



## **Second Meeting of CII National Committee on Pharmaceuticals 2017-18**

**Friday, 03 November 2017: 1430 hrs-1400 hrs**

**CII Central Office, New Delhi**

### **MINUTES OF THE MEETING**

The second meeting of CII National Committee on Pharmaceuticals (2017-18) was chaired by **Mr. Susheel Umesh**, Co-Chairman, CII National Committee on Pharmaceuticals and Managing Director & General Manager, Abbott Healthcare Pvt. Ltd on November 03, 2017.

Key issues discussed were:

#### **1) Ease of Doing Business:**

Mr Susheel Umesh mentioned that there is a need to draw a comparison of pharmaceutical industry with other industries. This assessment should be taken up to set a benchmark to review the pharmaceutical sectoral performance w.r.t. ease of doing business as compared to other sectors.

**Action Point:** To prepare a proposal on industry comparison in view of Ease of Doing Business in consultation with an appropriate agency/ partner and get buy in from Govt.

#### **2) Issue on APIs:**

The outline of API report being developed by CII in collaboration with KPMG was summarized to all the members. It was stated that although indigenisation is a good idea, however, there is a need to figure out the reasons of increasing overdependence on China. Some of the suggestions in this area were:

- The impact of indigenization on affordability and accessibility.
- The APIs can be prioritized and mapped based on the disease burden.
- Perspective of cost competitiveness is quite critical while suggesting measures for reducing API import dependency.
- Several different agencies are working on the issue of APIs *i.e.* DIPP, DoP, DCGI, Health Ministry. Members suggested that there should be one nodal department to address this issue.

- Members also suggested that Government of India can invest in friendly countries for captive plants especially for fermentation industry.

**Action Point:** To ensure that the CII-KPMG report addresses all the key API issues provide practical recommendations.

### 3) Pricing Issues:

It was pointed out by members that a significant number of brands *i.e.* 200 form 1 cases are stuck at NPPA for approval. This is depriving patients from essential drugs. Members recommended that the core issues need to be explored. For this, a detailed analysis is to be done to understand the pattern and arrive at the core issues.

**Action Point:** To do an assessment to figure out the core issues leading to brands being stuck at NPPA.

### 4) Issue on North East Incentives and subsidy capping:

Several companies with plants in Sikkim are awaiting the re-imbursement and subsidy under the North East Industrial & Investment Policy Promotion (NEIIPP), 2007.

**Action Point:** CII to drive this agenda impacting Ease of Doing Business and make a fact-based representation to Niti Aayog on the issue of North East Incentives and subsidy capping. CII to arrange for a meeting of industry delegation with Mr. Amitabh Kant.

### 5) Quality standards:

The outline of quality report being developed by CII in collaboration with PwC was summarized to all the members. It was mentioned that there is a general understanding that India would be adopting to WHO/GMP standards. The report should examine the level of industry preparedness, and challenges which Indian industry may face while upgrading to WHO GMP. Also, there is a need to assess whether industry is equipped in this direction, or some kind of assistance is needed from the government.

**Action Point:** To ensure that the CII-PwC report addresses the updates w.r.t. quality standards and suggest practical recommendations.

## **6) Issue of upgradation of skill sets of persons employed in pharma manufacturing units:**

The Drug Controller General of India (DCGI) has made it compulsory for all employees in pharmaceutical manufacturing units to get a skill upgradation certificate from the government's Life Sciences Skill Development Council (LSDDC) from 01-January 2018. It was stated by members that this deadline is difficult to meet as the volume of work involved is extensive.

**Action Point:** CII to make a formal representation to CDSCO for extension of timeline for skill upgradation.

## **7) Issue of Ethics Committee Accreditation:**

The Ministry of Health and Family Welfare has granted approval to making the accreditation of Ethics Committees (ECs), involved in supervision of clinical trials, mandatory with effect from 01-January 2018. Members pointed out that this timeline is also short and difficult to meet.

**Action Point:** CII to make a formal representation to Ministry of Health for extension of timeline for Ethics Committee Accreditation.

