Confederation of Indian Industry

CII PHARMA

First Meeting of CII National Committee on Pharmaceuticals 2017-18

Friday, 14 July 2017: 1030 hrs-1400 hrs

CII Gurgaon Office

MINUTES OF THE MEETING

The first meeting of CII National Committee on Pharmaceuticals (2017-18) was convened on July 14, 2017 under the Chairmanship of **Dr. Rajiv I Modi, Chairman, CII National Committee on Pharmaceuticals & Chairman and Managing Director, Cadila Pharmaceuticals Ltd.**

Dr. Modi welcomed the members apprising that CII has considered pharmaceuticals as a thrust area for our country. In this pursuit, CII has also evolved a logo of CII Pharma. Chairman stated that CII provides a uniform stature ethical platform to bring about significant changes and encouraged members to leverage this biggest industry platform to arrive at fruitful outcomes.

All the members introduced themselves and also brought out their expectations from CII. Some of the key expectations that were stated are as below:

1) To work towards favorable policies that further strengthens the pharma industry.
2) To enhance the reputation of Indian Pharma industry.
3) To promote the Ease of Doing Business (EoDB) in Pharmaceuticals.
4) "One industry- five associations"- To garner the possibility that all associations work together to arrive at a consensus on policy issues.

I) Terms of Reference:

Mr. Anjan Das referred to the suggested terms of reference requesting views of members. Members agreed to the suggested terms of reference.

II) Members of the CII National Committee on Pharmaceuticals:

Chairman mentioned that we have vast group of leadership as members of CII National Committee on Pharmaceuticals. The Committee shall be further enlarged and the members may suggest the names of colleagues, peers who would like to join the Committee to CII team.

III) <u>Making APIs and chemical intermediates produced in India, more competitive so that dependence on import from china is drastically reduced</u>:

- Chairman mentioned that one of the key initiatives of the Committee this year is to develop an actionated document on APIs as guidance from Industry.
- Chairman highlighted that it is well established that most of the pharmaceutical companies are getting intermediates from China. This may have a drastic effect on API industry especially, if China increases prices. There is a consensus that India should reduce dependence on imports by promoting ease of doing business ensuring stable pricing and affordability.
- CII had developed a white paper on APIs with BCG. Chairman stated that we need to revive this and develop a document that serve as advisory guidelines.
- Chairman sought feedback from the members on this initiative.

Feedback from the Members:

- Members acknowledged that this issue is very critical, strategic and also affects our security and safety.
- Members stated that lots of deliberation has already occurred on this, including Katoch Committee, cluster recommendations etc. However, nothing has materialized at ground level.
- Synchronicity is needed between Center and State for better cause-effect relationship.
- Members mentioned that credit of flagging API issue of China goes to CII and CII has done tremendous work on this in the past. We need to again quickly work in this area and suggest recommendations that are good for the Nation and the industry.

Action Points:

- To form a steering group to develop this actionated API document as a guidance from the Industry. We would develop this document in consultation with an agency. The vision is to have an API Policy in the coming years that would be of relevance to the nation as a whole.
- The plan is to first discuss this paper with the government and thereafter release it at the 14th National Pharmaceutical Conclave, scheduled in Dec' 2017.
- Timeline to form a steering group and complete the first draft by 15 September 2017.

IV) <u>Improving the quality standards of medicines made in India so that they have the best International standards and comply with the best quality norms of the World</u>:

- Chairman emphasized that we need to figure out how the Indian Pharma Industry can take lead in the next 2-3 decades. We need to develop a long-term solution in the form of a roadmap so that the quality standards of pharmaceuticals made in India are of global standards. This would be although long term, but a landmark initiative of CII.
- Chairman emphasized that the idea is to develop an ideal visionary quality standard that India should migrate in coming 3/5/10 years. We would develop a harmonized document that collates the best practices of US, Europe, UK, Japan, and India. The outcome would be futuristic FDA-CDSCO guidelines that serves as a gold standard. If and when this happens, we would be able to consolidate India's position in pharmaceutical sector in next 15-20 years.
- Chairman sought feedback from the members on this initiative.

