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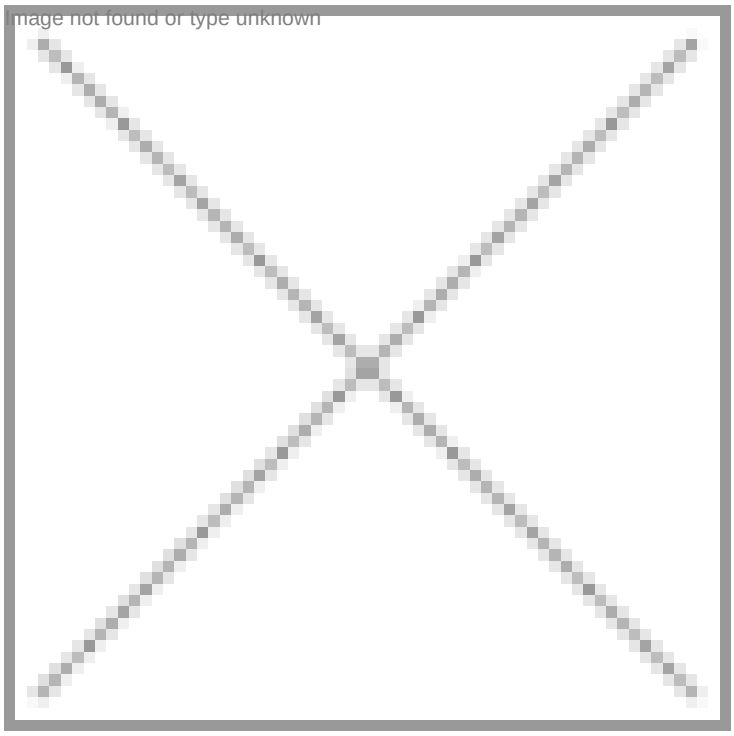


Drugs with LMOs to escape GEAC dragnet

The Mashelkar task force on recombinant drugs has got off to a flying start with the biotech industry leaders getting a chance to present their case to him in person in the Capital in mid-May. Many of the regulatory bottlenecks, repeatedly highlighted by BioSpectrum in the past 12 months, may be removed faster than expected. This is the message coming out of the first meeting of the Mashelkar Task Force. A Special Report

Makers of recombinant biotherapeutics can breathe easy. Soon they may not have to approach the Genetic Engineering Approval Committee (GEAC) of the Ministry of Environment and Forests (MoEF) for approval of such products. It may remove one layer from the complex regulatory system that exists in India.

In fact, during the meeting it was revealed that GEAC might have taken upon itself the task of regulating recombinant drugs by sheer mistake. GEAC officials argued that they had taken up the job on the basis of a set of guidelines issued by the Department of Biotechnology (DBT) many years ago, which had apparently assigned this task to GEAC.

Heat over imports

Kiran Mazumdar-Shaw told the Task Force that the country could tap a huge potential that exists in the opportunity to conduct contract research and manufacturing as an outsourced activity for foreign clients. This opportunity was lost due to the cumbersome procedures involved in getting permission for import of Genetically Modified Organisms (GMOs) used in these products.

Here, importers have to get the approvals from GEAC clearance under the Plant Quarantine Act for GMOs.

While this stymies the domestic industry, importers of various recombinant drugs have a relatively smooth passage into the country. She said the government unfairly permitted marketing of imported recombinant product without insisting on clinical trials. On the other hand, Indian manufacturers of the same products had to go through elaborate clinical trials. All countries have a stringent regulatory norm for recombinant drugs. Why should India be so lenient, she demanded.GEAC secretary DD Verma retorted that this was because manufacturing of recombinant drugs had much wider implications for the country in terms of environmental impact. Also, the marketing of imported drugs were permitted on the basis that the drug was already in the marketplace in the country of origin, which indicated that sufficient data existed to establish its safety in humans.

