



Confederation of Indian Industry

CII National Committee on Biotechnology

Monday, 22 July 2019, New Delhi

Minutes of the Meeting

1. Welcome Remarks by Dr Rajesh Jain - Chairman, CII National Committee on Biotechnology & Managing Director, Panacea Biotec Ltd.

Meeting started with a positive note and welcome remarks from Chairman with a note that CII National Committee on Biotechnology has taken many good initiatives in past years and need to continue them and take up more work on regulatory and policy issues. Now when India is aspiring to become 5 Trillion USD industry, there is big momentum across the ministries, decisions are fast and in such an environment we need to be very specific in our demands from government. Government is willing to discuss face-to-face and decisions are quick. Dr Jain suggested that we need to go with short, mid and long terms plans and suggestions and should talk more about impact we can make in terms of bigger public health or agriculture challenges that government is trying to solve.

Dr Jain also suggested to submit any and every policy paper and recommendation not only to DBT but also to MOHFW and other aligned ministries.

He requested every committee member to bring more players in Biotechnology space to this committee to have a big representation on policy makers.

2. Remarks by Dr Suresh Jadhav, Co Chairman, CII National Committee on Biotechnology & Executive Director, Serum Institute of India Pvt. Ltd.

Welcomes members and discussed issues related to single window clearance and possibility to showcase case studies from other parts of the world where single window clearance for vaccines has been implemented successfully.

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

A. Bio-Similiars

- Biosimilar market globally especially, USA and Europe market is bringing up many opportunities for this sector to make India hub for bio-similar. To support the industry and its funding challenges, Biosimilar industry need to be taken under I3, World Bank Programme by DBT that focus currently on vaccine.



B. Biodiversity

- Need to work on guidelines and regulatory issues regarding biodiversity. The firm K&S partners has released on this with CII in 2017 and this paper can be updated in reference of recent draft guidelines by GOI on biodiversity. Recent guidelines have many issues. Access to biological resources is been regulated and there are many challenges to be solved and represented.
- Many states do not have biodiversity board and many of existing boards are non-functional that hamper growth of innovations.
- Suggestion was made to submit a position paper on biodiversity.

C. Funding

- Government need support in creating a positive and catalytic environment for global fundings, VC/PE including early stage, seed and growth fund, which is currently seen as high risk investments for biotechnology sector due to its long gestation period. As marketing activity, We need few success stories to showcase and demonstrate the world that investments in biotechnology sector in India are safe and have high returns.
- Major investment programmes from GOI like Invest India and startup India has no definition for biotechnology sector.
- Response time from government bodies on funding applications need to be improved. China has faster response on funding applications and we need to learn from it.
- Startup India should allocate some fund for biotech sector separately.
- Pharma companies should be encouraged to invest in biotech companies. Country need few hits to prove world that we have capability and capacity

D. IP protection-Patents

- Biotech patent laws need reforms in India. Law is very old for biotechnology and it need major reforms.

E. Agri-biotechnology

- Agri biotech area is suffering badly in country. Clarification need to be sought from Government on few key aspects like how many tests need to be conducted on GM crops to bring to market, what kind of biosafety data



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is required, how long testing is required to get approvals and how many tests have to be conducted, duration of feeding studies need to be defined as 90 days testing is now seen ineffective by Indian regulators.

- IP and its application in agriculture need improvements
- A framework need to be made by government on selling price and royalties.
- IP protection is becoming a bottleneck to bring new technologies to India because many proprietary information's are asked which industry is not comfortable in sharing.

F. Gene editing and cell based therapies

- Regulatory framework for stem cells and cell based products are missing
- Definition of gene editing and cell based therapies need to be defined and formalized. A committee has been formed headed by Prof. Balram Bhargava Secretary DHR & Director General ICMR. Members suggested to make regular representations to this committee.
- CDSCO has made a draft on definition of stem cells and cell based products and it is in draft stage and CII need to make representations.
- Framework for pricing is needed, it is missing at present. A committee has been formed by GOI and we need to guide them.
- Gene editing has to come under regulatory framework. Dr Padmanabham is chairing a committee under DBT and CII can interact with committee and share its recommendations

G. Vaccines

- Due to cumbersome regulatory process, multiple clearances from multiple regulatory bodies in various ministries, Indian vaccine industry is suffering. Though we are the largest provider of vaccine across the world and many countries have eliminated public health issues like rubella and measles but we are unable to do it here,, so we need to enable policy makers by such international case studies.
- Concept of adult vaccines need to be introduced and regulatory framework need to be made.



- Purchase preference given in -central government undertaking, small scale sector other bodies should be removed in this era of liberalization especially in sector of biotech and vaccines when investments and gestation periods required to demonstrate success and show profitability are very high.

