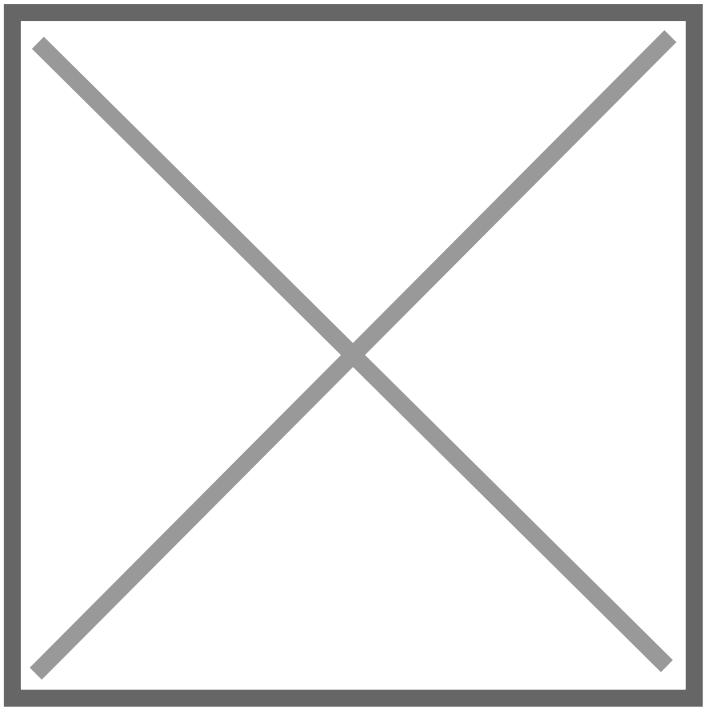
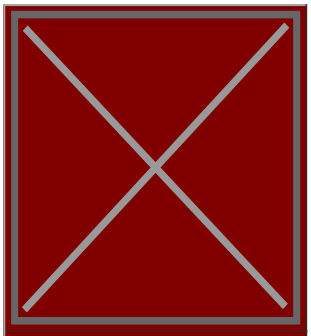
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Dr Mashelkar to head task force on rDNA drugs

11 May 2004 | News





Dr RA Mashelkar

The repeated knocks at the doors of the government by the biotechnology industry has been finally heard. The government has set up a national task force headed by CSIR chief, Dr RA Mashelkar to streamline the regulatory process involved in the approval of all recombinant DNA products. The Ministry of Environment and Forest (MoEF), which oversees the regulatory agency, Genetic Engineering Approval Committee (GEAC), issued the notification for setting up the task force on 20 April.

Dr Mashelkar told BioSpectrum that the first meeting of the Task Force will be held in New Delhi on 12 May. The task force has been asked to submit its report by May-end.

The Task Force members

1. Dr RA Mashelkar (chairman)
2. Secretary, Ministry of Environment and Forests
3. Secretary, DBT
4. Secretary, Ministry of Health
5. Director General, ICMR
6. Director General, Drug Controller General of India
7. Dr Amit Ghosh, co-chairman, GEAC
8. Dr CM Gupta, chairman, RCGM
9. Nominee of ABLE (Kiran Mazumdar-Shaw)
10. Nominee of CII
11. Nominee of FICCI
12. Desh Deepak Verma, joint secretary, MoEF.

Terms of Reference

1) Recommend a transparent streamlined regulatory mechanism and process for the use of LMOs in the pharma industry during the various stages of R& D testing, manufacture and use.

2) To recommend regulatory process and mechanism for import of LMOs in the pharma sector.

The 12-member task force will have three industry representatives from ABLE, CII and FICCI, besides senior government officials and scientists. It may be pointed out that the regulatory reforms in the biopharma sector had been identified by BioSpectrum as one of the Top 10 hurdles facing the industry and a national debated had since been initiated on this.

Dr Mashelkar's prescription to set right the ailments facing various industry sectors have been implemented by the government quickly in the last few years. So the mood is upbeat in the biotechnology community. "I commend the MoEF for having set up this task force. By appointing Dr Mashelkar to head this task force, the Ministry has shown its earnestness in being proactive to the needs of the biotech industry," said Association of Biotechnology-Led Enterprises (ABLE) president Kiran Mazumdar-Shaw. ABLE president had made a special presentation on the industry demands to HRD and Biotechnology Minister, Dr M M Joshi last January. Added ABLE director-general Nitin Deshmukh, "We are really heartened by this decision of the MoEF and look forward to an early resolution of the concerns of the industry on regulatory matters."

