



Confederation of Indian Industry

**First Meeting of
CII National Committee on Biotechnology (2018-19)**

Confederation of Indian Industry; 249-F, Sector 18, Udyog Vihar, Phase IV, Gurugram- 122015

10 August 2018; 1430-1700 Hrs

MINUTES OF THE MEETING

The first meeting of CII National Committee on Biotechnology (2018-19) was convened on August 10, 2018 under the Chairmanship of **Dr Rajesh Jain**, Chairman, CII National Committee on Biotechnology & Joint Managing Director, Panacea Biotech Ltd. and **Dr Mahesh Bhalgat**, as Co-chair, CII National Committee on Biotechnology and Executive Director and COO, Shantha Biotechnics Private Limited. The list of participants is given in the Annexure.

Dr Jain while welcoming the participants mentioned that Indian vaccine industry including biotechnology has made significant progress since last few years. It was highlighted that the Indian vaccine industry accounts for 76% of UNICEF tender volumes. Interesting times are just around the corner for biotech start-ups, biosimilars, vaccines, cell and gene therapy, and bio-agriculture, and these sub-sectors are all set to drive the future of biotech industry.

The work done by the Committee in the year 2017-18 was summarized to the group. The key outcomes included CII Recommendations for Guideline Changes in Vaccine Approval Procedures-II, report on Biotech Start-ups in India and its Global impact and the report on issues associated with Biodiversity Law and their compliance. It was suggested that the report on vaccines can be re-visited by the vaccine sub-group this year for any changes. The updated report can be taken up for representation by the group this year. It was further suggested that the report on Biodiversity Act to be submitted again to all relevant stakeholders including Ministry of Environment, NBA, DBT, Ministry of Health, and Ministry of Agriculture.

The following paragraphs summarize the key points discussed in the meeting:

1) Biosimilars

Discussion Points

- a) Members expressed a need for developing biomanufacturing competence. Manufacturing biosimilars is complex, capital intensive and requires technical expertise. Members suggested to create PPP model for contract manufacturing as well as reviving sick PSUs that already have the required infrastructure in place.
- b) An ecosystem that connects discovery, development and commercialization as well as intellectual property is highly called for. The entire value-chain from the concept to commercialization should be funded.
- c) Bio-betters are better than biosimilars and must be focused upon.
- d) It was pointed out that India is lacking in technology for bio-betters and biosimilars. For these areas, cell line development *i.e.* early stage development is very important and R&D is the key. MABs and human phage display libraries, which are cutting edge technologies should be focused adequately. There is a need for capacity building in R&D in India. Academic partnerships and investments from govt agencies would be very important. Members also pointed out that it needs to be decided if capacity building across entire value chain is required or focus should be on one component.
- e) Members highlighted that the animal models for pre-clinical studies are not available in India. Also, there is non-availability of affordable pilot plant facilities in India.
- f) Indian markets do not offer adequate return on investments. Cohesive efforts are needed from both government, and industry.
- g) Biosimilar guidelines are quite robust and act as the good policy document. There is a



need to tap more markets particularly RoW. Market access support for RoW with greater market penetration is needed.

Action Points:

- A Sub-Committee has been formed on Biosimilars with the following members:
 - 1) Ms Pushpa Vijayaraghavan
 - 2) Mr Jaspreet Singh
 - 3) Dr Gopala Krishna Dasika
 - 4) Dr Jitendra Kumar
 - 5) Dr Amitabha Bandyopadhyay
 - 6) Mr Sunil Thakur
- The Sub-Committee would prepare a document on Biosimilars outlining the specific issues with key recommendations.

