

**Status of Pending GEAC Proposals as on 30.4 .2005**

S. No	Title of the Proposal	Received on	Referred to	Status
<b>PHARMACEUTICALS</b>				
1.	Import and marketing of recombinant Bovine Somatropin from M/s. L.G. Chemicals Pvt. Ltd. New Delhi	18.7.2003	Dept. Of Animal Husbandry and Dairying, DBT, MoFPI.	<p>GEAC had approved Phase iii clinical trials on 8<sup>th</sup> Aug 2001.</p> <p>Clinical trials study report received on 18.7.2004. The proposal was considered in the 38<sup>th</sup> and 39<sup>th</sup> meetings of GEAC held on 27.11.2003 &amp; 3.2.2004.</p> <p>Clarifications from Dept of Animal Husbandry &amp; Dairying on the dept policy w.r.t import of milk &amp; milk products derived from animals subjected to bovine growth hormones, supply of adequate feed &amp; fodder and effect of this product on indigenous cows since the trials were conducted on crossbred cows on 6.2.2004.</p> <p>Reminders issued on 15.3.2004 and 7.4.2004.</p> <p>Report of IVRI on additional parameters received on 12.5.2004.</p> <p>Clarifications from Dept. of Animal Husbandry and Dairying are awaited.</p> <p>Reminder issued on 10.9.2004, 27.9.2004 and 20.10.2004.</p> <p>Clarifications sought from Dept. of Animal Husbandry and Dairying. Under process</p>
2.	Import and marketing of r-human DNA Hepatitis B Vaccine Hexavac. By M/s Aventis Pasteur India Ltd. From M/s. Aventis Pasteur's	16.1.04	DBT, DCGI, Director ITRC, Lucknow, Director, PGIMER, Chandigarh on 12.2.2004.	Reminder sent to DBT and DCGI on 4.3.2004 and 17.3.2004. Reminder sent to other experts on 17.3.2004.

	France.			<p>Comments from DBT have been received.</p> <p>The proposal was considered in the 40<sup>th</sup> GEAC meeting on 31.03.04. The committee decided to await the views of DCGI with specific reference to safety and efficacy of the product; and MOH/ICMR on the issue of bringing IPV component in the vaccine before taking a final view.</p> <p>Comments from DCGI have been received on 29.4.2004. Comments from MOH/ICMR are awaited. Reminder issued on 17.04.2004. It has been informed that the matter is under examination in consultation with ICMR. Comments received from ICMR dated 12.7.2004.</p> <p>The proposal was considered in the GEAC meeting on 11.8.2004. The Committee decided to await the views of MOH on the ICMR recommendation. Letter to MOH and DCGI issued on 24.8.2004.</p> <p>Reminder issued on 10.9.2004, 27.9.2004, 20.10.2004, 17.11.2004 and 20.12.2004.</p>
3.	Permission for import of r-hu-Epidermal Growth factor for manufacturing in India a fixed dose combination of 10 ug/GM and Silver Suphdiazin 1% as a Cream for Topical in burn cases from GGE and Biotechnology Cuba by M/s Glenmark Laboratories Pvt. Ltd. Mumbai	26.2.2004*	DBT & DCGI on 25.7.2002.	<p>* The proposal was earlier received in 31.5.2002. Accordingly, the proposal was referred to DBT and DCGI on 25.7.2002. Comments from DBT received on 8.8.2002 and DCGI 12.11.2002.</p> <p>Subsequently the company requested for closure of the case.</p>

				<p>At the request of the company the case was re-opened on 26.2.2004. The proposal was considered in the GEAC meeting on 15.4.2004.</p> <p>DCGI has been requested to clarify whether the request of the company for waiver of Phase-III clinical trials has been accepted on 21.4.2004. Reminder to DCGI issued on 13.5.2004 &amp; 14.6.2004.</p> <p>The matter was considered by the GEAC in the meeting held on 11.8.2004. The Committee decided to await the views of DCGI regarding the waiver of Phase-III clinical trials/ approval for PMS. Letter issued on 24.8.2004.</p> <p>Reminders issued on 10.9.2004, 20.10.2004, 17.11.2004 and 20.12.2004.</p>
4.	<p>Permission for import and marketing of finished product in India r-Human G-CSF, 300mcg in prefilled syringes by M/s Clarisis Life sciences Ltd. Ahmedabad from North China Pharmaceuticals (NCPC) Genetech Biotechnology Co, Ltd. China.</p>	12.8.2004	<p>Sent to DCGI, DBT, IISc Bangalore, IMTech, Chandigarh on 17.8.2004</p>	<p>Considered in the GEAC meeting on 13.10.2004.</p> <p>GEAC was of the view request for import and marketing cannot be considered without conduct of Phase III clinical trials in India. The applicant is accordingly advised to resubmit the revised application.</p> <p>The revised application should also include the additional information sought by DBT and expert member IMTech. Revised application has not been submitted.</p>
5.	<p>Permission for import and marketing of r-human Insulin Glulisine APIDRA by M/s. Aventis Pharma Ltd. Mumbai from Germany</p>	27.8.2004	<p>Sent to DCGI, DBT, IMTech, IISc, Bangalore, and ITRC. on 9.9.2004</p>	<p>Considered in the GEAC meeting on 13.10.2004.</p> <p>GEAC was of the view request for import and marketing cannot be considered without conduct of Phase III clinical</p>

