

Minutes of the meeting on issue concerning proposals for approval by GEAC held on 21.12.1993 at 11.00 A.M.

In accordance with the recommendation of the 8th meeting of Genetic Engineering Approval Committee (GEAC) held on 27.07.1993 regarding streamlining of the procedure for receiving proposals for approval by GEAC, the Drug Controller of India and Department of Biotechnology were invited to come for a discussion on 21.12. 1993 at 11.00 A.M. Since JS (JCK) had to be away on tour Director (HSMD) chaired the meeting. The list of participants is as follows:-

1. Dr. Y.P. Kakkar, Director, M/o E&F
2. Shri A.B. Ramteke, Biochemist for DCI, DGHS
3. Shri S.M. Sharma, Technical Officer, DGHS
4. Dr. P.K. Ghosh, Director, DBT
5. Dr. Rajesh Kapur, Principal Scientific Officer, DBT
6. Dr. R.R. Khan, Addl. Director, M/o E&F

2. The following issues were discussed and recommendations made:-

I. Procedure and sequence for receiving the applications concerning human & veterinary drugs:

3. It was explained on behalf of the Ministry that at present the applicant seeking clearance from GEAC has to apply directly to the Ministry of Environment and Forests. Subsequently Ministry of Environment and Forests have to confirm from DCI whether clinical trials have been conducted and the status of availability of the drug within the country. Since major responsibility for undertaking clinical trials and safety and efficacy of drugs in the country is that of DCI, it was suggested that DCI may receive all applications and forward this to Ministry after a thorough screening. There may be certain firms which are not approved /black-listed by DCI for manufacture/import of drugs. Such firms may be screened by DCI. Thereafter, the applications may be forwarded to the Ministry for being placed before GEAC after obtaining the views of expert in the area. Initial screening by DCI would also imply that DCI agrees with the claims (clinical trials) approval by competent authority in the country of origin made by the firm in his applications.

4. On behalf on DCI, it was pointed out that since the 1989 rules do not provide such procedure, DCI is asking applicants to directly approach the Ministry of Environment. However, if an office order to this effect is issued they would comply with the same and forward the application to MoEF after initial screening, as pointed out in para 3 above.

II. Evaluation of Proposals

5. On behalf of the Ministry of Environment & Forests it was explained that DBT has favoured that the Ministry could get the views of expert on individual proposals before they are placed before GEAC.

III. Participation of DCI in GEAC meetings

6. On behalf of the Ministry it was explained that during the VII & VIII meeting of GEAC, DCI could not attend the meeting due to other pressing assignments. Since a number of proposals concerning Drugs are being discussed in GEAC, it was desired by Chairman, GEAC that either DCI or his nominee should attend GEAC meetings. The representatives of DCI were requested to ensure that either DCI himself or his nominee may attend all future meetings.

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