 – 21 December 2017: Hotel Le Meridien, New Delhi
Draft Programme

Day 1

0930-1045 Hrs	Inaugural Session
Welcome Address	**Ms. Shobana Kamineni*** President, Confederation of Indian Industry (CII) & Executive Vice Chairperson, Apollo Hospitals Enterprise Limited Or **Mr. Chandrajit Banerjee*** Director General Confederation of Indian Industry
Setting the Context	**Dr Rajiv I Modi** Chairman, CII National Committee on Pharmaceutical Chairman & Managing Director Cadila Pharmaceuticals Ltd
Industry perspective	**Mr. Susheel Umesh** Co-Chairman, CII National Committee on Pharmaceuticals & Managing Director and General Manager Abbott Healthcare Pvt Ltd.
Special Address	**Shri Jai Priye Prakash*** Secretary Ministry of Chemicals and Fertilizers Or **Shri C.K. Mishra*** Secretary Ministry of Health & Family Welfare
Chief Guest	**Shri Ananth Kumar*** Honorable Minister for Chemicals and Fertilizers Or **Shri Mansukh L. Mandaviya*** Honorable Minister of State for Chemicals and Fertilizers Or **Shri Rao Inderjit Singh*** Honorable Minister of State for Chemicals and Fertilizers
Closing Remarks	**Mr. Rakesh Bamzai** Co-Chairman, CII National Committee on Pharmaceuticals & President Mylan
1045-1100 Hrs	**Networking Tea / Coffee**

1100-1300 Hrs	**Panel discussion: Building a robust roadmap to drive excellence in quality in pharmaceuticals**

India is amongst the most favorable destination for the manufacturing of pharmaceuticals. Indian pharmaceutical sector accounts for about 2.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms, 20 per cent of global exports in generics and is expected to expand at a Compound Annual Growth Rate (CAGR) of 22.42 per cent over 2015-20 to reach USD55 billion. However, there are many challenges being faced by Indian pharmaceutical industry. This session aims to discuss various issues, challenges, and ways to highlight the value preposition of Indian pharma globally. Hence, we need to continuously focus on developing capabilities in terms of quality that builds the global image of Brand India. This session would identify key areas of interventions in terms of quality to build the credibility of Brand India.

Session Moderator	Senior Representative, Pricewaterhousecoopers Private Limited (Pwc)
Panelists	**Mr. Prashant Kumar Pathak** Chief Executive Officer & Managing Director Delcure Lifesciences Ltd. **Mr. Chetan Gupta** Vice President- Corporate Affairs Emcure Pharmaceuticals Ltd **Mr. Rakesh Bhargava** Chairman, Fresenius Kabi Oncology Ltd.
Special Address	**Dr. G. N. Singh*** Drugs Controller General of India Central Drugs Standard Control Organization Or **Dr. S. Eswara Reddy*** Joint Drugs Controller General Of India Central Drugs Standard Control Organization
Special Address	**Ms. Samina Vaziralli** Executive Vice Chairman Cipla Ltd. Representative, USFDA Representative, WHO
Concluding Remarks	Senior Representative, Pricewaterhousecoopers Private Limited (Pwc)

Release of Quality Report in the session

Q&A

1300-1400 Hrs	**Networking Lunch**

1400-1530 Hrs	**Panel discussion: Indian API Pharmaceutical Industry - Risks, Challenges and Way Forward**

India's absolute dependence over APIs on China along with some European nations has been quite alarming. Indian API industry is plagued with issues revolving around increased dependence on Chinese API imports and a few non-compliance incidents. India is importing API's and intermediates worth 3 billion dollars from China, which is dictating the market in terms of availability and pricing today. This calls for an urgent need for India to have a re-look at its API strategy. The Indian industry is anticipating quick measures and moves on the Katoch Committee report (2015) and also robust steps where government steps-in as a key enabler for manufacturing top priority molecules which are in demand to prevent any emergency which may occur due the country's over dependency.