				<p>trials in India. The applicant is accordingly advised to resubmit the revised application. The revised application has not been received.</p> <p>Revised application received on 10.3.2005 has been circulated to members of the GEAC on 10.3.2005.</p> <p>Considered in the GEAC meeting on 13.4.2005 and deferred on want of DBT comments and some clarifications sought by Expert members.</p>
6.	Permission for Phase III Clinical Trails on r-h GCSF on humans by M/s Wockhardt Ltd. Mumbai	22.11.2004	Circulated to all Members of the GEAC on 2.12.2004.	<p>Considered in the GEAC meeting on 12.1.05.</p> <p>Additional information received from DBT.</p>
7.	Import of Finase PC enzyme from Germany for formulation and marketing in India by M/s Textan Chemicals (P) Ltd. from	3.3.2005	Circulated to all Members of GEAC on 3.3 2005.	Considered in the GEAC meeting on 13.4.2005. and deferred on want of comments from Animal Husbandry and experts.
8.	Import of r-Leisg-111 F by institute of Medical Sciences, BHU, Varanasi.	7.3.2005	Letter for circulation issued on 18.3.2005.	Considered in the GEAC meeting on 13.4.2005. and deferred on want of specific comments of DBT, DCGI and the Experts
9.	Permission for conducting Phase –1 trial of a preventive recombinant AIDS vaccine TBC –M4 by tuberculosis research Centre ( M/s Indian Council of Medical Research), chennai.	30.3.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
10.	Import of Denimax 16000 L by M/s Luminis Biotech Pvt. Ltd, Mumbai from m/s Novozymes, Denmark.	30.3.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
11.	Import of Aquazyme Ultra 1200 L by M/s Luminis Biotech Pvt. Ltd, Mumbai from m/s Novozymes, Denmark.	30.3.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
12.	Import of Denimax Acid XCL	30.3.2005	Letter for circulation	To be considered in the next

	by M/s Luminis Biotech Pvt. Ltd, Mumbai from m/s Novozymes, Denmark.		issued on 18.3.2005.	GEAC meeting schedule for 16.5.2005.
13.	Permission to import r-Natreacor & formulation to conduct a Phase-III CT. by M/s Synchron Research Services Pvt. Ltd. Ahmedabad from U.K.	19.4.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
14.	Permission to import and marketing for 16 IU LG Eutropin ( human Growth Hormone) L.G. Chemical Pvt. Ltd. N.Delhi.	24.3.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
15.	Revalidation of GEAC clearance for manufacture and marketing of recombinant Erythropoietin by M/s Wockhardt Ltd, Mumbai	1.4.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
16.	Permission for conducting Phase –III clinical trials of r insulin (Glargine) by M/s Wockhardt Ltd, Mumbai	1.4.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
17.	Permission for Conducting phase III of r- Insulin Lispro Cr-DNA origin) by Wockhardt Ltd. Mumbai	11.4.2005	Letter for circulation issued on 18.3.2005.	To be considered in the next GEAC meeting schedule for 16.5.2005.
<b>TRANSGENIC CROPS</b>				
18.	Permission for commercial release of Bt cotton hybrids NCS-145, 'Bunny' Bt and NCS -207 'Mallika' Bt by M/s Nuziveedu Seeds Ltd in the Central and South Zone.	3.3. 2005	Circulated to all Members of the GEAC on 7.3.2005	Considered in the GEAC meeting on 13.4.2005 It was decided to await the recommendations of ICAR and report of the DNA finger printing. To be considered in the GEAC meeting on 20.5.2005
19.	Permission for large-scale trials of ACH-155-1 with Cry 1 Ac gene by M/s Ajeet Seeds in the South Zone	12.5.2005	--	To be considered in the GEAC meeting on 20.5.2005
20.	Permission for large scale field trials and seed production of MRC-6355 BG-I for Central & South Zone by M/s Mahyco	26.4.2005	--	To be considered in the GEAC meeting on 20.5.2005
21.	Permission for hybrids MRC-	26.4.2005	--	To be considered in the GEAC

	7341 BG-II, MRC-7347 BG-II and MRC-7351 BG-II for Central & South Zone by M/s Mahyco			meeting on 20.5.2005
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