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Mashelkar Committee Report in force

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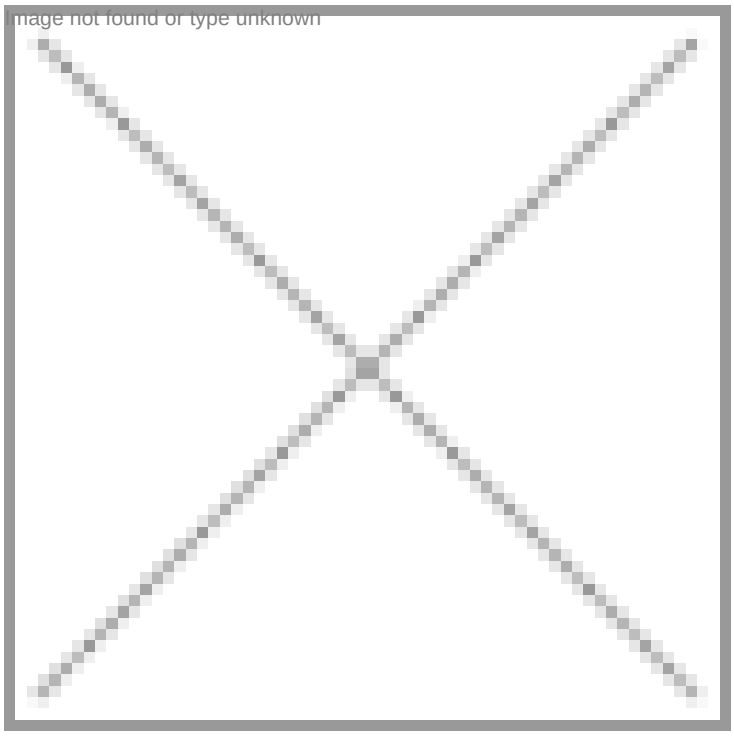

Mashelkar Committee Report in force

The report on recombinant pharma will give a huge boost to the biotechnology industry.

The Ministry of Environment and Forests (MoEF) has adopt- ed the recommendations made by the Mashelkar Committee (Task Force on r-Pharma) to streamline the regulatory process for the approval of all recombinant DNA products.

The recommendations were approved with minor amendments by an inter-ministerial meeting convened by the MoEF under the chairmanship of Dr Prodipto Ghosh, secretary, Environment and Forests, in the last week of March 2006. The recommendations have been notified with effect from April 1, 2006.

The industry is particularly pleased that the government has committed to certain timelines for approvals at different stages as the same practice was being followed by regulatory bodies in developed countries.

Hailing the report, Mukund Ranade, president - business development, Emcure Pharma, a Hyderabad-based biotech and healthcare company, said, " This is a welcome move, actually a historic development for the industry. This report will fulfil the long-standing demands of the industry."

Dr Vinod Mattoo, CSO, Eli Lilly India opined, "I am delighted. This is a welcome step forward in rationalizing the regulatory environment related to biotech products. The report is well thought of and is a big step forward in streamlining processes. The only caution would be to see the implementation of these recommendations, especially relating to establishment of a team for inspection purposes and the level of training and skill development which will be put in to develop this team."

"This will give a tremendous spurt to the r-pharma industry which has been asking for a hassle free environment."

-Dr RA Mashelkar, director general, CSIR

Almost two years back, the Department of Biotechnology (DBT) along with the MoEF had formed a Task Force committee under the chair of Dr RA Mashelkar, director general, Council of Scientific and Industrial Research (CSIR), to review the current framework for recombinant pharma and make suggestions to streamline the regulatory approval process. The National Task Force was set up in April 2004 and its recommendations were made on a consultative approach involving a large number of stakeholders spanning diverse interests. The draft report of the task force was submitted to the MoEF for further action in August 2005, and now the final report is ready for implementation.

