Decisions taken in the the 61st Meeting of the Genetic Engineering Approval Committee (GEAC) held on 14th December 2005.

The 61st Meeting of the Genetic Engineering Approval Committee was held on 14th December 2005 in the Ministry of Environment and Forests under the Chairmanship of Dr Amit Ghosh, Co-Chairman GEAC.

Decisions

1.0: Permission for import and marketing of enzyme (Phytase) from M/s Sunson Industry Group Co. Ltd, China by M/s Chembond Chemicals Ltd. Mumbai.

1.1 The Committee noted that views of the Experts and the Department of Animal Husbandry are awaited. During the deliberations it was also pointed out that information submitted by the applicant regarding product specification, manufacturing process and feed safety studies are not adequate to take a final view on the matter.

1.2 After detailed deliberations, the Committee decided to obtain the following information:

a. Product specification and purity profile.
b. Product manufacturing process.
c. Feed Safety Protocol and Feed Safety Data from country of origin.
d. Comments of the Department of Animal Husbandry.
e. Regulatory status of product in China and other countries.

1.3 Decision on the proposal was therefore deferred.

2.0: Permission to conduct phase III clinical trials of r-Human Granulocyte Colony Stimulating Factor (rh GCSF) and scale-up of the production process for R&D purpose only by M/s Biocon Ltd. Bangalore.

2.1 The Committee noted that the company proposes to conduct open, multicentre study, to evaluate efficacy and safety of rh GCSF in patients with chemotherapy induced neutropenia. The total number of patients to be enrolled is around 50. The Member Secretary informed the Committee that information regarding the Investigator and Centers where the clinical trials would be conducted, have been recently furnished. It was noted that the Company has identified 7 centers for conduct of clinical trials.

2.2 The Committee also noted that the pre-clinical toxicity data was examined by the RCGM in its meeting held on 27.10.2005 wherein it was noted that the product is safe for conducting human clinical trials. The Committee further noted that the product r-Human Granulocyte Colony Stimulating Factor (rh GCSF) is a drug approved for marketing in India.

2.3 On the issue of safe handling of the product, the Committee noted that the Company is complying with the requirements under ISO 9001: 2000 Quality Management system, ISO 14001: 1996 and ISO 18001: 1999 Environmental, Occupational Health and safety Management system guidelines and DBT's guidelines for safe handling and disposal of recombinant culture.

2.4 After detailed deliberations and taking into consideration the recommendation of RCGM and the Expert members, the Committee approved the conduct of clinical trials with r-Human Granulocyte Colony Stimulating Factor (rh GCSF) developed by the Company in India and scale –up of the product process for R&D purpose.

3.0: Permission for conducting phase III clinical trials on r-Streptokinase and scale-up for R&D purpose by M/s Biocon Ltd. Bangalore.

3.1 The Committee noted that the Company proposes to conduct a randomized, comparative, multicentre study to evaluate efficacy and safety of r-Streptokinase in patients with acute myocardial infarcation. It is proposed to enroll about 60 patients at two centers namely department of Cardiology. St John's medical College hospital, Bangalore and Narayana Hrudayalaya Institute if Cardiac Sciences, Bangalore.

3.2 The Committee also noted that the pre-clinical toxicity data was examined by the RCGM in its meeting held on 27.10.2005 wherein it was noted that the product is safe for conducting human clinical trials. The Committee further noted that the product r-Streptokinase is a drug approved for marketing in India.

3.3 On the issue of safe handling of the product, the Committee noted that the Company is complying with the requirements under ISO 9001: 2000 Quality Management system, ISO 14001: 1996 and ISO 18001: 1999 Environmental, Occupational Health and safety Management system guidelines and DBT's guidelines for safe handling and disposal of recombinant culture.

3.4 After detailed deliberations and taking into consideration the recommendation of RCGM and the Expert members, the Committee approved the conduct of clinical trials with r-Streptokinase developed by the Company in India and scale-up of the product process for R&D purpose.

4.0: Permission for import of EPREX R(Epoetin alpha) from M/s. Fisher Clinical Services, Singapore for conducting phase III clinical trials in India by M/s Synchron Research Services Pvt Ltd. Ahemdabad.

4.1 The Member Secretary informed the Committee that the Company has requested for deferment of the case to the January 2006 meeting as they are in the process of firming up their drug supplier and distributor in India. The proposal was therefore not considered by the Committee.

B. Pharmaceuticals (Reconsideration Cases)

5.0: Permission to conduct large scale process optimization studies (R& D purpose only) of oral insulin IN –105 precursor, for the production of oral formulation of recombinant human Insulin by M/s. Biocon Ltd Bangalore.

5.1 The Committee noted that the above request was considered by the GEAC in the meeting held on the 10th October 2005, wherein the Company was advised to submit details regarding the containment conditions and the details of the chemical disinfection protocols they propose to use. The Committee considered the information submitted by the Company and noted that the information furnished is satisfactory.

4.5.2 After detailed deliberations and taking into consideration the recommendation of RCGM, DCGI and the Expert members, the Committee approved the request for conduct of large scale process optimization studies of oral insulin IN –105 precursor, for the production of oral formulation of recombinant human Insulin for R& D purpose only.