DBT secretary, Dr MK Bhan, admitted that a typed attachment to the RCGM (Review Committee on Genetic Manipulation) many years ago might have caused this misunderstanding. The new co-chairman of GEAC, Dr Asim Ghosh, too admitted that the agency had no role to play in the evaluation of clinical trials of recombinant drugs.

The MoEF secretary, Dr Prodipto Ghosh, informed in the first meeting of Mashelkar Task Force in New Delhi on May 12 that GEAC would confine its role to approving biotech products, which are in the form of Living Modified Organisms (LMOs).

What is heartening to the industry is that Dr Ghosh has clearly proposed that GEAC would exclude itself from product approvals pertaining to products genetically engineered from LMOs but LMOs themselves.

Welcoming Dr Ghosh's proposal, the president of Association of Biotechnology-Led Enterprises (ABLE), Kiran Mazumdar-Shaw said that it was equally important for GEAC to ensure that its role was limited to "inactivating" LMOs before they are released into the environment.

She also suggested that regulators need not differentiate between recombinant DNA (r-DNA) drugs and conventional drugs in conducting pre-clinical and clinical trials. The safety and efficacy parameters for both the type of drugs are the same. There was just a question related to whether r-DNA drugs should undergo only the "Bio-equivalence" measurements or whether they too should be subjected to Phase III clinical trials.

While this may be good news, Dr Ghosh has redefined the priorities of GEAC in his presentation to the task force. He reiterated that GEAC would be the agency responsible for evaluating the environmental impact caused by LMOs, assess environmental risks and estimate the benefits that are likely to accrue to the society.

Another crucial remark of Dr Ghosh was that GEAC would approve products only if the environmental impact realizes a net benefit to society. This may become a contentious issue especially in the bio agriculture sector. Because, the only bioagri product approved so far, the Bt cotton has generated a lot of controversies with both the supporters and opponents offering differing views on its benefits.

The removal of LMO-based products from GEAC's purview had other supporters too. Director-general of Indian Council of Medical Research (ICMR) Dr NK Ganguly informed the task force that non-LMO based recombinant products could be approved by the Drug Controller General of India (DCGI).

Dr Ganguly also informed that DCGI and ICMR have acquired the expertise to regulate recombinant therapeutics. The government is setting up a testing lab at a cost of Rs 3.6 crore at the National Institute of Biologicals (NIB) for these products. A special committee has also been set up under DCGI to handle recombinant drug products.

He clearly stressed the fact that GEAC had no role to play in the drug approval process and further Schedule Y of Drugs and Cosmetics Act had been modified to reflect recombinant products.

The Drug Controller Dr Ashwini Kumar told the Task Force that it was essential to treat recombinant drugs similar to other drugs and there was no requirement to evaluate these products on the lines of genetically modified crops and LMO-based end products. He reasoned that the two other regulatory agenciesâ€"the Institutional Biosafety Committee and the Review Committee on Genetic Manipulation (RCGM) were already doing the job of evaluating the safety aspects of the use of LMOs and environmental contamination of these in the drug manufacturing processes.

Another key industry supporter was DBT secretary Dr MK Bhan. He emphasized the need to set up a single regulatory agency to handle recombinant drugs. Dr Bhan indicated that there was a need to set up a comprehensive, extensive and integrated regulatory agency that had a high level of expertise to evaluate, approve and regulate recombinant drugs in a dedicated manner. This was the system followed by Federal Drug Agency (FDA) of the US.

Some highlights of various presentations at the Task Force

Dr MK Bhan

The DBT secretary said that the biotech industry did not have comprehensive documentation to reflect a professional level of product development evaluation. He suggested that it should be made mandatory to encourage industries to have a "Product Development Plan".

Dr Mashelkar's Response: This would be an ideal model but would require an evolutionary process to get there as it might require time and a change in mindset.

