Decisions taken in the 46th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 8th September 2004.

Opening Remarks of the Chairman

At the outset, the Chairman (Dr. Amit Ghosh) welcomed all the members. He further informed that the Mrs. Veena Chhotray, Additional Secretary, MoEF and Chairperson GEAC was unable to attend the meeting due to unavoidable official duty. Therefore, at her request he would be chairing the GEAC meeting.

Decisions

1. Permission to conduct Human Clinical trials on r-h Interferon Alpha 2b (INFERON) by M/s Virchow Biotech Pvt. Ltd. Hyderabad.

1.1 The representative of DCGI informed that the Pre clinical trials data and protocols for Phase-III clinical trials are under evaluation by the RDAC and would be taken up in the next RDAC meeting. Keeping in view the explanation given by the DCGI, the GEAC accorded approval for conduct of Phase-III clinical trials subject to clearance from DCGI. It was agreed that to avoid a situation of conflict, the clearance for Phase-III clinical trials under 1989 Rules would be issued only after the proposals has been recommended by RDAC. The Committee requested the DCGI representative to forward the minutes of the RDAC meeting to the Member Secretary in all such cases in future.

2. Permission for conducting clinical trials of combined Rabies DNA Vaccine (Veterinary use) indigenously manufactured by M/s Indian Immunologicals Ltd, Hyderabad.

2.1 After detailed deliberation and taking note of the fact that the company representatives were not available for providing the requisite clarification, the Committee concluded that the following information need to be obtained before taking a final view on the proposal:

a. The company should furnish information on the association of DNA with germ-line of recipients to DBT and comments of DBT on the above matter should be obtained.
b. Clarification from DCGI on the status of approval for conduct of Phase-III clinical trials for the combined rabies DNA vaccine for veterinary use.
c. Since the information furnished by the company is not as per the GEAC proforma, revised application/ information needs to be furnished.
d. A letter should be issued to the company not to initiate Phase-III clinical trials without the approval of GEAC.

3. Ex-post facto approval for conducting phase III clinical trials and permission for manufacture and marketing of rh -PDGF-BB (Healace 0.01%) by M/s Virchow Biotech Pvt. Ltd. Hyderabad.

3.1 The Committee took note of the comments received from the Experts and recommendation of RCGM on the adequacy of the containment facilities and other clarifications submitted by the company.

3.2 After detailed deliberations, the Committee concluded that a copy of the clinical trials reports may be made available to the Expert with the request that he may forward his comments before the next GEAC meeting. It was agreed that the proposal would be reconsidered in the next GEAC meeting.

4. Permission for conducting large-scale seed production, and large scale field trials transgenic Cotton hybrid containing cry I Ac. On an area of 40 hectares in kharif 2004 from M/s Ajeet seeds Ltd. Aurangabad.

4.1 The Member Secretary informed the Committee that DBT vide letter dated 4.8.2004 has reiterated that the applicants using MON-531 event (cry 1Ac gene) need not come to RCGM for approval but can go for conduct of large scale field trials under GEAC and also ICAR trials as the event MON-531 was evaluated for its biosafety. This decision would be applicable to all the 15 sub-licensee who have been permitted by RCGM to receive Bt cottonseeds expressing Cry 1Ac gene (MON 531) gene from M/s Mahyco. Further, it has been stated that the opinion of RCGM would be applicable to all the sub-licensees irrespective of the fact whether they are centrally notified varieties/ hybrids or not. This has been endorsed by RCGM in its meeting held on 16.8.2004.

4.2 The Committee noted that as per the earlier decision, the recommendation of RCGM would be applicable to all Bt cotton varieties/ hybrids containing Cry 1Ac (MON 531 event) provided the following three criteria are fulfilled:

a. Confirmation that the hybrid contains Cry 1Ac MON 531 event itself.
b. The protein expression is equal or higher than the Bt cotton hybrids approved for commercial cultivation.
c. Establishing the morphological equivalence to the corresponding non-Bt varieties by DNA fingerprinting.

4.3 The Committee gave an opportunity to the representative of the company to provide necessary clarification before the Committee wherein issues related to Bt gene protein expression level, homozygousity and stability of the parental line of Bt gene etc was discussed.