"What we need is a proactive, efficient and knowledge driven regulatory system which adds value, both for the industry and consumer's health," commented New Delhi-based Panacea Biotech joint MD Rajesh Jain. "This move has come at the right time when the biotech industry is jumping into the next orbit of change at the global level."

The task force will have a tough task on hand. Industry leaders have been quick with key suggestions to help the task force with the tasks ahead.

"The foremost task should be to evolve steps to straighten out the hurdles and make the regulatory process more transparent, time-bound and lastly but not the least, ensure pleasant transactions between industry and regulatory agency by way of simplified procedures," suggested India's leading home-grown biotech company, Shantha Biotechnics chairman and MD Varaprasad Reddy.

Echoing similar sentiments, Dr SD Ravetkar, senior director, Serum Institute of India, Pune, said "The key areas on which the task force should focus on are single window clearance, standardizing the operations, regular committee sittings, and minimum paper work for clearance. Besides, it should also make suggestions how best the government can implement its recommendations. Unless the recommendations are implemented, there is no point in forming the task force or committees."

Another biotech pioneer, Dr Krishna Ella, CMD, Bharat Biotech, Hyderabad, too welcomed the appointment of a visionary like Dr Mashelkar to head the task force. His agenda to the task force is:

- Amend the Environment Protection Act (EPA) 1986 and exclude medical biotechnology from its purview;

- Various companies working on highly infectious organisms can be brought under EPA regardless of whether they are working on recombinant or non-recombinant products.

- Must look critically at non-GMP imports from countries such as China and Russia.

Dr Dhananjay B Patankar, head biotechnology, Intas Pharmaceuticals, Ahmedabad has formulated a big agenda. "The task force should look at safety, efficacy and protecting the environmental issues. It should work on rational and scientific bases and streamline the existing bottlenecks without compromising the standards. It should come out with clear and transparent system of regulations that would help the biotechnology companies. Considering opportunities in contract and clinical research and contract manufacturing, the system should provide facilities for the biotechnology companies not to lose the opportunity. At the same time, the task force should also look at safeguarding the interests of the common man."

Added Dr Swati Piramal, director, strategic planning and communication, Nicholas Piramal India Ltd, "Setting up of the Task Force is a move in the right direction, especially with Dr Mashelkar at the helm of affairs. However, the real need is to quickly build capabilities and mechanisms that will implement these and earlier recommendations."

Dr Vijay Datla, chairman, Biological E, Hyderabad said the task force formation was a positive development in the right direction and hoped the Committee would come out with recommendations for timely clearance of the proposals and rationalization of regulatory framework. "This was essential for the growth of the biotech industry which is suffering for want of clear-cut guidelines," he observed.

He wanted the committee to look into:

- GEAC working within the scope of the framework laid;

- There should be a single window for clearance like GEAC and RCGM under one body under the chairmanship of an eminent person with Biotechnology background;

- Permission for Human clinical trial should not be under the purview of GEAC and their role to be restricted to Environment;

- Having regular and standard dates for GEAC meeting and information to be provided through the Internet.

While there is universal support to the task force, many entrepreneurs feel that some more hands-on industry representatives should be part of the expert panel to enhance its profile and work.

" Dr Mashelkar has the vision and commitment to nurture home grown technologies. However, I strongly believe that a scientist, who has hands-on experience with recombinant DNA based pharmaceuticalproducts should also be inducted into the Task Force," commented Shantha's Reddy. "The whole exercise will lose its weight unless the task force has industry representation, for which it is targeting at," added Serum's Ravetkar.

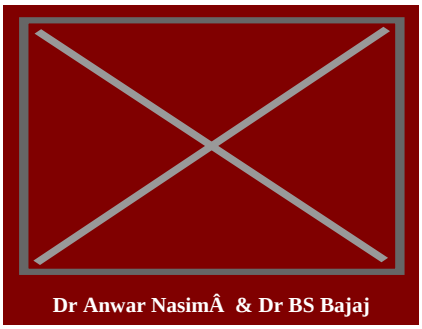
The Task force has been requested to take into account the recommendations of the Govindarajan committee on re-engineering the regulatory process. Also, the chairman has been given the option to co-opt persons with required expertise. Hopefully, the task force will increase the industry representation and pave the way for a bright future for biopharma.