## **8) Issue of Drugs (Sale and Distribution) Rules, 2017:**

Members mentioned that the Union Minister of Health and Family Welfare is issuing draft of the Drugs (Sale and Distribution) Rules, 2017 aiming at removing ambiguity on regulations to facilitate sales of drugs online.

**Action Point:** Members to make a representation on the issue of E-pharmacy. Mr. Amitabh, Novartis, Mr Chetan, Emcure and Mr Umang, Mylan with CII secretariat to make a formal representation/ position paper on Drugs (Sales and Distribution) Rules.

## **9) Issue on OTC drugs:**

CDSCO has decided to create a category for over-the-counter medicines. For this, CDSCO has formed a high-level committee of subject matter experts to frame an exclusive schedule of over-the-counter (OTC) drugs.



**Action Point:** CII to consolidate inputs from the members on list of proposed drugs to be categorized as OTC and the proposed regulatory framework. The inputs to be submitted to CDSCO for their consideration.

**10) 14<sup>th</sup> National Pharmaceutical Conclave:**

Members were apprised on the progress of CII's 14<sup>th</sup> National Pharmaceutical Conclave scheduled on 20-21 December' 2017, and were requested for their active participation.

**Action Point:** CII secretariat to meet GoI officials for getting their diary blocked for this event, and members also to join for these meetings.



## **ATTENDEES LIST**

### **Mr Susheel Umesh**

Co- Chairman, CII National Committee on Pharmaceuticals  
Chairman and Managing Director, Abbott Healthcare Pvt. Ltd.

### **Mr Srini Srinivasan**

Managing Director  
Hospira Healthcare India Pvt. Ltd. (a Pfizer company)

### **Mr Ashok Bhattacharya**

Executive Director / Country Manager  
Takeda Pharmaceuticals India Pvt Ltd

### **Mr Prashant Kumar Pathak**

Chief Executive Officer & MD  
Delcure Lifesciences Ltd.

### **Dr Azadar Khan**

Senior Vice President- Corporate Relations  
Sun Pharmaceutical Industries limited

### **Mr Rakesh Bhargava**

Chairman  
Fresenius Kabi Oncology Ltd.

### **Dr Aman Gupta**

Deputy General Manager- Regulatory Affairs  
Cadila Pharmaceuticals 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 C. Venkataraman**

Director – Corporate Services  
Lupin Pharma

### **Ms Jyotsna Ghoshal**

Senior Director-Corporate Affairs  
Merck

### **Ms Aastha Gyani**

Associate Director- Government Affairs  
Abbott Healthcare Pvt Ltd.



Confederation of Indian Industry



**Mr Jagdish Kumar**

Consultant  
Alembic Pharmaceuticals Limited

**Mr Amitabh Baxi**

Head, Government & Public Affairs  
Novartis

**Mr Umang Chaturvedi**

Head of Policy – India & Emerging Markets  
Mylan Laboratories Ltd

**Mr Kawaljeet Singh**

Assistant General Manager – Policy- India and Emerging Markets  
Mylan

**Mr Amardeep Singh**

Vice President - Corporate Affairs  
Jubilant Life Sciences Limited

**Mr Vipul Gupta**

Associate Director  
Cipla Ltd.

**Ms Neha Karnik**

Senior Manager – Corporate Affairs & Policy  
Cipla Ltd.

**Mr Atul Tandon**

Director – Strategy & Commercial Excellence  
Astra Zeneca

**Ms Suneela Thatte**

Vice President, Global Operations  
Quintiles

**Mr Agnideep Mukherjee**

Asst. Vice President – Life Sciences Knowledge Banking  
Yes Bank

**Dr Ajay Kumar Sharma**

Director – Government Affairs  
Organisation of Pharmaceutical Producers of India (OPPI)

**Mr Prem Singh Rawat**

Organisation of Pharmaceutical Producers of India (OPPI)

**Mr P K Khanna**

GM- Marketing  
DCM Shriram Industries

**Mr Anjan Das**

Executive Director  
CII



Confederation of Indian Industry



**Mr Jibak Dasgupta**

Director  
CII

**Ms Namita Bahl**

Deputy Director  
CII

**Mr Bharat Asthana**

Executive  
CII

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