

Brief record of the 38th Meeting of GEAC held on 27.11.2003.

The 38th meeting of the GEAC was held on 27.11.2003 at 10.30 AM in the Ministry of Environment and Forests under the chairmanship of Ms. Meena Gupta, Additional Secretary, MoEF. List of participants is annexed.

1.0 Opening Remarks of the Chairman

The Committee welcomed the new Chairperson Ms. Meena Gupta, Additional Secretary, MOEF.

2.0 Confirmation of the Minutes of the 37th Meeting of the GEAC held on 13th June, 2003

The Chairman referred to the minutes of the 37th Meeting of GEAC held on 13th June, 2003, which were circulated to all members. The minutes were confirmed with the following modification:-

4.1 Import and Marketing of r-Human Interlukin – 2 (rhuIL-2) from Laboratories Pablo Cassara SRL Argentina by M/s. Glenmark Lab. Pvt. Ltd. Mumbai

M/s. Glenmark Lab. Pvt. Ltd. Mumbai had submitted a proposal for import and marketing of r-Human Interlukin -2(rhuIL-2) from Laboratories Pablo Cassara SRL Argentina. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA of drug.

4.2 Import and marketing of r-Human Growth Hormone, Manufactured by Shanghai United Cell Biotechnology Co. Ltd. China by M/s. V. H. Bhagat & Co. Mumbai.

M/s. V. H. Bhagat & Co. Mumbai had submitted a proposal for import and marketing of r-human Growth Hormone, Manufactured by Shanghai United Cell Biotechnology Co. Ltd. China. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.3 Permission for Import and marketing of r-human Growth Hormone, Manufactured by State of Israel, Jerusalem from M/s. Sherya Life Sciences Pvt. Ltd. Mumbai

M/s. Sherya Life Sciences Pvt. Ltd., Mumbai had submitted a proposal for import and marketing of r-human Growth Hormone, Manufactured by State of Israel, Jerusalem.

In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.4 Permission for import of r-human, GM-CSF (Granulocyte Macrophage Colony Stimulating Factor) under test license for R&D/stability Studies, By M/s. Gland Pharma Ltd. from China

M/s. Gland Pharma Ltd. from China had submitted a proposal for import and marketing of r-human, GM-CSF (Granulocyte Macrophage Colony Stimulating Factor) under test license for R&D/stability Studies. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.5 Permission for Import and marketing of r-human granulocyte colony stimulating factor 300mcg/ml manufactured by (GCSF) from Centre of Molecular Immunology, Cuba by M/s. Biocon Biopharmaceuticals Pvt. Ltd. Bangalore.

M/s. Biocon Biopharmaceuticals Pvt. Ltd. Bangalore had submitted a proposal for import and marketing of r-human granulocyte colony stimulating factor 300mcg/ml manufactured by (GCSF) from Centre of Molecular Immunology, Cuba. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.6 Permission for import and marketing of r-human erythropoietin alpha 2000 IU/ml and 4000 IU/ml) from Centre of Molecular Immunology, Cuba by M/s. Biocon Biopharmaceuticals Pvt. Ltd., Bangalore

M/s. Biocon Biopharmaceuticals Pvt. Ltd., Bangalore had submitted a proposal for import and marketing of r-human erythropoietin alpha (2000 IU/ml and 4000 IU/ml) from Centre of Molecular Immunology, Cuba. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.7 Permission for Import and marketing of r-human Interleukin – 2 (rh-IL-2) from Jiangsu Kingsley Pharmaceuticals Inc. China M/s Emucure Biotech Ltd., Pune

M/s Emcure Biotech Ltd., Pune had submitted a proposal for import and marketing of r-human Interleukin – 2 (rh-IL-2) from Jiangsu Kingsley Pharmaceuticals Inc. China. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.8 Permission for import and marketing of r-human erythropoietin 2000 IU and 4000 IU manufactured by M/s Shenzhen SPEC-Bio-Pharmaceuticals Industry Co. Ltd., China by V.H. Bhagat Co. Mumbai

M/s V.H. Bhagat Co., Mumbai had submitted a proposal for import and marketing of r-human erythropoietin 2000 IU and 4000 IU manufactured by M/s Shenzhen SPEC-Bio-Pharmaceuticals Industry Co. Ltd., China. In view of the Comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.9 Permission for import and marketing of r-human granulocyte-Macrophage colony stimulating factor (rhGM-CSF) by M/s Emcure Biotech Ltd., Pune from Shanghai Hygene Biopharma Company Ltd., China.