N Suresh

Indo-Pak biotech initiative picks up

Indian companies are sitting up to take notice of the potential Pakistan market holds. And Pakistanis are tired of paying a price as high as seven times are looking for alternative suppliers for several vaccines, diagnostic kits and other bio-industrial products. A lot of ground has been covered since Dr Anwar Nasim acknowledged India as a viable option at the recently concluded BioAsia 2004 in Hyderabad early this year. The Chairman of Pakistan's National Commission of Biotechnology, Dr Nasim who had led the Pakistan delegation to India, is now back home spearheading the case for cooperation in

biotechnology.



Dr Anwar NasimÂ & Dr BS Bajaj

Government-to-Government cooperation works out to a slow process, he had nodded agreement. In spite thatÃ¢â?¬â?of the nine Asian nations that signed the declaration for formation of Federation of Asian Biotech Associations (FABA)Ã¢â?¬â? Pakistan has moved the fastest. However, even with five MoUs in town and two of them in the private sector the tangible progress will be visible only towards the end of this year, believes Dr BS Bajaj, Chair of AIBA, southern chapter.

Bajaj's expectation is in line considering that senior officials of Biological E are planning a Pakistan-visit in the second quarter of FY05. Biological E is in preliminary stages of negotiation with AMSON Vaccines and Pharmaceuticals Pvt Limited, Pakistan. Supplying anti-snake venom is one of the areas they are exploring. AMSON is also negotiating with Transgene Biotek for technology sharing possibilities, informed Dr AK Sadhu Khan, a senior official at Transgene. Both the companies admit that the communications with AMSON consultant Dr Uzair-ul-Ghani are on and positive though too preliminary to make any projections whatsoever.

"Complex technology transfers are not under consideration for Indian Immunologicals. We have been talking to the Amson Consultant Ghani exploring the opportunity to cater to human rabies vaccine demand in Pakistan. In sourcing from India, there is a clear price advantage for Pakistan. However, it is in too preliminary a stage to comment on it," said KV Balasubramaniam, CEO, India Immunologicals.

An almost non-existent pharma and biotechnology industry in Pakistan makes available the whole range of win-win collaboration opportunities. While AIBA is helping Pakistan to set-up its biotech association, Hyderabad-based Magene Life Sciences is making progress on providing training in tune with the training and technology sharing MoU the company signed during BioAsia. Two-year-old Magene specializes in basic biology research in areas such as in-vitro cell based assay development. The company has recently added training to its list of activities in order to fill an industry-academia gap. According to its director and CSO Dr Gita Sharma the dynamics of what kind of training is required, how it is to be disseminated and the size of the batch are all under discussion with Pakistan. As far as the company is concerned the training can take off as early as June but the complexities involved in getting the first batch of trainees from Pakistan will take its time.

With areas of cooperation ranging from bioagri to vaccines to bulk-drugs it is up to the industry to seize the opportunity. The ease of accessibility of markets and regulations taking kind note of Indo-Pak collaborations would be the key in opening up the sector, as would be the grant of visas. And to take it further all that is required is one success story.

Nandita Singh, CyberMedia News

High profile CII biotech mission heads to USA

CII is organizing a high profile biotech delegation to San Francisco to make a splash during the BIO2004 convention (6-9 June 2004). Coinciding with the annual BIO Convention BIO 2004, it also stands alone as an opportunity for the international biotech community to meet with representatives of an upward looking and extremely competitive biotech industry. The delegation consisting of 35 members from different walks of the biotech industry will have Dr MK Bhan, secretary, Department of Biotechnology, as the Patron and Hari S Bhartia of Jubilant Organosys as the leader of the Mission. The mission comprises Avesthagen, Biocon, Birla Institute of Scientific Research, Chembiotek, Jubilant Organosys, Ocimum Biosolutions, ICICI Knowledge Park, Genome Valley, Government of Karnataka, Tata Consultancy Services, Shantha Biotech, SRL Ranbaxy, Neeman Medical International, Panacea Biotec and more.