Kiran Mazumdar-Shaw, President, ABLE and CMD, Biocon, Bangalore:

The ABLE president highlighted five key problems facing the industry in this area. These are:

â€¢ Multiple regulators

â€¢ Multiple ministries

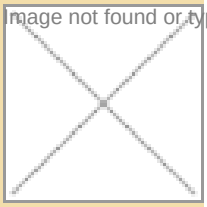
â€¢ Lack of coordination between regulators

â€¢ Overlapping and duplication of responsibilities of these regulators

â€¢ Lack of linear progression in the approval process

She wanted a clear flow-chart for the regulatory process. She also stressed the importance to have clear time lines for product approvals.

Mahima Datla, Nominee of FICCI and VP, Biological E, Hyderabad:



She supported Dr Bhan's suggestion and said the industry was looking forward to a system that simplified the regulatory approval procedure by having a single licensing authority to issue all licenses and permissions pertaining to recombinant drugs. There was also no need to reinvent the wheel in terms of evaluation procedures as there was exhaustive information available from the World Health Organization (WHO), US FDA and other international regulatory agencies that are much ahead in terms of regulatory procedures for recombinant drugs.

Dr Sandhya Tewari and DB Patankar, CII:

CII representatives felt that a biotech drug was essentially a drug and therefore the clinical trials should be supervised by the DCGI. The RCGM should be responsible for research and manufacturing. It was also important to clearly demarcate the roles and responsibilities of each regulatory agency to ensure that there was no overlap or duplication. Dr Tewari said it was critical to ensure that only experts evaluated the drug applications. Professional experts should be part of the evaluation committees. CII presented a comprehensive paper delineating the various roles of regulatory agencies.

Overall, the first meeting of the Task Force had been useful for the biotech industry. In fact, Dr Mashelkar indicated that the meeting provided valuable inputs on the role of GEAC in regulating LMOs. The industry is hopeful that Dr Mashelkar's reports will herald a new era in the Indian biotech sector.

The Task Force chairman, Dr RA Mashelkar, director-general, CSIR, has asked Dr Bhan to make a separate presentation on the need for a "Biotech Regulatory Authority."

The task force is expected to submit the report by July-end. Dr Mashelkar had indicated that he might hold another meeting with industry leaders and also consult at least 50 experts before submitting his report.

N Suresh

The tasks before the Task Force

The tasks before the Task Force

The Genetic Engineering Approval Committee (GEAC), which is a key biotech regulatory agency, is part of the Ministry of Environme
Prodipto Ghosh, had made a comprehensive presentation on the current and desired regulatory framework for recombinant therapeu
streamlined, hassle-free environment for regulatory approvals.

His suggestions to make this happen include:

â€¢ To identify bottlenecks and constraints

â€¢ To recommend transparent and streamlined procedures for regulatory approvals

â€¢ To identify the perceived problems faced by the biotech industry

â€¢ To address issues pertaining to the uncertainty of timelines in the regulatory approval process

â€¢ To understand the existing regulatory rules for product and process approvals

â€¢ To clarify the decision making process in the approval procedure by clearly demarcating the responsibilities of the various regula

â€¢ To address the complaints received from industry with respect to the infrequency of GEAC meetings

â€¢ To address suggestions made by industry to represent themselves at GEAC meetings

â€¢ To address complaints received from industry with respect to GEAC reacting to third party/media reports without verifying the fac

Many of the issues have recently been addressed by the regulator. He outlined these proactive measures:

â€¢ GEAC has eliminated the unpredictability of its meetings by meeting on the second Wednesday of every month. This has becom

â€¢ GEAC has addressed the transparency issue by posting all the decisions taken at GEAC meetings on its website

â€¢ GEAC has started inviting industry representatives to be present at GEAC meetings to clarify any issues that may raised at these eliminate delays

â€¢ A Task Force on agri biotech products under the chairmanship of Prof. MS Swaminathan was set up and the task force has subm this sector.