For the first time all leading Indian Vaccine manufacturers of India have come together and under the aegis of CII and have approached Ministry of Health & Family Welfare, DCGI and ICMR for resolving the issues and challenges faced by Indian Vaccine manufacturers. The initiative is led by Dr. Rajesh Jain, Joint Managing Director, Panacea Biotec, India’s leading Vaccine manufacturing company. Dr. Rajesh Jain, who is globally acknowledged as one of the top 40 leaders in the Biotechnology industry, is also Chairman of CII Committee on Biotechnology.

Under the leadership of Dr. Rajesh Jain, all seven leading vaccine manufacturers approached the Union Health Secretary, Sh .C K Mishra, Jt. Secretary-R, Sh. K L Sharma, Dr. G N Singh, Drugs Controller General of India (DCGI), Dr. V G Somani, Joint Drugs Controller, Dr. Eswara Reddy, Joint Drugs Controller & Mr Ramakrishna, Deputy Drugs Controller and presented the issues faced by Indian Vaccine manufacturers and sought their support in easing the business environment & regulatory difficulties to facilitate manufacturing of more and more innovative vaccines in India in line with Govt. of India’s mission of Make in India.

The overwhelming support from Ministry, DCGI and other drugs control department officials received, paved the way for organization of a National Conference on Vaccine Industry in India – Current Status and Future Prospects in association with CII, Ministry of Health and DCGI office to deliberate in detail on the regulatory issues faced by Indian vaccine manufacturers & prepare a comprehensive guideline cum policy document for modification of existing regulatory pathway. Indian Vaccine industry requires urgent regulatory and financial
reforms for increasing accessibility, growth and sustained competitiveness. The current regulatory pathway is cumbersome and results in delays of up to 3-5 years in introduction of a new vaccine into the market.

The Conference was attended by representatives of Govt. organizations, Ministries, DCGI officials and all leading private and public sector Vaccine manufacturers, NGOs, international organizations like GAVI, WHO etc.

Dr. Rajesh Jain, who was the Convener of the Conference, said in his inaugural address that it is time that vaccine manufacturers and regulators come together and resolve issues faced by the Indian vaccine manufacturers to pave the way for early and timely introduction of innovative vaccines by Indian manufacturers not only to meet demands of Govt. of India for its Universal Immunization goals but to meet the ever growing demand of immunization carried out by WHO, GAVI etc. in third world countries. Dr. Jain appreciated the overwhelming support and very positive response received from Union Health Secretary, Sh. C K Mishra, Sh.K L Sharma, Jt. Secretary, Ministry of Health, Govt. of India and Indian regulators led by Dr. G N Singh, DCGI & Dr. V G Somani, Jt. Drugs Controller to the need for carrying out regulatory reforms for facilitating ease of doing business and promoting innovation in Indian Vaccine industry. Dr. Jain said this is a momentous occasion where entire vaccine industry, regulators and Govt. Ministries have assembled on one platform and are ready to listen to the legitimate demands of the vaccine industry particularly long and cumbersome regulatory pathway followed for various R&D and manufacturing approvals. He applauded the directives of the Secretary - Health to present a draft report from the vaccine industry to the Govt. within two weeks’ time for their consideration and assured that Indian vaccine industry leaders and CII will consult regulators and will be able to present comprehensive report and policy documents for modifying existing regulatory guidelines within stipulated time.

Further elaborating on the industry demands, Dr. Jain said that Vaccine industry want to Minimize unnecessary paper work, Maximize Innovation, Capitalize Mission Indradhanush by developing vaccines faster which are accessible for our country’s National Immunization Program in a timely manner. Of course we will need to align our thoughts & strategy around expedited Clinical Trials to save both huge costs and time. For furthering Innovation we need: are “Regulatory Innovation Cell” with Dedicated DDC and Inspectors to look after it. Our Industry requests for: One Application, One Window, One Team (CDSCO, RCGM, DBT, and ICMR), One Process that is, Online Process, One Month clearance. All Experts from different fields to meet at FDA, Bhavan; Application can be assessed online through protected passwords for regulatory team; No response in 30days means process is approved

Sh. C K Mishra, Secretary, Ministry of Health said "Indian vaccines manufacturers should accord prime importance to meeting domestic demand, upscale research and development related work, and also take initiatives in developing critical vaccines such as Pneumococcal conjugate vaccine (PCV)and Human Papillomavirus (HPV) vaccines.

