Confederation of Indian Industry

CII National Committee on Pharmaceuticals

Tuesday, 16 July 2019, New Delhi

Minutes of the Meeting

1. **Mr Vivek Kamath - Vice Chairman, CII National Committee on Pharmaceuticals & Managing Director, MSD Pharmaceutical Ltd**

(a) Welcomed the members of the National Pharmaceutical Committee

(b) Requested members to identify key issues of the sector and develop sub-groups that can focus on each of those key issues. Suggested CII to collect inputs from other members who are not present in meeting. Briefed about pain points, status of industry and recommendations to discuss further and take forward-

- Need to revive growth in the local and international market amidst tight regulatory regime abroad
- Need for an independent ministry of pharmaceuticals not just a Department
- The image of the healthcare industry needs to improve through changing perceptions
- Roadmap of India to become the Pharmacy of the World
- Need to have a consultation with the government on what their expectation is from the pharmaceutical industry in the next 5-10 years

2. **Key issues and recommendations suggested by Members present in meeting:**

a. Active Pharmaceutical Ingredient

- Need to build self-sufficiency of the industry in terms of API and innovations are needed to grow this business. We are presently dependent on China.

- Need to submit recommendations to the government on the setting up of chemical parks for manufacturing of active pharmaceutical ingredients. Indigenous industries have closed down due to cheap imports. Chemical

parks need to have better mechanisms for environmental clearances which is very important part of manufacturing of API and bulk drug SMEs. **CII had prepared a document on the same which need to be revised and submitted**

- In 2015 a Committee was formed by VH Katoch for setting up of industrial parks for production of bulk drugs and intermediates. This was submitted to Department of Pharmaceuticals, but no action has been taken as yet. **Need to take it up.**

- What can the government do in the long run to help the API industry to flourish by helping produce low cost good quality API by bringing back collaborations with government institutes in API. This would be in alignment with the Make in India Policy. **Need to prepare a document.**

- API industry needs support of the government. Key raw materials needed for the API industry are gas, steam, power are difficult to procure independently for small scale industries. Need a cluster based approach for setting up industrial parks

b. Revival of Image of the Pharmaceutical Industry

- The pharmaceutical industry has a lot of negative publicity and perceptions which need to be eliminated . There is a need to revive image which is not only affecting business but also hitting the consumer

- Need to harmonize efforts of all stakeholders towards image perception. Need to engage with the government in a pro-active way rather than in a reactive manner. Harmonization of all stakeholders including multiple associations was suggested. CII is the best platform. Introspection needs to be done on what needs to be harmonized before we go to the government.

- The issue with the image of the manufacturing industry is not only in India but is a global problem hence need global campaigns

- The pharmaceutical industry has a lot of negative publicity and perceptions which need to be revived, as it is not only affecting the growth of the industry but also hitting the consumer
- Quality around consistency of products need to be focused upon.

c. Research & Development and Innovation

- Need to increase our participation in global clinical research
- Government should encourage innovation by increasing investment
- Non-infringeable patent process should be introduced
- Need to incentivize Research & Development to introduce innovations
- SMES do not have capacity to innovate so collaborations are important between research institutions and API industry to innovative and remain competitive. India should work on incentivizing SMEs to promote the industry. China is actively doing this.
- How can the pharmaceutical industry adapt to digitalization and Artificial Intelligence ?
- Innovation needs to be supported by government. Northern India has negligible presence in R&D space compared to other states
- Innovation, not only in terms of product development but also in terms of talent , capacity, technology and awareness building should be done.

d. Pricing

- How to bring about the balance between price rationalization and quality. Need clarity on product pricing control policy
- Stability in pricing policy needed. There needs to be a consultative process for pricing with the industry. A predictable environment on pricing is needed
- **Trade Margin Rationalization:** The industry supports trade margin rationalization however, it is important to understand the formula that is being used. Anything subjective submitted to NPPA gets interpreted differently. NPPA should look at audited report of the industry that carries the stamp of law. Whatever tool is being used by the NPPA,

patients' welfare should be prepared keep in mind as well as save industry from harassment

