Ministry of Environment & Forests
HSM DIVISION

Subject: Minutes of 15th Meeting of the Genetic Engineering Approval Committee held on 04.11.1997.

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The 15th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 04.11.1997 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, New Delhi- Chairman
2. Dr. Sushil Kumar, Director, Central Institute of Medicinal and Aromatic Plants, Lucknow-Co-chairman
3. Shri Vijai Sharma, Joint Secretary, MOEF, New Delhi.
4. Dr. P Das Gupta, Drug Controller General of India (DCGI), New Delhi.
5. Dr. P.K.Gosh, Advisor, Department of Biotechnology, New Delhi.
6. Dr. (Ms.) Sulbha Gupta, Department of Science and Technology (DST), New Delhi.
7. Dr. T.V. Ramanaiah, P. S. O., Department of Biotechnology, New Delhi.
8. Dr. R.P. Sharma, Project Director, Indian Agricultural Research Institute (IARI), Pusa, New Delhi.
9. Dr. (Mrs.) S. Kulshrestha, Jt. Director, Directorate of Plant Protection, Quarantines and Storage, Faridabad.
10. Shri S.K. Tondon, Assistant Drug Controller, DCGI, New Delhi
11. Shri M.A. Patel, Sr. Dy. Director, National Productivity Council, New Delhi.
12. Shri Gajraj Singh, Development Officer, Department of Industrial Policy Promotion, M/o Industry, New Delhi.
13. Dr. R.R Khan, Director, Ministry of Environment and Forests, New Delhi.
14. Ms. Madhu Gupta, Research Assistant, MOEF, New Delhi.

2. Chairman welcomed the participants and requested Shri Vijai Sharma, Joint Secretary to give the background of various proposals being considered in the 15th Meeting of GEAC. The following Agenda Items were taken up for discussion.

AGENDA ITEM NO. 1: APPLICATION FOR IMPORT AND MARKETING OF RECOMBINANT FOLLICLE STIMULATING HORMONE IN FINISHED FORM BY M/S INFAR (INDIA) LTD., CALCUTTA.

3. M/s INFAR (India) Ltd., Calcutta has applied for import and marketing of recombinant Follicle Stimulating Hormone(r-FSH) in finished form from Netherlands. r-FSH (trade name RECAGON or PUREGON- Follitropin- beta which contains org. 32489 as active substance) is used for treating female infertility and is available as a freeze dried product. In India, it is proposed to market it under the brand name RECAGON. It is produced from Chinese Hamsters Ovary (CHO) Cell line. Clinical trials have been carried out in the country of export. The following points emerged from the discussion.

(1) DCGI informed that r-FSH is being introduced for the first time in India. The results of the clinical trials as reported by the firm have been found to be satisfactory. DCGI has further obtained the comments of Indian Council of Medical Research (ICMR) which has recommended that ICMR has no objection for marketing of the product provided Post Marketing Surveillance (PMS) is carried out. DCGI was of the opinion that clinical trials in India are not necessary since the product is already being used in nearly 24 countries around the world. However, PMS data should be generated within one year and submitted to DCGI for review.

(2) Co-Chairman pointed out that the information supplied by the firm revealed that several batches were contaminated. Since details of the type of contamination are not available, the firm should clarify as to how many batches were found to be contaminated and what is the extent of sale of the product in various countries.

(3) Adviser, DBT explained that r- FSH has high biochemical purity (more than 99%). However, the problem of contamination of batches is controllable. Based on the supplementary information on the product, DBT is satisfied that the product may be allowed for import and marketing provided the firm generates PMS data on at least 150 patients over a period of two years.

4. It was decided that the firm may be asked to give clarifications as to:

(i) How many batches were found to be contaminated; and
(ii) What is the extent of consumption of the product in the country of origin within a period of time.

The available information supplied by the firm will be reviewed by DCGI, DBT and MoEF before taking a decision in the matter. It was further decided that the approval of the product would be subject to generation of PMS data over a period of two years on at least 100 patients which have to be reviewed by DCGI. It was also decided that first five batches of the imported product would be tested at Central Drug Laboratory,

Calcutta and would be verified by DCGI. The quantity of the product to be allowed for import and marketing in the country would also be decided by the DCGI.