"I must congratulate the government on the implementation of the report. There have been 11 Mashelkar committee reports so far-on higher education, drug and pharma R&D, spurious drugs, etc and the implementation of this report has been the fastest among all the committees that I have chaired. This will give a tremendous spurt to the r-pharma industry which has been asking for a hassle free environment", said Dr Mashelkar, the architect of the report.

"The implementation will considerably rationalize and simplify the regulatory approval procedure without diluting the stringency of scrutiny of the safety and efficacy data as well as environmental safety considerations."

-**Confederation of Indian Industries (CII)**

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According to the Task Force Report, LMOs (Living Modified Organisms) are defined as only those organisms modified by r-DNA techniques through human interventions where the end product is a living modified organism. The report has rationalized the regulatory procedure for five categories of LMOs and they are as follows:

- Indigenous product development, manufacture and marketing of pharmaceutical products derived from LMOs but the end product is not a LMO This category has been further divided into two parts namely (i) organisms falling under Risk Group I and II and (ii) Risk Group III and above. The approval of the Genetic Engineering Approval Committee (GEAC), which under the MoEF has been acting as the key biotech regulator providing environmental clearance to all products using genetically modified organisms, is required only for organisms falling under Risk Group III and IV.

While no approval of GEAC is required for Phase III clinical trials under this category, the Drug Controller General of India (DCGI) will approve the human clinical trials based on the recommendation of the Review Committee on Genetic Manipulation (RCGM) and product approval based on the results of the clinical studies.

- Indigenous product development, manufacture and marketing of pharmaceutical products where the end product is a LMO In this category, since the end product is a LMO, the probability of risk due to accidental release is higher and therefore the GEAC will be responsible to evaluate the environmental impact caused by handling and large-scale use/release of LMOs. Accordingly the GEAC should consider and approve Phase III human clinical trials. The GEAC should approve environmental release based on the environmental risks Vs. benefits analysis, which takes into consideration the recommendation of RCGM and results of the clinical trials. The DCGI should examine the data on the toxicity, allergenicity and QC tests and recommendation of RCGM before approving human clinical trials. The DCGI should also take into consideration the views of the GEAC on the safety of the product for conduct of human clinical trials from environmental angle. The DCGI should be responsible for evaluation of product efficacy and safety based on the data generated during human clinical studies prior to market authorization.

- Import and marketing of LMOs as drugs/pharmaceuticals in finished formulations where the end product is a LMO Since this scenario pertains to import of LMOs, the only activity envisaged within the country prior to issue of market authorization is the conduct of human clinical trials and therefore the approval of the GEAC for conduct of Phase III clinical trials as outlined in Protocol would be applicable

- Import and marketing of LMOs as drugs/pharmaceuticals in bulk for making finished formulation where the end product is a LMO This scenario involves setting up of facilities for formulations and conduct of clinical trials within the country before market authorization. The end product being an LMO approval of RGCM, GEAC and DCGI as outlined for the second category would be applicable.

- Import and marketing of products derived from LMOs as drugs/pharmaceuticals in bulk and/or finished formulations where the end product is not a LMO Approval of the GEAC is not required for this category. This scenario in terms of environmental risk falls under the least risk category since there is no exposure to LMOs within the country. Therefore approval under Rules 1989 of EPA would not be required.

The report also specifies the timelines for various approvals by the regulatory committees-RCGM approval for pre-clinical animal studies: 45 days; DCGI approval for human clinical trials protocol: 45 days; DCGI examination of clinical trial data and response: 90 days; and concurrent DCGI and GEAC decisions: 45 days.

Another important highlight of the report is that it has recommended the constitution of a Standing Technical Advisory Committee on Biotechnology Regulation under the chairmanship of an eminent scientist to redress and look into the various regulatory aspects and make issue-based recommendations on case-by-case basis prior to any deviation from the regulatory mechanism.

Hailing the report, the Confederation of Indian Industries (CII) in a press release stated, "The implementation will considerably rationalize and simplify the regulatory approval procedure without diluting the stringency of scrutiny of the safety and efficacy data as well as environmental safety considerations. It is laudable that the government has taken serious note of the long standing concerns of the industry and decided to implement the recommendations of the task force that included several industry nominees in addition to representatives and heads of different government bodies".