H. Others:

- Diagnostics can be considered as part of this committee from biotech perspective.
- Precision Medicine: Genome Based Therapies. Clarity is needed on policies around personalized medicines. ICMR authorities need to be guided because they says that they do not have enough supporting data and understanding to take any decision in this matter.
- National programme on bovine TB/animal TB is recommended and if this can come under one health programme by Gol.
- Large animal facilities are needed. Facility that ICMR is planning in genome valley on Hyderabad has to be functional.
- We need to address ICMR dictate on biological materials. As per this dictate, not a single drop of blood or serum or plasma or tissue sample or biological material cannot go out of country for any purpose without their prior permission or NOC.

4. Interaction with Dr Renu Swarup, Secretary, Department of Biotechnology

Dr Renu Swarup, Secretary, Department of Biotechnology addressed members, by answering to a question from members on Government vision for agri-biotechnology industry, by saying that BioAgri is an important sector to achieve desired aspirations for the whole Biotechnology sector. She has suggested industry to be more ambitious and keep targets higher. She is open on listening and taking collective discussions on key issues. She also suggested to come with short term and long term action plan to work upon. She made remarks on government initiatives in biotechnology sector and expectations from industry and CII to strengthen the Government initiatives:

- DBT has major emphasis to build startup ecosystem for next five years, Bio clusters- the knowledge clusters are seen as solution to bridge the industry-academia gap. Bio-Clusters comprise DBT institutes, startups and companies as part of it. These knowledge clusters need to be strengthened by co-location and co-developmental activities by academia and industry to complement strengths. Government want to bring large companies as part of these clusters. At Bio clusters, collaboration between innovator and acquisition partner need



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to be setup at early stage so technologies can be developed easily where adoption will be successful.

- GOI has major emphasis on creating startup ecosystem. New technologies coming from startups ecosystem and their timely engagement with large industry is important and CII to create platform that can bridge gap between large industries and startups to help them in scale-up their technologies and suggest how government can play a role to support.
- She discussed on proposal from CII on Stimulating Private Sector's Investment in Research; Technology Development & Commercialization and expressed interest in taking it forward. CII team has submitted proposal post committee meeting.
- She discussed on purpose of Global Bio-India which to showcase India as one single large and strong unit strong in biotechnology to deliver world class solutions. DBT bilateral partners in many countries are excited for collaborations and partnerships through this event.
- Industry support is needed to create world class human resource and she requested industry with CII to create a report on HR needs for biotechnology sector to create a road map and DBT want to work on this either alone or in partnership with ministry of HR.

5. Representations and detailed Notes requested from members:

- Dr Ezhil Subbian, CEO, String Bio Pvt Ltd; Dr Nupur Mehrotra, Co founder, Premas Biotech Pvt Ltd ; Mr Jitender Kumar, Director and Head, Bangalore Bioinnovation Centre and Mr BN Manohar, Managing Director, Stempeutics Research Pvt Ltd was requested to submit a detailed note or represented on issues with suggestions, they raised.

6. Actions to be Taken

- Copy of last year papers and publications to be shared with members.
- Members to Volunteer in core group/s

CG 1 Funding: Thrust Areas:

- Future of Biosimilar industry in participating 100 Billion Dollar Bio economy industry in India by 2025
- Funding for all interested companies (tripartite agreement between Government +Promoter+ PE) exit option for PE investor

Leading Members: Mr Sunil Thakur and Ms Pushpa Vijayaraghavan



CG 2 Agri-Biotechnology: Thrust Areas

- Bio Diversity,
- Bringing predictability in Regulatory framework (type of tests needed, biosafety requirements, time etc.)
- Pricing, IP

Leading Members: Dr Deepa Tiku, Mr Rajendra Barwale

CG 3 Innovations and technology: Thrust Areas

- Innovation
- Technology,
- SME ,
- funding up to phase 3 beyond 50:50 participation to 100% funding as grant, equity, soft loan on long term 10-20 years

Leading Members: Dr Jitendra N. Verma and Dr Nupur Mehrotra

CG 4 Gene and Cell based Therapies: Thrust Areas

- Regulatory Framework

Leading Members: Mr BN Manohar

CG 5 Vaccines: Thrust Areas

- Adult immunisation to be made mandatory, government to advertise and issue immunisation guidelines,
- Enable IPV production in India
- Vaccines industry to be taken out of Price control
- price preference for Public sector companies to be abolished
- Vaccine development Phase1,2,3 application to have 30 days' time for approval or deemed approval
- Phase 3 application should not require phase 3 DS and DP batch data compulsory for getting phase 3 trial protocol approval.
- Post approval changes to be permitted with 30 days

Leading Members: Dr Suresh Jadhav and Mr Manoj Grover



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CG 5 Medical Devices: Thrust Areas:

- To be decided by Core Group members to take forward

Leading Members: Dr Purnima Sharma