

14th National Pharmaceutical Conclave 2017 at Delhi

During the inaugural session on 20th December, 2017, Co-Chairman, CII, National Committee on pharmaceuticals emphasized the need for maximizing the Pharmaceutical opportunity for India and informed the audience that though India was the pharmaceutical hub in the past, in the recent times China has become the major player and around 60% of the Active Pharmaceutical Ingredients are imported from China to India.

The first panel discussion was on the topic, building a robust roadmap to drive excellence in quality in pharmaceuticals. The session discussed ways and means to identify key areas of intervention in terms of superior quality drugs compared to the global market. Presently, there are lot of delays in bringing out new drugs by Indian drug companies. To stay relevant and develop a competitive advantage both the Indian pharma industry and the government agencies shall work synergistically to focus on developing capabilities in terms of quality.

The theme of the second panel discussion was driving India's export/import competitiveness. Dr.Rao, President, IPA in his opening remarks urged the Indian pharma industries to compete with global companies to have novel ideas and manufacture value added biosimilars. India is exporting drugs to 210 countries including US. Though China is the biggest exporter, their quality is reported to be falling short in standards. India has to be more competitive by intensive diversification and the next wave of renovation and innovation needs to be taken up. Counselor, Embassy of Uzbekistan to India during the panel discussion urged for joint venture in this regard.

The third panel discussion was on Risks, Challenges and way forward for the Indian API Pharmaceutical industry. The main areas of discussion was the issue of key starting material requiring to be imported by India and generic chemicals are needed to be imported from China special economic zones are required to be formed for taking up developmental activities in India. Dr.Katoch, NASI-ICMR, noted that nurturing by government of weak industries is required for enabling them to produce pharmaceuticals at affordable cost and policies for assured market. He advised the Indian industries to be a player and not a trader. MD, TEVA India informed that recently China was asked to stop some of the products due to substandard quality. China products are cost effective due to heavy subsidy of government. India shall aim for new technologies like flow reactors and new developments aiming for long term gains. From the present stage of importing, India should become a leader in exports of APIs by reinventing novel products as we have the required technology. Responding to the challenge and synthesis of new chemical entities, HWB presented the high scope of medical applications of heavy water, deuterium switch - deuteration of drugs by deuteration of the Active Pharmaceutical Ingredients (APIs) of the drugs. It was explained that when H is replaced with D it increases the life time of an active drug lowering the dose and increasing retention time in the body, without changing any other biological properties. FDA has approved the first deuterated drug produced

by TEVA by a simple swap of six hydrogen with deuterium in the existing drug resulting in improved version. The presentation included a list of deuterated drugs which are in pipeline waiting for the final approval. To support this noble cause for societal benefit and self-sufficiency, the panel was informed that HWB is ready for collaborative agreement for continuous supply of heavy water including the analytical supports to Indian companies.

The fourth panel discussion was on the topic, Ease of doing business in pharmaceuticals. This session aimed to bring out various difficulties, amount of efforts and time spent to get multiple clearances especially for initiating business in India in pharmaceutical sector. Joint Drug Controller General of India informed that for speeding up the process of clearances of new drugs, presently the clinical trials are being reduced from three to one. Both the technical and APEX Committee review the proposals simultaneously. However, pharma companies suggested that if the drugs are already in use abroad for more than three years the clinical trials for clearances may be waived off.

The fifth panel discussion was on Fourth generation technologies in pharmaceuticals – Revolutionizing Healthcare emphasizing on improvements in operational performance and product quality. To improve efficiencies of the processes pharma companies have already made the roadmap for the next three to five years. It was also highlighted that industries which seize the first initiative will have a sustainable competitive advantage in terms of improved supply chain operations, fundamentally improved processes, innovative products and enhanced productivity. Presentation of HWB emphasized the advantages of Indian industries of ready availability of continual supply of the crucial raw material heavy water which was being imported till now. Advantages of deuterated versions of drugs shall be the next generation medicine. HWB's capability for supply of O¹⁸, as societal support used for PET scan substituting the costly imports and also Deuterium Depleted Water which can be used as adjuvant therapy during Chemo sessions for cancer patients were also emphasized.

The sixth panel discussion was on Robust pharmaceutical policy to meet India's pharma goals and explain the pharmaceutical policies on various issues to meet the requirements of changing business environment, boost innovations, advanced manufacturing and R&D with affordable and accessible health care.

HWB officials also had also interacted with pharma companies like Cipla Ltd., Dr.Reddy's Laboratories, Pfizer, Cadila, TEVA India, KPMG, Reliance GeneMedix, Abbott Healthcare Pvt. Ltd. They were also informed about the proposed theme meeting aiming for creating awareness and sensitizing the issue. Dr.V.M.Katoch, NASI-ICMR Chair, Drug Controller General of India, President, Indian Pharmaceutical Association, Joint Drug Controller (India), Department of Pharmaceuticals, NIPER, Mohali, CSIR were also enthusiastic to know about the new development, deuterated drugs and the advantages like higher potency, longer retention time resulting less dosage and lower side effects.

HWB officials also had a meeting with office bearers of CII wherein it was discussed that for sensitizing the pharma industry about the medical application of Heavy Water, CII can support the theme by keeping one full session/workshop and round table conferences during the zonal meetings to be held at Mumbai, Bangalore, Hyderabad and Kolkatta.

The second day of the conclave included interactions between academia and pharmaceutical industry. It was emphasized that if worked together synergically, both academic and pharma researchers can accomplish more results. Director, NIPER, Mohali and Director General, CSIR explained the modalities for the same. Co-Chairman of CII, National Committee on Pharmaceuticals and Chief Executive Officer, Niti Ayog concluded the session emphasizing the need for collaborative development of novel and high efficacy drugs by close working of Pharma R&D groups with academic centers.

HWB officials also had a meeting with Apejay Stya Research Centre, Gurgaon regarding medical applications of heavy water as well as Deuterium Depleted Water (DDW). The meeting was attended by Associate Director, Head of both Chemistry and Microbiology Group along with the marketing head. This group is already having experience in dealing with deuterated compounds. They are very enthusiastic for further discussion and entering into collaborative agreement for development and production of deuterated compounds along with marketing of Dueterium Depleted Water after obtaining the due clearances and approvals.



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"Maximizing the Pharmaceutical Opportunity for India - Vision and Roadmap: 2025"

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Ministry of Chemicals & Fertilizers
Government of India

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Panelists: **DR. ANURAG KUMAR**, **DR. SURESH K. SHARMA**, **DR. RAJESH K. SHARMA**, **DR. ANIL K. SHARMA**, **DR. RAJESH K. SHARMA**

Documents and brochures on the table in the foreground.