- Barcoding issue: Mandate given for barcoding is not implementable especially for MSMEs
- Resort to a Simple prospective batch price implementation
- Manufacturers should not be punished for higher price charged by retailors
- Can medicines priced at less than Rs. 5 be excluded from price control
- Fall Clause Issue: Industry needs to be aware of this issue. Procurement guideline in 2017 from Ministry of Revenue which says that pharmaceuticals that have an expiry date should be exempted from fall clause but has not gone down with public procurement of DPIIT. CII can spearhead this and advocate the restriction of fall clause to financial year
- NLEM list is being revised. **CII can hold a meeting with the NLEM Committee to put forward industry's view point on how 'essentiality' can be determined**
- DPCO: Some prices are not realistic as they don't even cover the price of raw materials used
- **Need to form a Task Force for submissions of regulatory challenges to the different ministries related to exports in the different markets.**

e. Regulatory

- Frequent regulatory changes by CDSCO
- Pharma sales have increased by 3.6% but the profitability has gone down. Both domestic and international regulatory pressures are there that need to be addressed.
- Para 19 pricing crisis of DPCO needs to be discussed
- Regarding pricing there should be single jurisdiction

- Schedule M upgradation to WHO-GMP. Major concern for SMEs where govt support needed. Govt. has come up with PTOS where there are operational issues that needs to be addressed
- Need a strong IPR regime for protection of IP
- 2015- Announced to be the year of Bulk Drug Policy which is still not implemented. Need to take up this issue
- IPO patent has been linked to price control exemption in a DPCO amendment
- Impact of privacy of data bill on the pharma industry in terms of cross border elements need to be assessed

f. Exports

- Exports should grow at a higher rate. Explore new markets beyond USA such as Japan, China and Indonesia and need to discuss strategy involving government on this.

- China can be both an opportunity and a threat for the pharmaceutical industry. China has put together 2 think tanks to displace India in the area of generic drugs. **CII can form a similar think tank to deal with this issue and also study the opportunities in Chinese market. In the past CII had a task force that dealt with Pharmaceutical Business with China. There is a need to revive that Task Force.**

- Revision of Foreign Trade Policy- Revision of foreign trade policy is due in September and a **core group needs to be created** that will send recommendations timely. 2 schemes MEIS and SEIS will be replaced as a result subsidies initially provided to exporters will go. Schemes that are WTO compliant will now take its place. Industry inputs will be needed. Consultation needs to be held with MoCI on how compensation can be provided to exporters under the new scheme. **CII needs to be a part of all Foreign Trade Advocacy happening all over the world.**

3. AYUSHMAN BHARAT Interaction with Dr Arun Gupta, Executive Director, National Health Authority

i. Key points addressed by Dr. Arun Gupta

(a) Objective of Ayushman Bharat is to bring down the cost of healthcare and make it affordable for all. Ayushman Bharat is likely to bring about parity in the hospitalization rates of the top and bottom 40%. Conservative estimates say that there is a shortage of 45000 beds. The government rates will be significantly lower than what big hospitals generally charge to patients. In India there is no scientific method of arriving at procedure cost due to which the DHR has been appointed to do the same. Hospitals have been involved.

(b) In AB-PMJAY the government is not procuring anything, rather facilitating the provision of services. 16000 hospitals who are currently with AB-PMJAY have their own way of procuring medicines. Therefore requested the pharma members to directly get in touch with hospitals

(c) Importance of Electronic Health Record: NIC (e-hospital) and CDAC (e-sushrut). With the help of electronic heath records cost of health will come down drastically

ii. Other issues discussed on Ayushman Bharat

(a) Industry needs idea on the expectation of the government from pharmaceutical industry for Ayushman Bharat and requested for a centralized approach for procurement of drugs? Dr Gupta clarified on this by saying that NHA is not disturbing procurement process of hospitals.

(b) ESI corporation: Is it possible to finalize rate contract and circulate it to state governments

(c) Pharmaceutical Industry can share a document to the National Health Authority on how the industry can compliment the efforts of the government in provision of Universal Health Coverage.

4. ACTIONS TO BE TAKEN

i. Mr. Vivek Kamath requested the members to share a short note elaborating the points and giving the nuances of the issue brought up (Background, potential solution, stakeholders)

ii. 5 sub-groups to be formed (members to volunteer the group they wish to participate in)

- Image Building/Reputation of the Pharmaceutical Industry
- Active Pharmaceutical Ingredients
- Ease of Doing Business- Policy and Regulatory Issues
- Innovation
- Export of Drugs

iii. White paper to be prepared on Ayushman Bharat elaborating how the pharma industry can play a role.

iv. CII paper and recommendations on API industry need to be revived

v. Form/Revive Task Force on Business with China

vi. CII to hold a meeting with the NLEM Committee on the revision of NLEM list

vii. Vision Document 2030 to be discussed further