M/s Emcure Biotech Ltd., Pune had submitted a proposal for import and marketing of r-human granulocyte-Macrophage colony stimulating factor (rhGM-CSF) by M/s Emcure Biotech Ltd., Pune from Shanghai. In view of the comments received on the proposal, GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

4.10 Permission for manufacture and marketing of r-Hepatitis-B Vaccine finished product at the existing manufacturing unit by M/s Biological E. Ltd., Hyderabad.

M/s Biological E. Ltd., Hyderabad had submitted a proposal for manufacture and marketing of r-Hepatitis-B Vaccine finished product at the existing manufacturing unit. Committee decided to visit the manufacturing unit by Small Sub-Committee and after receiving their report if it is favorable, can be approved by the Department.

4.11 Permission to undertake seed production of transgenic cotton hybrid seed in 200 ha in Northern states namely RCH-134 Bt, RCH-138 Bt by M/s Rasi Seeds (P) Ltd., Attur, Salem.

M/s Rasi Seeds (P) Ltd., Attur, Salem had submitted a proposal to undertake seed production of transgenic cotton hybrid seed in 200 ha in Northern states namely RCH-134 Bt, RCH-138 Bt. Committee decided to defer the proposal on want of MEC and RCGMs report.

4.12 Permission to undertake seed production of transgenic cotton hybrid seed in 127 ha namely Bt. MRC-6301, Bt.MRC-6160, Bt.MRC-6304, Bt-MRC-6703, Bt. MRC-6322, Bt. MRC-6918, Bt. MRC-6928 by Mahyco, Mumbai.

M/s Mahyco, Mumbai had submitted a proposal to undertake seed production of transgenic cotton hybrid in 127 ha namely Bt. MRC-6301, Bt.MRC-6160, Bt.MRC-6304, Bt-MRC-6703, Bt. MRC-6322, Bt. MRC-6918, Bt. MRC-6928. Committee decided to defer the proposal on want of MEC and RCGMs report.

Other Items

Agenda Item No. 5.

5.1 Amendment of Condition stipulated by GEAC for import of Crude Degummed Soyabean oil by Care from USA.

M/s Care from USA had submitted a request to Amendment of Condition stipulated by GEAC for import of Crude Degummed Soyabean oil. Committee rejected the proposal and asked to furnish the following additional information:

- (i) Where they get the refines
- (ii) Post market surveillance
- (iii) Consult Department of Commerce, Department of Consumer Affairs and Public Distribution, Women Development and PFA (Health).

5.2 Manufacturing and marketing of FMD (food and mouth disease) vaccine by M/s Brilliant Industries, Hyderabad.

M/s Brilliant Industries, Hyderabad had submitted a proposal for manufacturing and marketing of FMD (food and mouth disease) vaccine. After detailed discussions GEAC accorded approval from environmental angle subject to conditions stipulated by DBT and other statutory requirement under EPA.

5.3 Import and marketing of r-Human Interferon alpha 2 B manufactured by Tiaman Hualida Bio-Engineering Company Ltd., China by M/s Hindustan Bio Sciences Ltd., Hyderabad

M/s Hindustan Bio Sciences Ltd., Hyderabad had submitted a proposal for Import and marketing of r-Human Interferon alpha 2 B manufactured by Tiaman Hualida Bio-Engineering Company Ltd., China. GEAC rejected the proposal on non-submission of required additional information.

