Decisions taken in the 49th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 8th December 2004.

The 49th Meeting of the Genetic Engineering Approval Committee was held on 8th December 2004 in the Ministry of Environment and Forests under the Chairmanship of Shri Suresh Chandra, Special Secretary & Chairperson GEAC.

Decisions

1.0 Permission to import Erythropoietin (EPREX-with HAS, EPREX-without HAS and Neorecormon) from Europe for test analysis by M/s. Wockhardt Ltd. Mumbai.

1.1 The Committee considered the request for import of the following products from Europe for isolating API and testing the same for detailed structural analysis.

- EPREX-with HAS (150 vials of 10000 IU/ml), from M/s Jhonson & Jhonson Ltd.
- EPREX-without HAS (150 vials of 10000 IU/ml), from M/s Jhonson & Jhonson Ltd.
- Neorecormon(150 vials of 10000 IU/ml), from M/s F. Hoffmann-La Roche Ltd.

1.2 The Committee noted that the GEAC in its 23rd meeting held in July 2000 had approved the manufacture and marketing of r-Erythropoietin in India by M/s Wockhardt, Mumbai. However the company has not submitted their application for revalidation of the GEAC clearance as per the provisions of Rule 13 (ii) of the Rule 1989.

1.3 After detailed deliberations, the committee was of the view that the information furnished does not clarify whether the product to be imported is same as the product available in the country. Views were also expressed that the reasons for the proposed import and justification for not revalidating the GEAC clearance need to be clarified by the applicant.

1.4 Decision on the proposal was therefore deferred.

2.0 Permission for import of Denimax 399S from M/s. Novonozymes, Denmark by M/s. Lumis Biotech Ltd. Mumbai.

2.1 The Member Secretary informed the Committee that the present application is for import of Denimax 399S –A cellulase enzyme produced by Novozymes Denmark. The enzyme is used for washing of denim.

2.2 The Committee discussed at length the information submitted by the applicant and was of the view that the proposal lacks clarity on whether the enzyme contains single host organism or multiple organisms, source of gene and purpose of import. The certificate from the supplier also does not clarify whether the final product contain infructuous or transformable DNA.

2.3 The Committee gave an opportunity to the representative of the company for providing the necessary clarifications. After detailed deliberations the Committee concluded that the following information should be made available to GEAC for consideration of the proposal:

a) Purpose of import and details of value addition proposed by the company. This should include information on the composition of the byproduct generated (if any), its use or/ and method of disposal.

b) Certificate from the suppliers that the end product does not contain transformable DNA.
c) Undertaking that the enzyme is imported with the sole purpose of value addition and subsequent export and that the product would not be used within the country for any purpose other than the proposed value addition prior to export.

2.7 Decision on the proposal was deferred.

3.0 Permission for import of recombinant HIV Vaccine tg AACO9, for conduct of Phase I Clinical Trials from M/s. Targeted Genetics Corporation, Seattle, USA by M/s. National AIDS Research Institute (ICMR) Pune.

3.1 The Committee noted that the present application is for import of recombinant HIV Vaccine tg AACO9 to conduct Phase-I clinical trials by M/s. National AIDS Research Institute (NARI) Pune. A MOU has been signed between NACO, ICMR and IVAI in December 2000 to facilitate the development of safe, effective and accessible preventive aid vaccine and carry out Clinical trials in India. As part of this commitment Phase I clinical trials is planned at NARI. Human clinical trials have already been initiated in four European sites, two in Belgium and two in Germany.

3.2 After detailed deliberations and taking into consideration the national importance of the project, the Committee requested DBT to examine the proposal and forward their comments to the Chairman GEAC. The Committee authorized the Chairman GEAC to take a final view based on DBT's comments.

4.0 (a) Permission to conduct Phase III Clinical trials of Osteoform –rh-Parathyroid Hormone (1-34) manufactured by M/s. Virchow Labs Ltd. Hyderabad.

4.0 (b) Permission to conduct Phase III Clinical trials of interlukin-2 by M/s. Zenotech lab Ltd. Hyderabad.

4.0 (c) Permission to conduct Phase III Clinical trials of tetravalent combination vaccine (DTwP + Hepatitis B) manufactured by M/s. Biological E. Ltd. Hyderabad.

