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GEAC under fire

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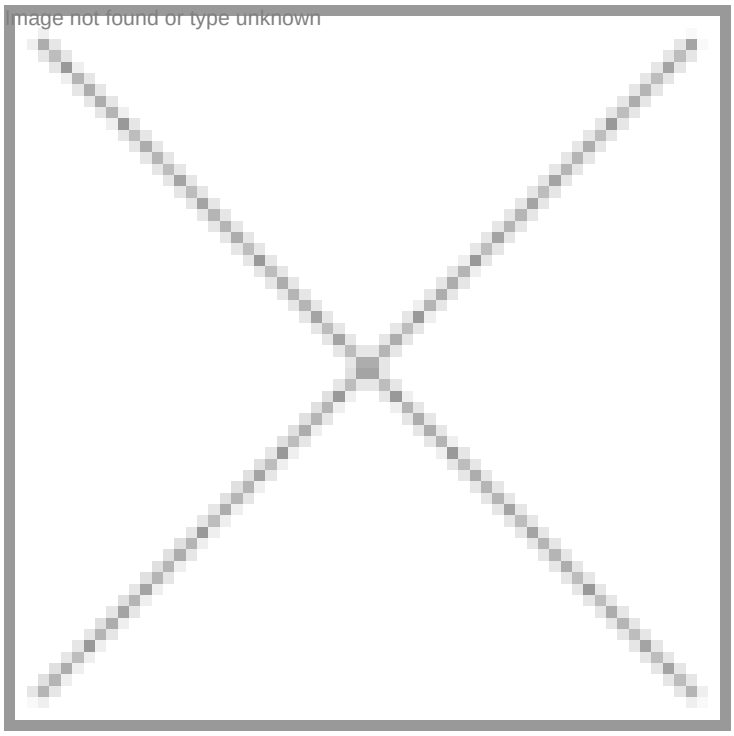

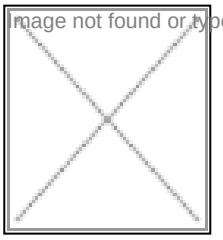

A key biotechnology regulator, the Genetic Engineering Approval Committee (GEAC), has been a topic of animated discussion at various industry forums for quite some time. Particularly, this committee, which is part of the Ministry of Environment and Forests (MoEF), has been the object of stringent criticism mainly for its lack of expertise and its nebulous structure. Many of its recent decisions have come under the industry scanner for lack of any direction.

The November 27 decision of the committee to ask for an inquiry into the manufacturing of a recombinant streptokinase (a blood-clot busting drug) by a domestic biotech icon, Shantha Biotechnics, Hyderabad, and the threat to take action against the company has added fuel to the fire against the regulator. In this case, most experts feel that GEAC has overstepped its authority. And it has poached into the domain of another regulator, the Drug Controller General of India (DCGI), the agency which authorizes clinical trials of all drugs prior to commercial use. In Shantha's case, the DCGI has apparently evaluated the relevant data and given the nod for limited manufacturing and trials of streptokinase. As the drug involves the use of recombinant techniques, in due course, Shantha's application would have landed up before GEAC for final approval

This issue has brought the focus again on the competence of GEAC as a specialized regulator for this highly sophisticated technology sector. The first thing that strikes any observer is the fact that GEAC has no defined structure. Most other regulatory agencies in the country have a well-defined structure unlike the GEAC whose head is there in an ex-officio capacity. No wonder this agency has had at least five temporary heads in 2003 alone. The committee is entirely made up of officials drawn from various government agencies and it thus lacks continuity in taking up its multi-speciality role. Isn't it time a

more permanent structure is put in place for this key regulatory agency? This is certainly the question uppermost on the minds of almost all the players in the biotechnology sector.

A former chief of GEAC had stressed the need to bring in the views of various stakeholders into the committee's decision making process at least six months back. Now there are signs that this may actually become a reality in the next few months as the agency is planning to hold widespread consultations with the public across many cities, make available as much data as possible to the public for scrutiny and usher in transparent procedures. The realization has dawned among policy makers that this was one of the glaring gap in its functioning. The process should actually go beyond these routine administrative steps. There should be a national debate on the structure of GEAC and it should be immediately given concrete structure with a widely respected biotechnology expert as the head and a full-fledged team of multi-disciplinary experts with requisite autonomy to keep close tabs on a technology sector that can cause immense harm or contribute immense benefits to the human kind if directed properly.