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A comatose regulator, GEAC kills Indian biotech

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The biotech industry leaders are calling this extraordinary state of inaction of the biotech regulatory agency GEAC as the "Jayanthi whiplash" which sent its 16 members into a near coma state for more than 24 months. The shadow Prime Minister of the leading Bharatiya Janata Party (BJP), Mr Narendra Modi, called the status of environment ministry's inaction as "Jayanthi Tax" on industry. The reference is to the former minister, Ms Jayanthi Natarajan, who until recently lorded over the ministry as its head, for 30 months, from July 2011-to-December 2013 until she was replaced by Mr M Veerappa Moily in a surprise cabinet reshuffle.

The facts about the regulatory inaction during Ms Natarajan's stewardship of Environment Ministry which handles GEAC is stark. The regulatory body used to meet once a month, on every second Wednesday, since 2005 to clear biotechnology products which are required to get a compulsory approval for its environmental impact from this regulatory agency.

GEAC has met only six times during the 30-month tenure of Ms Natarajan. More devastatingly, the last two meetings have taken place after a gap of a year each, which has literally choked the growth of biotech industry that was growing at over 18 percent every year since 2006.

As a result, close to 100 important biotech products, many of them life-saving and cost-effective substitutes for imported high-priced medicines, are pending clearances. Millions of India's patients are keenly awaiting the release of these products to prolong their lives impacted by various dreaded diseases.

Data compiled by BioSpectrum throws some startling facts. After Ms Natarajan took over as the minister in July 2011, the GEAC met five times-September, October, and December 2011, February 2012 and April 2012.The next meeting was 14 months later on April 11, 2013. The meeting took some decisions. But the minutes of the meeting have not been made public nearly 11 months later. This meeting was the first one of the reconstituted committee which had 16 members.

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Since April 2013, GEAC has slipped into a "coma" probably on the cues from the minister. "We thought the regulator was only in a hibernation mode, meeting twice in a span of 24 months. But now it appears to be in a state of coma. Can the good Mr Veerappa Moily, the new minister, revive the regulators from its comatose state," asked a worried director of one of the country's top biotech companies.

Ms Natarajan had vigorously defended her reign at the ministry when Mr Modi referred to the overall "Jayanthi Tax". The facts speak for themselves who is right. Under Ms Natarajan's predecessor, Mr Jairam Ramesh, who was also considered to be vehemently against the biotech industry, did actually better during his tenure with biotech regulatory clearances. His only blemish was the "misuse" of ministerial prerogative to stop the commercialization of genetically-modified brinjal crop in February 2010 despite it getting the GEAC approval.

During the 27-month tenure of Mr Ramesh, from May 2009 to July 2011, GEAC met 17 times, almost once in 45 days and cleared medical and other products at a fast pace. In fact, a GEAC meet had taken place just a few days before his being shifted to another ministry on July 6, 2011.

BioSpectrum contacted the current chairman of GEAC, Mr Hem Pande, to know the reasons for the non-functioning of the regulatory agency. Mr Pande, in his capacity as an additional secretary in the Ministry of Environment, chairs the GEAC meeting. Mr Pande and his office chose to ignore all the emails and reminders seeking clarifications and meeting requests from BioSpectrum.

Dr Ranjini Warrier, secretary of GEAC, who is tasked with the responsibility of convening the regulatory agency's meetings refused to comment on the reasons for the inexplicable conduct of the regulatory agency.

BioSpectrum has spoken to several members of this regulatory body and sought their inputs, on condition of anonymity, due to the sensitive nature of the issue. Most members were at a loss to explain the extraordinary state of affairs. They are all expert members who meet in New Delhi when an official meeting is convened by the Ministry of Environment. The current committee's tenure is for three years, from March 2013 to March 2016. And there has been no work at the regulatory agency for almost a year since the new committee was set up.

Some members concede, informally, that the inaction of the regulatory agency could be due to the extra caution being taken by the environment ministry officials due to the intervention of the Supreme Court of India, in two issues-trials of genetically modified crops and clinical trials of drugs developed abroad.But this is just a fig leaf to conceal inaction explained an industry leader. The court has not put a ban on the work of the biotech regulator. There are only some observations related to allowing field trials and clinical trials.

Explained Dr Seetharama Nadoor, executive director of bioagri industry group, ABLE-AG, "The honourable Supreme Court has not agreed to the plea of petitioners of a Public Interest Litigation (PIL) to ban field trials of the GM cropsthat are already going on under strict regulatory-vigilance standards." Because of the high visible campaign against GM crops in the country, the regulatory agency has become identified with only this sector and its work in clearing recombinant DNA and other biotech-based medical products hassuffered in the circumstances.