4.1 The Member Secretary explained that the above proposals pertain to approval of GEAC for conduct of Phase–III clinical trials in India. The request was considered by the GEAC in the last meeting but decision on the proposal were deferred in light of the decision taken in the 46th GEAC meeting wherein it was agreed that GEAC clearance would be issued only on receipt of RDAC recommendation. Since a number of proposals are pending for want of DCGI/RDAC decision, the Committee, took a view in the previous meeting that the decision taken in the 46th GEAC meeting may need to be reviewed.

4.2 After detailed deliberation and taking into consideration the RCGM recommendations, the GEAC accorded approval for conduct of Phase III clinical trials subject to DCGI clearance.

5.0 Import and marketing of L.G. Leucostim injection of r-h G-CSF by M/S. L.G. Life- sciences Pvt. Ltd. New Delhi from Dong-A Pharmaceuticals, Korea.

5.1 The Committee noted that the above proposal was considered by the GEAC in its meeting held on 13.10.2004 wherein the company was advised to submit additional information sought by DBT related to gene sequence, virus freedom characterization, bio-reactor parameters, purification methods, and other details related to certification etc. are

relevant to assess the suitability of the product for conduct of Phase III clinical trials. The Member Secretary informed that the Company has submitted the additional information sought by DBT vide their letter-dated 16.11.2004. The DBT representatives informed that they have not received the additional information. It was agreed that the relevant information may be again forwarded to DBT for their comments. The Committee requested DBT to expedite their comments so that the proposal may be considered in the next GEAC meeting.

5.2 Decision on the proposal was deferred.

6.0 Import of Parental lines of herbicides tolerant corn by M/s. Monsanto India Ltd., from M/s. Monsanto Republic of South Africa.

6.1 The Committee noted that the above request was considered by the GEAC in the meeting held on 11.8.2004 wherein DBT was requested to provide details of the consultation held by DBT with respect to herbicide tolerant corn as well as details of similar proposals approved by RCGM. It was also decided in the earlier meeting that the views of MOA and ICAR on the above matter would also be obtained.

6.2 The Committee considered at length the comments received from DBT, RCGM, ICAR and MOA. On the recommendations made by the Task Force on Agriculture Biotechnology under Prof M S Swaminathan, views were expressed that low priority sector identified in the task force report is with a view to ensure that large amount of public funds are not invested in research by public institutions. However, this should not be construed as a ban on research or development of technology by private institutions. The Committee also noted that the first set of pollen flow studies on herbicide tolerant corn has been completed and the request of the company for import of additional seeds is for conducting further biosafety studies.

6.3 Because of the out-crossing nature of corn, some members expressed concern on the ecological and socio-economic impact due to commercial cultivation of herbicide tolerant corn. They were of the opinion that these aspects need to be adequately considered before arriving at a policy decision. Since the company is undertaking research activities with a commercial perspective in mind, it was felt that research of such nature should be permitted only after detailed deliberations on the future implication of such activities. On this issue another set of views were expressed that the various concerns can be addressed only after generation of scientific data for which research is necessary. Some expert members suggested that in addition to pollen flows studies, data required for assessing the ecological and socio-economic impact should be firmed up at this stage itself and protocols for conducting such studies should be reviewed by the GEAC.

6.4 The Member Secretary RCGM informed the Committee that the above issues were discussed in the RCGM meeting held on 28.9.2004 wherein RCGM was of the opinion that there is no harm in development and perfecting the technology as generation of data on the technology is necessary for taking a decision on the suitability of that particular technology to Indian agriculture and addressing the concerns of GEAC and other bodies.

6.5 On the comments received from Ministry of Agriculture and ICAR, the Committee was of the view that the comments are of a general nature and do not provide specific guidance to the GEAC. Since Ministry of Agriculture is the nodal Ministry for taking a view on the food security issues, MOA may be advised to submit their considered opinion on whether the country would benefit from the commercial cultivation of herbicide tolerant corn. They may also indicate the kind of studies and data required for arriving at a policy decision.

6.6 After detailed deliberations it was decided to await the considered opinion of Ministry of Agriculture before taking a final view on the proposal. The Ministry of Agriculture should confer with ICAR and any other relevant organization that they deem fit and then send their considered opinion to GEAC. Decision on the proposal was deferred.

Date of the Next GEAC Meeting: The next GEAC meeting would be held on 12th January 2005.