Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 24th Meeting of the Genetic Engineering Approval Committee held on 12.10.2000.

****

The 24th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 12.10.2000 under the Chairmanship of Dr. A.K Kundra, Special Secretary in the Ministry of Environment and Forests. List of participants is annexed.

The Chairman welcomed the members. He informed them about the change effected in the Ministry regarding handling of the GEAC work, which is now being handled in the Conservation and Survey (CS) Division. The Convention on Biological Diversity (CBD) and the Biosafety Protocol, which have been negotiated and adopted recently under the aegis of the CBD, are being handled in CS Division. He apprised them that Dr. G.V Sarat Babu, Additional Director and Dr. Sujata Arora, JOINT Director will now look after the GEAC also.

The Chairman referred to the minutes of the 23rd meeting of GEAC held on 30th June 2000, which were circulated to all the members. As there were no comments from the members, the minutes were confirmed.

Agenda Item No. 3.1 (F.No. 10/9-2000-CS)

Import and marketing of Epokine Injection (r- human erythropoietin), manufactured by M/s Chail Jedang Corporation, Seoul, Korea by Alkeem Laboratories, Mumbai.

M/s Alkeem Laboratories, Mumbai had submitted a proposal for import and marketing of (r-human erythropoietin) Epokine Injection from Chail Jedang Corporation, Seoul, Korea in the brand name "Epokine". As Phase III clinical trials have been conducted in Korea only and the efficacy of the drug is yet to tested in the Indian population, the Committee decided that the proponents may be allowed to conduct Phase III trials by limited import of the product as per the standard criteria. The limited import will be subject to the following condition.

"Each batch should accompany with the certificate stating that the product is free from adventitious viruses like HBV, HCV, HIV etc. as tested by PCR, RT-PCR etc."

The report of the trials may be examined by DBT and DCGI and referred to GEAC for consideration of final clearance.

Agenda Item NO. 3.2 (F.No. 18/3/2000-CS)

Import and marketing of r-Human Erythropoietin Epoetin from M/s Dong-A Pharmaceuticals.

M/s Emcure Pharmaceutical Ltd., Pune had submitted a proposal for the import and marketing of r-Human Erythropoietin "Epoietin" in the brand name "Epooron" from M/s Dang-A Pharmaceuticals Ltd., Korea. As Phase III clinical trials have been conducted in Korea only and the efficacy of the drug is yet to tested in the Indian population, the Committee decided that the report of the trials maybe examined by DCGI and referred to GEAC for consideration of final clearance. The Committee decided that the proponents may be allowed to conduct Phase III trials by limited import of the product as per the standard criteria.

Agenda Item NO. 3.3 (F.No. 10/6/2000-CS)

Import and marketing of Leucostim (r-Human Granulocyte colony stimulating factor) from M/s Dong-A Pharmaceuticals Ltd., Korea.

M/s Emcure Pharmaceuticals Ltd., Pune, had submitted a proposal for the import and marketing of Leucostim (r- human granlocyte stimulating factor) in the brand name 'Lieucostim' from M/s Dong –A Pharmaceuticals Ltd., Korea. As phase III clinical trials have not been conducted even in Korea, where the product is manufactured, the proposal for import and marketing of the product was not agreed to.

Agenda Item NO. 3.4 (F.No. 10/3/2000-CS)

Import and marketing of r-interferon alfa 2a injection from M/s Dong-A Pharmaceuticals Ltd., Korea.

M/s Emcure Pharmaceuticals Ltd., Pune had submitted a proposal to this ministry for the import and marketing of r-interferon alfa 2a injection from M/s Dong–A pharmaceuticals Ltd., Korea. As Phase III clinical trials have not been conducted even in Korea, where the product is manufactured, the proposal for import and marketing of the product was not agreed to.

Agenda Item NO. 3.5 (F.No. 10/4/2000-CS)

Import and marketing of Growtropin (r-Human Growth Hormone) (r-HGH) by M/s Dong-A Pharmaceuticals Ltd., Korea.

M/s Emcure pharmaceuticals Ltd., Pune. Had submitted a proposal for import of Growtropin from M/s Dong- A pharmaceuticals, Korea As the phase III clinical trials have been done in Korea, and some adverse reactions of the drug have been reported the committee decided that the proponents may be allowed to conduct phase III clinical trials

by limited import of the product as per the standard criteria. The Report of these trials may be examined by DCGI and referred to GEAC for Consideration of Final Clearance.

Agenda Item NO. 3.6 (F.No.17/12/1998-CS)

Import and marketing of r-PEG interferon Alfa 2b 50 ugm, 80 ugm, 100 ugm, 150 ugm form Fulford (India) Ltd. from M/s sehening plough corporation, Brinny, Ireland.

M/s Fulford (India) Ltd. had submitted the proposal for import and marketing of r-PEG interferon alpha 2b form M/s Sehening Plough Corporation, Brinny, Ireland. As the proponents have not submitted data on immunogenic of r-PEG interferon alpha 2b, the committee suggested that the same may be sought, and referred to DBT and DCGI for comments. The matte may then be brought before the GEAC for consideration.

Agenda Item NO. 3.7 (F.No.17/2/1998-CS)

Import and marketing of r-Hepatitis B Vaccine by V. H. Bhagat and Co. from M/s Chaug Chun Institute of Biological Products China

The GEAC in its 20th meeting had earlier approved the proposal to conduct Phase III clinical trials. It was also decided the DCGI would consult ICMR on the results of the clinical trials for examination by the Toxicological Review Panel of ICMR. The DCGI communicated the results of clinical trials conducted by the applicant and recommended the GEAC may give final clearance on the proposal. The DCGI further informed that for products which are approved and used in other countries and are found safe and efficacious after Phase III trials, the DCGI accord market authorization in the country, and there is no need to refer the matter to ICMR.

The GEAC approved the proposal, on the condition that Post Market Surveillance data will be submitted.

The Chairman invited the members to spell out nay other relevant aspects relating to the functioning of the Committee. The Member Secretary mentioned that there is a need for establishing/ strengthening monitoring mechanism. Also in the light of the biosafety protocol, the Rules need to be examined, vis-à-vis, the protocol for effective implementation of biosafety. Earlier, the DBT was requested to prepare a base paper on monitoring mechanism for production and use of recombinant products in the country. The Committee recommended that the DBT may be requested to expedite preparation of this base paper, in collaboration with MOEF. The paper may also examine whether provision of the existing rules need to be reviewed in light of provisions of protocol.

The meeting ended with a vote of thanks to the Chair.

LIST OF PARTICIPANTS

1. Dr. A. K. Kundra, Special Secretary, MoEF, New Delhi- **Chairman**
2. Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow (U.P.) – **Co-chairman**
3. Dr. K. K. Tripathi, Department of Biotechnology, New Delhi.
4. Dr. A.B. Ramteke, Deputy Drugs Controller, Directorate of Health Services, New Delhi.
5. Shri Suraj Bhan, Executive Engineer, Central Pollution Control Board, Delhi.
6. Dr. (Mrs.) S. Kulshrestha, Medical Toxicologist, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and Storage, Faridabad.
7. Prof. A.K. Bhatnagar, Department of Botany, University of Delhi, Delhi.
8. Dr. G.V. Sarat Babu, Additional Director, MoEF, New Delhi.
9. Dr. Sujata Arora, Joint Dircetor, MoEF, New Delhi.
10. Ms. Madhu Gupta, Research Associate, MoEF, New Delhi.