Decisions taken in the 48th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 10th November 2004.

The 48th Meeting of the Genetic Engineering Approval Committee was held on 10th November 2004 at 10.30 AM in the Ministry of Environment and Forests under the Chairmanship of Dr. Amit Ghosh, Co-Chairman GEAC and Director IMTECH Chandigarh.

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

1.1 The Committee noted that recommendations of RCGM have been received whereas comments from DCGI are still awaited. The Member Secretary briefed the Committee regarding the decision taken in the 46th meeting wherein it was agreed that to avoid a situation of conflict, the clearance for Phase-III clinical trials under 1989 Rules would be issued only after the proposals has been recommended by RDAC. In the above meeting the DCGI representative was requested to forward the minutes of the RDAC meeting to the Member Secretary in all such cases in future. The Member Secretary informed the Committee that even after repeated reminders comments of DCGI/minutes of RDAC have not been received.

1.2 The Committee noted that in light of the decision taken in the 46th GEAC meeting, the proposal cannot be considered now. Since a number of proposals are pending for want of DCGI/RDAC decision, the Committee, was of the view that the decision taken in the 46th GEAC meeting may need to be reviewed. It was agreed that the above matter may be reconsidered in the next GEAC meeting. Accordingly decision on the proposal was deferred.

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

2.1 The Member Secretary briefed the Committee on the recommendations received form RCGM and IMTech. The committee noted the request of the company is similar to the request made in Agenda Item no. 4.1. It was therefore agreed that final decision on the above proposal could be taken only after review of the earlier decision taken in the 46th GEAC meeting. The matter may therefore be discussed in the next GEAC meeting.

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

3.1 The Member Secretary briefed the committee on the recommendations received form RCGM. Since the request of the company is similar to the request made in Agenda Item no. 4.1 and 4.2, it was concluded that the decision taken therein would be applicable in this case also.

4.0 Permission for manufacture and marketing of r-human Epidermal growth factor by M/s. Bharat Biotech International Ltd. Hyderabad.

4.1 The Member Secretary briefed the Committee on the comments received from Director IMTech, Director CDRI and DBT. The Committee noted that information on various aspect such as composition of the gel, composition of the Placebo used in the studies, sterility studies undertaken on the test product, etc, is either sketchy or not available.

4.2 After detailed deliberations, the Committee concluded that the applicant may be advised to submit the requisite information. Decision on the proposal was deferred.

5.0 **Ex-post facto approval for conducting phase III clinical trials and permission for manufacture and marketing of rh -PDGF-BB (Healace 0.01%) by M/s Virchow Biotech Pvt. Ltd. Hyderabad**.

5.1 The committee noted that RCGM recommendation on adequate containment facilities has been received on 9.9.04. The RCGM recommends that the facilities are adequate for R&D and production of purified recombinant products from LMOs. The Member Secretary briefed the Committee on the comments received from Director CDRI vide letters dated 19.8.2004 and 17.9.2004. The Members observed that CDRI has not made any adverse comments on the proposal and therefore a final view may be taken based on the recommendations received from other experts.

The Committee noted that DBT and IMTech have recommended the proposal. The applicant has also obtained the approval of DCGI for conduct of Phase-III clinical trials under the Drugs and Cosmetic Rules. Based on the recommendations received from DBT, DCGI and IMTech the Committee approved the request of the company.

6.0 Import and marketing of Injection Lispro (r-DNA) Human Insulin by M/s Eli Lilly and Company (India) Pvt. Ltd. Gurgaon---Waiver of conditions stipulated in clearance letter dated 15.1.1997.

6.1 The Member Secretary informed the Committee while according approval for import and marketing of the product, a number of conditions were stipulated. The company has requested for waiver of the following two conditions stipulated vide clearance order dated 15.1.1997.

Condition No. i- "Approval of the injection insulin lispro is subject to the approval given by the Drug Controller General Of India who would satisfy himself about the efficacy and safety of the product before allowing any general us. The following quantities may be allowed to be imported.

Injection Insulin Lispro -10,000 vials"

Condition No. v - "The above product imported by the firm should not be sold or diverted for any pother purpose".

6.2 Regarding condition no i, the Member Secretary informed the committee that the company in the original application had specified the quantity for import. Accordingly DCGI

and GEAC accorded approval for import of 10,000 vials. In view of the market demand, the company has requested for waiver of the condition stipulating limited import. The Committee noted that DCGI vide letter dated 31.3.98 has waived the condition for limited import. The committee agreed for waiver of condition specifying the quantity of import (10,000 vials).

6.3 Regarding condition No. v, the Member Secretary explained that this clause has been stipulated with a view to ensure that imported product is not used for any research activity or development of a new product without the approval of GEAC. The committee was of the view that deletion of the above condition may not be advisable. However, it was agreed that condition may be amended as follows:

"The above product imported by the firm should not be diverted for any purpose other then those mentioned in the original application".

Date of the Next GEAC Meeting: The next GEAC meeting would be held on 8th December 2004.

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