World Health Organization
COUNTRY OFFICE FOR India

सत्यमेव जयते
Department of Pharmaceutical
Ministry of Chemicals & Fertilizers
Government of India

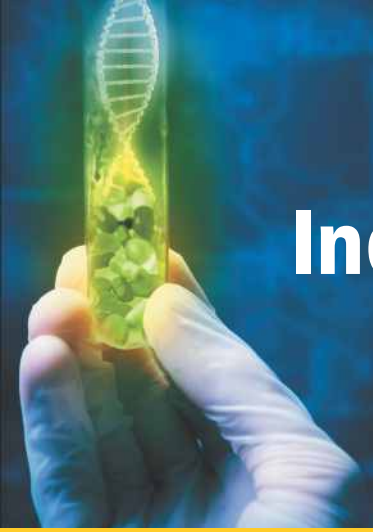
FICCI

India Pharma Summit 2013-14

Enhancing India's Global Role in Supply of Generic Medicines

"Focus on Strengthening Domestic Landscape of Active Pharmaceutical Ingredients, Regulation of Drug Trials and Fostering Innovation"

20th March, 2014
Centrum Hall, World Trade Centre, Mumbai



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The Indian Pharmaceutical Industry is currently valued at $26 billion and stands 14th in terms of value. Globally adjudged as the third largest in terms of volume, the sector is growing at 14% per year. The growth of the sector has been driven by high quality and competitively priced exports to both developing countries as well as high regulated markets of US and EU.

Federation of Indian Chambers of Commerce and Industry in partnership with Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India and WHO India Country Office is organizing the 5th edition of the India Pharma Summit 2013-14 on March 20th, 2014 at World Trade Centre, Mumbai.

India is emerging as a world leader in generic pharmaceuticals production, supplying 20% by value of the global market for generic medicines. Growth of Indian Pharmaceutical Industry is linked to the goal of Universal Health Coverage (UHC) under the 12th Five Year Plan set by no less than the Honorable Prime Minister of India. Hence, the critical importance of the summit

In this year's edition, the focus of the Summit would be on strengthening domestic landscape of Active Pharmaceutical Ingredients, Regulation of Drug Trials and Fostering Innovation.

Follow-up of the Past Summits

As an outcome of the previous Summits, Task Forces have been set up for R&D and Drug Discovery, HRD & Capacity Building and leadership in Clinical Research & Medical Devices.

Subsequent to the recommendations of the IPS 2012, three Regional Good Manufacturing Practices (GMP) Strengthening Workshops for Indian Pharmaceutical Manufacturers, focusing on GMP in production of Active Pharmaceutical Ingredients and Oral Solid Dosage forms were organized at Hyderabad, Ahmedabad and Chandigarh.

Who Should Attend:

- Decision-makers from: Think tanks/ Notified Bodies/Government
- Government Regulators
- Pharmaceutical and Biotech Industry
- CROs
- Public Health Organizations
- Venture Capital & Private Equity
- Academicians/ Research Institutions

What to Expect:

- Understanding different Stakeholder perspectives on the challenges in domestic production of API and sharing best practices on the API collaboration networks and international standards of GMP
- Better understanding of the new regulatory regime for the conduct of clinical trials in India including the way forward to address the challenges being faced by the pharmaceutical industry
- Enhancing the innovative capacity including technology transfer and priority setting for Research & Development based on the public health needs of developing countries like India and explore mechanisms which secure access and affordability
- Deliberations on Strategic Policy Roadmap and other key issues in Pharmaceuticals in India
- Understanding the challenges and solutions to the scourge of Indian Drugs Safety and Quality

