Decisions Taken in the 50th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 12th January 2005.

The 50th Meeting of the Genetic Engineering Approval Committee was held on 12th January 2005 in the Ministry of Environment and Forests under the Chairmanship of Shri Suresh Chandra, Special Secretary & Chairman GEAC.

Decisions

1.0 Permission for Phase III Clinical trials on r-h GCSF manufactured by M/s. Wockhardt Ltd. Mumbai.

The Committee took note of the comments received from RCGM, DCGI and IMTech. Since RCGM is the technical body constituted under Rules 1989, the Committee was of the view that specific comments on the safety and efficacy of the product for conduct of human clinical trials should be submitted by RCGM. The Member Secretary RCGM clarified that recommendation of RCGM on the adequacy of the pre-clinical trials and safety of the product based on the pre-clinical data would be made available to the GEAC for taking a final view.

After detailed deliberations, the Committee requested RCGM to give their views/recommendations on the following:

1. Safety of the product on the basis of evaluation of the pre-clinical data on toxicology and allergenicity.
2. Adequacy of the information on the analysis of the product in terms of impurity profile.
3. Adequacy of the containment facilities.

Based on the comments received from RCGM and after receiving additional information required, the Committee authorized the Chairman GEAC to take a final decision.

2.0 Permission for import and marketing Avonex (Interferon beta-1a) manufactured by Biogen B. V., Robijnlaan 8, 2132 WX. Hoofddrop, The Netherlands, by M/s. Nicholos Piramal India Ltd. Mumbai.

The Committee noted that the product Avonex (Interferon beta-1a) to be imported from the Netherlands for marketing in India by M/s Nicholos Piramal India Ltd., has been registered and approved for marketing in Netherlands, Austria, Denmark, France, Germany, U.K., U.S.A., Brazil etc. The product has also been approved by USFDA in May 2003, European Commission in June 2003 and EMEA. However, Phase III clinical trials have been not conducted in India.

The Committee noted that both experts from DBT and CDRI have recommended the import of the above product. DBT has further recommended PMS instead of Phase III clinical trials.

The Committee discussed at length the need for conduct of Phase III clinical trials in India prior to granting market authorization. After detailed deliberations the Committee approved the proposal for PMS for two years.

The Committee also requested DCGI to forward the PMS reports received by the Directorate for information of the GEAC in all the cases in future.

3.0 Permission for import of Nature Valley Granola Bars by M/s. General Mills India Pvt. Ltd., Mumbai, from U.S. A.

The Committee noted that the Nature Valley Granola Bars to be imported from USA contain ingredients like Soy (such as soy protein, soy oil and soy lecithin), Corn (corn derived products such as high fructose corn syrup) and Canola Oil.

The Committee also discussed at length the comments received from Ministry of Food Processing Industry. The Committee also took note of the fact that representatives of MOFPI, MOH and MOC were not available for giving their comments. Since the policies of these Ministries have direct relevance on matters related to food policy, the Committee was of the view that these departments should invariably be represented in the meetings to guide the GEAC. The Committee therefore requested Chairman GEAC to write to the respective Secretaries of MOH, MOFPI and MOC in this regard.

After detailed deliberations, the Committee decided to await the views of MOH, MOFPI and MOC as well as additional information/clarification from the company on whether the product contains ingredients derived from GM food crop and if so the percentage of GM content. Decision on the proposal was therefore deferred.

4.0 Permission to conduct Phase III Clinical trials of combined Rabies DNA Vaccine (veterinary use) by M/s Indian Immunologicals Ltd. Hyderabad.

The Committee noted that the above proposal was discussed in the 46th Meeting of GEAC on 8.9.2004 wherein the company was advised to submit the following details:-

1. Information on the association of DNA with germ-line of recipients to DBT for their comments as directed by DBT vide their letter dated 18.3.2003.
2. Revised application/ information submitted as per GEAC proforma.
3. The company was also directed not to initiate Phase-III clinical trials without the approval of GEAC.

The Member Secretary informed the Committee that the additional information submitted by the Company was examined by RCGM in its meeting held on 27.10.2004. The RCGM noted that the plasmid DNA of r-DNA rabies vaccine (DRV) or combination rabies vaccine (CRV) was not detectable in the DNA of germ line tissues and concluded that the product seems to be safe and not integrated in the germ line tissue of experimental animal. However, RCGM has further expressed that number of animals used is too small to assess the probability and such an issue should be monitored when the vaccine is used in larger population of target animals.