The CII release further added, "The proposed new system clearly separates different scenarios based on their risk potential and creates a graded system of scrutiny with a more detailed assessment for product categories where the risk concern is higher. The earlier system had caused a lot of overlapping responsibilities among different bodies, and duplication of work. The new system will allow each body to focus on its core area of evaluation (biological safety, environmental safety, drug efficacy, etc.) and also reduce the burden of by removing unnecessary workload of these bodies". The clarity on regulation for emerging areas like contract research and manufacturing was also hailed by the CII.

Rolly Dureha

Comprehensive stem cell policy soon

National guidelines on stem cell research and therapy are on the anvil

The Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) are jointly finalizing the draft national guidelines on stem cell research. The draft guidelines are expected anytime based on which the final policy will evolve.

Recently the final meeting of the expert committee in charge of framing the national regulatory guidelines for stem cell therapy was held and it invited comments from all stakeholders on the draft before finalizing the regulatory norms. These views have been received and are being incorporated.

The draft guidelines will be hosted on the ICMR/DBT website inviting comments from the general public. It is believed that the document will be available in the public domain for about three months, post which the comments will be collated, analyzed and incorporated, if required, in the final document.

These guidelines essentially provide a framework and practical guide for researchers after taking into account the scientific, ethical and legal aspects for derivation, propagation, banking and use of stem cells for research and therapy. It comprehensively addresses the entire gamut of issues related to not only the ethically sensitive embryonic stem cell arena but also the adult stem cells and the cord cells.

The national guidelines will reaffirm India's current stand in this arena that stem cell research should be promoted in the country with appropriate safeguards. They will be of a 'regulatory nature' and are aimed at giving a direction and thrust to stem cell research in the country, in view of its potential clinical use.

In the case of embryonic stem cell, the guidelines provide a complete oversight process that will ensure that the research is conducted in a responsible and ethically sensitive manner and complies with all the regulatory requirements pertaining to biomedical research in general and stem cell research in particular. They cover all derivations of human embryonic stem cell lines and research that uses such cells. A salient feature of the guidelines is setting up a of a high level committee which will clear any research proposal involving previously derived human embryonic stem cell lines; all proposals will have to be submitted to the committee which will review them speedily.

Besides elaborating on what areas of research are permitted, it also outlines, "what should not be done" or is not permissible. For example, embryonic stem cell research involving in vitro culture of any intact human embryo for longer than 14 days is not permitted nor is research involving introduction of embryonic cell into human or non-human primate blastocyst. The guidelines also ensure that only surplus embryos will be used for research after obtaining permission from the couple and generating embryos for the sole purpose of obtaining stem cells is strictly banned.

Some other prohibited research areas include transfer of blastocysts/human embryos generated by SCNT/parthogenetic to a human or non-human uterus; research involving the directed non-autologous donation of stem cell lines to an individual; research in which any cells of a pluripotent nature are combined/grafted with a human or non human embryo/foetus.

The document also outlines the criteria for derivation and study of human somatic stem cell lines from the umbilical cord and placenta or human somatic tissue; Research on anonymized human embryonic stem (ES) cell lines, embryonic gamete (EG) cell lines or somatic stem (SS) cell lines; Research involving the grafting of human ES, EC or SS cells into non human adults or legally competent humans. In addition, the guidelines elaborate on the related technical issues like the banking and distribution of human ES cell lines, the critical informed consent process, protecting the anonymity and privacy of the donor, etc.

Once the final guidelines take shape, it will be imperative to pass them as legislation so that the stipulated norms can be strictly enforced. The deterrent of punitive action will go a long way in preventing unethical and fraudulent research as was recently seen in the Korean stem cell researcher, Hwang Woo Suk's case. The national guidelines should thus become the Holy Grail of any future research foray in the stem cell arena.

Rolly Dureha