DRAFT PROGRAMME

08:30-09:30 Hrs	Registration
9:30- 09:45 Hrs	Seating
9:45- 10:45 Hrs	Inaugural session Session Moderator FICCI
09:45-09:55 Hrs	Welcome Address/ Theme address Dr Habil Khorakiwala, Chairman FICCI Life Sciences Council, Past President FICCI and Chairman Wockhardt Group
09:55-10:05 Hrs	Special Address Dr Nata Menabde, WHO Representative to India
10:05 -10:15 Hrs	Special Address Dr Poonam Khetrapal Singh, Regional Director, WHO-South East Asia Region
10:15-10:30 Hrs	Keynote Address Dr Kiran Majumdar Shaw, Chairman & Managing Director, Biocon Ltd*
10:30-10:45Hrs	Inaugural Address Ms. Aradhana Johri, Secretary, Department of Pharmaceuticals
10:4510:55 Hrs	Concluding Remarks Mr Pankaj Patel, Chairman, FICCI Pharmaceuticals Committee and Managing Director, Zydus Cadila
10:55-11:00 Hrs	Release of Knowledge paper/ Position paper
11:00-11:15 Hrs	Tea Break
11:15-12:30Hrs	Session I Improving Domestic Landscape of Active Pharmaceutical Ingredients (API) including convergence towards international quality standards With increasing costs of pharmaceutical products and the emergence of low-cost competitors in the Indian market, the issue of cost, safety and quality for the API manufacturers is of utmost importance today since it remains a significant driver for the growth of the Industry. The session will focus on the current regulatory requirements for the quality of APIs, challenges with respect to compliance with global standards of manufacturing and emphasize on continuous improvement in the Regulated Environment to meet the changing dynamics in API manufacturing.
12:30-13:30Hrs	Lunch Break
13:30-14:50Hrs	Session II Fostering R &D and Innovation in India- Moving towards an R & D Policy in India It is time when the generic companies in India need to focus exclusively on the development of new molecules and innovation models. The pharmaceutical market needs new alternatives and strategies, and for these new products, innovation or "re-innovation" is inevitable. The distinction between innovative and generic activity is losing its significance in the last few years. The session will focus on strengthening the R&D and innovation models in the Pharma sector in India to generate better business outputs in Healthcare delivery.
14:50-16:15Hrs	Session III Streamlining the Regulatory Landscape of Conduct of Clinical Trials in India The regulatory regime for clinical trials poses many challenges for the pharmaceutical and biopharmaceutical companies. There has been approx.50% decline in the clinical trials over the year due to stringent norms; however this should not happen at the cost of innovation. This session will focus on streamlining and striking a balance in terms of regulations, ethics and transparency in Clinical Trials for innovative drug development at a time when there is a rise in the Disease Burden in India.
16:15-16:30Hrs	Tea Break
16:30-17:30 Hrs	Vision and Way Forward With increasing costs of pharmaceutical products and the emergence of low-cost competitors in the Indian market, the issue of cost, safety and quality for the Pharma is of utmost importance today since it remains a significant driver for the growth of the Industry. This session will focus on the vision of various Departments of the Government in contributing to the policy framework for the Pharma Industry

*tentative

About Organizers

सत्यमेव जयते

Department of Pharmaceutical
Ministry of Chemicals & Fertilizers
Government of India

The Department of Pharmaceuticals was created on 1st July 2008 to be a focused Department of Government of India for fostering growth of the Indian Pharmaceutical Industry. The Department has been assigned several functions including inter-alia promotion of Research, Education and Training, Public Private Partnership, international Cooperation, Inter- Sectoral cooperation, Industrial Cooperation, Environment and Hazard Management and Pricing and Availability of Medicines. The Department of Pharmaceuticals discharges their functions through active consultations with stakeholders to formulate new schemes/ proposals/ strategies for promoting growth of the Pharmaceutical Industry

FICCI

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies. FICCI has contributed to this historical process by encouraging debate, articulating the private sector's views and influencing policy.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry.

FICCI draws its membership from the corporate sector, both private and public, including SMEs and MNCs; FICCI enjoys an indirect membership of over 2,50,000 companies from various regional chambers of commerce.

FICCI provides a platform for sector specific consensus building and networking and as the first port of call for Indian industry and the international business community.

Our Vision: To be the thought leader for industry, its voice for policy change and its guardian for effective implementation.

Our Mission: To carry forward our initiatives in support of rapid, inclusive and sustainable growth that encompass health, education, livelihood, governance and skill development.

To enhance efficiency and global competitiveness of Indian industry and to expand business opportunities both in domestic and foreign markets through a range of specialised services and global linkages.

World Health Organization
COUNTRY OFFICE FOR India

World Health Organization is the United Nations' specialized technical agency for Health. It is an inter-governmental organization and works in collaboration with its member states. WHO's objective is the attainment by all people of the highest possible level of health. Equitable access to essential medicines for priority diseases is one of the requirements for fulfilling the fundamental right to health. WHO's Medicines' Strategy is based on four key objectives: strengthening national medicines policy, improving access to essential medicines, the quality & safety of medicines, and rational use of medicines.

WHO India Country Office collaborates with the Government of India and relevant stakeholders within the framework of the collaborative Country Cooperation Strategy (CCS), to actively support the development and implementation of national health policies, strategies and plans in the area of Essential Medicines & Pharmaceuticals, including access, quality and safety of medicines and impact of intellectual property rights on public health.

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Yes, we would like to participate

☐ FICCI Member ☐ FICCI Non Member

Delegate Details

Name of Organization: . . . . . .

Address: . . . . . .

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Country: . . . . . .

Pin/Zip: . . . . . .

Phone: . . . . . .

Fax: . . . . . .

Organization Type: . . . . . .

FICCI Membership Number (for those registering as member) . . . . . .

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