Decision taken in the 47th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 13th October 2004.

Decisions

1 Permission for import of finished product for marketing in India r-human Granulocyte colony stimulating factor injection (G-CSF) 300 mcg in prefilled syringes and vials by M/s Claris Life sciences Ltd. Ahmedabad, from North China Pharmaceuticals (NCPC) Genetic Bio- Technology Co., Ltd, China.

1.1 The Committee noted that the Director IMTech had not recommended the proposal in view of the fact that the information on whether the final product does or does not contain any host vector derived DNA necessary for determining whether the product is efficacious and safe had not been furnished. Further, the chapter on 'DNA relating to environmental risks" though indicated in the index does not form part of the report. Further the Committee also noted that DBT has informed that information on various aspects such as gene sequence, virus freedom characterization, bio-reactor parameters, purification methods, and other details related to certification etc. is either not available or very sketchy.

1.2 After detailed deliberations the Committee concluded that the request of the company for import and marketing of the product in India cannot be considered without conduct of Phase-III clinical trials. It was agreed that the company may be advised to submit the revised application for Phase III clinical trials. The revised applications should also include the requisite information sought by DBT and expert member IMTech which are considered necessary for evaluating the efficacy and safety of the product for conduct of Phase III clinical trials.

2 Permission for import and marketing of M/s L.G. Leucostin ® Injection r-human Granulocyte colony stimulating factor Filgrastim (G-CSF) 75μ, 150μ, and 300μ by M/s L.G. Life sciences India Ltd. New Delhi from Dong-A Pharmaceuticals Co. Ltd. Korea.

2.1 The Committee noted that DCGI and Director(s) CDRI and IMTech have recommended the proposal for import and marketing in India. The Committee also noted that the agreement between the company and M/s Synergy Waste Management Co. for proper disposal of biomedical waste, which has expired on 31.3.2004, has been renewed and his valid upto 15th August 2005. However, the Committee was of the view that the information sought by DBT related to gene sequence, virus freedom characterization, bio-reactor parameters, purification methods, and other details related to certification etc. are relevant to assess the suitability of the product for conduct of Phase III clinical trials and the information should have been submitted by the company as per the GEAC proforma.

2.2 Since the request of the company and additional information sought by DBT is similar to the request made in Agenda Item no. 4.1, it was concluded that the decision taken therein would be applicable in this case also.

3. Permission for import and marketing of r-human Insulin Glulisine APIDRA by M/s Aventis Pharma Ltd. Mumbai from Aventis Pharma Deutschland Germany.

3.1 After detailed deliberations the Committee concluded that the above product being a new drug would require to undergo Phase III clinical trials prior to its consideration for import and marketing as per the decision taken in the earlier two Agenda Items at 4.1 and 4.2.

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 the company's request for conduct of large scale trials of ACH 33 I Bt hybrid was considered by the GEAC in the meeting held on 8.9.2004. The additional information sought by the Committee has been received on 6th October 2004 and was circulated to the members during the meeting. Additionally the company has requested approval for seed production in an area of 40 ha.

4.2 The Committee also gave an opportunity to the project proponent to present their case.

4.3 The Committee deliberated the information submitted by the company regarding the gene sequencing and the data on the level of protein expression in the Bt hybrid developed by the company. After detailed deliberation the following decisions were taken:

a) The large-scale trials should be conducted during proper cropping season in tandem with the ICAR trials.
b) Seed multiplication may be initiated by the Company in an area of 40 ha.
c) Data generated from off season trials cannot be considered for evaluating the performance and suitability of the hybrid for commercial release.

5. Request from M/s Syngenta India Ltd. on Biosafety feeding Studies need to be conducted.

5.1 The Member Secretary informed the Committee that M/s Syngenta India Ltd. is working on new transgenic protein called Vegetative Insecticide protein (Vip 3 A) derived from Bacillus Thuringiensis (Bt) for control of lepidopteron insect in crop plant. The company vide their letter dated 2.9.2004 has requested GEAC to advise on whether any additional studies on feeding to cattle and fishes etc. are required.

5.2 During the deliberations it was observed that prescribing the biosafety guidelines is essentially the responsibility of RCGM. Previously in the case of M/s Mahyco certain additional biosafety studies has been thought necessary considering that it is the first case of its type. However, it is only desirable that RCGM takes a comprehensive view of these matters. Therefore, the decision on the request of the company regarding conduct of additional studies on feeding to cattle, fish etc should be taken in the appropriate forum, which in this case is the RCGM.

5.3 The Member Secretary RCGM informed that the company had not approached RCGM with this request. However, he assured that the above matter would be deliberated in the next RCGM meeting scheduled to be held shortly.

6 Request from M/s Mahyco on Biosafety feeding Studies on Bt cotton Bollgard II.

6.1 The Member Secretary informed the Committee that the request from M/s Mahyco vide their letter dated 2nd September 2004 is similar to the request made by M/s Syngenta at Agenda Item No. 5.1. The Committee reiterated that the request should be considered by RCGM only while taking a holistic view.

6.2 Some of the members expressed the view that in the case of Bollgard II, we are dealing with a new gene and the aspect on the need for conducting nutritional studies on cows and buffaloes should be duly taken into account by RCGM in its deliberations.

7. Request received from M/s L.G. Life Sciences for the revalidation of the products approved in 2000 – 2002.

7.1 The Committee concluded that the present request of the company for revalidation is pre-mature. It was agreed that the project proponent may be advised to approach the GEAC for revalidation about three months prior to the expiry of the validity along with the PMS report. To a suggestion regarding the need for development of a proforma for revalidation, the Member Secretary RCGM informed the Committee that a proforma has been developed by DBT and this could be circulated to the members for their comments. The proforma adopted by GEAC could be circulated to the applicant for submission of the relevant information for revalidation of the GEAC clearance.

8. Permission for waiver of Phase III Clinical trial for r-Human Erythropoietin (rhEPO) manufactured by M/s V.H. Bhagat Life Sciences, Mumbai from M/s Shenzhen SPEC Bio-pharmaceuticals Industry Co., Ltd. China.

8.1 The Committee noted that the company's request for waiver of Phase III Clinical trial for **r**-Human Erythropoietin (rh-EPO) was rejected by the GEAC in the meeting held on 9.6.2004 on the following grounds:

8.2 On the present request of the company the Committee noted that there is no new information meriting reconsideration of the earlier decision. Hence the Committee rejected the request of the company.

Date of the Next GEAC Meeting: The next GEAC meeting would be held on 10th November 2004.

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