On being asked about the over debated issue of genetically modified crops, Dr K VijayRaghavan, secretary, Department of Biotechnology (DBT) mentioned, "Personally I think we have over-reacted. The current debate is focussed on only one aspect. There are other table top technologies such as genome engineering and bio-engineering. I feel the false debate is taking away wheels of the science and widening of thisdebate is required."

According to Dr Virander S Chauhan, director, International Center for Genetic Engineering (ICGEB), New Delhi, "The GEAC has not met since a year now. This doesn't make sense. People say that scientists don't have the communication skills to articulate their views but still politicians should not over-run science. Personally we are looking very silly in the eyes of the world."

Voices from the industry about the non-functioning of GEAC has been muted so far. Most of the biopharma companies have focused their attention on the near-killing of clinical trials activity in the country due to a Supreme Court order."Well I believe GEAC activity must be continuous and even if thereis a ruling of the Supreme Court, the GEAC must continue to meet and go forward. Many things have affected the outcome of my work. I created something meaningful and significant. And it has been put on a slow trackby lack of funding, regulations, and clarity of guidelines,"mentioned Dr Villoo Morawala-Patell, managing director and chairman, Avesthagen, Bangalore.

When asked about GEAC not being able to function properly, Dr MK Bhan, former secretary, DBT, mentioned, "What is sad is that we have not been able to improve our regulatory scenario. So is the motto improvement or hard-stop? You don't stop a child to go out on to the street and play because he will get hurt. Because on apositive note, that is how experiences come through. You don't stop living fearing something might go wrong. Ideology and prejudice rather than ethics and safety are driving this."

Many leaders of the scientific community agree with Dr Bhan's observations. Dr Deepak Pental, professor of genetics and former vice chancellor of Delhi University, is very introspective. "Why is the GEAC not being allowed to function? After all nobody is suggesting that government is not the final authority. But in this case, when there are three ministries and bureaucrats on one side and the one ministry on the other side, this is enough to point towards the passage of the BRAI (Biotechnology Regulatory Authority of India) bill. Who would like to work in this area when we first fund it and then don't care enough later? How long will we ignore scientists and science for politics? The reason for this chaos is that we as scientists have not worked as a team and raised enough voices."

Some Hopes

Even though GEAC was in existence since early 1990s, its initial meetings were sporadic. After the biotech industry came into being after 1999, intense campaigns resulted in the government agreeing to regular monthly meetings to clear pending proposals.

One of the most appalling facts about the last ever meeting of GEAC in April 2013 is that most of the key members were absent. According to the regulatory agency's charter, the presence of one-third of the 16 members is enough to constitute a quorum. There may not have been a quorum at that meeting suspect industry leaders. BioSpectrum tried its best to get information on the proceedings of the April 2013 meeting without any success.

However, some good news is on the way. BioSpectrum understands that GEAC may meet very soon. The new minister, Mr Moily has turned his attention to this agency. Mr Moily is set to meet the industry during the annual edition of Bangalore India Bio in Bangalore on February 10, 2014. He may want to avoid the ire of the country's biotech leaders on this count. Also, sources in the GEAC indicated that the regulator may clear 35-40 long pending product applications.

Earlier, the Maharashtra government in December 2013 granted No Objection Certificates (NOCs) to 28 applications from seven companies for confined field trials. Despite the opposition from within the state government, the chief minister of the state decided to give the nod on a case-to-case basis. The NOCs have been granted to transgenic varieties of brinjal, cotton, maize, rice, and wheat. The companies granted clearances include Ankur Seeds, Bayer Bio Science, Dow Agro Sciences India, Mahyco, Monsanto India, Pioneer Overseas Corporation, and Syngenta Bio Sciences. The government's Central Institute for Cotton Research has also been given an NOC. The move has got support from the union agriculture ministry.

Meanwhile Ms Aruna Rodrigues, an anti-GM activist whose public interest litigation (PIL) in the Supreme Court is going on, was quoted as saying that the Prime Minister has an agenda to foster biotechnology with the support of USA. "If the Prime Minister has overruled Ms Jayanthi Natarajan and appointed a new environment minister to do his bidding, then science goes out of the window," she mentioned in her statement to media.

The anti-GM activists are expected to oppose any such move both in courts and on streets. With the parliament likely to meet in February 2014 again before the elections, it would be interesting to see how the things turn out for the crucial BRAI bill and the GEAC.

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