



Minutes of the First meeting of Biopharmaceuticals Industry Platform held on March 4, 2009 at FICCI Federation House, New Delhi

List of participants: Annexure- I.

Points Discussed

The following issues of concerns to the industry were highlighted and discussed during the meeting.

1.0 Vaccines

1.1 Research Professionals: The industry expressed the need for highly trained research professionals with a clear understanding of the regulatory requirements of the biopharmaceuticals. It was expressed that there is a severe shortage of experienced manpower in various areas required by the industry like protein purification, gene sequencing, proteomics, genomics, bioinformatics etc for industrial application. Further, there was also lack of experienced human resource in pre-clinical and clinical trials. Strong need for specific training programme was felt in the above areas as well as access to global trained manpower.

1.2 Substrates and facilities for Vaccine Development: Support for Vaccine Development is required on various fronts such as accessing WHO approved cell lines, data on animal models, availability of adjuvants, bacterial and viral vaccine strains. The Government with the help of institutes like NCCS, Pune may look at concept of creating cell line banks to resolve the problem. Availability and development of clinical trial site for vaccine development was also discussed.

Three working groups were proposed to look into these issues-

- Working Group on Cell lines
- Working Group on Animal Models
- A working group on clinical trial site development

2.0 Biologics/Biogenics

2.1 Business Opportunity: Biogenics today offers a tremendous opportunity for the Indian biotech industry. The current global pharmaceutical market is at \$75 billion and is expected to grow to \$150 billion by 2015. By the year 2010, nearly 90% of the products would get off patent. This would open up the market, currently worth \$40 billion, and growing at over 20% per year if the regulatory requirements are met. Industry is finding difficult to manage the risk of development of biogeneric and the issues of regulatory approval especially for the import and marketing of biogenerics products. It was expressed that Department of Biotechnology should look into the issue of trading companies that import and market the products with the approval of DCGI and without any regulatory requirement of RCGM/GEAC.

2.2 In addition there is a need for adequately trained manpower who can manage the biogeneric development and marketing. The Indian scientists abroad with expertise in the field could be identified and their expertise suitably channelized for the industry.

2.3 There are Indian scientists abroad whose expertise could be channelized in the country. However, there is a need to develop a mechanism of tapping such



resources, and having a formal mechanism of identifying such people and the Government is required to support these people.

2.4 It was proposed that BIPP could include development of biogenerics and include provision for the same in its guidelines.

Letters to be written to DBT, DCGI and MoEF by FICCI on behalf of Industry for including development of Biogenerics in BIPP and to get the Protocol V of the Mashelkar Committee amended, which has been notified by the Ministry of Environment and Forests for import and marketing of biogenerics/therapeutic proteins without pre-clinical or clinical trials for marketing approvals as it denies level playing field to the domestic biotech industry.

A working group was constituted on Biogenerics to look at the various aspects including regulations, priorities for development, infrastructure requirements.

3.0 Infrastructure: Affordable infrastructure for new entrepreneurs was the need for the industry. The technology parks and biotechnology parks presently offer a very high rate for their incubator services.

4.0 Trade: There was a need for an agency that would act as a Trade and Investment Promotion body catering to the Indian companies to highlight the opportunities that exists in India for global biopharmaceuticals business. The agency will help in attracting foreign investment in the country. Working group on Biopharma to send a write-up to DBT on the issue of substandard imported products in the Indian market and its adverse effects. .

5.0 New Drug Discovery Systems (NDDS): High costs and long duration, involved in drug discovery prompted optimization of known drugs by developing improved formulations particularly NDDS. This would open up big opportunities for India as new formulations of a drug already in clinical use should ideally be subjected to rationally abbreviate clinical trials, and resulting early launches in huge domestic market would give edge to Indian companies. Early leads of Indian companies in NDDS employing Liposome Technology and Nanosome Technology have encouraged some in the industry and large number of academic institutions to follow the lead. Initial strides, however, are impeded because of:

5.1 Want of pharmaceutically compatible nano-materials and their manufacture in India. R&D needs to be intensified and BIPP support should be extended for development of polymers for nano-drugs and vaccines.

5.2 Regulatory guidelines need to be framed to ensure that all requisite studies are conducted and redundant testing/trial or studies are not imposed that cause delays in commercialization. It is notable that different NDDS formulations of the same. Active Pharmaceutical Ingredients (API) are different products because of the intended properties imparted by the uniquely designed carrier.

5.3 For developing regulatory guidelines for the industry to comply and the Drug Authorities to enforce, necessary co-ordination of empowered committee of DBT



may be established with DCGI/DGHS and or other agencies involved in the regulation of NDDS based formulations.

5.4 In the second Phase studies may be taken up to meet the requirements of global market.

5.5 If a product made in India is more effective and less toxic and/or has other superior features that merit consideration, inferior alternative imports shall be disallowed.

6.0 Both Pre-clinical/Toxicology and clinical trial centers be set up in North and East as South and West already have such centers. DBT recognized such centers may be given priority for BIPP funded projects and these, in turn, should offer discounts for BIPP funded projects

7.0 IPRs: There is a need to generate IPRs in the biopharma sector. There has to be a mechanism for infringement analysis, processes available and their validation. Dr. Rama Mukherjee to suggest an IPR expert who can help in setting up these mechanisms.

8.0 Stem Cell Therapy: A strategy paper is required to record the present status of Stem Cell research and infrastructure and what needs to be done. It was decided that a meeting of companies involved with stem cells and NCBS would be organized in Bangalore to take the agenda forward. This will constitute the working group on Stem cell therapy.