CII will also be coordinating an "India Evening", a short conference to highlight the strengths, accomplishments and opportunities for partnerships with the biotech sector in India. A traditional Indian reception is also being planned by CII. Hari Bhartia, Mission Leader, informed, "I am very happy to lead the CII Biotechnology Delegation to the US. We have indeed put together an impressive program for the Mission. Apart from the company visits and one-to-one meetings, the Program for 7

June looks to be very promising. The topics that will be focused upon include: (1) 'Clinical Research & ServicesÃ¢â?¬â? Global Clinical VillageÃ¢â?¬â•Exploring New Horizons for Speed, Cost and Quality.' The session will discuss how India can do it fast, do it well, and do it at less than half the cost at global standards. (2) 'Bioinformatics and Contract Research' session will focus on highlighting the potential in this area. (3) 'Financing and Fostering Biotech Ventures and IPR'. The session will discuss how fostering the right kind of partnerships might be the answer." He also informed that the panelists are key players in their fields in India and also international speakers will be invited to give a global perspective in each session.

It may be mentioned that BIO has chosen CII as the official contact for participation from India. According to
Dr Sandhya Tewari, CII director, "The organization has formulated a multi-pronged approach to maximize the visibility for Indian participants. CII is coordinating an "India
Pavilion" at the BIO Exhibition. The Pavilion will provide an opportunity for companies and organizations from India, including state governments to showcase the unique strengths India has in this arena."

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Arogyapacha raises IPR controversy

Arogyapacha raises IPR controversy

Seems like the famed Kerala's "Arogyapacha" model of benefit sharing between industry, research institutions and tribal community for traditional knowledge is running into troubled waters. First the state forest department raised the first obstacle by not allowing Kanis, the tribal community of Thiruvananthapuram Agasthyar Forests to cultivate or take out the Arogyapacha (Trichopus zeylanicus) from the forests saying that it was not classified as a "micro-produce". Now a US-based firm has claimed that it owns the copyright and patent for "Jeevani", the herbal vitalizer developed out of Arogyapacha jointly by Kanis, Tropical Botanical Garden and Research Institute and Arya Vaidya Pharmacy of Coimbatore.

The executive vice president of the Kerala State Council for Science, Technology and Environment, Dr MS Valiathan opined that it is not yet clear whether Arogyapacha rights', which are being contested by US-based companies, could be patented. He added that a patent could not be claimed for herbal formulationsÃ¢â?¬â•only drugs made from herbs qualify. A clear legal opinion on the matter is yet to emerge. The case could be fought only on grounds of trademark violation, he said.

Meanwhile, attempts by CyberMedia News to elicit the opinion of Director of TBGRI Dr GM Nair did not yield any result. The queries related as to what legal remedy was TBGRI resorting to contest the claim made by the US based firms on copyright of Jeevani drug and how much amount was realized as result of the Tripartite agreement between Kanis, TBGRI and Arya Vaidya Pharmacy.

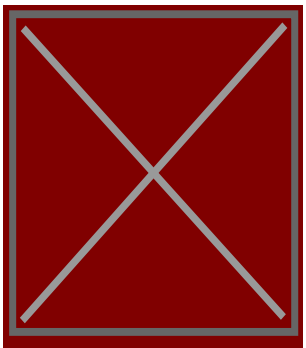
The controversy over the US firms claims surfaced when TBGRI went for a global tender for giving international marketing license for Jeevani as its seven-year contract with Coimbatore Arya Vaidya Pharmacy was over. The alleged violation of rights happened in a month after TBGRI director made a presentation of Jeevani on a biodiversity seminar in New Delhi. According to this deal, Kanis had been receiving royalty from the drug's sales proceeds, claim TBGRI officials. It may be recalled that the herb also enabled a tribe to earn patent for the first time in the world.

The Arogyapacha issue raises several issues regarding the IPR for traditional knowledge, the rights of tribal to cultivate useful herbs and generate income and licensing of such knowledge to industry. It is maintained that in Korea cultivators of Ginseng, an energy enhancing herb have benefited out of commercialization of the herb under an arrangement with the industry.

If for some bureaucratic reasons or otherwise, if TBGRI or CSIR does not act in time and fight out the Arogyapacha issue, India's further claims on rights of its vast traditional knowledge would be at stake. On the one hand Arogyapacha is a perfect model of benefit sharing evolved between tribal, research and industry. On the other hand it also serves as an important lesson for the scientific community in the country to follow proper procedures to protect its IPR.