5.4 Import and Marketing of Recombinant Bovine Somatotropin from L.G. Chemicals, Korea by M/s L.G. Chemicals Pvt. Ltd.

M/s L.G. Chemicals Pvt. Ltd. had submitted a proposal for Import and Marketing of Recombinant Bovine Somatotropin from L.G. Chemicals, Korea. Committee decided to circulate the IVRI report to all the members of GEAC and will be decided to call a separate meeting with the Chairperson of GEAC with the Department of Animal Husbandry, NDRI, Karnal and IVRI, Bareilly.

5.5 Manufacture and Marketing of recombinant Streptokinase by M/s Shantha Biotechnics Pvt. Ltd., Hyderabad

M/s Shantha Biotechnics Pvt. Ltd., Hyderabad had submitted a proposal for Manufacture and Marketing of recombinant Streptokinase.

A Bangalore based NGO, Anikethan has complained that Shantha Biotechnics has manufactured and tested the medicine Streptokinase on poor people at Osmania General Hospital, Hyderabad and other hospitals. It is reported that about 8 persons died at Care Hospital, Hyderabad. No compensation was paid to the poor patient families. It is also reported that the company has shifted to Jayadev Institute of Cardiology, Bangalore.

DBT is of the view that clinical trials are conducted only after obtaining the approval of DCGI and also Human Ethics Committee of the concerned hospitals. The trials are conducted with the consent of the patients. DBT has advised that the NGO may contact the concerned authorities at the Osmania General Hospital and Care Hospital since the matter does not fall within the purview of GEAC.

The company has clarified that Human Clinical trials have been conducted with the approval of RCGM and DCGI. No approval from GEAC has been taken in view of the revised procedure outlined in the DBT guidelines and hosted on DBT Website. On this matter it may be noted that the DBT had recommended human clinical trials vide their letter dated 07.05.2002 subject to obtaining permission from GEAC and DCGI. The revised guidelines have been hosted on DBT Website only in October, 2003. Hence they have violated the rules.

Further, it may be recalled that the revised step-wise procedure for development of r-DNA Pharmaceuticals developed by DBT was placed for discussion in the GEAC meeting dated 13th June, 2003. However discussion was deferred at the request of DBT. We are now given to understand that the revised procedure has been hosted on DBT Website without the formal approval of GEAC. To ensure uniformity and consistency in the policies followed by DBT and MoEF regarding clearance procedures under 1989 Rules, DBT may be advised to consult both RCGM and GEAC before finalizing any new guidelines and decided by the committee to withdraw the revised procedure hosted by DBT on Website. Committee decided to reject the proposal.

5.6 Base paper prepared by DBT to suggest modifications in the existing administrative and procedural requirements for rDNA Drugs, Pharmaceutical and Therapeutics and transgenic crops.

It was decided to discuss further after receiving the comments from the member of the GEAC Committee so the consolidated view may be taken on.

6.0 Vote of Thanks

List of the Participants who attended the 38th meeting of the GEAC held on 27th November, 2003 in the Ministry of Environment & Forests, New Delhi

S. No.	Name of the participant
1.	Ms. Meena Gupta, Chairman, GEAC
2.	Dr. Sushil Kumar, Co-chairman, GEAC
3.	Shri Ashish Bahuguna, Joint Secretary, MOA – Member GEAC
4.	Shri D.D. Verma, Joint Secretary, MoEF – Member GEAC
5.	Dr. T.V. Ramanaiah, Scientist F, DBT – Member GEAC
6.	Dr. S.K. Mahajan, Member, GEAC
7.	Dr. Vasantha Muthuswamy, ICMR – Member GEAC
8.	Dr. (Mrs.) S. Kulshrestha, Medical Toxicologist, DPPQS – Member GEAC
9.	Shri A.B. Ramteke
10.	A.K. Bhatnagar
11.	Shri Subhash Chand
12.	Shri Prakash Tiwari, ICAR
13.	Shri P.S. Raju, CSIR
14.	Shri Dinesh Kumar, Under Secretary, Ministry of Commerce
15.	Dr. D.R. Chawla
16.	Dr. R. Warriar, Member Secretary, GEAC
17.	Mrs. Madhu Gupta, Research Assistant, MoEF
18.	Shri S.R. Kardar