Working Groups and Action Point

Six working groups were formed as follows:

1. Working Group on Cell lines
2. Working Group on Animal Models
3. Working Group on Clinical Trial Site Development
4. Working Group on Biosimilars
5. Working Group on Stem Cells Therapy
6. Working Group on New Drug Delivery Systems

1.0 Working Group on Cell lines

Convener: Dr. Sanjay Singh, Genova Biopharmaceuticals, Pune

Members: Dr. Tapan Chakraborti, IMTECH, Chandigarh

Dr. G. C. Mishra, NCCS, Pune

Dr. Sanjay Singh to suggest names from the industry for this group.

1.1. The group would work with the objective of creating the availability of WHO approved cell lines through specialized banks. The group would also work towards cell lines development and characterization for master cell lines and working cell lines.

1.2 The group will meet at Pune to coordinate for processes with NCCS.

2.0 Working Group on Animal Models

Convener: Dr. V. K. Vinayak, Panacea Biotec, New Delhi

Members: Dr. Naveen Khanna, ICGEB, New Delhi

Dr. Sudhanshu Vrati, NII, New Delhi

Dr. Vinayak to suggest names from the industry for this group.

2.1. The group would work towards developing the infrastructure and for procurement of animal model (Efficacy and Immunogenicity Model)

2.2. DBT is planning a center at Faridabad, which will help in all the processes related to vaccines development. The Platform on Animal model can be based in the vaccines center. There should be a list of the animal models that are most worked on, as not all the animal models can be made available.

3.0 Working Group on Clinical Trial Site Development

Convener: Dr. Arun Bhatt, ClinInvent and Mr. Rajat Goyal, IAVI

Members: Dr. Arun Bhatt to suggest names from the industry for this group.



- 3.1. The objective of the group would be to create a National Clinical Trials Network
- 3.2. The group to suggest what are the clinical sites required in the country after regional mapping.

4.0 Working Group on Biosimilars

Convener: Dr. Murtaza H. Khorakiwala, Wockhardt

Members: Dr. Rama Mukherjee, ARA Healthcare

Dr. V. K. Vinayak, Panacea Biotec

Dr. Vinayak to suggest names from the industry for this group.

Safety and Pharmacology will be the focus area for the group.

4.1. DBT is planning to make two incubators operational in Faridabad and Mohali and the group can contribute to the initiative. The group is required to give a list on the kind of clinical centers required for Biologics/Biogenics.

4.2. Dr. Khorakiwala to send a note on the issues and the areas of priorities for Biopharma. It can also cover the kind of infrastructure and support that is required.

4.3. Consideration of Biologics/Biogenics in BIPP is a request from industry. FICCI to write a letter to DBT giving the industry request to consider including Biologics/Biogenics under BIPP

4.4. DBT may consider starting DBT – Industry Partnered Fellow-ship that will be made available for fellows who are excellent in R&D and not in manufacturing.

4.5. In order to promote the opportunities that exist in the Biopharma sector, it was proposed that a project Advantage India kind of scheme could be run where an outside group can be involved.

4.6. For the clinical trial data acceptability issue, DBT may consider forming a group of 5-6 experts with involvement of US-FDA to gain an understanding towards improving the existing facilities in India so that the data from Indian CROs institutes can be acceptable for regulatory approvals abroad.

5.0 Working Group on NDDS

Convener: Dr. J N Verma, Life Care Innovations, Gurgaon

Members: Prof. A N Maitra, Delhi University

Prof. G K Khuller, PGIMER, Chandigarh

Dr. Nasir Ahmed, CellMax, Aligarh

The working group is to address to the deliberated and related issues concerning NDDS based pharmaceuticals / biotherapeutics.



Department of Biotechnology
Ministry of Science & Technology
Government of India



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of Commerce & Industry

6.0 Working Group on Stem Cells Therapy

Convener: Dr. Mrinalini Chaturvedi, Cryobanks

Members: Dr. Mrinalini to suggest names from the industry

The group will coordinate with NCBS, Bangalore to understand and discuss how stem cells therapy can be taken forward in the country in the presence of Dr. Jyotsana Dhawan, Stem Cell Research Institute and Dr. Alok, CMC - Vellore



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Ministry of Science & Technology
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Annexure - I

List of Attendees

Industry Platform Members

Ms. Meenu Batolar, Head - Regulatory Affairs, Biogen Idec Biotech India Pvt. Ltd
Dr. Arun Bhatt, President, ClinInvent Research Pvt Ltd
Dr. Sanjay Singh, CEO, Gennova Biopharmaceuticals Ltd.
Dr. Jitendra N. Verma, Managing Director, Life Care Innovations Pvt. Ltd.
Dr. Murtaza H. Khorakiwala, Executive Director, Wockhardt Ltd.
Dr. V K Vinayak, President - Biophama R & D, Panacea Biotec
Mr. Pradeep Jain, GM - Corp Communications & Business Development, Panacea Biotec

Prospective Members

Dr. Rama Mukherjee, Managing Director, Ara Healthcare Pvt. Ltd.
Dr. Mrinalini Chaturvedi, Medical Director, Cryobanks International Private Limited

DBT

Dr. M K Bhan, Secretary, Department of Biotechnology
Mr. N S Samant, Joint Secretary, Department of Biotechnology
Ms. Prachi Saroop, Director, Department of Biotechnology
Dr. K K Tripathi, Senior Advisor, Department of Biotechnology
Dr. T S Rao, Advisor, Department of Biotechnology

FICCI

Mr. V K Topa, Advisor to Secretary General, FICCI
Ms. Bishakha Bhattacharya, Additional Director, FICCI
Ms. Noopur Singh, Assistant Director, FICCI
Ms. Geetika Mehrotra, Research Associate, FICCI