AGENDA ITEM NO. 2: IMPORT AND MARKETING OF SAIZEN (RECOMBINANT DNA – HUMAN GROWTH HORMONE)

5. The application for import and marketing of Saizen has been moved by Serum Institute of India Ltd., Pune. The product is used to correct growth failure in children with growth hormone deficiency. It is produced by using mammalian cell line.

6. The product has undergone clinical trials in India at three places, namely, AIIMS, New Delhi, Wadia Hospital, Bombay and Apollo Hospital, Madras. DCGI mentioned that the above product is the first of its kind and has also been tested at Central Drug Laboratory, Calcutta and is reported to conform to the specifications.

7. Adviser, DBT mentioned that the product is free from viral contaminants.

8. The above product is also being marketed in a number of countries like Germany, Australia, Sweden, USA, UK, Belgium, France, Spain, Austria and Italy.

9. It was also decided that the above product may be cleared for import and marketing from environmental angle provided:

(a) Each batch marketed in India should carry a certificate that the product has been tested for the absence of viral contaminants by ELISA TESTS using appropriate mouse antibodies by PCR/RT-PCR methods to ensure absence of SV40, papilloma, Rous Sarcoma, HIV, HBV and EBV.
(b) The applicant should generate post market surveillance data on at least 100 patients over a period of two years and submit it to DCGI for review.

10. It was also decided that the quantities of the product to be imported for marketing should be decided by DCGI.

AGENDA ITEM NO. 3: APPLICATION FOR IMPORT AND MARKETING OF EUVAX-B VACCINE (RECOMBINANT HEPATITIS B) BY M/S RANBAXY, NEW DELHI

11. The proposal is regarding import and marketing of recombinant Hepatitis B Surface Antigen HbsAg manufactured by LG Chemicals, Korea. The clinical trials have been conducted in children and adults in the country of origin. No serious or adverse reaction was reported. The product is already used in many countries like Korea, Malaysia, Vietnam and Philippines.

12. It was decided that the proposal may be cleared for import and marketing from environmental angle subject to the following conditions:

(a) Each batch marketed in India should carry a certificate that the product has been tested for the absence of viral contaminants by ELISA TESTS using appropriate mouse antibodies by PCR/RT-PCR methods to ensure absence of SV40, papilloma, Rous Sarcoma, HIV, HBV and EBV.
(b) The applicant should generate post market surveillance data on at least 100 patients over a period of two years and submit it to DCGI for review.

13. It was also decided that the quantities of the product to be imported for marketing should be decided by DCGI.

AGENDA ITEM NO. 4: MARKETING OF SOMATOTROPIN INJECTION (RECOMBINANT DNA – HUMAN GROWTH HORMONE) BY M/S ELI LILLY RANBAXY LTD. NEW DELHI

14. The above proposal was discussed in the 13th meeting of GEAC held on 14th November, 1996. In this meeting, it was decided that it should be referred to D/o Biotechnology for their examination. DBT sought some additional information from the firm on the product and the comments of DBT recommending the proposal have now been received. Other expert like Dr. Ramesh Kumar from AIIMS, New Delhi and Dr. C.M. Gupta, Institute of Microbial Technology, Chandigarh have also recommended the proposal.

15. Advisor, DBT informed that clinical trials on the above recombinant product have been conducted in various countries like Austria, Greece, U.K. etc. and the results indicate that the formulations are safe and effective.

16. It was decided that the product maybe allowed for import and the company may also generate post Marketing Surveillance on 100 patients for a period of up to two years. This data should be examined by DCGI. The quantity of the injections to be imported by the firm will also be decided by DCGI.

17. It was also decided that each batch marketed in India should carry a certificate that the product has been tested for the absence viral contaminants by ELISA TESTS using appropriate mouse antibodies by PCR/RT-PCR method to ensure absence of SV40, papilloma, Rous Sarcoma, HIV, HBV and EBV.

ANY OTHER ITEM

18. Chairman expressed his anxiety over a number of proposals pending for consideration by GEAC. In a number of cases, comments from experts have not been received so far. He requested the concerned Departments to expedite their comments so that a decision could be taken by GEAC on these proposals at the earliest.

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