2) Vaccines

Discussion Points

- a) The CII Recommendations for Guideline Changes in Vaccine Approval Procedures-II prepared last year needs to be updated
- b) Two position papers, already available on Vaccine Purchase Policy and on reforms required in the procurement of vaccines should be taken up for representation

Action Points

- A Sub-Committee has been formed on Vaccines with the following members:
 - 1) Dr Suresh Jadhav to lead the Sub-committee
 - 2) Dr Rajesh Jain
 - 3) Dr Mahesh Bhalgat
 - 4) Ms Pushpa Vijayaraghavan
 - 5) Ms Mahima Datla
 - 6) Mr Udit Mangal
- The Sub-Committee would prepare the Document on Vaccines II.

3) Stem Cell and Gene based Therapies/ Regenerative Medicine

Discussion Points

- a) The stem cell and gene therapy sector provides ample opportunity.
- b) There is a need to simplify regulatory framework. While CDSCO and ICMR have two guidelines, one unified guideline is needed.
- c) Conducting clinical trials in this sector poses difficulties.
- d) Recently, there has been a Draft Gazette Notification in April 2018 on definition of stem cell therapy.
- e) Several stem cell and gene based products are entering the market in Europe, Japan, US, Korea.
- f) There is fast track approval system in US, EU and Japan for cell and gene therapies. The products that are evaluated as Good products are given the status of Advanced Therapy Medicinal product so that the regulatory process is fast tracked and the product enters the market much earlier rather than the regular cycles of Phase I, II and III. Similar fast track regulatory processes are also needed in India.



- g) Precision medicines are showing tremendous growth in US and China.
- h) There is a need to focus on the sector for appropriate regulations.

Action Points

- A Sub-Committee on Regenerative Medicine has been formed with the following members:
 - 1) Mr BN Manohar to lead. And also suggest more companies to be a part of this Sub-Committee. RMS Re-grow to be one of them
 - 2) Mr Amit Chopra
 - 3) Mr Subramani Ramachandrappa
- The Sub-Committee would prepare a document on Regenerative Medicine outlining the specific issues with the suggestions.

4) Agri-Biotechnology

Discussion Points

- a) Members stated that there is no clarity in the regulations in this sector.
- b) There are issues relating to trials in this area

Action Points

- A Sub-Committee on Agri-Biotechnology has been formed with the following Members:
 - 1) Dr Arvind Kapur
 - 2) Dr Venkatesh Devanur
 - 3) More members to be suggested by the Sub-Committee
- The Sub-Committee would prepare a document outlining the issues and the recommendations in Agri-Biotechnology sector.

5) Ease of Doing Business in Biotechnology sector (including Start-ups)

Discussion Points

- a) Biodiversity Act, one of the major hurdles needs to be addressed urgently.
- b) Some issues of start-ups can be addressed under Ease of Doing Business.
- c) There exists a shortage of funds for start-ups in biotech domain.

Action Points

- Biodiversity Report to be forwarded to the concerned authorities and subsequent meetings.
- A Sub-Committee on 'Ease of Doing Business' to be formed.
- Following members agreed to be a part of the Sub-committee:
 - 1) Ms Deepa Tiku
 - 2) Dr PM Murali
 - 3) Dr Jitendra Kumar
- The Sub-Committee to decide specific topics to be taken up under the broad theme of Ease of Doing Business in Biotechnology Sector.
- The specific issues of Biotech Start-ups to be taken up separately in Start-up Council chaired by Mr Kris Gopalakrishnan.
- The sub-Committee on Start-ups can hold one or two meetings in the incubator itself.



6) Biomedical Devices

Discussion Points

- a) There is an increasing focus on developing biomedical devices due to shorter development time unlike other biological products.
- b) Regulatory hurdles, scale-up, tender obstacles are some the challenges affecting this sector.

Action Points:

- Prof Padmanabhan would suggest specific areas that needs to be tackled in this sub-sector
- A Sub-Committee would be formed if the statistics bring out the potential of this sub-sector in biotechnology
- The Sub-Committee if formed, would be led by Mr Udit Mangal. Other Sub-Committee Members include: Dr Amitabha Bandyopadhyay, Dr Purnima Sharma and Dr Jitendra Kumar

7) Key Events 2018-19:

2nd National Biotechnology Conclave: CII will be organizing the 2nd National Biotechnology Conclave, its flagship annual event in partnership with the key Ministries and stakeholders. It will be held on 22nd November 2018 at New Delhi.