The Health Secretary said that the Government is committed to putting together resources for Mission Indradhanush. Mission Indradhanush is a government initiative to ensure full immunization of all children in India. He said that, he has already shared Ministry of Health’s plan for the next five years giving details of type of Vaccine to be incorporated in the Universal Immunization Program and now industry has to gear up and meet the deadline. Mr. Mishra also lauded the efforts of Indian vaccines players in leaving a mark on global landscape as leading supplier of vaccines to world, and said that it is encouraging to witness that there has never been an instance of shortage of vaccines in India. He asserted that the entire Indian Healthcare industry has to get involved for an effective healthcare delivery in India and "we must move from ‘health for all’ to ‘health by all’, whereby the vaccine industry has a critical transformational role to play."
Sh. C K Mishra also launched a position paper titled as “The Make in India Imperative – Position Paper on Regulatory and Policy Changes required for Sustained Competitiveness of the Indian Vaccine Industry prepared by Sathguru Consultants and CII in consultation with Dr. Rajesh Jain and other vaccine manufacturing companies for consideration of the regulators and Government.

Dr. GN Singh, Drug Controller General of India (DCGI), said that the government will form an expert group to examine regulatory issues for Indian vaccine industry. This expert group would work towards speedy resolution of issues in time-bound manner without compromising critical aspects like quality, patient safety and patient management, he said.

Ms. Mahima Datla, Managing Director of Biological E, chaired the panel discussion on ‘Regulatory Obstacles faced by Vaccine industry’. The speakers very effectively highlighted the need to bring about changes in various permissions required for carrying out R&D for new vaccines, unnecessary and cumbersome pathways for obtaining NOC in the form of Form-29 and the resulting delays in introducing new vaccines in the market.

Dr. Rajesh Jain, highlighted the need of developing a mechanism or creating an environment in India on the lines of USA, where new vaccine manufacturing or R&D companies are funded and have raised funding to the tune of over 1 billion US dollars. He said that In India though Department of Biotechnology supports innovation and grants funding, but it is negligible and does not enthuse Indian manufacturers as risk in carrying out R&D on new Vaccines and clinical trials are huge and can be up to 100 Crores and if that fails, no Indian company’s balance sheet has appetite to absorb that kind of loss. Ms. Bindu Dey, Secretary, Department of Biotechnology said that though govt. of India has created some enabling environment, it is not enough and more needs to be done to support R&D in Indian vaccine industry and she will take up the issue with the Government.

Dr. VG Somani, Jt. Drugs Controller (India) while chairing the concluding session, said DCGI office is aware of the complexities of the various laws, regulatory approvals and several inspections in the existing process and pains
of the vaccine industry. However, he assured that, Govt. of India and DCGI office is now ready to take up major reforms in the regulatory procedures and wants vaccine industry to identify its pain points and come up with a very comprehensive guidelines which an expert committee will review and implement at the earliest.

Dr. Jain in his concluding remark said that, it is an historic moment and on behalf of Indian vaccine industry, he assures all the regulators that this time industry will leave no stone unturned and will present the comprehensive regulatory reform guideline as quickly as possible. Dr Jain thanked the Secretary & Jt. Secretary -Ministry of Health and DCGI for lending their hand and giving assurance to the vaccine industry that their legitimate reform demands will be considered to boost Indian vaccine industry. He said that India cannot be Pharmacy of the world if Indian vaccine industry is not promoted and innovative products are not introduced by Indian manufacturers in timely manner and on demand basis, however for this all the stakeholders of the vaccine industry will have to work in symphony and improve R&D and manufacturing capability of the Indian vaccine manufacturers to meet the Government’s mission —of Make in India. Dr. Jain praised the efforts of Mrs. Pushpa Vijayaraghvan of Sathguru Consultants for putting together position paper on Regulatory and Policy Changes required for Sustained Competitiveness of the Indian Vaccine Industry in association with CII. Dr. Jain also thanked Ms. Charu Mathur, Ms. Nidhi Narain and other members of CII for their exemplary work in coordinating with all industry, regulators and Governments in organizing this all important National Conference.