R Sreekumar, CyberMedia News

India should take lead in biotechnology through regional cooperation



Dr Maharaj K Bhan

Regional cooperation should be taken as a priority, in dealing with biotechnology. This was an overwhelming sentiment during the second conference on biotechnology for Asian development, organized by the New Delhi-based NGO, Research and Information System (RIS) for the Non-Aligned and Other Developing Countries in collaboration with CII and IUCN Regional Biodiversity Programme and supported by UNESCO and Department of Biotechnology (DBT).

Addressing the inaugural session, KC Pant, deputy chairman, Planning Commission and chairman RIS Governing Council, pointed that for some time now it has been a discussion on the potential of biotechnology for development. "After various meetings, seminars etc, it is a well established fact that these technologies provide valuable tools for meeting a number of developmental challenges in different areas. Now, I hope the biotech industry in India further gears up to foster growth in Asia through regional cooperation and exploitation of synergies effectively."

Not just that, it is also important to address the concern over the "asymmetric" global Intellectual Property Rights (IPRs) regime that has failed to protect traditional knowledge from biopiracy. The gene-rich developing countries need to guard against any form of biopiracy, the conference acknowledged. RIS director-general Nagesh Kumar added, "There is an asymmetric treatment by the global regime for IPR protection of knowledge resulting from modern innovation systems vis-Ã?Â -vis the products of traditional knowledge system and biodiversity that actually represents the work of the generation of farmers."

The regional cooperation would help promoting biotech, capacity building and addressing biosafety related issues on priority basis. There is no denying about the benefits of regional cooperation. Dr Sachin Chaturvedi of RIS rightly pointed out, "Asian countries collectively can do wonders in rapid growth of biotech in this part of the globe. But we still have some unanswered questions in front of us, such as, how to have the governments to come forward to lend support and facilitate alliances? What do we need from them? Each and every stakeholder of this community has to be clear on that. Further there are issues like funding biotech research."

According to Dr M K Bhan, secretary, DBT, "So far we were engaged in making strategies for prospective frontier areas in biotechnology sector. It has been observed that there has been a big difference in the outlook of public and private sectors. This can only be worked out after discussing biotech issues together, interacting with each other and sharing knowledge." He also emphasized the urgent need for educating the leadership in universities, institutes etc. for promoting private partnership. "We need to understand the practical way of securing success," remarked Dr Bhan. The feel good factor to be sustained India should hope to become the leader in South Asia, if not the entire globe.

Faiz Askari

FICCI proposes industry-friendly mechanism

The entire global scenario relating to the environmental protection laws is undergoing a change. And the Indian government has also decided to re-evaluate the constraints faced and raised by the biotech industry. Government authorities are also considering to draw up new rules replacing Rules 1989 of the Environmental Protection Act, 1986 that will comply with the Cartagena Protocol. On this issue, FICCI submitted its recommendations to the Ministry of Environment and Forests. Among the suggestions made are changes in the risk categories as defined in the annexures to the rules, changes to the title and clearer definition of the term gene-technology.

A letter of recommendations sent by FICCI to the environment secretary raised some extensive and serious suggestions. It is mentioned in the beginning, that the risk categories defined in the annexures of the rules need to be reworked. FICCI has suggested that microorganisms under category 1 should be exempted from regulations. The microorganisms in this category meet 95 percent of the requirements of the pharma industry. On the other hand, FICCI has asked for stringent regulations to govern categories 2 and 3. It has also suggested that a task force comprising scientists and scientists-turned-entrepreneurs be constituted. Explaining this point, Amit Mitra, secretary general, FICCI said, "There is an urgent need to streamline regulatory mechanism for biotech, apart from policy reforms like single window clearance to unleash the growth in the sector."

Moreover, coming back to the recommendations by this industry organization, it is emphasized that it would be responsible for redrafting the rules, keeping in view the requirements of protecting the environment, nature, plant, animal and human health, while promoting/facilitating the safe use of Living Modified Organisms (LMOs) and enhancing productivity. It has also been suggested that the redrafted rules be discussed with industry bodies FICCI, All India Biotech Association and other such organizations.

Among the other submissions made by FICCI is the inclusion of a biotechnology industry representative on the Genetic Engineering Approval Committee (GEAC). FICCI has suggested that it may be included as a non-voting member of the committee. It has also called for greater inter-ministerial co-ordination.

Faiz Askari

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