Members were requested for the following:

- Suggest the theme, sessions and speakers to shape a meaningful programme
- Promote this Conclave among the members' networks
- The members are requested to commit funds for organization of the programme
- Members are requested to participate in the proposed Conclave through presentations and deliberations

**Annexure****List of Participants**

S. No.	Name	Designation	Organization
1	Dr Rajesh Jain	Chairman, CII National Committee on Biotechnology & Jt. Managing Director	Panacea Biotec Ltd.
2	Dr Mahesh Bhalgat	Co-Chairman, CII National Committee on Biotechnology & Executive Director and COO	Shantha Biotechnics Private Limited
3	Dr Arvind Kapur	Managing Director	Acscen HyVeg (P) Ltd.
4	Dr Venkatesh Devanur	Managing Director	Agrilife
5	Dr Purnima Sharma	Managing Director	Biotech Consortium India Limited
6	Mr Amit Chopra	Managing Director	Thermo Fisher Scientific India
7	Dr Davinder Gill	Chief Executive Officer	MSD Wellcome Trust Hilleman Laboratories
8	Dr Jitendra N. Verma	Founder & Managing Director	Lifecare Innovations
9	Dr Kiran Marthak	Global Head- Clinical Development	Lambda Therapeutic Research Limited
10	Mr Subramani Ramachandrappa	CMD	Richcore India
11	Dr Gopala Krishna Dasika	Sr. Vice President and Head- Biologics Division	Pfizer Healthcare India Pvt. Ltd.
12	Dr Manoj GROVER	Senior Manager – Public Affairs	Sanofi Pasteur India Pvt. Ltd
13	Dr Jitendra Kumar	Director and Head	Bangalore Bioinnovation Centre (BBC)
14	Dr Amitabha Bandyopadhyay	Associate Professor	Dept. of Biological Sciences & Bioengineering (BSBE), IIT Kanpur
15	Mr Jaspreet Singh	Vice President - Quality	Intas Pharmaceuticals Ltd
16	Mr Pushpa Vijayaraghavan	Director	Sathguru Management Consultants P Ltd
17	Mr Vineet Chadha	Partner, Innovations Fund, Private Equity	Tata Capital Limited
18	Mr N Venkat	Co-founder & CEO	Vyome Biosciences
19	Dr Ezhil Subbian	Co-founder	String Bio Pvt Ltd
20	Mr Jaspreet Singh	Vice President - Quality	Intas Pharmaceuticals Ltd
21	Mr Ravi Menon	Senior Business Adviser	SKP Business Consulting LLP



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S. No.	Name	Designation	Organization
22	Dr Deepa Tiku	Partner	K & S Partner
23	Mr Udit Mangal	Business Manager	Pluss Advanced Technologies Pvt. Ltd.
24	Mr Sunil Thakur	Director and Chief Operating Officer	Quadria Capital Advisors Private Limited
25	Professor G. Padmanaban	Director	Department of Biochemistry IISC (via Telecon)
26	Mr Lakshminarayana Neti	COO	Biological E (via Telecon)
27	Dr Suresh Jadhav	Executive Director	Serum Institute of India Limited (via Telecon)
28	Dr PM Murali	Managing Director / President	Evolva Biotech Ltd/ABLE (via Telecon)
29	Mr BN Manohar	Managing Director	Stempeutics Research Pvt. Ltd. (via Telecon)
30	Mr Anjan Das	Executive Director	CII
31	Ms Shalini Sharma	Principal	CII
32	Ms Namita Bahl	Deputy Director	CII
33	Ms Vidhi Sanghavi	Executive	CII