6.0: Permission for import & marketing of Recombinant Bovine Somatrotropin from M/s L G. Chemicals, Korea by M/s L G. Chemicals Pvt. Ltd., New Delhi

6.1 The Committee considered the clarifications submitted by the Department of Animal Husbandry in response to the queries raised by the GEAC in its meeting held on the 10th October 2005 and noted

that the Department has suggested that the following parameters needs to be monitored while conducting the study in the two organized farms:

- Metabolic profile of animal which includes effect to rBST on body temperature, growth rate, body weight, body fat of animal (cow).
- Milk yield per lactation including rise/fall in milk fat during different stages of lactation.
- Animal Health issues which includes mastitis, infertility, animal reproductive performance during different season, effect of rBST during pregnancy
- Level of IGF-1 (Insulin like Growth factor-1) in milk
- Level of Xanthine Oxidase (Protein enzyme) in milk
- Productivity and Herd life
- Economics of production before and after use of rBST
- Post marketing Surveillance.

6.2 The Committee was of the view that trials need to be conducted as per the protocol suitable for Indian conditions, keeping in mind the shortage of feed and fodder supply. It was pointed out that in the absence of adequate feed; there is a tendency for deposition of pesticide residue in the adipose tissue of animals injected with bovine Somatrotropin. The protocol should therefore address this issue adequately. Views were also expressed that without completion of the safety studies, the milk produced during the trials should not be sold.

6.3 The Committee also noted that the Dept of Animal Husbandry does not permit import of milk and milk products from animals subjected to the exposure of Bovine growth hormones/ Bovine Somatrotropin / Estrogenic substances. To a query on the implication of the above policy on the export of milk and milk products if we permit the use of r-Somatrotropin, it was clarified by the Dept of Animal Husbandry that there will be no implication on trade during the trial period and subsequently if it is approved, the national treatment policy will apply in case of imports also.

6.4 After detailed deliberations, it was decided that the Company may be advised to submit the following details:-

a. A detailed protocol for the proposed feed study. The feed study should include the following parameters:-

   - Metabolic profile of animal which includes effect of rBST on body temperature, growth rate, body weight, body fat of animal (cow).
   - Milk yield per lactation including rise/fall in milk fat during different stages of lactation.
   - Animal Health issues which includes mastitis, infertility, animal reproductive performance during different season, effect of rBST during pregnancy.
   - Level of IGF-1 (Insulin like Growth factor-1) in milk.
   - Level of Xanthine Oxidase (Protein enzyme) in milk.
   - Composition of milk (proteins, fat content and minerals)
   - Pesticide residue in milk (only relevant pesticide which get deposited in the adipose tissue.
   - Productivity and Herd life.

b. Details of the organized farms where the feed study would be conducted along with their consent letter and commitment that milk derived from animals treated with r-Somatrotropin during the trials would not be sold.

c. The names of the veterinary doctors responsible for monitoring the feed study and laboratories where the analysis of the samples is done. The analysis should be done in a Government recognized laboratory for this purpose. The names of the pesticide for which facilities are available in the laboratory also needs to be indicated.

d. The Department of Animal Husbandry has recommended 100 elite animals for the trials for a period of two years. However, the Committee is of the view that the type of animals, number and period of trials should be decided in consultation with a Bio-Statistician so as to represent the several scenarios under Indian conditions (genetic make-up of the animals, feed conditions, etc).

e. Economics of the additional milk vis-à-vis cost of hormone and additional feed (i.e before and after use of Somatrotropin).

f. Approval of the Ethics Committee where the trials would be conducted.

6.5 Decision on the proposal was therefore deferred.

Date of the Next GEAC Meeting

It was decided that the next GEAC meeting would be held on 11.1.2006. ****

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***** *The meeting is now scheduled for 13.1.2006*

List of the Participants who attended the 61st meeting of the GEAC held on 14th December 2005 in the Ministry of Environment & Forests, New Delhi.

S. No.	Name of the participants
1.	Dr Amit Ghosh, Co-Chair GEAC
2.	Shri. D. D. Verma, JS, MoEF and Vice-Chair
3.	Dr Vasantha Muthuswamy, Chief BMS, ICMR
4.	Dr S Kulshrestha, Secretary, Central Insecticide Board and Registration Committee
5.	Dr. T.V. Ramaniah, Director DBT, Member GEAC
6.	Dr. S. K. Mahajan, Member GEAC
7.	Shri R K Bansal, Director, Ministry of Food Processing and Industries.
8.	Shri S P Shani, DCGI, Technical Officer
9.	Dr. Chetna Brat, Sr. Dy, Adviser, RPBD, CSIR
10.	Dr J P Chaurasia, CSIR
11.	Dr. R. Warrier, Additional Director & Member Secretary GEAC
12.	Ms. Madhu Gupta, Research Officer, MoEF

Special Invitees

1.	Dr. K. K. Tripathi, Advisor, DBT
2.	Dr S K Srivastava, Director (Trade), Dept of Animal Husbandry and Dairying and Fisheries.
3.	Dr R K Gupta Assistant Commissioner (Trade), Dept of Animal Husbandry and Dairying and Fisheries.

Company Representative

1.	Dr A V Sriram, M/s Biocon, Bangalore.