Decisions taken in the 45th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 11th August 2004.

Opening Remarks of the Chairman

At the outset, the Chairman welcomed all the members. He further informed that the Mrs. Veena Chhotray, Additional Secretary, MoEF and Chairperson GEAC was unable to attend the meeting due to unavoidable official duty. Therefore, at her request he would be chairing the GEAC meeting.

Decisions

1. 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.

1.1 The Committee gave an opportunity to the applicant to present their case. The representative of the company clarified that composition of the gel as well as other expedients used in the preparation has been provided in the dossier submitted to the DCGI. There is no antibiotic in the preparation and the formulation is only for use in case of diabetic foot patients.

1.2 On the procedural lapse the Committee noted this matter has figured earlier in some other cases and is essentially linked up with the different procedures stipulated as a result of certain streamlining initiatives by the DBT.

1.3 Since the present request is for manufacture, the issue of adequacy of containment facility at the R&D and manufacturing premises was also discussed. Keeping in view the explanation given by the company as well as comments of Member Secretary, RCGM and experts, the Committee decided to await the recommendation of RCGM regarding the biosafety aspects including the adequacy of the containment facilities before taking a final view.

2. Permission to conduct Phase III clinical trials on r-human interferon alpha manufactured by M/s Cadilla Healthcare.

2.1 Taking note of the recommendation made by RCGM and the observations made by the representative of DCGI, the GEAC accorded approval for conduct of Phase-III clinical trials subject to clearance from DCGI.

3. Permission to manufacture finished dosages form imported crystals of r-human Insulin from M/s Bioton Co. Ltd. Poland by M/s Shreya Life Sciences Pvt. Ltd, Mumbai.

3.1 The Member Secretary informed the Committee that the GEAC in its 35th meeting held on 6th March, 2003 had approved for Phase III Clinical trials and in its 42nd meeting held on 12.5.2004 approved the import and marketing of r-human Insulin from M/s. Bioton Co. Ltd, Warszawa, Poland by M/s Shreya life Sciences Pvt. Ltd. Mumbai. The present proposal is for import of bulk recombinant crystals of r-human Insulin from Bioton Co. Ltd.

Poland from the same source and manufacture of finished dosages form of recombinant human Insulin in the manufacturing facility located at Aurangabad.

3.2 The representative of the company was called to provide necessary clarifications before the Committee. It was clarified by the company representative that M/s Shreya Life Sciences Pvt. Ltd. Aurangabad is the works address while the registered office of the company is at Mumbai i.e. Shreya Life Sciences Pvt. Ltd. Mumbai. The technology agreement signed by this Singapore Company has the approval of PAB in the Ministry of Commerce & Industry. As regards the USP grade of the recombinant human insulin crystals are concerned, the company representative informed that he would enquire and submit the information. It was also clarified that the branded product "Gensulin" on which the clinical trial data has been generated is manufactured from the same bulk/ process as the r-human insulin crystals proposed to be imported for further formulations in India.

3.3 The Committee took a view that once information about the USP grade of the recombinant human insulin crystals to be imported is certified by the manufacturer as well as the company, the proposal may be placed before the Committee for consideration.

4. Permission for import to conduct Phase II clinical trials in Indian cancer patients of Monoclonal antibody hR3 (thera CIM manufactured by r-DNA technology by Biocon Biopharmaceuticals Pvt. Ltd. Bangalore from Center of Molecular Immunology, Havana city, Cuba.

4.1 The Committee noted that the proposal is for import of humanized monoclonal antibody hR3, which is produced, in murine myloma NSO cell line intended for cancer treatment, which is a new line of treatment. The Member Secretary informed the Committee that the present request is for limited import of 1500 vials for conduct of Phase-II clinical trials. It was noted that the product is manufactured by Center of Molecular Immunology, Havana City, Cuba.

4.2 During the deliberations one of the expert members observed that the dossier provides information on various methods and tests to be carried on the cell line/clones as well as the final product. However, the documentation submitted does not include the details pertaining to tests on the animal viruses, the following of seed lot system of MCB and MWCB, the passage level of the clones used for the production of the product, genotypic and phenotypic testing results of MCB and MWCB and expanded population doubling banks of the host cells, karyology of the passage level as well as the proof of carrying out product characterization viz., passage level, protein sequencing etc. The acceptability of pre-clinical toxicity data and Phase-I human clinical trial data also need to be taken into consideration.

4.3 The Committee also took note of the comments received from IMTech and DCGI. After detailed deliberations, the Committee was of the opinion that such type of product is highly desirable to be produced in the country for the benefit of the cancer patients. However, the in-process quality control should be kept at utmost priority for the safety of the patients. Since this would be the first experience of a monoclonal product to be tried in human subjects suffering with cancer, the complete information with proof on the in-process quality control of the humanized monoclonal antibodies should be in place. The applicants may therefore be asked to submit the complete dossier for further consideration by the Committee.

Pharmaceuticals (Reconsideration Cases)

5 Permission for import and marketing of r-human Hepatitis B vaccine a component of Hexavalent vaccine (Hexavac) by M/s Aventis Pasteur India Ltd. New Delhi.