Session Moderator	**Mr. Utkarsh Palnitkar** Partner and Head-Life Sciences KPMG, India
Panelists	**Mr. Vivek Save** Managing Director & Country Head India Lonza India Pvt Ltd **Mr. Naresh Gupta** President, Lupin Pharma Ltd **Mr. Vivek Vasudev Kamath** Sr. Director, CVM, PHI & Market Access MSD Pharmaceuticals Ltd.
Special Address	**Shri Ajay Narayan Jha*** Secretary Ministry of Environment, Forests & Climate Change Or **Dr. V.M. Katoch*** Or **Mr. Amitabh Kant***, CEO, NITI Ayog
Special Address	**Dr Rajiv I Modi** Chairman, CII National Committee on Pharmaceuticals Chairman & Managing Director Cadila Pharmaceuticals Ltd **Mr. Rakesh Bamzai** Co-Chairman, CII National Committee on Pharmaceuticals & President, Mylan
Closing Remarks	**Mr. Utkarsh Palnitkar** Partner and Head-Life Sciences KPMG, India

Release of API Report in the session

Q&A

1530-1700 Hrs	**Panel discussion: Biopharmaceuticals and Fourth generation technologies in pharma- Present and future**

Biopharmaceuticals have caused an archetype shift in disease cure and has led to an enhancement in the quality of life of patients with various diseases not cured by standard line of therapy. Biopharmaceuticals represent 7.5% of all drugs in the market and account for ~10% of the total expenses for marketed drugs. The usage of biopharmaceuticals are increasing at the rate >20% per year. The Conference aims to address key regulatory, scientific, and commercial challenges and opportunities in biopharmaceutical space. Further, many large pharma companies are starting to realize the potential of the fourth-generation technologies like artificial intelligence and how it can help improve efficiencies. The Sessions would also lay down strategies for adoption and application of these fourth-generation technologies along the R&D pipeline to optimize the discovery and development of novel therapies with better outcomes, that are faster and cheaper.

Session Moderator	**Mr. Satish Reddy** Joint Managing Director & COO Dr. Reddy's Laboratories Ltd
Panelists	**Mr. Dilip Surana** Chairman & Managing Director Micro Labs Limited **Mr. Jatish Narottamdas Sheth** Director Srushti Pharmaceuticals Pvt. Ltd. . Representative Member, OPPI, IDMA, BDMA, IPA
Special Address	**Dr. K. VijayRaghavan*** Secretary Department of Biotechnology Or **Shri Chandra Prakash Goyal*** Joint Secretary Department of Biotechnology
Keynote Address	**Mr Annaswamy Vaidheesh** VP South Asia & Managing Director, India GlaxoSmithKline Pharmaceuticals Ltd. **Mr. Srini Srinivasan** Managing Director Hospira Healthcare India Pvt. Ltd. (a Pfizer company)
Concluding Remarks	**Mr. Satish Reddy** Joint MD& COO Dr. Reddy's Laboratories Ltd

Q&A

DAY 2

0930-1100 Hrs	**Panel discussion: Ease of doing business in Pharma**

India is looking to make pharma more conducive for growth and to boost investment in the sector. Ease of Doing Business is highly desired by the industry, as the amount of effort and time spent to get multiple clearances from multiple agencies sometimes becomes overwhelming. A single interactive e-portal (e-window) like the Sugam portal to facilitate application with proper guidelines on movement of the application to various clearance agencies and an empowered committee to resolve emerging issues is a forward approach. This session aims to bring forth the various difficulties faced by the pharma industry, especially in respect of initiating business in India and improving the regulatory mechanism for the pharmaceutical sector. The sessions would also focus on action plans for states that will require them to sharpen focus on improving ease of doing business in pharmaceuticals.

Session Moderator	**Mr. Susheel Umesh** Co-Chairman, CII National Committee on Pharmaceuticals & Managing Director and General Manager Abbott Healthcare Pvt Ltd.
Panelists	**Mr. Sharad Tyagi** VP, OPPI & Managing Director Boehringer Ingelheim India Pvt Ltd
	Mr. Madhav B Shriram DCMSR
	Mr. Hari S Bhartia Co Chairman and Managing Director Jubilant Life Sciences
Special Address	**Shri Rajneesh Tingal*/ Shri Sudhansh Pant*** Joint Secretary Ministry of Chemicals and Fertilizers
	Shri Bhupendra Singh* Chairman, National Pharmaceutical Pricing Authority
Special Address	**Dr Rajiv I Modi** Chairman, CII National Committee on Pharma Chairman & Managing Director Cadila Pharmaceuticals Ltd
	Ms. Samina Vaziralli Executive Vice Chairman, Cipla Ltd.
Closing Remarks	**Mr. Rakesh Bamzai** Co-Chairman, CII National Committee on Pharmaceuticals & President, Mylan

Release of API Report in the session
Q&A

1100-1115 Hrs	**Networking Tea / Coffee**

1115-1230 Hrs	Interactions between academia and the pharmaceutical industry- Some experiences and scaling up

There is little doubt that academic and pharma researchers can accomplish far more together than either can do alone. Several nascent ideas and research works are rattling around already in the minds, labs, and notes of academic researchers – which is one reason why pharma R&D groups should work closely with academic centers. However, many of these collaboration opportunities are being left on the table. This session would aim to explore the mechanisms of pharma-academia R&D collaborations and summarize some key takeaways.

