Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 14th Meeting of the Genetic Engineering Approval Committee held on 25.07.1997.

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The 14th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 25.07.1997 under the Chairmanship of Shri Vinod Vaish, Additional Secretary in the Ministry. The following officers participated in the meeting.

1. Shri Vinod Vaish, Additional Secretary, MOEF- Chairman
2. Shri Vijai Sharma Joint Secretary, MOEF.
3. Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow.
4. Shri S.C. Bansal, Director, Foundation for Applied Research in Cancer, New Delhi.
5. Dr. T.V. Ramanaiah, Principal Scientific Officer, Department of Biotechnology, New Delhi.
6. Dr. S.K. Mahajan, Head, Molecular Biology and Agri. Division, BARC, Bombay.
7. Prof. Subhash Chand, Centre for Biochemical Engineering, IIT, New Delhi.
8. Dr. (Mrs.) Vasantha Muthuswamy, Chief (BMS), Indian Council of Medical Research, New Delhi.
9. Shri S.K. Tandon, Asstt. Drug Controller, DCGI, New Delhi.
10. Shri A.K. Pradhan, Technical Officer, DCGI, New Delhi.
11. Dr. R.R. Khan, Director, Ministry of Environment and Forests, New Delhi.

Agenda Item No.1: Manufacture of Genetically Engineered Hepatitis B Surface Antigen (HBsAQ) Vaccine by M/s Shantha Biotechnics Pvt. Ltd., Ranga Reddy Distt., Andhra Pradesh.

2. The proposal was earlier considered in 13th meeting of GEAC and was deferred on the suggestion of Advisor, Department of Biotechnology since it was then under consideration of RCGM. The firm was given environmental approval by MOEF for conducting human clinical trials after the same was recommended by DBT. However, the firm represented that phase-3 human clinical trials were already conducted by the firm at two centers namely Nizam's Institute of Medical Sciences, Hyderabad and KEM Hospital, Bombay and were presented before the representatives of DCGI and DBT on 7.5.97 where it was concluded that the vaccine developed by M/s Shantha Biotechnics is of high purity and standard quality and is effective and safe. Based on these conclusions, M/s. Shantha Biotechnics was granted NOC by DCGI for commercial production of vaccine. The firm has requested that the environmental clearance for manufacture of HBs Ag Vaccine given by MOEF. The following points emerged from the discussion:

(i) The clinical trials in 120 healthy adults at Nizam's Institute of Medical Sciences and 114 volunteers at KE M Hospital did not reveal any harmful effects (except one female subject who developed general urticarial rash within in a few minutes of vaccination) and ere well tolerated by the subjects.

(ii) The capability of the firm to produce the high quality vaccine has been certified by Central Research Institute (CRI), Kasauli and the firm fulfills the requirements of Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP). CRI is a statutory authority under the Drugs and Cosmetics Act. Necessary condition be prescribed that every batch of the vaccine will have to be tested by CRI before it is marked. The need for generation of post-marketing surveillance information was highlighted and it was stressed that it should be carried out for at least 2 years and the results made available to DBT and DCGI.

(iii) The host organism namely, Pichia Pastoris is a yeast, is non- pathogenic and does not manifest any toxic or allergic effects. The purity of the finished product is according to WHO standards.

(iv) Besides efficacy of the vaccine through clinical trials, the risk assessment of the production facilities is also required to be seen. It was pointed out that under Impact Assessment Notification, 1994 brought out under Environment Protection Act, 1986; detailed Environment Management plan is required to be made. There is an Institutional Biosafety Committee with a representative of DBT as member which is required to meet at periodical intervals to review and monitor the safety aspects of the manufacturing operations and the implementation of the Environment Management Plan. Routine monitoring is to be carried out by the local Pollution Control Board for air and water emissions.

(v) Maximum safeguards be taken to see that no accidents occur for which necessary condition be prescribed.

(vi) Standard procedures for disposal of used vials and syringes have to be followed by the users.

3. It was decided that subject to the above conditions, M/s Shantha Biotechnics Pvt. Ltd., may be given environmental approval for manufacture of Genetically Engineered Hepatitis B Surface Antigen Vaccine.

Agenda Item No. 2: Import and Marketing of Erythropoietin by M/s Boehringer Mannheim India Ltd., New Delhi.

4. In respect of the above proposal, it was pointed out in the 13th meeting of GEAC that there are reports of certain poisoning incidents associated with some products belonging to M/s. Boehringer. In view of this, the antecedents of the firm may be checked from DCGI. DCGI has now confirmed that the poisoning incident was due to another product by the firm and the firm continues to hold license for the import of number of schedules "C" drugs under the Drugs and Cosmetics rules. It was pointed out the erythropoietin for which application has been made is already approved in the country of origin namely, Germany. Chairman enquired from the representative of DCGI as to what is the surety that the product will be imported from the parent company in Germany. DCGI mentioned that as per the procedure followed by DCGI, the license no. is communicated to the parent company and an undertaking is obtained from the manufacturer that only the approved product will be supplied to the license. No license is issued unless DCGI is sure that the product is manufactured by the parent company. Chairman desired on the basis of the points raised during the meeting that DCGI should obtain a certificate from their counterpart in Germany that the product is approved in their country for unrestricted use.

5. Co- Chairman mentioned that the necessary condition be given in the approval that a standard procedure will be followed for the disposal of vials and syringes in respect of expired drugs. It was mentioned by the representative of DCGI that all expired drugs are required to be returned to company for safe disposal.

6. It was decided that after the receipt of the certificate from Drug Controller of Germany about the approval of the drug for unrestricted use in their country, the permission to import and marketing of Erythropoietin by M/s Boehringer Mannheim may be given.

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

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