5.1 The Member Secretary informed the Committee that the above request was discussed in the 40th meeting of GEAC held on 30.3.2004 wherein it was decided that advice from Ministry of Health regarding the issue of bringing IPV component in the vaccine may be sought.

5.2 The Committee noted that the recommendation of ICMR is in favour of integrating IPV component in the vaccine. However, it was decided to await the views of MOH and DCGI before taking a final view on the proposal.

6 Permission to manufacture fixed dose combination of silver sulphadiazine and rhu- epidermal growth factor (EGF) as a tropical cream by M/s Glenmark Pharmaceuticals Pvt. Ltd. Mumbai.

6.1 The Member Secretary informed the Committee that the above request was discussed in the 41st meeting of GEAC held on 15.4.2004 wherein DCGI was requested to clarify whether Phase-III clinical trials as recommended by the Directorate vide their letter dated 6.8.2003 and 4.11.2003 has been waived.

6.2 The Committee gave an opportunity to the representative of the company to clarify whether they have received any formal communication from DCGI regarding waiver of Phase-III clinical trials or approval for PMS. It was clarified that no such communication has been received till date. The DCGI representative informed that communication on the above matter is being issued shortly.

6.3 The Committee decided to await the views of the DCGI before taking a final view on the proposal.

7. Import of Parental Lines of herbicide tolerant Corn by M/s Monsanto India Ltd., from M/s Monsanto Republic of South Africa (RSA).

7.1 The Member Secretary informed the Committee that M/s Monsanto India Ltd. proposes to import 50 gm each of 4 inbred parental lines and one single cross line of herbicide tolerant transgenic corn seeds containing CP4 EPSPS gene (event NK 603) from M/s Monsanto South Africa for the purpose of research only. As per the 1998 DBT Guidelines, the import has been approved both by RCGM and NBPGR. However the proposal has been referred to GEAC in the context of the requirement under the Cartagena Biosafety Protocol (CBP) wherein the regulatory authority of the Country of Export (Republic of South Africa) has sought clarification from the National Authority of the importing country on whether the decision taken to allow import of parental lines is in accordance with the objectives of the Cartagena Biosafety Protocol and whether the permit has been issued by an authorized authority.

7.2 Referring to the report of the Task Force on Agricultural Biotechnology under Prof. M.S. Swaminathan, some members pointed out that research and development of herbicide tolerant crops has been recommended as a low priority area. Since the company is undertaking research activities with a commercial perspective in mind, some members were of the view that research of such nature should be permitted only after detailed deliberations on the future implication of such activities. Views were also expressed that impact of herbicide tolerant crops on the ecology, social and economic aspects also needs due consideration before a policy decision on the above matter is arrived.

7.3 The representatives of DBT informed that RCGM has convened a consultative meeting of various stakeholders before taking a view to permit research activities on herbicide tolerant corn. The Members requested DBT to provide details of the above consultation as well as details of similar proposals approved by RCGM. The Member Secretary RCGM clarified that the only proposal approved by RCGM is presently under consideration of the GEAC. The Committee also took note of the fact that the representative of MOA and ICAR were not available for giving their comments. It was therefore, decided that the view of MOA and ICAR on the above matter would also be obtained.

7.4 Decision on the above proposal was therefore deferred.

8. Permission to import Non-Hazardous Non GMO, BSL 1, microorganisms towards Research & Development by M/s Biocon Ltd., Bangalore.

8.1 The Committee noted that many such cases are referred to the GEAC in the light of the directions issued by Indian Custom Authorities to get an import permit from MoEF under Rules 1989. The requirement of the Indian Custom Authorities is based on the interpretation of PPQA in conjunction with the list of organisms under the Schedule of Rules 1989.

8.2 The Committee noted that the MOA is issuing necessary guidelines for operation of PPQA order. It was decided that the GEAC would issue a letter clarifying that only Genetically Modified Organisms falls under the purview of the 1989 Rules until issuance of operational guidelines by MOA.

9. Import of Nature Valley Granola Bars by M/s General Mills India Pvt. Ltd., Mumbai.

9.1 The Committee noted that approval of GEAC is being sought for import of food products such as Nature Valley Granola Bars made from rolled oats containing various ingredients such as soy, corn and canola oil. The Committee was of the view that the applicant may be advised to submit full details of the case as per the requisite proforma for its consideration.

10. Issue of NON GMO Certificate for the purpose of export to:

10.1 The Committee noted that MoEF has been receiving request from various exporting companies for issue of non-GMO certificate. The Ministry in such cases has issued a certificate stating that the GOI has not approved the commercial release of any transgenic crops except Bt. Cotton into the environment. The Committee agreed with the current practice.

11. Complaint from Federation of Environment and Developmental Organizations (FEDO) Gross Violation of Statutory provisions of environment protection Loss of Human lives and illegal clinical trials.

11.1 The Committee noted the representation received from FEDO and requested the Member Secretary to submit full facts of the case after receiving requisite clarifications from the DCGI.

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