The Committee also noted that DCGI has conveyed 'No objection' for conducting clinical trial with indigenously developed combined Rabies DNA vaccine for veterinary use on 17.12.2003.

After detailed deliberations the Committee approved the request for conduct of Phase–III clinical trials subject to the condition that studies on integration of plasmid DNA in the germ line tissue be assessed in larger population of larger animals.

5.0 Permission for manufacture and marketing of r-human Epidermal growth factor by M/s. Bharat Biotech International Ltd. Hyderabad.

The Committee noted that the above proposal was discussed in the 48th Meeting of GEAC held on 10.11.2004 wherein company was asked to submit additional information sought by DBT. The Committee also noted the recommendations received from DBT. Some views were expressed that clarifications on the following need to be obtained:

a. In the accelerated stability studies of the product, the protein content is reducing but the activity of the product is going up which is not a normal phenomena.

b. The percentage of the protein in the total formulation.

c. Whether the total number of patients includes only control cases or the experimental cases as well.

The Committee gave an opportunity to the company representatives to provide necessary clarifications. It was clarified that the total number of patients indicated in the report includes both control and experimental cases. On the other issues, the company representatives agreed to re-look into the information furnished in the context of issues raised by the Committee and submit the requisite clarifications.

The Committee also took note of the fact that many of the members have not received a copy of the additional information. The Committee advised the project proponent to ensure that the documents are circulated to all members both in electronic form as well as hard copy well before the next GEAC meeting.

After detailed deliberations, the Committee decided to await the additional information/clarification on protein content in the formulation and results of the accelerated stability studies. Decision on the proposal was therefore deferred.

6.0 Suggested Time Frame for Bt cotton approval during kharif 2005 by various regulatory agencies

The suggestions made by the All India Crop Life Association regarding the time frame for Bt Cotton approval in the North Zone, Central Zone and South zone.

Views were expressed that the date of sowing and harvesting is dependent on many external factors such as onset of monsoon, release of canal water, etc. Therefore the Committee may

not accept the stipulated time frame. After detailed deliberations, the Committee took a view that all efforts would be made by the concerned agencies to ensure timely submission of reports/recommendation to the GEAC. As far as GEAC is concerned, the Chairman expressed that the GEAC meetings are being held every month and therefore there is no difficulty in considering the proposals received by them complete in all respect.

7.0 Spread of illegal Bt Cotton in Gujarat and other States.

The representation received from the 'All India Crop Biotechnology Association' regarding the rampant production, sale and cultivation of illegal Bt seeds in Gujarat and other cotton cultivating states was discussed at length. Representative of MOA and Member Secretary GEAC also briefed the Committee on the action taken report by MOA and MoEF respectively.

The representative of MOA pointed out that the existing Seed Act does not cover transgenic crops. He therefore requested GEAC to authorize the Seed Inspectors to confiscate illegal seeds and also authorize laboratories for testing as per the provisions of Rules 1989.

The Committee also requested the Chairman GEAC to write to the Chief Secretaries of the concerned States to take necessary action in controlling the production, sale and cultivation of illegal Bt cotton seeds.

8.0 Draft ground rules for operationalizing the good practices in environmental regulation.

Referring to the procedural guidelines formulated by MoEF to streamline the working of the regulatory bodies, the Member Secretary informed the Committee that some aspects of the best practices guidelines was discussed in the 47th GEAC Meeting held on 13th October 2004. In the above meeting it was decided that the draft ground rules prepared by the Member Secretary would be circulated to the Members of the GEAC for their inputs before hosting it on MoEF web page.

Members were invited to give their comments or alternately forward their comments in writing. It was agreed by the Members that, written comments, if any, would be circulated before the next GEAC meeting.

9.0 Presentation of Biosafety website developed by DBT.

Dr T. V. Ramaniah, Director DBT briefly presented the highlights of the Biosafety website developed by DBT and requested the Members to forward their comments in writing. The comments would be taken into consideration while finalizing the contents of the website.

Date of the Next GEAC Meeting: The next GEAC meeting would be held on 10th February 2005 instead of 9th February 2005.

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