Session Moderator	**Mr. Dilip Shanghvi** Managing Director Sun Pharmaceuticals Ltd.
Panelists	**Mr. Adar C. Poonawalla** CEO Serum Institute of India Ltd.
	Mr. Madan Mohan Reddy Chairman, Pharmexcil & Director Aurobindo Pharma Ltd
	Director, IIT
Special Address	**Prof. Raghuram Rao Akkinepally*** Director – Mohali NIPER
	Dr. Soumya Swaminathan* Director General ICMR
	Dr. Girish Sahni* Director General CSIR
Keynote Address	**Mr Sanjiv Navangul** Managing Director Johnson & Johnson
	Mr. Naresh Gupta President Lupin Pharma Ltd.
Concluding Remarks	**Mr. Dilip Shanghvi** Managing Director Sun Pharmaceuticals Ltd

Q&A

1230-1330 Hrs	Valedictory Session
Key Takeaways	**Dr Rajiv I Modi** Chairman, CII National Committee on Pharmaceuticals Chairman & Managing Director Cadila Pharmaceuticals Ltd **Mr. Rakesh Bamzai** Co-Chairman, CII National Committee on Pharmaceuticals & President Mylan
Special Address	**Ms. Rita A Teaotia*** Secretary Department of Commerce Or **Shri Ramesh Abhishek*** Secretary Department of Industrial Policy & Promotion (DIPP) Or **Shri C.K. Mishra*** Secretary Ministry of Health & Family Welfare
Chief Guest	**Shri Jagat Prakash Nadda*** Honorable Minister for Health & Family Welfare Or **Shri Suresh Prabhakar Prabhu*** Honorable Minister for Commerce & Industry And **Shri C R Choudhary*** Honorable Minister of State Commerce & Industry Or **Shri Ashwini Kumar Choubey*** Honorable Minister of State for Health & Family Welfare Or **Ms. Anupriya Singh Patel*** Honorable Minister of State for Health & Family Welfare
Vote of Thanks	**Mr. Susheel Umesh** Co-Chairman, CII National Committee on Pharmaceuticals & Managing Director and General Manager Abbott Healthcare Pvt Ltd.

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OPTIONAL SESSIONS

0930-1030 Hrs	Access & Sustainable Healthcare New India
Session Moderator	**Representative from IPA, OPPI, BDMA, IDMA**
Panelists	**Members from Committee**
Special Address	**Mr. Jitender Singh, PMO** **Dr. Sambit Patra, PMO**
Keynote Address	**Shri M. Ayyappan** CMD HLL Lifecare Limited **Shri Vinod Kumar Saxena** MD Indian Medicines Pharmaceutical Corporation Limited. Ltd.
Concluding Remarks	**Representative from IPA, OPPI, BDMA, IDMA**
Q&A	

1030-1130 Hrs BA/BE Equivalence...Right Path?

BA/BE equivalence is a key step for all new molecules reaching the market as they ensure the performance of the drug is matching the reference drug, and which will work in a desired fashion. To make India a quality oriented market place for the domestic market, some stake holders feel bioequivalence data should be made mandatory prior to grant of license for manufacturing of all drugs including those who are already in the market. This will reduce spurious drug menace from the country. However, whether BA/BE reports are mandatory for those molecules which are already there in the market and have been performing without any ADR is something which should be debated. And secondly, is this the only way to ensure quality and efficacy across the market..?

Session Moderator

Panelists

Special Address

Keynote Address

Concluding Remarks

Q&A

1130-1230 Hrs Loan Licensing/Contract manufacturing Right Perspective?

Loan licensing has been compared with non-standard manufacturing practices and an entry point for array of undesired FDCs and push sales products. However, this may not be the case always, as on the other hand to stay competent with respect to market demands and overseas competitions, a licensed manufacturer adhering to appropriate quality standards could be the right answer..so what may be the right perspective here...? an absolute stop or a go-ahead provided the right parameters are met...

Session Moderator

Panelists

Special Address

Keynote Address

Concluding Remarks

Q&A