Feedback from the Members:

- Indian generic industry is answer to healthcare solutions worldwide. Branding of Indian generic pharma industry is very important.
- Members reinforced that there is a need to come out with a quality document done in a systematic fashion. This document will ensure that India is competitive to make, develop and design in India and would pull further FDI Investments in India.
- India has already reached a state where we can manufacture quality standard medicines. Cost advantage vs. quality advantage needs to be addressed. This would be a long-term vision to be achieved step by step.
- It was emphasized that the biggest cost factor lies in the facilities like effluent treatment systems where China has an edge. Members enquired the possibility of soft funding from government on this.
- As Indian generic pharma Industry is gradually progressing towards speciality generics which incurs higher R & D costs, there is a need to build stature in these markets. Image building is very important in US and other countries.
- This would be the first of its kind document that will give roadmap to government a so that making pharmaceuticals in India attains global market.

Action Points:

- To form a steering group to develop this ideal visionary quality standard roadmap that India can migrate to in coming years. We would develop this roadmap in consultation with an agency.
- The plan is to first discuss this roadmap with the government and then subsequently release it at the 14th National Pharmaceutical Conclave, scheduled in December' 2017.
- Timeline to form a steering group and complete the first draft by 31 October 2017.

V) <u>Ease of Doing Business (EoDB) in Pharmaceutical Sector</u>:

- Chairman mentioned that Ease of doing business is a National initiative.
- Chairman suggested that the leadership of all member companies can collectively go under the banner of CII and meet Ministers in a structured fashion. This will bring significant impact.
- CII has an EoDB report with KPMG. We need to champion this report.
- Apart from generic EoDB parameters, we need to bring forth EoDB parameters that are specific to pharmaceutical sector, particularly in states that are focusing on pharma so as to attract businesses in states.
- Chairman informed the group that DoP in collaboration with CII is planning to do three conferences on EoDB in pharma sector in 3 cities- Bangalore, Mumbai and Delhi. Chairman encouraged members to provide complete participation for these upcoming conferences. This will be a good platform under the banner of CII, wherein leadership of all pharma companies could share their ideas with government.
- Chairman sought feedback from the members on EoDB initiative.

Feedback from the members:

- Members acknowledged that promoting EoDB in pharmaceuticals is a priority. Some of the areas that need attention are clinical trials, pricing, generic issues, center-state coordination, new drug approvals etc.
- Members pointed out that in India, drug discovery programs are lacking. We need to set up R & D centers in India. It was mentioned that New Industrial Policy is in the making which has a very important clause on R & D tax incentives.
- Members also raised concern on UCPMP (Uniform Code for Pharmaceutical Marketing Practices) as nothing has been heard till now from the government.
- Members wanted to check the possibility of conducting the CII-DoP EoDB Conference in other states like Punjab/ Chandigarh.

Action Points:

- To discuss the EoDB report at various possible forums with the government.
- Collate the inputs relating to EoDB in pharmaceutical sector, particularly in focused states.
- Active participation in the upcoming CII-DoP conferences on EoDB.
- Timeline to form a steering group so that the member companies based out the event locations can champion the joint event with CII-DoP conferences team on EoDB complete by mid of August 2017.

VI) <u>New Pharmaceutical Policy</u>:

- Chairman sought feedback of the members on the New Pharmaceutical Policy.
- Members stated that the draft policy as on date is ambiguous. At present, it has different interpretations. There is a need for a uniform clear policy.

VII) <u>CII's National Pharmaceutical Conclave 2017</u>:

- Chairman informed that CII would be organizing flagship event *i.e.* 14th National Pharmaceutical Conclave on 20-21 Dec, 2017.
- The aforesaid two publications *i.e.* API Paper and Quality roadmap, after consultations with the government would be launched at the Conclave.