4.4 After detailed discussion the Committee was of the view that the document provided by the company was not satisfactory and the company may be advised to submit the following documents:

a) Sequence of the form of Cry 1Ac gene present in the hybrids for which large scale trials is being sought should be attached along with the certificate issued by M/s Mahyco to confirm that the ACH 33 I contains Cry 1Ac MON 531 event.
b) In Table 1A, 1B & 2 it was noticed that concentration of Cry 1Ac ratio in terms of dry weight: wet leaves is always 2.5. This is statistically extremely improbable considering the number of observations made. The company may be asked to explain this fact and provide details of the protocol for collection of this data.

4.5 Decision on the proposal was therefore deferred.

5. Permission for conducting large-scale field trials on transgenic Bt cotton hybrid containing Cry IA(C) gene (MON 531 event) and seed production in 100 ha during kharif 2004 by M/s Tulasi Seeds Pvt. Ltd. Guntur.

5.1 The Committee gave an opportunity to the representative of the company to present their case. To a query on the source of data on gene protein expression it was informed that the data was collected and analyzed by the company in their own laboratory. Regarding the morphological uniformity of the Bt parental line it was clarified that the company has so far completed two backcrossing to achieve a uniformity of 87.5% to the non-Bt counterpart. The representative also informed that they are in the process of further backcrossing to achieve the desired level of homozygousity (99%).

5.2 The Committee was of the view that conducting large-scale trials at this stage could draw no meaningful results. The Committee advised the company to complete the backcrossing to the desired level before approaching the GEAC for permission to conduct of large-scale trials. The Committee therefore rejected the proposal.

6. Requests from M/s Mahyco for additional seed production of Bt Cotton seeds (Bollgard II) containing the stacked Cry 2A(b) and Cry1A (b) genes in kharif 2004.

6.1 The GEAC in its 44th meeting held on 14th July 2004 accorded approval for the above hybrids for large scale field trials and seed production of MRC-7160 BGII, MRC 7301 BGII and MRC-7326 BG II in an area of 5 ha each. The company has now requested the GEAC to permit an additional area of 20 ha of seed production for the above hybrids.

6.2 The Committee gave an opportunity to the company representative to clarify the need for this additional requirement. The Committee noted that the Bt hybrids as well as the technology adopted in Bollgard II are relatively new. Therefore, there is a need to demonstrate the technology at varied micro agro-climatic locations. The GEAC therefore approved the request of the company.

7. Permission to manufacture finished dosages form imported crystals of r-human Insulin from M/s Bioton Co. Ltd. Poland by M/s Shreya Life Sciences Pvt. Ltd, Mumbai.

7.1 The Committee noted that as per the information furnished by the company the specification of insulin crystals proposed to be imported from Bioton Co. ltd. Poland fulfils the criteria of USP. A certificate from Central Drug Laboratory (CDL) confirming the same has been submitted. The company has also confirmed that the source of Gensulin and recombinant human insulin crystals proposed to be imported are from the same source of GMO maintained and used by Bioton Co. Ltd. Poland.

7.2 Taking note of the fact that the GEAC had earlier approved the import of r-human insulin in finished form by the company from the same source as well as the information furnished by the company, the GEAC accorded approval for import of r-Human insulin in crystal form and marketing of the product in finished form within the country.

8. Permission for import to conduct Phase II clinical trials in Indian cancer patients of Monoclonal antibody hR3 (thera CIM manufactured by r-DNA technology by Biocon Biopharmaceuticals Pvt. Ltd. Bangalore from Center of Molecular Immunology, Havana city, Cuba.

8.1 The Committee gave an opportunity to the company representative to present their case. During the discussion the company representative explained the methodology adopted for humanization of the antibody.

8.2 Taking note of the recommendation made by the Experts and DCGI, the GEAC accorded approval for limited import of the product (1500 vials) for conduct of Phase-II clinical trials.

9. Permission for approval of Bt. Cotton hybrid Gujarat –151 by Gujarat State Seeds Products Association, Ahmedabad.

9.1 The Member Secretary briefed the Committee on the request of M/s Gujarat State Seeds Products Association, Ahmedabad. The Committee noted that there is no evidence that the Association has acquired the technology through the prescribed regulatory process as per Rules 1989. It was also noted that the request is intrinsically linked to the Navbharat 151 case of illegal Bt cotton production, which is subjudice in the Hon'ble High Court of Gujarat. The Committee was of the view that the matter may be considered only after the legal tangles are resolved.

Date of the Next GEAC Meeting: The next GEAC meeting would be held on 13th October 2004.

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