VIII) <u>Other Issues Affecting Pharmaceutical Industry on day-to-day basis</u>:

- Members also discussed other day to day significant policy issues that affect the pharmaceutical industry.
- The issues included Clinical trials related to new molecules, Healthcare delivery system as a whole, Voluntary licensing, Pricing issues, Approval of new drugs, Policies on clinical research and regulations, Exim Policy, Issues relating to Pharmaceutical care including medication errors, Environmental issues, Risk based inspections, Inspections of R & D and plants
- Chairman requested members to submit papers/ comments/ recommendations on these critical micro day-to-day issues that affect our pharma industry.
- Timeline to compile the issues on each of the heads by 31 August 2017.

WAY FORWARD

- CII team would create four steering groups to anchor the following initiatives of the Committee this year:
  Steering Group I- Develop a document on API recommendations.
  Steering Group II- Develop a harmonized document on Quality.
  Steering Group III- Inputs on EoDB report.
  Steering Group IV- Papers on issues faced by Pharma Industry on day-to-day basis.

- Develop API paper and Quality roadmap, discuss the developed documents with the government and release at the 14th NPC scheduled in Dec' 2017.

ATTENDEES LIST

Dr. Rajiv I Modi
Chairman, CII National Committee on Pharmaceuticals
Chairman and Managing Director, Cadila Pharmaceuticals Ltd

Mr. Sridhar Ranganathan
Managing Director
Allergan India Pvt. Ltd.

Dr. Rao V.S.V. Vadlamudi
President, IPA, Director, St. Peter's Institute of Pharmaceutical Sciences
Indian Pharmaceutical Association

Mr. Bharat N. Shah
President, OPPI & Managing Director
S. Kant Healthcare Ltd.

Mr. Prashant Kumar Pathak
Chief Executive Officer & MD
Delcure Lifesciences Ltd.

Mr. Apurva Shah
Chairman ACRO & Group Managing Director & Co-founder
Veeda Clinical Research

Mr. Madhav Bansidhar Shriram
Deputy Managing Director
DCM Shriram Industries Limited

Mr. Anurag Khera
Senior Vice President - CORPORATE AFFAIRS
Glenmark Pharmaceuticals Limited

Mr. Nickil Baswan
Vice President - Corporate Affairs & Policy
Cipla Ltd.

Mr. Chetan Gupta
Vice President- Corporate Affairs
Emcure Pharmaceuticals Ltd

Mr. Amardeep Singh
Vice President - Corporate Affairs
Jubilant Life Sciences Limited

Mr. Balinder Singh
Senior Principal
DUA Consulting

Dr. Kiran Marthak
Director - Head Global Clinical Development
Lambda Therapeutic Research Limited

Mr. C. Venkataraman
Director – Corporate Services
Lupin Pharma

Mr. Kuldeep Wakhloo
Director – Corporate Services
Lupin Pharma

Ms. Aastha Gyani
Associate Director- Government Affairs
Abbott Healthcare Pvt Ltd.

Mr. Khomba Singh
Associate Director- Government Affairs
Abbott Healthcare Pvt Ltd.

Dr. Viraj Suvarna
Medical Director
Boehringer Ingelheim India Pvt Ltd

Mr. Umang Chaturvedi
Head of Policy – India & Emerging Markets
Mylan Laboratories Ltd

Mr. Jyostishman Boruah
Head-Knowledge Management and Strategic Medical Affairs
Abbott Healthcare Pvt Ltd.

Mr. Kawaljeet Singh
Senior Manager - Corporate Affairs
Cipla Ltd.

Ms. Neha Karnik
Senior Manager – Corporate Affairs & Policy
Cipla Ltd.

Mr. Pramod Kumar
Senior Manager (Regulatory Affairs)
Serum Institute of India Ltd.

Mr. Dev Ranjan Mukherjee
Head – Corporate Affairs
Cadila Pharmaceuticals Limited

Mr. Ratnesh Lal
Head Government Affairs
GlaxoSmithKline Pharmaceuticals Ltd.

Mr. Utkarsh Palnitkar
Partner and Head- Life Sciences
KPMG, India

Mr. Agnideep Mukherjee
Asst. Vice President – Life Sciences Knowledge Banking
Yes Bank

Mr. Anjan Das
Executive Director
CII

Mr. Jibak Das Gupta
Director
CII

Ms. Namita Bahl
Deputy Director
CII

Mr. Bharat Asthana
Executive
CII

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